

Point Of Care Program Manual

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POINT of CARE PROGRAM MANUAL

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SECTION I.1 Introduction

Point-of-care technologies are quickly becoming part of the transformation of the Health care landscape. In the right situations, when implemented properly and thoughtfully, Point-of-Care-Testing (POCT) can have a positive impact on operational efficiency and patient Care, As POCT can be an effective means of improving efficiency and outcomes and responding to essential healthcare needs among large populations.

POCT is most advantageous when patient treatment can be improved by rapid results. The full potential of POCT is best realized in situations or disease states where having the result immediately available is imperative to treatment. Also, in a situation where the patient can receive real-time counseling based on the test results (e.g., Hgb A1c testing for diabetic status or PT/INR testing to monitor coagulation therapy), POCT becomes highly beneficial.

When properly integrated, POCT allows healthcare workers to capture clinical data quickly and accurately, and streamline workflow and efficiency. POCT, for the right tests in the right situations, can improve consistency, accuracy, patient engagement, patient satisfaction, and ultimately patient outcomes.

The laboratory is often the starting point in the diagnostics chain, and ultimately responsible for ensuring that lab results are accurate and beneficial to the provider and to the patient. Whether lab testing takes place within the laboratory or at the patient’s side, laboratory professionals who understand the intricacies of testing and the importance of proper laboratory processes to ensure quality have an obligation to be involved in the oversight and growth of POCT. When the patient situation derives more improvement from a POC test intervention than from lab results performed in the core lab, this actuality takes precedent over other concerns. This can be related to a lack of understanding or training of non-laboratory staff who are typically involved in POCT or as a result of test limitations and misuse of POCT in extreme environmental conditions. Laboratory professional have the skill set and obligation to influence decisions that will encourage appropriate POCT usage where it is most beneficial to improve patient care, and this offers another opportunity for them to be an integral part of the future of diagnosis.

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Section I.2 General Guideline

1.Purpose

1.1 The purpose of this document is to provide standardized management of Point of Care Testing (POCT) devices and procedures throughout the **MOH hospital -Jeddah, (KFGH)** as recommended by the CBAHI thereby ensuring a cost efficient and clinically effective analytical service. This applies to all POCT devices used as a basis for medical intervention whether purchased, loaned or gifted.

1.2 This document applies to any member of staff within **King Fahad general hospital-Jeddah** (or managed areas of KFGH), who use a POCT device, are responsible for an analyzer, act upon or record results produced by POCT devices, which includes all medical, nursing, laboratory, information technology staff and other members of healthcare teams.

1.3 A POCT tests /device includes the following:

- Blood gas analyzer
- Glucose meter
- Urine dipstick
- Hemoglobin meters
- Coagulometer
- Cardiac markers .

The above list is not an exhaustive list, and other devices may be included.



2.0 ABBREVIATIONS

- POCT : Point of Care Testing
- EQA: External Quality Assurance
- GP: General Practitioner
- INR; International Normalized Ratio
- IT :Information Technology
- LIS :Laboratory Information System
- HIS: Hospital Information System
- QA :Quality Assurance
- QC: Quality Control

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- CBAHI: Central Board for accreditation of Health institutions.
- CLIA: Clinical Laboratory Improvement Amendments.
- SOP: standard operating procedure.
- CAP: quality assurance programs.

3.0 Introduction

3.1 A POCT can be defined as any analytical test performed on a patient by a healthcare professional outside of the conventional Laboratory setting. As a result this is a test that can be used for diagnosis, monitoring or prognosis and may be acted upon resulting in medical intervention on a patient.

3.2 POCT when used properly and appropriately can have huge patient advantages as it provides a result quickly and hence allowing for a rapid decision to be made. However, if used inappropriately and by untrained staff incorrect results can be produced and acted upon that may lead to patient harm.

3.3 This document is to provide a working directive for all areas that utilize POCT in their clinical management of a patient thereby reducing the risk to patients and staff

4.0 Scope

4.1 The policy applies to all directorates and departments who use POCT device.

5.0 Equality & Diversity

5.1 KFGH is committed to the provision of a service that is fair, accessible and meets the needs of the individual.



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6.0 Definitions



6.1 Point of care testing (POCT) device is any device can provides a diagnostic, prognostic or therapy maintenance result.

6.2 CBAHI standards are the accreditation body which assesses all Laboratory medicine & Blood bank department to ensure adherence to the international standards

6.3 Waived & Non Waived POCT : If the point-of-care testing procedures are identified by CLIA as waived while others are moderately complex. A site performing only waived tests must have a “Certificate of Waiver” license but will not be routinely inspected. They must however adhere to manufacturer’s instructions for performing the test.

“Good Laboratory Practice” dictates appropriate quality testing practices as outlined in the CLIA moderate and high complexity test requirements. These include the training of testing personnel, competency evaluation and performance of quality control.

6.4 Quality control (QC) : is a method to test if a POCT device is operationally sound. These are ideally done on a daily basis or at least prior to the use of a device. The frequency of testing is determined by the Laboratory medicine & Blood bank department.

6.5 External quality assurance /Proficiency testing (EQA) is sent out by the Laboratory medicine & Blood bank department usually on a monthly basis and it determines the safe operation of a POCT device from operator to result. It also compares the result to other users across the Saudi Arabia.

6.6 Validation

Means the confirmation by examination and the possession of objective evidence that the particular requirements for a specific intended use are fulfilled.

6.7 Verification means the application of the validation process only to a nonconforming aspect of an otherwise validated reagent (new lot).

Verification can comprise activities such as:

1. performing alternative calculations
2. comparing a new design specification with a similar design specification
3. undertaking tests and demonstrations
4. Reviewing documentation prior to issue.



TEAM MEMBERS TEAM MEMBERS

7.0 Roles & Responsibilities

7.1 The Medical director of Laboratory medicine & Blood bank department has overall responsibility to ensure the safe operation of all POCT within **KFGH**

- In conjunction with POCT group He/She is responsible for setting overall strategy and policy to support the effective identification and management of risks that are associated with the acquisition, use, maintenance and repair of POCT devices.
- Advises and assists on the appropriate procurement of POCT devices to ensure that they are clinically valid and safe and have uniformity across **the KFGH**.
- Assists with interpretation of results
- Troubleshooting where possible
- EQA coordination and interpretation
- Assistance with writing of standard operating procedure (SOP)
- Comparability to the laboratory method if available



7.2 Clinical and Service Directors are responsible for ensuring that all staff are trained and competent to use the POCT devices within their division. To ensure that the training records are shared with Laboratory medicine & Blood bank department who must hold a central bank of all those trained. They must also ensure that there is appropriate focus within their division and as advised by the POCT program to have a nominated individual within each department (**SITE POCT COORDINATOR**) who may liaise for all aspects of POCT.

7.3 Biomedical Engineering Department (BME) are responsible as follows:

- To ensure processes are in place so all devices are under appropriate service contracts and are maintained to manufacturer's guidelines
- To keep a record of all service interventions, planned and corrective maintenance
- To keep a record of all devices within **the KFGH** and to regularly update to ensure that all devices are appropriately monitored by Laboratory medicine & Blood bank department.



7.4 POCT Group/ Coordinators are responsible as follows:

- Advising the **KFGH** on the selection, procurement, maintenance, quality control (QC), external quality assurance (EQA). This group will be represented on and report to the Medical Director of Laboratory medicine & Blood bank department)
- To ensure that the POCT policy is adhered to.
- Responsible for the periodic review of the POCT policy and the terms of reference of the POCT committee
- To ensure that the POCT policy is adhered to and followed when devices are being requisitioned and to ensure that the POCT adds to the patient pathway by ensuring clinical effectiveness.

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- To be the contact point for the **KFGH** for all analytical aspects of POCT
- Will ensure the validation/verification, and implementation are appropriately completed.
- To distribute EQA
- To interpret EQA reports and to send useful feedback to the POCT users
 - Respond to areas that do not adhere to safe practice such as failing to complete QC and regular EQA participation
- Where appropriate to write SOP's for users and to offer advice to others regarding content
 - To assist with any suggested and appropriate laboratory comparisons
 - To highlight any clinical errors/queries to the POCT clinical lead

7.5 Link Persons (SITE POCT coordinator)

- To be the contact point for POCT in their clinical area
- Act as a cascade trainer.
- Ensure QC and EQA are performed
- Ensure safe use of any POCT device under the guidance of their Clinical and Service leads.
- Ensure ongoing competency of staff

All staff using/operating POCT

- Ensure that they are trained to use the equipment
- Ensure they use the equipment for its intended purpose
- Ensure they comply with this Policy
- To report any incidences involving POCT through Waqaya.
- Ensure patients using POCT equipment off site know how to use it and take appropriate care of it, including returning it to the **KFGH**

8.0 Point of Care Testing (POCT)

8.1 Rationale this is a test that sits outside of Laboratory medicine and blood bank department and its use can be beneficial in the following:

- Where clinical management in an acute setting is enhanced by the result of a diagnostic test.
- Where the result in a clinic setting will ensure more effective counseling of the patient and/or change in therapeutic management.
- Where the result ensures safe practice of further intervention.

8.2 Standard Operating Procedures (SOP)

All POCT devices must have an SOP, which is subject to regular review and are available to and followed by all operators of the device. The SOP must be written to standards required by CBAHI.

8.3 Patient Results and Connectivity.

8.3.1 Where possible all POCT should have IT connectivity to laboratory data systems. If this is not possible then the device should have localized software that can be monitored by Laboratory medicine and blood bank department, thereby acting as a reservoir of patient results should they need to be recalled.

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8.3.2 If connectivity is not possible then the results must be manually recorded in a **KFGH** approved logbook that details the following information; operator, date, patient, patient hospital number, lot number of test, result. All completed logbooks should be returned to POCT Group.

8.4 Quality Control (QC).

8.4.1 QC and EQA together ensure the safe working practice of a device and together can often detect an analytical fault that may result in wrong results being reported.

8.4.2 Following proper quality control procedures is essential. Lack of quality control can result in serious misinterpretations of test results.

8.4.3 All test procedures require that a fixed number of quality control (QC) samples be run at pre-determined intervals. QC samples are samples which contain a known concentration of the analyte being measured. If the result of the QC sample is not within its expected range, it is an indication that patient samples would give erroneous results. **If QC results are out-of-range, patient samples may not be run.**

The point of care testing coordinator will be responsible for the purchase and storage of acceptable quality control material.

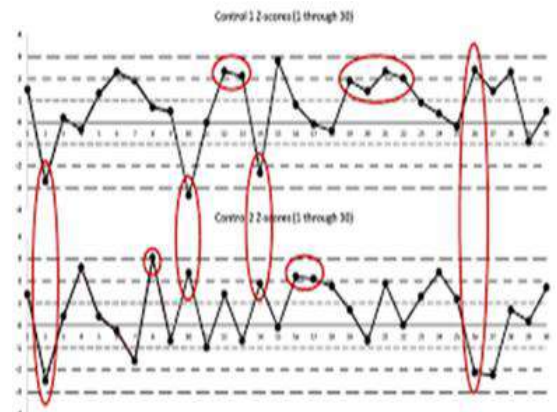
***Frequency:** The frequency of such testing depends on the assay being performed. Review the specific test procedure.

***Number:** Generally, one QC sample within the reference (normal) range is required, and at least one abnormal sample. Thus a minimum of two, and sometimes three samples are to be run each time a QC check is done. Refer to the specific test procedure.

***Expected values:** For each QC sample, the laboratory will establish the expected range. These ranges reflect the technical imprecision of the test and the biologic variation that is considered significant. The laboratory will also establish a flow sheet to aid in interpretation of the QC results, to determine whether patient results will be reliable. POCT coordinator will be available at all times to help with interpreting results of QC samples and advising whether patient testing may proceed.

8.4.4 The key performance indicator for QC testing is imprecision.

As the number of QCs tested builds up, it is possible to calculate the imprecision (or degree of reproducibility) of your QC testing on the POCT device.



Westgard Multirule System Titles

- 1_{2s} rule
- 1_{3s} rule
- 2_{2s} rule
- R_{4s} rule
- 4_{1s} rule
- $10_{\bar{x}}$ rule

Used when 2 levels of control material are analyzed per run.

Quantitative QC Module 7 2

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Imprecision, expressed as a coefficient of variation [CV%], is calculated using the formula:

$$CV\% = (\text{standard deviation [SD]}/\text{mean}) \times 100\%$$

As a general rule, the lower the imprecision, the better the performance of the device. Your local laboratory or your specialist POCT provider can help you assess whether the performance of your device meets acceptable analytical standards, as there are a set of internationally accepted analytical goals for most laboratory tests, including some common POCT tests

8.4.5 Any site that has a device must participate in regular EQA and where possible QC. If this is not adhered to it may result in the removal of devices until it is deemed safe to return them. This is not relevant to devices that patients use at home.

8.5 External Quality Assurance (proficiency testing)

8.5.1 Principles

- External Quality Assurance (EQA), sometimes referred to as Proficiency Testing, is an essential part of assuring the quality of the testing process.

-It is a system designed to objectively assess the quality of results obtained by comparing the performance of different methods and different testing sites.

-This comparison between different testing sites is often referred to as peer comparison.

-All participating health centers analyze an identical unknown specimen on their POCT equipment and send the results to the EQA provider.

-The EQA provider sends a report to the health center detailing their performance.

-EQA complements internal quality control to help assure the POCT operator and the patient that the test results are valid.

8.5.2 EQA Providers

-EQA programs are provided by suppliers known as quality assurance programs (QAP).

-For example: Perform the health center enrolls in the QAP's EQA program for the tests being performed. The -QAP will periodically send multiple specimens to the POCT operator.

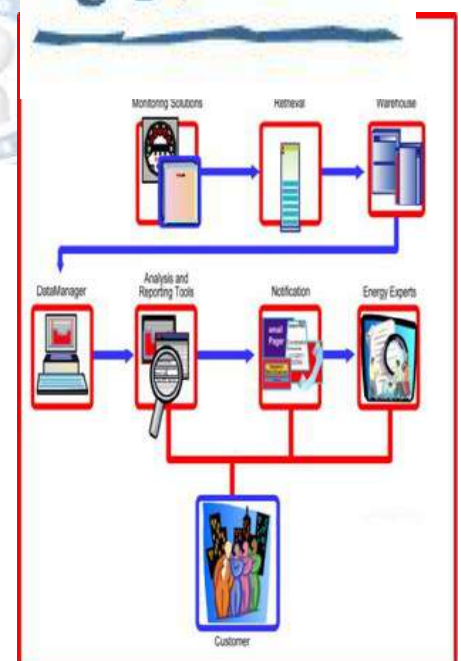
-These are tested according to a time schedule and the results returned to the QAP.

The QAP compares each health center's results with other participants and/or a "correct answer" and sends a report to the health center which shows this comparison.

8.5.3 Who Performs the EQA

-The EQA samples should be assayed in the same manner as a patient sample.

-Therefore the POCT operator who performs the patient samples should run the EQA samples.



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8.5.3 Reviewing EQA Performance

The POCT Coordinator reviews this report which shows whether the analytical performance of the POCT instrument is clinically acceptable and comparable to other users of this instrument.

-This report also allows long term monitoring of analytical performance allowing early detection of problems. -If required corrective action should be taken.

-All corrective action should be documented.

8.6 Data Capture and Reporting Results

8.6.1 The results obtained from POCT testing should at least be recorded but more appropriately, become part of the patient record.

8.6.2 While POCT should be used for tests where the result can be acted upon immediately, this does not mean that the results should be discarded; retention in the patient file remains essential.

8.6.3 An international standard is available for facilitating the connectivity of POCT devices to information systems and many purchasing organizations will only introduce POCT devices if that connectivity can be achieved.

8.6.4 IT is also integral to the POCT device itself including software that requires operator identification, patient information scanning and quality control checks before the system can be operated.

8.6.5 Desirable IT Related Capabilities of POCT Equipment

The following list includes features which are not possible on older legacy devices but are becoming more readily available on newer instruments.

- Bidirectional data communication to allow patient data to be downloaded to the device and results matched with patient data to be fed back to the information system

- Use existing infrastructure – an instrument that utilises existing communication infrastructure to capture/transfer results will avoid the costs of changing or upgrading the existing network. It is highly desirable that all POCT results be transferred electronically to an appropriate database

- Wireless connectivity for POCT devices is now available and allows more flexibility where devices are used • Security of access and data is essential to ensure patient confidentiality If results are to be transferred to outside users, intranet



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encryption of results should also be considered

- Devices should be “plug and play” in that they can be connected to any database/LIS/HIS system
- Device should use common docks, ports and wiring for communication
- Ability to scan patient barcodes to facilitate entry of patient information
- Allow regular monitoring of QC data to evaluate system performance.



9.0 Procurement of Point of Care Testing Equipment

There are two steps to the procurement of a POCT device.

9.1 The first step is to obtain the approval from the POCT Committee. This preliminary step in the procurement is to ensure the following criteria has been considered /met:

- Is there a clinical need?
- How does it benefit the patient?
- Has it been discussed with the laboratory?
- Can Laboratory medicine and blood bank department offer a solution to meet the need?
- Is it cost effective?
- Does it have end to end connectivity?
- How does it compare with the laboratory methodology?
- What devices are available in **the KFGH**?

9.2 The second step is the submission of an Authority to Invest site which is the ministry of health (regional lab) These 2 processes are shown below in a flow diagram to demonstrate the steps involved.

9.3 As per Medical Devices policy, the POCT committee are committed to the standardization of equipment across the **KFGH**. The reasons for this are as follows:

- Reduce risk to patients by ensuring equipment commonality.
- Reduce the range of consumables purchased.
- Reduce maintenance.
- Reduce training requirements.
- Reduce purchasing cost by use of competition and purchasing power.
- Reduce lifetime costs.
- Improve patient care.

9.4 Role of the POCT committee

9.4.1 To obtain approval from the POCT committee. A Point of Care Testing Request Form (Appendix 1 of this policy) should be submitted to the committee as much detail and evidence as possible should be submitted to ensure that full consideration is given. The group will review

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the application in light of the tests available in Laboratory medicine and blood bank department and what devices are available in the **KFGH**.

The committee should have representation from all major directorates to ensure that the application has full consideration. If the proposal accepted Laboratory medicine and blood bank department will offer their assistance with the regional lab /ministry of health that needs to be submitted to the Investment Group.

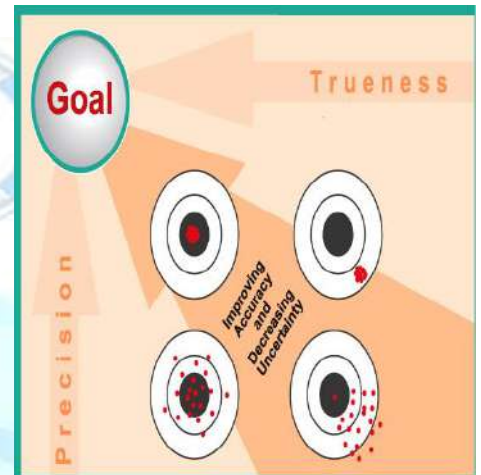
9.4.2 Role of Procurement The involvement of Procurement will depend on the device being requested and how the device will be procured but commercial and business support will be provided to ensure the needs of the **KFH** are met. This may involve application to a framework, or a tender process (**ALGHALYGY –ALMOSNAFATE**)

10.0 Equipment Evaluation

10.1 Any equipment that is to be trailed must be done with the oversight of Laboratory medicine and blood bank.

10.2 Evaluations will usually be undertaken by Laboratory medicine and blood bank which will allow where possible direct comparison with laboratory methodologies.

10.3 Informal visits of representatives and leaving equipment without prior consent from Laboratory medicine and blood bank is not permitted.



11.0 Reporting Adverse Incidents

11.1 Any incident that occurs as a result of equipment failure, failure of correct training, or other invention must be reported through .Biomedical department.

11.2 All relevant POCT incidences should be highlighted to the POCT Coordinator and the Medical director of the laboratory medicine and blood bank.

11.3 POCT incidence trends will be reviewed at the POCT committee.



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12.0 Audit

12.1 Audits will be conducted by **both KFGH** staff and where possible by POCT coordinator to ensure compliance with this policy.

12.2 The findings of the audits must be fed back to the Medical director of the laboratory medicine and blood bank and the actions will then be decided and discussed with the relevant clinical areas.

12.3 POCT audits will also be reviewed at the POCT committee



13.0 Training

13.1 Only staff that have been trained and deemed competent should operate POCT devices.

13.2 Following procurement, and installation, relevant staff must be trained, including a nominated POCT site coordinator. The training plan should initially be implemented by the manufacturer with an ideal training level of 75% of relevant staff prior to a device. The practical session should be conducted in small groups to enable each trainee to experience using the POCT technology in a practical 'hands-on' sense and gain

Confidence prior to commencing patient testing

Training should cover both the theory and practice of conducting POCT and include the following aspects as a minimum requirement:

- Setting the clinical scene (disease process and pathophysiology)
- Clinical utility and significance of the test
- Recommended frequency of performing the test
- Clinical decision limits or reference intervals
- Performance characteristics of the POCT instrument and its technical limitations
- Patient preparation and sample collection requirements (including correct preservative or anticoagulant)
- Reagent preparation and storage



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- How to perform the test on the device (including calibration)
- How to interpret, report and act on POCT results (including those outside the measuring range of the device and outside the predefined clinical decision limits for the test)
- The principles and practice of quality control and external quality assurance
 - Maintenance and common trouble shooting
 - Occupational health and safety issues including infection control practices, waste management
 - Compliance with accreditation requirements (if appropriate)



At the completion of formal training, trainee competency should be determined by written and practical assessment. Trainee competency should be assessed in a practical sense by both the successful conduct of a routine POCT test (ideally the entire testing procedure not just analytical) in the presence of the POCT Operator and by a written assessment through a series of short questions to ensure key theoretical concepts have been grasped. Successful trainees should receive a competency certificate (**POCT user Card**) at the completion of initial training.



13.3 POCT user Card:

A certificate of competency should detail a certificate number, the name of the trainee, summarise the competency skills obtained for the POCT test(s) and device(s), have a fixed expiry date (generally one or two years from the date of issue), and be signed and dated by the training organisation.



13.4 Recertification is required by regulation every six months for the first year, then annually. (Hold certified card-**POCT user card**)

13.5 If a POCT operator fails a competency review (for example because their QC/ EQA performance has been poor, their level of testing activity has fallen below minimum requirements (less 80%), or they exhibit a high rate of analytical errors with their testing), then they should be retrained before being recertified

13.6 All staff performing POCT must take a colour blindness test in order to be allowed testing privileges. Colour blind staff will not be permitted to perform test which require colour discrimination.



13.7 Regular training should be provided after the installation. Where possible the training should be a mixture of manufacturer, POCT coordinator and POCT site coordinator.

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13.8 For many devices update training is required to ensure safe practice.

13.9 A record must be maintained by each individual area and all training records must be sent to the laboratory medicine and blood bank. This record must be kept up to date.

13.10 Where possible barcodes/passwords will be issued. No operator will share these with another member of staff. This will be in line with the **KFGH** IT policy.



14. SAFETY AND WASTE DISPOSAL

14.1 It is essential that the same standard of safety and waste disposal is observed for the POCT location as for any other laboratory, hospital ward or other healthcare center.

14.2 The following procedures are for guidance and are not intended to replace the standards already established in any certified accreditation that previously exists for the location where POCT is performed.

14.3 Safety All POCT procedures should be performed in such a manner that there is no compromise to the safety or well-being of the patient or device operator:
The devices should be operated using the manufacturer's instructions
Any electrical components should be checked for safety before the instrument is first used
The device should be cleaned as per the manufacturer's instructions at the prescribed time or immediately after there has been any excess blood or body fluid contamination



14.4 Hygiene

It is important to prevent the spread of possible infection at the POCT location and hand washing is generally considered the most important measure to achieve this.

Hands should be washed: (Five moment) Using either plain soap or alcohol based hand rub

Before patient contact

After patient contact

After contact with body fluids

irrespective of whether gloves are worn or not

After removal of gloves.

Gloves should be used as an adjunct to hand hygiene when taking samples for POCT as contamination of hands with blood or body fluid can be expected. Gloves should be changed and hands washed between each patient.

Your 5 Moments for Hand Hygiene



Moment	When	Why
1	BEFORE TOUCHING A PATIENT	Clear your hands before touching a patient when approaching their care. To protect the patient against harmful germs carried on your hands.
2	BEFORE CLEAN/ASEPTIC PROCEDURE	Clear your hands immediately before performing a clean/aseptic procedure. To protect the patient against harmful germs, including the patient's own, from entering their body.
3	AFTER BODY FLUID EXPOSURE RISK	Clear your hands immediately after an exposure risk to body fluids and after glove removal. To protect yourself and the healthcare environment from harmful patient germs.
4	AFTER TOUCHING A PATIENT	Clear your hands after touching a patient and their immediate surroundings, when leaving the patient's care. To protect yourself and the healthcare environment from harmful patient germs.
5	AFTER TOUCHING PATIENT SURROUNDINGS	Clear your hands after touching any object or surface in the patient's immediate surroundings, when leaving the care of the patient but not their bedside. To protect yourself and the healthcare environment from harmful patient germs.



World Health Organization

Patient Safety
A World Alliance for Better Health Care

SAVE LIVES
Clean Your Hands

14.5 Decontamination

The instrument work area should be cleaned daily and all blood and body fluid spills cleaned up immediately. The work area should be kept clean by scrubbing with hot soapy water. This will remove rather than kill micro-organisms therefore strong scrubbing of the complete area is important.

Decontamination of the work area is necessary in the case of contamination from blood or body fluids.



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A more rigorous procedure is necessary using chlorine generating bleach (household bleach).

Use a solution of 1 part bleach to 10 parts water

Wear gloves

Remove the bulk of the contamination using absorbent towels and soapy water

Apply bleach

Leave for 10 minutes

Rinse and dry .

14.6 Waste Disposal

Sample collecting lancets and reagents (cuvettes/strips) should be considered as hazardous 'sharps' and disposed of in an approved sharps container.

Each individual device operator is responsible for the 'sharps' they have used.

Other waste material such as tissues or swabs contaminated with blood or body fluid should be disposed of in an infectious material plastic bag (yellow) and incinerated



SECTION I.3 Co-coordinator

POCT Coordinator will be responsible for:

- 1-Evaluation of instruments.
- 2-Implementation of test methods.
- 3-Training and certification of testing personnel.
 - All staff using POCT shall receive training in the correct use of the equipment and in performing the procedure, proper patient identification and preparation; specimen collection, preservation, processing and accurate result reporting.
 - A documented procedure manual must be developed for Point of Care Testing and must be conveniently available to user.
- 4-Competency testing: Some elements of competency assessment include, but are not limited to:
 - Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing.
 - Monitoring the recording and reporting of test results, including, as applicable, reporting critical results.
 - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
 - Direct observation of performance of instrument maintenance and function checks, as applicable.
 - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
 - Evaluation of problem-solving skills.
 - Competency must be reassessed at least annually. During the first year that an individual is performing such patient testing, competency must be assessed every six months. It may not be necessary to assess all of the above elements for each individual on an annual basis. The Program Director should identify and incorporate the elements most pertinent to the testing being performed.
 - Documentation of training and competency validation is maintained in the employee's unit based personnel file.
- 5-Evaluation of quality control results and corrective actions as needed.
- 6-Instrument maintenance and documentation according to manufacturer's instructions.
- 7-Continuous review of all documentation and present reports of performance to the Point of Care Testing Committee.
- 8-Monitor internal and external proficiency testing. Sub-optimal performance on proficiency testing is brought to the immediate attention of the Point-of Care Testing Committee, which determines corrective action.
- 9-Preparation of POCT policy and procedure to be reviewed by POCT committee.

Section I.4 Committee

A-COMMITTEE MEMBERS

-The POCT Committee is chaired by the Clinical Laboratory Director and includes the following people or their designees; Hospital Medical Director, POCT Coordinator, Medical Nursing, Surgical Nursing, Ambulatory Administration, Quality Improvement, Risk Management, Purchasing. Representatives, and others as necessary are invited to participate.

B-COMMITTEE Tasks

- 1-Reviews for approval all requests to establish Point-of-Care Testing taking into consideration the following issues:
 - Medical need for immediate turnaround time.
 - Procedure complexity.
 - Appropriate CLIA certification for requested testing (e.g. waived, moderately complex, PPMP, etc.).
 - Ongoing testing proficiency.
 - Cost.
- 2-Evaluation, selection and purchase of POCT equipment .
- 3-Any proposal to establish POCT testing must be referred to the POCT Committee for approval.
- 4-Clinical Laboratory personnel are assigned to assess technology available for the requested POCT testing. Vendors who market laboratory test kits, reagents, and instruments will be referred to the laboratory. The Clinical Laboratory evaluates and recommends items to the Point-of-Care Testing Committee before purchase is approved.
- 5-The Point-of-Care Testing Committee assigns oversight of the testing to the appropriate clinical laboratory staff. The department performing the testing ensures that testing complies with all pertinent accrediting agencies .
- 6-Arranges for evaluation of all POC test devices/kits by central laboratory and approves all such devices/kits before they are put into service.
- 7-All sites performing Point-of-Care testing must be authorized to do so by the POCT Committee for each test performed.
- 8-Monitors all Point-of-Care Testing sites for compliance & proficiency as required
- 9-Reviews reports of performance for all areas performing laboratory testing and recommends corrective action as necessary.
- 10-The Committee meets at least quarterly with conclusions, recommendations, and actions documented in the minutes. The Committee Chair reports annually to the Clinical Performance Improvement Committee.

SECTION I.5 Blood Gases Sampling

A-Purpose

To insure good blood gases sampling for accurate blood gases test result without any harm to the patient .

B-RESPONSIBILITY

The Point of Care Testing site staff.

2-The Point of Care testing site coordinator.

3-The Point of Care testing coordinator.

4-The laboratory medical director

C-Policy

-1-Ensure the patient understands the procedure and gives their valid consent.

Consent may not be possible in certain clinical scenarios, such as a critically ill patient with rapid decompensating or a patient with an altered level of consciousness and This should be clearly documented.

2-Inspired oxygen concentration and temperature parameters are required to interpret arterial blood gases accurately.

3-Identify possible risk of bleeding and haematoma formation post procedure and, where appropriate, to prevent puncture until coagulation is corrected.

4-Identify any areas of excoriation/infection, poor perfusion or other puncture sites. If any of these are present the site should not be used.

5- Assess maximum pulsation to ensure radial artery is optimum site for successful puncture. The dominant hand will be used to perform puncture .

6-Confirm patency of ulnar artery circulation and assess collateral circulation to the hand in the event of radial artery damage.

7- Bring the radial artery to a more superficial plane

8-Apply pressure for a minimum of 5 minutes or until no signs of bleeding are observed. Ask for assistance if necessary.

9-Minimize trauma to the artery.

D-Procedure

1- Equipment List

- Sterile dressing pack
 - Sterile gloves and apron
 - Trolley
 - Clean tray or receiver
 - Sterile gauze & tape
 - Sharps container
 - 2% Chlorhexidine in 70% alcohol wipe.
 - Pre- heparinized arterial blood gas syringe (some syringes are vented or self filling, others require user to draw back to fill – check manufacturer's instructions)
 - 23 G needle for sampling with safety device.
- 2- Explain and discuss the procedure with the patient. Obtain valid consent in all cases except in emergencies when the patient is unable to consent
- 3-Check the concentration of oxygen the patient is breathing and body temperature at time of sampling.
- 4-Check the patient's current coagulation screen, platelet count, medical history and prescription chart for anticoagulation therapy.
- 5- Prepare trolley and take to bedside.
- 6-Wash hands with soap and water.
- 7-Assume a stable and comfortable position.
- 8- Inspect and assess the tissues and anatomical structures surrounding the intended sampling site.

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7- Locate and palpate the radial artery with the middle and index fingers of the non-dominant hand..

9- Perform the modified **Allen test**

Modified Allen's Test

To determine that collateral circulation is present from the ulnar artery in the event of thrombosis of the radial artery.

- Position the patient's arm on a firm flat surface with the wrist extended (Hyperextension of the wrist should be avoided, as it will obliterate a palpable pulse).
- Compress both the radial and ulnar arteries with the index and middle fingers of both hands.
- Ask the patient to clench and unclench fist until blanching of distal skin occurs
- Release your pressure over the ulnar artery and assess skin color and refill – approximately 5 seconds after release of the artery, the extended hand should blush owing to capillary refilling. If blanching occurs, palmar arch circulation is inadequate and sampling could lead to ischaemia of the hand
- Document poor filling in the patient's notes. DO NOT proceed in the tested arm

10-Clean hands and open the pack and place equipment onto it.

11-Withdraw the plunger of the ABG syringe before the puncture.

12- Withdraw the plunger of the ABG syringe before the puncture.

13- Place a sterile field under the patient's wrist and maintain aseptic technique throughout the procedure.

14-Clean hands and then clean site with 2% chlorhexidine in 70% alcohol wipe and allow to dry.

15-Apply sterile gloves, take care not to touch the puncture site after cleaning.

16-Uncap the ABG syringe, attach the 23 G needle and hold it with two fingers of the dominant hand.

17- Angle the needle at 30–45°, with the bevel of the needle up just distal to the planned puncture site.

Whilst palpating the radial pulse proximal to the planned puncture site, advance the needle slowly, aiming in the direction of the artery until a flashing pulsation is seen in the hub of the needle.

18 -Slowly aspirate by gently pulling the plunger of the arterial gas syringe to a minimum of 1mL of blood for the sample (check recommended amount of blood as directed by manufacturer's guidelines). If using a vented sample syringe, aspiration is not required as the syringe will fill automatically.

19- Withdraw the needle, immediately followed by application of pressure using a gauze swab.

20- Discard the sharp into a sharps container. Promptly return the wrist to the neutral position following sampling.

21- Dispose of equipment safely.

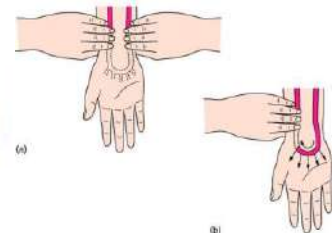
22-Expel any air bubbles from the syringe, and cap the arterial syringe

23-Label with patient's identification at the patient's bedside.

24-Send sample immediately to area of ABG analysis machines such as radiometer –istat.... Etc.

25-Check puncture site and apply a clean, sterile gauze dressing. Secure with tape.

26-Clearly document rationale for procedure in patient's notes and verbally communicate arterial analysis findings to relevant ordering doctor.



E-Forms

Competency check list for blood gases sampling

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SECTION I.6 Proficiency

A-Purpose

The purpose of this procedure is to outline the pre-analytic, analytic, and post-analytic steps for proficiency testing (PT) including alternate assessments

B-RESPONSIBILITY

- 1 The Point of Care Testing site staff.
- 2-The Point of Care testing site coordinator.
- 3-The Point of Care testing coordinator
- 4-The laboratory medical director .

C-Policy

The Point of Care Testing program adheres to the laboratory medicine & blood bank for Proficiency Testing and is enrolled in all available PT for all waived & nonwaived analytes tested by sites under the program. Alternate assessments are used for the tests performed in this lab which there is no commercially available PT. (spilt sample

I-Receipt

Ordering of Proficiency Testing

1. The Coordinator of POCT program will review available PT from MOH approved providers and order the appropriate products.
2. Order confirmation should be stored with the proficiency testing binder.
3. The POCT staff utilizes a PT tracking form to monitor the product shipment receipt, results to provider and result evaluation. The PT tracking form resides in the PT binder for the appropriate year. POCT staff will fill out the form as each step is completed. This ensures the team can identify when an issue needs to be investigated.

II- Preparation

- All survey samples will be handled according to the kit instructions. For time sensitive samples, the POCT staff will schedule the survey at a time convenient for the sites, but within the allotted survey time period.
- Sites are expected to accommodate requests from the POCT staff to complete the survey within the allotted survey time period.

D-Procedure

Failure to complete the survey may lead to discontinuation of POCT at the site

I-Testing

- 1-Survey samples will be tested in the same manner as patient samples. Results will be recorded on the proficiency testing survey.
2. Results must be submitted to the provider prior to the due date listed within the event paperwork. The POCT staff will track all sites to ensure timely submission of results.
3. Once submitted, result forms will be given to the medical Laboratory Director for review and signature of the attestation sheet.

II-Alternate Assessments(split sample)

A. Alternate assessments must be conducted according to laboratory policy. Sites that perform non-waived/waived testing for which no commercial PT products are available must have a policy to conduct proficiency testing. Refer to individual site procedures.

III-Specimen Storage

1. Specimens should be handled and stored according to the providers' kit instructions. Surveys managed by the POCT staff are stored in cold room (hematology lab) on the POCT shelf.
2. Survey samples that have sample remaining after testing should be saved under appropriate conditions until results have returned and evaluation is completed.

IV-How to handle testing cycle when shipment has not been received.

1. The shipment dates are noted on the PT tracking form. The POCT program will contact the appropriate provider to determine shipping status if the event has not arrived within 5 days after the noted shipping date.

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2. Testing sites that order and receive their own shipments must notify the POCT program immediately of missing shipments.

3. Testing events that cannot be replaced will require performance of alternate proficiency.

V- Review of PT results

1. All Proficiency Testing Results are initially reviewed by the Site Coordinator, Site Director and coordinator program within 10 business days of receipt of hard copy .Wherever possible contact your PT provider to have an email alert sent when reports are ready.

2. Complete the review and investigation (if required) using the Un satisfactory Proficiency Testing investigation form

3. The review should include when applicable:

-Evaluation of the SDI to identify possible analytical problems:

-The SDI of one results exceeds +/- 2

- Average SDI exceeds +/- 1.5

-The difference between the largest and smallest SDI is >4

-Evaluation of the graphs for patterns or trends, such as:

*. Persistent bias

*. Increase in length of bars

*. Flip in bias

- Evaluation of any un-graded analytes ; compare results to majority of respondents, described in the PT summary report that accompanies the PT report.

4. An investigation shall be completed for failures as well as indications of potential problems. Maintain copies of investigation data with raw data, report and evaluation form for future reference if needed.

5. The investigation summary should include clinical implications.

6. Remedial or corrective action should be reflected in patient testing as well as proficiency testing.

(Example: corrective action for clerical error for proficiency involved a review by a second person before submission would only be acceptable if the same process was implemented for all patient test results that are manually entered.)

7. The POCT Coordinators will ensure all PT Evaluation Worksheets are completed with the appropriate time frame. Utilizing the PT tracking form, they should follow up on all result reports not received within 1 month of submission. They will submit them to the medical Director for review and final sign off.

E-Forms"

1-Un satisfactory Proficiency Testing investigation form

2- Corrective active form

3 Proficiency testing tracking form.

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SECTION I.7 Testing Documentation & Reporting

A. Purpose

- On-going mechanisms to monitor accurate patient test management. & recording
- To improve performance and ensure high quality care for patients.

B. Responsibility

- The Point of Care Testing site staff.
- The Point of Care testing site coordinator..
- The laboratory medical director.

C. Policy

1-The Point of Care Testing site staff shall:

- Follow all procedures as written
- Only perform testing for which they are trained and certified.
- Sign off on all testing performed.
- Report and document any critical values immediately to the physician.

2-The Point of Care testing coordinator shall:

- Review all testing results (patient and controls) on a weekly basis and to document this review.
- Address with testing staff any incomplete or inaccurate testing records, any failures to follow established procedures, or any issues identified by the POCT program staff
- Forward records to the laboratory medical director monthly.

3-The laboratory medical director shall:

- Review all testing records and logs monthly
- Review proficiency results as needed

Perform periodic site visits to ensure compliance with all procedures.

D. Procedure

All testing will be documented in the Patient Medical Record and on the testing Log.

.All lot numbers and expiration dates will be documented. All controls will be indicated.

All testing personnel must sign off on the Patient Log for all testing performed.

Any unusual or unexpected test results must be followed up. Troubleshoot any technical or reagent.

If unexpected results are received, send a specimen to the laboratory and report any discrepancies to the POCT central administrative office.(Ext no 10057)

Any results exceeding established Critical Values, as defined in the procedure manual, must be verified.

The physician must be notified immediately and all actions documented. If the patient's physician is unavailable, a covering physician may be called.

All Patient Result must be filed in the patient's chart and a copy must be filed in a Point of Care Testing log book.

-Electronic recordkeeping can substitute for manual recordkeeping, if included in the procedure manual.

E-Forms &Chart

- Point of Care Testing log book.
- Critical result reporting form.
- Critical result scenario.
- Corrective Action plan Form..

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SECTION I.8 Temperature Monitoring

A-Purpose

To describe the procedure for the monitoring of room TEMPERATURE . In addition to fridges which are used for reagents store as temperature values affect test procedures or instrument operation.

B-Responsibility

The Point of Care Testing site staff.
The Point of Care testing site coordinator .
The laboratory medical director .

C-Policy

- 1-Using the log sheets for both room temperature & fridge as
 - Room temperature once /day
 - Fridge .Each 8hrs /day (three time daily)
- 2-Not use the poct operation until the temperature problem is resolved.
- 3-When the temperature is affecting fridge , notify the charge or designate who will then contact Engineering..
- 4- Document the corrective action taken

D-Procedure

- 1-Using the log sheets for both room temperature & fridge as
 - Room temperature once /day
 - Fridge .Each 8hrs /day (three time daily)
- 2-delaying instrument operation until the temperature problem is resolved
- 3-move the instrument to an area of the ward not experiencing the problem
- 4- When the temperature is affecting fridge , notify the charge or designate who will then contact Engineering..
- 5-Document the corrective action taken in the table at the bottom of the chart
- 6-Notify POCT coordinator to verify reagent quality after unscheduled maintenance

5-Forms

- 1-Temperature monitoring of fridge
- 2-Temperature monitoring of room temperature
- 3-Temperature range chart
- 4-Unscheduled Maintenance Of Instruments .

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SECTION I.9 Competency assessment of Users

A-Purpose

- On-going mechanisms to monitor accurate patient test management.
- Competency assessment is one method used to ensure that staff (employees and Medical staff) who perform Point of Care Testing are proficient in test procedure(s) and reporting test result(s).

B-Responsibility

All POCT users.

C-Policy

- All POCT users are trained and evaluated after training and thereafter will be evaluated annually for competency.
- When new test methodology or instrumentation is instituted, employees are re-trained and reevaluated.
- The POCT coordinator and department supervisors will develop a program for Competency assessment and acceptability standards based on the training protocol, procedure manual, and department policies, evaluate common group deficiencies, review current policies and procedures, and take corrective action to improve performance.
- Successful trainees should receive a competency certificate (**POCT user Card**) at the completion of initial training.

D-Procedure

I-The competency assessment includes the following as applicable:

- Direct observation of employee or Medical Staff performing test for Proper instrument use.
- Compliance with QC policy and procedures.
- Patient/specimen identification.
- Specimen procurement and handling.
- Testing of sample.
- Documenting and reporting of results.
- Knowledge of factors that influence test results.
- Troubleshooting ability.
- Adherence to standard precaution.

II- Review of records or logs:

- Review of QC records
- Review of Proficiency Testing Survey if Applicable.
- Review of corrective action log.
- Review of patient test result.

III-And / or Written examination to assess competency in:

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- Knowledge of test method , instrument , reagent , & procedure manual.
- Qc policy & procedure.
- Specimen criteria for acceptable sample .
- Test performance.
- Reporting criteria and action.
- Troubleshooting.
- Standard precaution .

The employee is expected to answer 80% of the question correctly, if less , he /she will gave opportunity to be retrained.

IV-POCT user Card:

- A certificate of competency should detail a certificate number, the name of the trainee, summarise the competency skills obtained for the POCT test(s) and device(s), have a fixed expiry date (generally one or two years from the date of issue), and be signed and dated by the training organisation.
- Recertification is required by regulation every six months for the first year, then annually. (Hold certified card-**POCT user card**).

V-Documentation

- Competency is assessed by any two methods listed above and the documents recorded in personal file.
- The supervisor will document whether the employee meets the standard.

VI-Corrective action plan

Corrective action of unsatisfactory employee will be taken and documented.

5-Forms

Competency Checklists.

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SECTION I.10 Blood or Other Body Fluid Spills

A-Purpose

To appropriately contain and disinfect spills of blood or other body fluid.

B-Responsibility

- The Point of Care testing site coordinator.
- The Point of Care Testing site staff.

C-Policy

- All members of the healthcare team will manage spills of blood or other body fluids according to facility procedure.
- Training of POCT users are done on safety precaution within the training program and revolution through competency there after .

D-Procedure

I-Spill Response Kit

A basic spill response kit containing the following items will be maintained in a sharps container or other puncture resistant container

- Utility gloves and medical examination gloves .
- (Face protection (eye wear and mask, or full face shield .
- Plastic apron or other similar article .
- Shoe covers .
- (Concentrated disinfectant (chlorine bleach .
- A container for constituting and applying 10% bleach solution .
- .-A dust pan/brush, forceps, tongs or other mechanical device to pick up sharps or broken glass .
- Package of paper towels or other suitable absorbent material .
- Biohazard bags for the collection of contaminated spill clean-up items .

II-Blood Spill Cleaning Procedure

- Household bleach is used as a standard disinfectant. An alternative disinfectant may be used provided this disinfectant is recognized as effective and used at the appropriate dilution and contact time.
- Minimize traffic in the spill area.
- Don personal protective equipment, including suitable gloves, plastic apron, face shield or goggles and fluid repellent mask, and shoe covers.
- Collect any sharp objects with forceps or other mechanical device and place in a sharps container. Do not use your hands for this purpose.
- Contain and absorb the spill with paper towels or disinfectant-soaked paper towels and place in a biohazard bag.
- Using disinfectant, clean the spill site of all visible blood.
- Spray the spill site with 10% household bleach and allow to air-dry for 15 minutes
- After the 15 minute contact time, wipe the area down with disinfectant-soaked paper towels. Discard all disposable materials used to decontaminate the spill into a biohazard bag. Decontaminate any reusable items with disinfectant.
- Send contaminated cleaning articles for reprocessing or dispose.
- Remove and dispose of personal protective equipment.
- Wash your hands .

E-Forms

- spill incident form
- Safety &infection control competency checklist .

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SECTION I.11 Color-discrimination Testing Policy

A-Purpose

To establish a procedure for the testing of individuals who may have a color impairment.

B-Responsibility of:

- POCT coordinator.
- Users (Doctors, Technicians & Nurses) involved in Point of Care Testing.
- Ophthalmologist doctors.

C-Policy

- Personnel who are involved in testing of patient samples will be evaluated for Color-discrimination Testing .
- Some ancillary test results are visually read and color differentiation should not be interpreted by those who are color-blind or visually impaired, until complete testing has been done to determine degree of impairment.
- Point of Care Coordinator or designee will conduct testing during the new POCT training and Orientation. The Concise Edition of Ishihara's Test for color Discrimination will be utilized for initial evaluation of health care provider .
- The clinic of ophthalmology will further evaluate the employee who requires additional information prior to participation in ancillary testing and determine if the employee is able to perform bedside testing procedures.
- Documentation will be forwarded to the appropriate Nurse Manager and Director of Nursing.

D-Procedure

- The plates are designed to be positioned correctly in a room that is light adequately by daylight.
- The introduction of direct sunlight or the use of electric light may produce some discrepancy in the results because of an alteration in the appearance of shades of color.
- The plates are held 75 cm. (arm's length) from the subject and tilted so that the plane of the paper is at right angles to the line of vision.
- When it is convenient only to use electric light, it should be adjusted as far as possible to resemble the effect of natural daylight..
- The numerals, which are seen on plates, are stated, and each answer should be given without more than three seconds delay.
- Plate number 11 is traceable. It is not necessary in all cases to use the whole series of plates.
- Plates 12, 13 and 14 may be omitted if the test is designed merely to separate the color defectives from those with normal color appreciation.
- An assessment of the readings of plates 1 to 11 determines the normality or defectiveness of color vision. If 10 or more plates are read normal, the color vision is regarded as normal, if only 7 or less than 7 plates read normal, the color vision is regarded as deficient
- In reference to plate 9, only those who read the numeral 2 and read it easier than those on plate 8 are recorded as abnormal. It is rare to find a person whose recording of normal answer is 9 or 8 plates. An assessment of such a case requires the use of other color vision tests.

E-Forms

- Color discrimination form.
-

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SECTION I.12 Performance Improvement

A-Purpose

- Performance Improvement (PI) is an ongoing process, encompassing all facets of the Point of Care Testing (POCT) process.
- Start from patient preparation and specimen acquisition (pre-analytical), test analysis or examination (analytical), and test result reporting (post-analytical).
- PI also extends to the interactions with and responsibilities to patients, physicians and other personnel of the facility.
- PI is evaluating, monitoring, documenting and communicating – all for the purpose of removing obstacles to quality patient testing.
- PI assures the accurate, reliable, and prompt reporting of test results.
- PI provides methods to evaluate the effectiveness of its policies and procedures.
- PI provides methods to identify and correct problems; and provides methods to assure the adequacy and competency of the staff.

B-Responsibilities

- The Point of Care Testing site staff.
- The Point of Care testing coordinator.
- The laboratory medical director.

C-Policy

General Quality Principles:

- Quality in the entire test system is of foremost importance.
- All testing personnel must be trained properly.
- The POCT site will maintain a quality control system to assure continued precision and accuracy of laboratory results.
- *The POCT site will participate in approved proficiency testing (PT) program, when applicable.
- *The POCT site coordinator and site staff will participate in PI activities as requested by the medical Laboratory Director and the POCT committee
- Each POCT site will ensure that all PI policies and procedures, evaluations of the effectiveness of these policies.
- Procedures and identification and corrective actions of identified problems area maintained in the POCT Procedure Manual.
- The policies and procedures of the PI program will be approved by the Laboratory medical Director ,when first written, by signature and date.
- The Laboratory medical Director will review the policies and procedures annually.

D-Procedure:

Data Collection and Analysis

- 1-Clinical indicators have been identified to monitor the quality of services.
- 2-These indicators are objective variables used to monitor the quality and/or appropriateness of important aspects of care.
- 3-Comparative data is collected and analyzed based on the indicators selected.
- 4-Conclusions must be made related to the comparison followed by recommendations and a plan of action formulated to solve or reduce the problem of to take the opportunity to make improvements.
- 5- Corrective action must be implemented which identifies who and what is expected to change,
 - who is responsible for implementing the action
 - what action is appropriate
 - when the change is expected to occur.

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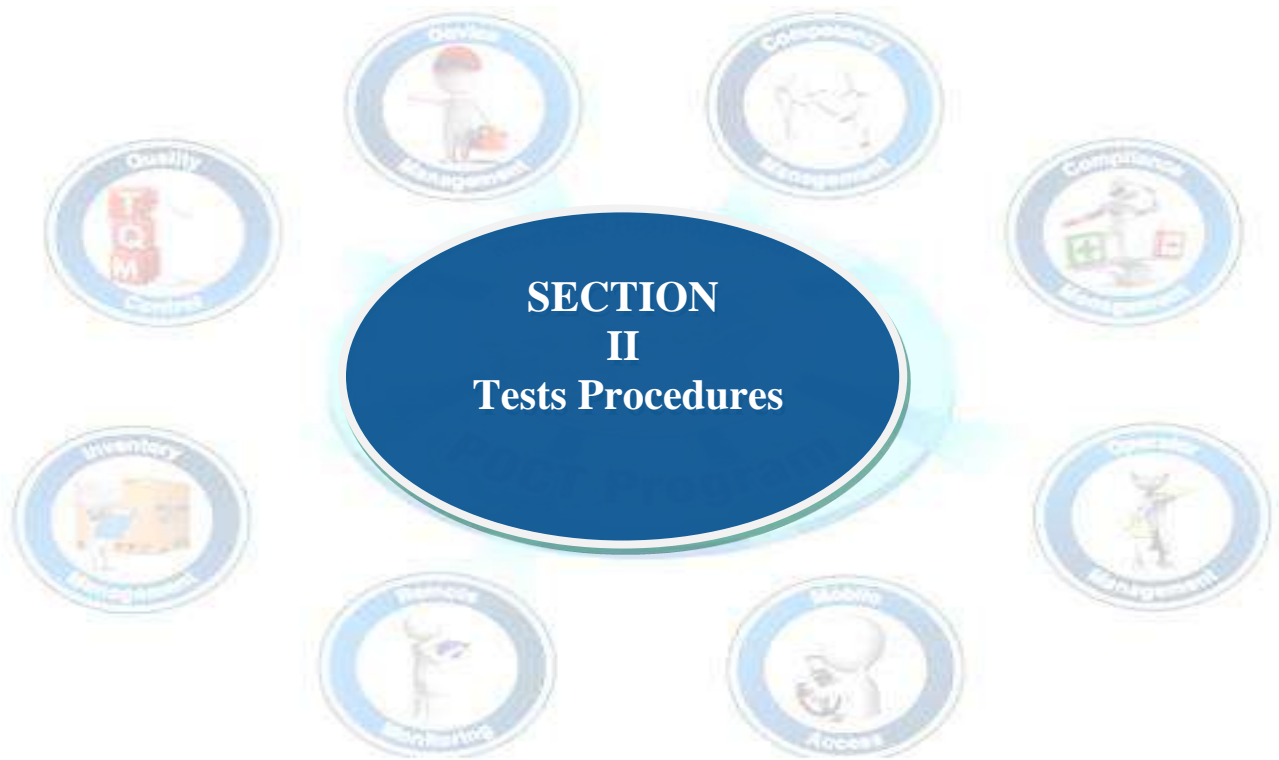
- 6- An assessment of the actions implemented must be made and improvements must be documented.
- 7- This is accomplished using the same monitoring procedures used to indicate the problem or opportunity for improvement.
- 8- This follow-up assessment will determine whether the corrective action has resulted in the expected solution.
- 9- Evaluation activities must be continued to ensure that the problem does not recur or improvement is sustained.
- 10- If there has been no resolution, a reassessment must be made and new action implemented.

E-Forms

- Point of care site inspection check list .
- Point of Care Testing (POCT) Checklist for Site Compliance.
- Quality Assurance Monitor Report..



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SECTION II.1 – Urine Dipstick - Chem

A-Purpose

- To provide optimal Urinalysis Dipstick Point of Care Testing services to our patients and to provide consultations directed to the medical staff.
- It is essential that the quality of results and timeliness of their availability are assured. The following guidelines for Urinalysis Dipsticks are a necessary step for achieving these goals and for complying with the laboratory accrediting requirements.

B-Responsibility

- The Point of Care Testing site staff.
- The Point of Care testing site coordinator .
- The laboratory medical director .

c-Policy

- Properly trained and certified physicians, nurses or qualified technical personnel may perform Urinalysis Dipstick testing outside the laboratory, under the authority and licensure of the laboratory medical director.

Principle

The Diagnostic Strips for Urinalysis Chem 10 using Bayer Multistix are firm plastic strips to which are affixed several separate reagent areas. These tests may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection.

Glucose - This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.

Bilirubin - This test is based on the coupling of bilirubin with diazotized dichloraniline in a strongly acid medium. The color ranges through various shades of tan.

Ketone - This test is based on the development of colors ranging from buff-pink, for a negative reading, to purple when acetoacetic acid reacts with nitroprusside.

Specific Gravity - This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentrations.

Blood - This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetra methylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause the color development to continue to blue.

pH - The test is based on the double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.

Protein - This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.

Urobilinogen -This test is based on a modified Ehrlich reaction, in which p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

Nitrite -This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of Gram negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h)quinolin-3-ol to produce a pink color.

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Leukocytes - Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.

D-Procedure

I-Reagents, Controls

- Clear Dry Urine Collection Container.
- Label Pen
- Multistix 10 SG
- Quantimetrix Level 1 and Level 2 Urinalysis Dipstick Controls
- Timer or Watch with a Second Hand
- Disposable medical gloves.

Reagents And Controls Must Be Labeled With: Date Received, Date Opened, Expiration Date As Well As The Signature Of The Person Putting Them Into Circulation!

- Store at room temperature between 15-30 °C .
- Do not use product after expiration date.
- Do not store the bottle in direct sunlight.
- All unused strips must remain in the original bottle.
- Do not remove desiccant from bottle.
- Do not mix lot numbers.
- Do not touch reagent areas of the reagent strips.

*The reagent tests areas are ready to use upon removal from the bottle and the entire reagent strip is disposable.

*The strips are to be read visually. Accurate timing is essential to provide optimal results. The reagent strips must be kept in the bottle with the cap tightly closed to maintain reagent activity.

* To obtain optimal results, it is necessary to use FRESH, well-mixed ,UN centrifuged urine.

*New lots of reagent will be compared against old lots by the POCT coordinator staff before new lots are placed into use.

II-Control Storage and Stability

- Store at 2-8 °C before initial use. Do not freeze. When stored at 2-8 °C, the controls are stable until the expiration date stated on the label.
- On initial use remove the controls from the refrigerator and allow to come to room temperature (25 - 25 °C), about 15 to 30 minutes.
- After the initial use, the opened Control Bottles are to be stored at room temperature. Do not store above 30 °C. When stored at room temperature (20-25 °C) the controls are stable for one month. Room temperature expiration date must be noted on the control bottle label when the bottle is opened

Universal Precautions apply.

- Clearly label a clean collection container with the patient's name and date.
- Collect 10 - 15 mL of urine in a clean container and test it as soon as possible.
- Do not centrifuge. The use of urine preservatives is not recommended.
- If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.
- Nitrite results are optimized by using a first morning specimen or one that has incubated in the bladder for four hours or more.
- Prolonged exposure to room temperature may result in microbial proliferation with the resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Bacterial growth from contaminating organisms may cause false positive blood reactions from the peroxidases produced. In random urine

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specimens from females.' a positive result for leukocytes may be due to a source external to the urinary tract.

III-Quality Control

For optimum performance, accuracy of reagent strips must be confirmed and documented by testing known negative and positive controls once per day if patients are tested, and when a new bottle of reagent strips is first opened.

Level 1 and Level 2 controls are used for this daily validation.

--Remove cap and invert bottle. While holding dipstick, gently squeeze the sides of the dropper bottle, and touch the drop of fluid to the dipstick. Draw across the reagent pads, thoroughly saturating each pad. Do not aspirate excess control back into the bottle. Turn dipstick on its side and drain excess control onto absorbent material.

-Wipe off dropper tips and recap controls.

-Read the urine dipsticks by comparing reagent blocks to the Color Chart on the label, at the proper time interval, in accordance to the Reagent Procedure.

-All control results must be documented on the testing log. Be sure control and reagent lot numbers are recorded on the log sheet.

-If controls are successful, indicate so on the Testing Log. If not, determine the cause and rectify. Document everything. Notify your POCT site supervisor or the POCT testing coordinator for technical assistance if needed.

IV-Proficiency Testing

Two split challenges are sent per year, two samples per challenge. When proficiency testing samples arrive, run them promptly, as you would patient samples, and forward the results to Point of Care office.

V-Patient Testing

-Testing should be performed with adequate lighting. Inadequate light can lead to incorrect color comparisons. Testing should not be done by those with limited color discrimination, or those who have not yet been tested for color discrimination.

-Collect FRESH urine specimen in a clean, dry container. Label specimen container with patient's name (preferably before giving it to the patient). Wear disposable medical gloves.

-Mix urine well immediately before testing.

-Remove one strip from bottle and replace cap.

-Completely immerse reagent areas of the strip in FRESH urine and remove immediately to avoid dissolving out reagents.

-While removing, run the edge of the strip against the rim of the urine container to remove excess urine.

-Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent area and / or contamination.

*Visually compare reagent area to corresponding Color Chart on the bottle label at the time specified.

HOLD STRIP CLOSE TO COLOR BLOCKS AND MATCH CAREFULLY. Avoid laying the strip directly on the Color Chart, as this will result in the urine soiling the chart.

**Proper read time is critical for optimal results:

- Glucose and bilirubin at 30 seconds after dipping
- Ketone test at 40 seconds
- Specific gravity at 45 seconds
- pH, protein, urobilinogen, blood and nitrite at 60 seconds
- Leukocytes at 2 minutes.

VI-Results And Interpretation

Results with the Diagnostics Reagent Strips are obtained in clinically meaningful units directly from the Color Chart comparison. All expected reference ranges are indicated on the Patient Result Form.

A routine urinalysis includes reporting of:

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- 1-Appearance: Clear, Hazy, Cloudy, Turbid
- 2-Color: Colorless, Straw, Yellow, Amber, Etc.
- 3- Specific Gravity: Note Result
- 4- Leukocyte Esterase: Negative, Trace, 1 +, 2 +, 3 +
- 5- Nitrite: Positive or Negative
- 6- pH: 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0
- 7- Protein: Negative, Trace, 1 +, 2 +, 3 +, 4 +
- 8- Glucose: Negative, Trace, 1 +, 2 +, 3 +, 4 +
- 9-Ketones: Negative, Trace, Small, Moderate, Large
- 10-Blood: Negative, Trace, 1 +, 2 +, 3 +, 4 +
- 11-Bilirubin: Negative, Small, Moderate or Large.
- 12-Urobilinogen: 0.2, 1.0, 2.0, 4.0, 8.0

Note: If results are not expected levels, send a specimen to the laboratory. Report to POCT coordinator any significant differences in POCT level vs. laboratory level.

G-URINE Normal Reference rang

Color: NR straw-yellow	Appearance: NR Clear-Hazy
Urobilinogen:NR Up to 1 mg/dl	Nitrites:NR negative
Blood:NR	Ketone:NR Negative
Specific Gravity:NR 1.010-1.030	Leukocytes:NR Negative
Protein:NR Negative-Trace	pH:NR 4.5-8.0
Bilirubin:NR Negative	Glucose:NR Negative

VII-Documentation:

All patient results are to be recorded on the Result Log and in the patient's record.
All reference ranges are noted on the Reference Range sheet that should be in each patient's chart.

VIII-Limitations

- *As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.
- *All positive results should be confirmed and/or followed-up by repeat testing at the laboratory.
- Electronic recordkeeping can substitute for manual recordkeeping, if included in the procedure manual.

E-Forms

- QC daily check list
- Point of Care Testing patient result log book
- Temperature monitoring of fridge
- Temperature monitoring of room temperature.

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SECTION II.2 – Blood Glucose

A-Purpose

To determine quantitative blood glucose at the bedside and deliver an accurate and fast result to improve patient care and patient outcome.

B-Responsibilities

- The Point of Care Testing site staff.
- The Point of Care testing site coordinator .
- The laboratory medical director .

C-Policy

- Glucose in the blood reacts with the enzyme NAD-glucose dehydrogenase on the test strip. The chemical reaction releases NADH, which then reduces Phenanthroline quinine.
- A voltage is applied across the test strip.
- The current generated from the sample is proportional to the concentration of glucose in the sample.

D-Procedure

I-Reagents & Supplies:

- Test Strips
- Lancets & Lancing Device
- Control solutions

II-Reagent Storage and Stability

- FreeStyle Optium H Blood Glucose Test Strips are sealed in individual foil packets
- Store the test strips at temperatures between 4° and 30°C. Storage outside this range may cause erroneous results.Keep away from direct sunlight and heat.
- Do not use the test strips beyond the expiry date printed on the foil packet and outer box.
- Use the test strip immediately after opening the foil packet.
- Do not use wet, bent, scratched or damaged test strips.
- Use the test strip only once and then discard.
- Use FreeStyle Optium H Blood Glucose Test Strips only with the FreeStyle Optium H Meter.

III-Specimen Collection:

- The patient identification must be verified by the operator by following the hospital patient identification policy. Medical Record number and Patient full name must be verified before specimen collection.
- Safety and Infection control Standard precautions must be followed accordingly with hospital policies & procedure for collecting and handling blood specimens.(Please review lab safety IPPs; Sample Collection and Preparation)
- FreeStyle Optium H Blood Glucose Test Strips are designed for use with fresh whole blood samples.
- Before obtaining a fingertip blood sample, clean and dry the sample site completely. The presence of alcohol can result in an error code/inaccurate results. If possible hang the arm down before lancing the finger to increase the blood flow. Use the sample immediately.
- Venous or arterial whole blood samples collected in tubes containing heparin or EDTA can be used within 30 min. Do not use tubes containing fluoride or oxalate

IV-Procedure of analysis

- *Clean and dry the sample site completely.
- *Open the test strip packet by tearing at the notch.
- *Insert the contact bars into the test port.
- *Push the test strip into the test port until it stops.
- *Lance the finger to obtain a drop of blood.
- *Touch blood drop to white target area at tip of test strip while the Apply Sample prompt appears in the display window.
- *Hold finger in place until test begins.
- *Test will start when sample is detected.

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*The following messages may mean there is a blood glucose result that requires immediate attention or there may be a problem with the test strip:

- LO means the blood glucose may be lower than 20 mg/dL (1.1 mmol/L).
- HI means the blood glucose may be higher than 500 mg/dL (27.8 mmol/L).
- Test. Error E-3 means there may be a test error.
- Test Error E-4 means the blood glucose may be too high to be read by the system.
- If any of these messages show, check that the meter is calibrated correctly and repeat the test with a new test strip.

V-Limitations of Procedure

- This test strip is not designed for use with serum or plasma samples.
- Blood glucose results are displayed as mg/dL or mmol/L. It is important that you confirm the correct unit of measure is displayed on your meter with each test result. If you have questions about the unit of measure on your meter, please contact Customer Service.
- Use between 15° and 40°C and 10% and 90% relative humidity for best results.
- Haematocrit range is 20%-70%.
- Test results may be erroneously low if the patient is severely dehydrated, severely hypotensive, in shock or in a hyperglycaemic-hyperosmolar state (with or without ketosis).
- Do not use during intravenous infusion of high-dose ascorbic acid or during xylose absorption testing.

VI-Calibration

- The Freestyle Optium H meter must be calibrated for every new box of test strips using the calibrator strip supplied in box. Failure to calibrate properly will cause incorrect results.
- With the lot number facing upward, insert the contact bars of the calibrator into the monitor. The monitor will turn on automatically.
- The lot number of the calibrator strip and test strip foil package will appear in the display window
- Check that the last 5 digits of the lot number on the test strip foil packet and test strip insert match the 5 digits on the meter display and test strip calibrator. Calibration is complete.
- Use only the calibrator supplied with the test strips. Keep the calibrator until all the test strips in the box have been used then discard the calibration strip.

VII-Quality Control (QC)

- Low and High controls must be performed on each individual Freestyle Optium H glucose meter daily. Quality control must be performed prior to testing a patient sample.
- QC ranges are located on the package insert of Test strips. Retain package insert until box of test strips has been used.

- *Remove a test strip from its foil package
- *Insert the three black lines at the end of the test strip into the strip port.
- *Push the test strip in until it stops – the meter turns on automatically.
- *Check date and time displayed are ok
- *Check lot number for box of test strips
- *To mark the test as a control test, Press and Release the middle button once. A QC bottle will be displayed.
- *Apply control solution to the test strip and the meter begins the test.
- *When the test is complete the control result will be displayed in the display window. Record the result in the QC record book.
- *If QC is acceptable proceed with patient testing.
- *If QC is outside manufacturers limits repeat. If the QC is still out contact the Abbott.
- *Control results and ranges should be documented and signed by the users (Daily QC sheet).
- *Control and test runs are only carried out by authorized certified POCT users.
- *Corrective actions should be carried out, documented in the attached log sheet and signed by the operator for each Control failure.
- *POCT coordinator will be responsible for submitting monthly QC chart to the lab medical director
- *Medical director and POCT coordinator will be responsible for education, training and certification of all POCT users.
- *POCT Coordinator is responsible for monitoring the performance and Competency of the users

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*Annual renewal of certified personnel will be based on their competency assessment

*Comparison of patients' results should be performed between all Freestyle Optium H glucose meters located outside the lab and blood glucose measuring device in the lab every 6 months to ensure that all machines in different department work properly.

VIII-Proficiency testing

should be performed periodically and monitored by POCT Coordinator

IX-Maintenance

-Avoid getting dirt, dust, blood, control solution, or liquid in the meter test strip port.

-Clean the outside of the meter using a damp cloth and mild soap. It is acceptable to clean surface with 70% Alcohol or 10% bleach or 10% Ammonia.

-Do not clean the strip port .

-Do not pour liquid into the strip port or onto the buttons.

-Do not immerse the meter in water or other liquid.

-The meter will display a small battery icon when it is necessary to change the battery.

-Periodic maintenance checking should be documented according to manufacturer instruction.

-A log book should be available near by the machine to sign and to report messages.

-Unscheduled maintenance should be documented in the attached log sheet.

X-Result Reporting

Report blood glucose result to physician.

Document all results on HIS in the patient file Or result log sheet.

XI-Reference rang

-Fasting whole blood glucose:65-95 mg/dL.

-Postprandial whole blood glucose<126.

N-Critical result

Lower limit: 36 mg/dl

Upper limit: 405 mg/dl

* Criteria for sending specimen to the laboratory:

-If patient result does not correlate with the clinical presentation, the test should be repeated. If the result is still unexpected, a blood specimen should be sent to the laboratory

-If the patients result equal or exceed the critical values as mentioned before.

E-Forms

-Daily Qc Of glucometer.

-Glucometer maintenance check list.

-Patient LOG for Glucometer.

-Patient LOG For Glucose Critical Result Reporting.

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SECTION II.3– Blood Gases

A-Purpose

How to process and analyze ABG samples properly on ABL™ 800 and RAPIDLAB 1265 .

B-Responsibilities

- The Point of Care Testing site staff.
- The Point of Care testing site coordinator.
- The laboratory medical director .

C-Policy

ABL™ 800 and RAPIDLAB 1265 are a modular analyzers measuring blood gases, electrolytes, oxygen saturation and total Hb in whole Blood.

P02 : Use the amperometry Clark measurement principle: measurement of current generated by the reduction of oxygen

PCO2: Use of Severinghouse principle: potentiometric measurement of the pH change in the electrode caused by CO2.

pH, Sodium, Potassium, are potentiometric electrodes.

tHb and sO₂: Light absorption in whole blood is measured at four different wavelengths.

D-Procedure

I- SPECIMEN COLLECTION AND HANDLING

Identification of blood sampling should be performed by authorized personnel only.

- The samples is basically arterial but it could be venous or capillary
- Samples should be withdrawn in a syringe coated with neutral heparin which is the **only anticoagulant allowed**
- Thoroughly mixing immediately of blood samples is a must.
- Air bubbles should be removed before capping the syringe.
- Properly label the sample following standard procedure with full name, medical record number, date and time of sample collection.
- Safety and infection control standard precautions must be followed when collecting and handling blood specimens.
- The sample should be analyzed immediately. If samples are not analyzed within 10 minutes, it should be kept on ice for a maximum of 30 minutes.
- Dirt or clogs in sample spaces may cause slow equilibration of the temperature of the sample and interfere with the analyses of samples correctly.
- Segmenting of the sample stream upon insertion may place voids opposite the electrodes, so uninterrupted introduction of the sample is necessary.
- Ensure adequate mixing of the sample since homogeneous distribution of blood cells through the sample is necessary because junction potentials of the electrodes are sensitive to the presence of erythrocytes.

II-Procedure Of Analysis

- For **ABL800** basic and **RAPIDLAB 1265** Check the analyzer is in the ready mode.
- For **ABL 800** Lift the syringe inlet flap and **Insert** sample
- For **RAPIDLAB 1265** insert the sample directly into sample port.
- Select Mode for both machines (arterial, venous or capillary)
- *Press Start.

The needle will move out of the inlet or out of sample port into the syringe to aspirate the sample.

*Enter the information on the patient Identification screen. For more details refer to (Sampling procedures in ABL™ 800 basic Operator's Manual or if you use **RAPIDLAB 1265** you can see the operator guide manual)

*Be aware of the aspiration time of samples which appears on devices touch screen then remove the sample and print the result.

III-Quality Control

- QC with the 4 levels for ABL 800 and 3 levels for RAPIDLAB 1265 should be carried out for accurate performance.
- QC must be run once every 8 hours for both machines.

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*FOR ABL 800 Basic Control solutions are packed in ampoule boxes .

Each ampoule box contains an insert sheet with the BARCODE that contain control range and expiry date for particular lot of control boxes.

*FOR RAPIDLAB 1265 Control cartridge located inside the machine will run automatically.

The range of different parameters programmed previously by service application

-Control results and ranges should be documented and signed by the users (Daily QC sheet)

-Control and test runs are only carried out by authorized certified POCT users

-Corrective actions should be carried out, documented in the attached log sheet and signed by the operator for each Control failure.

-POCT coordinator will be responsible for submitting monthly QC chart to the lab medical director.

-Additional QC should be performed after any troubleshooting or preventative maintenance, which might alter performance.

-Medical director and POCT coordinator will be responsible for education, training and certification of all POCT users

-POCT Coordinator is responsible for monitoring the performance and Competency of the users.

-Annual renewal of certified personnel will be based on their competency assessment.

-Comparison of patients' results should be performed between blood gases machines located outside the lab and blood gas device in the lab every 6 months to ensure that all machines in different department work properly.

IV-Proficiency testing

should be performed periodically and monitored by POCT Coordinator

V-Maintenance

-Maintenance schedule log sheet should be placed on each machine, periodic maintenance checking should be documented according to manufacturer instruction.

-A log book should be available near by the machine to sign and to report messages

-Unscheduled maintenance should be documented in the attached log sheet.

VI-RESULT REPORTING

-Report blood gases and electrolytes results immediately to physician

-Document all results on HIS in the patient file.

VII-Reference Range

Blood gases Test	Units	Gender	Reference range	Specimen
pH		both	7.35-7.45	Arterial
PCO ₂	mm Hg	male	35-48	Arterial
		female	32-45	Arterial
tCO ₂ (HCO ₃) ⁻	mEQ/L	both	19-24	Arterial
PO ₂	mm Hg	both	83-108	Arterial
sO ₂	% saturation	both	94-98	Arterial
BE		both	±2	Arterial

VIII -Critical Value

Blood gases Test	Units	Lower limit	Upper limit	Specimen
pH		7.2	7.6	Arterial, capillary
PCO ₂	mm Hg	20	70	Arterial, capillary
tCO ₂ (HCO ₃)	mEQ/L	10	40	Arterial
PO ₂	mm Hg	40	-----	Arterial
PO ₂ (children)	mm Hg	45	125	Arterial
PO ₂ (newborn)	mm Hg	35	90	Arterial

Criteria for sending specimen to the laboratory:

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- If patient result does not correlate with the clinical presentation, the test should be repeated. If the result is still unexpected, a blood specimen should be sent to the laboratory
- If the patients result equal or exceed the critical values as mentioned before.

E-Forms

- Daily Qc Of Blood gases.
- Blood gases maintenance check list.
- Patient LOG For Blood gases Critical Result Reporting.



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SECTION II.4– I stat Pro-time

A-Purpose

- The i-STAT PT/INR test is a whole blood determination of the prothrombin time used for monitoring oral anticoagulant (warfarin) therapy.
- The test determines the time required for complete activation of the extrinsic pathway of the coagulation cascade when initiated (activated) with a thromboplastin.
- The PT/INR test result is reported as an International Normalized Ratio (INR) and, optionally, in seconds. The INR is the recommended method of result reporting for monitoring of oral anticoagulant therapy.

B-Responsibilities

- The Point of Care Testing site staff.
- The Point of Care testing site coordinator.
- The laboratory medical director .

C- Policy

Properly trained and certified physicians, nurses or qualified technical personnel may perform PT/INR by Istat procedure testing outside the laboratory, under the authority and licensure of the laboratory medical director.

D-Procedure

I-Specimen Collection

***Suitable Specimens for PT/INR**

- Fresh whole blood without anticoagulant collected in a plastic syringe or plastic evacuated tube without clot activators or serum separators. Device used to transfer sample to cartridge must be plastic.
- Fresh capillary whole blood dispensed directly into the cartridge from the finger

***Criteria for Specimen Rejection**

- Evidence of clotting
- Specimens collected in glass syringes or tubes or with anticoagulant of any kind
- Other sample types such as urine, CSF, and pleural fluid

***NOTE: Avoid the Following Circumstances**

- Drawing a specimen from an arm with an I.V.
- Stasis (tourniquet left on longer than one minute before venipuncture)
- Extra muscle activity (fist pumping)
- Hemolysis (alcohol left over puncture site, or a traumatic draw)
- Icing before filling cartridge
- Time delays before filling cartridge

II-Reagent Storage Requirements

***Verification of Cartridge Storage Conditions during Shipment**

-On receipt of new cartridges, Perform liquid QC on the cartridges and document results on the Record of QC Documentation Log.

***A. Refrigerated cartridges**

- Store at 2 - 8 °C. Do not allow cartridges to freeze.
- Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Do not use after expiration date.
- Verify that the refrigerator did not exceed the limits of 2° to 8°C.
- Record the temperature of refrigerator on temperature log sheet.
- Cartridges must remain in pouches until time of use. Do not use cartridge if pouch has been punctured.
- Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

***Remedial Action:**

- If the temperature is outside the range of 2° to 8°C, quarantine the cartridges in the storage refrigerator.
- Notify the Site Coordinator of the temperature failure.
- DO NOT USE the cartridges from this refrigerator.

B. Room temperature cartridges:

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- Cartridges at room temperature 18° to 30°C are good for 14 days. Mark the room temperature expiration date on each cartridge.
- Do not return cartridges to the refrigerator once they have been at room temperature.
- Record the daily room temperature on temperature log sheet
- Return any cartridges that are beyond the 14-day room temperature stability to the site coordinator for tracking purposes.

C. i-STAT PT/INR Liquid Controls, Levels 1 and 2

- Store at 2 to 8 C.
- Do not use after expiration date on box and ampoules.
- Record date and time removed from refrigeration. Control solutions may be stored at room temperature for up to 4 hours. If left out longer than 4 hours at room temperature, they should be discarded.

III-Quality Control

Prior to performing quality control, determine if additional preparation is required.

Liquid Control preparation:

***PT/INR Control Level 1 and Level 2**

- + i-Stat PT/INR controls are contained in 6-ml vials. Separate 6 ml vials contain 103 ml of calcium chloride solution for reconstitution.
- Prior to testing, vials containing the lyophilized plasma and CaCl₂ reconstituting fluid should stand at room temperature for a minimum of 45 minutes.
- Reconstitute only one level of control plasma at a time. **CONTROL SOLUTIONS MUST BE USED IMMEDIATELY** (less than 30 seconds) **AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.** Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial.
- Allow the vial to sit at room temperature for 1 minute
- Mix the contents by swirling gently for 1 minute, then inverting slowly for 30 seconds.
- Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard the reconstituted fluid and start over with fresh vials.
- Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the PT/INR cartridge. **NOTE:** additional PT/INR cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

***Running the controls:**

- Put on gloves.
- Press the On/Off key
- Press the Menu key
- Press 3 to select Quality Tests.

NOTE: Always remember to analyze control materials in the Control pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration Menu. Do not analyze controls under the Patient Test pathway. This must be done before inserting the test cartridge into the analyzer. The analyzer allows 15 minutes to insert the cartridge after the last keystroke.

- Press 1 to select Control.
- Press "Scan" to scan Operator ID
- Press "Scan" to scan Control Lot number
- Press "Scan" to scan the cartridge lot number from the box or manually enter the number using the keypad and press Enter.
- Fill cartridge with the control (see below). Insert cartridge.
- Enter 1 for i-STAT Level 1. Enter 2 for i-STAT Level 2.
- Results will appear. At the bottom of one of the result pages, you will see 1- Test Options
- Select 1.
- You will now have the following options:
 - Next level
 - Repeat level
 - History

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Using these options will allow you to continue your Quality Control testing without having to start again at the top of the QC menu.

Control Evaluation:

1. Document results on the Record of QC Documentation Log and compare results to the ranges to determine acceptability.
2. The operator performing the quality controls is responsible for evaluating the controls and performing any necessary corrective actions. If the results are out of range, corrective action must be documented on the Record of QC Documentation Log.
3. If all results are within expected ranges, use the cartridges as needed. Transmit the results when finished.
4. The result statistics will be reviewed monthly by the Medical director.

***Quality Control Corrective Action:**

1. If any liquid control result is unacceptable, patient testing can not be performed until the problem has been resolved. Use another analyzer or send the specimen to the Clinical Laboratory.
 2. Repeat any out of range control, verifying that the control procedure above has been followed carefully.
 3. Document all the results and corrective actions on Record of QC Documentation Log
 4. If new control solutions fail a second time, analyzer, control solutions and cartridges should be pulled from use and the POCT program notified ([10075](#)).
- An investigation will be done to determine the cause of failure.

IV-Testing Procedure

Caution: The i-STAT PT/INR cartridge is designed to accept a sample between 20 and 45 micro liters.

A single drop of blood from either a finger puncture or as formed at the tip of a syringe will typically be within this range. If a larger volume is delivered to the sample well, use caution when closing the cartridge as excess blood may be expelled from the cartridge. The i-STAT PT/INR test can be performed using capillary or venous samples.

***Finger Stick:**

1. Follow hand hygiene protocol and put on gloves.
2. Turn the analyzer on and press 2 for i-STAT Cartridge.
3. Scan or enter the operator ID and patient ID. Repeat if prompted.
4. Remove cartridge from foil pouch and place the cartridge on a flat surface. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
5. Prepare lancet device and set aside until needed.
6. Clean and prepare the finger to be sampled. Allow finger to dry thoroughly before sampling.
7. Prick the bottom side of the fingertip with the lancet device.
8. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first drop of blood. **Avoid strong repetitive pressure (“milking”)** as it may cause hemolysis or tissue fluid contamination of the specimen.
9. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
10. Apply sample until it reaches the fill mark indicated on the cartridge.
11. Fold the sample closure over the sample well.
12. Press the rounded end of the closure until it snaps into place.
13. Insert the cartridge into the cartridge port until it clicks into place. When using a PT/INR cartridge, the analyzer must remain on a level, vibration-free surface with the display facing up during the testing cycle.
14. Select tests to be reported.
15. Enter additional parameters on the Chart page if required:
 - Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
 - Patient temperature can be entered as degrees Centigrade .
 - FIO2 can be entered as the numbers of liters or as a percentage of oxygen a patient is receiving
 - Press the → key to return to the results page
16. View results shown on the analyzer’s display screen.
17. Remove the cartridge after “Cartridge Locked” message disappears. The analyzer is ready for the next test.

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18. Remove gloves and perform hand hygiene.

Venipuncture:

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device **cannot contain clot activators or serum separators**.
- If a second measurement is required, a fresh sample should be obtained.
- Note: Some experts recommend drawing and discarding a (venous) sample of at least 1.0 mL prior to drawing sample for coagulation testing.

1. Follow hand hygiene protocol and put on gloves.
2. Turn the analyzer on and press 2 for i-STAT Cartridge.
3. Scan or enter the operator ID and patient CSN. Repeat if prompted.
4. Remove cartridge from foil pouch and place the cartridge on a flat surface Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
5. Apply sample until it reaches the fill mark indicated on the cartridge.
6. Fold the sample closure over the sample well.
7. Press the rounded end of the closure until it snaps into place.
8. Insert the cartridge into the cartridge port until it clicks into place. When using a PT/INR cartridge, the analyzer must remain on a level, vibration-free surface with the display facing up during the testing cycle.
9. Select tests to be reported.
10. Enter additional parameters on the Chart page if required:
 - Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
 - Patient temperature can be entered as degrees Centigrade or Fahrenheit
 - FIO2 can be entered as the numbers of liters or as a percentage of oxygen a patient is receiving
 - Press the → key to return to the results page
11. View results shown on the analyzer's display screen.
12. Remove the cartridge after "Cartridge Locked" message disappears. The analyzer is ready for the next test.
13. Remove gloves and perform hand hygiene

V-Documentation

Dock meter after each test performed to transmit results. During network downtime, results are held in analyzer until they can be transmitted to patients' electronic medical record

VI-Reference Ranges

The tested ranges are those ranges that were tested during functional sensitivity and linearity testing.

TEST	Reference Range	Critical Value Range	Analytical Range
PT/INR	* PT 11.0-13.7 sec (age 6 months to adult) *PT-INR values for Warfarin Anti-Coag Therapy: -Standard 2.0-3.0 -High Intensity 2.5- 3.5	INR >5 POCT INR >5 Core Lab	0.9-8.0

VII-Troubleshooting

A. Analyzer:

1. **No display:** Either if the display screen remains blank, after a cartridge has been properly inserted or after the On/Off key has been pressed, the batteries should be replaced.
2. **Cartridge Locked:** Cartridge Locked appears on the screen during the testing cycle to indicate that the cartridge or simulator is locked in the analyzer and should not be removed. **A cartridge or simulator must be removed only after the Cartridge Locked prompt disappears from the screen.** Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the Cartridge Locked prompt will remain on the screen. If this occurs, wait until the analyzer deactivates (display screen blank) and press the On/Off key. The analyzer will try to reset. **If the Cartridge Locked prompt**

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does not disappear, do not attempt to remove the cartridge. Contact the Point of Care Testing program: (10057)

3. **Low Battery:** Recharge battery in Downloader/Recharge or swap with extra rechargeable battery.
4. **Electronic simulator fail** will appear if the analyzer has not successfully completed the electronic simulator test..
5. **CLEW expiring, Upgrade required,** Point of Care Testing would need to perform a software update.
6. **Messages and Quality Check Codes:** If a problem is detected during a testing cycle, the cycle will be stopped and a message box will appear on the screen. The messages will identify the code number. Refer to i-STAT's technical bulletin(s) to determine the meaning of the code number and the suggested action. If the analyzer deactivates before the detected problem is addressed, the message box will reappear the next time the On/Off key is pressed. Document all problems on the Instrument Corrective Action Log and notify Point of Care Testing.

□ **Temperature out of Range error message:** The analyzer must be moved to an area where the temperature is between 18-30° C. Equilibration can take up to 30 minutes.

□ **Other error messages:** Refer to the Point of Care Testing program:(10057)

7. **i-STAT Dropped:** Run simulator prior to patient testing.
8. **Power Outage or Disaster scenario:** Adaptors are available from the POCT program to allow i-STAT to run on regular 9V batteries. Contact the POCT program for assistance.

B. Cartridge: * Instead of Results:**

1. Test the patient specimen with a new cartridge. If *** reappears, send the sample to the Clinical Laboratory for analysis. The sample may contain a substance that interferes with the test.

2. If *** are obtained for the same test performed on an additional (different) patient, contact Point of Care Testing for assistance: the Point of Care Testing program: (10057)

. (This problem may have been caused by improper cartridge storage).

Technical support may be contacted 24 hours x 7 days at 0501117506.

VIII-Alternative method

Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory service guide

E- Forms

QC documentation log.

Point of Care Testing patient result log book.

Temperature monitoring of fridge .

Temperature monitoring of room temperature.

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SECTION II.5– I stat CG4 &CG8

A-Purpose

-The CG8+ cartridge is designed to directly measure glucose, sodium, potassium, ionized calcium, Hematocrit, pH, pCO₂, and pO₂, while calculating values for hemoglobin, TCO₂, HCO₃, BE and sO₂. The CG4+ cartridge directly measures pH, pCO₂, and pO₂, and lactate and calculates values for TCO₂, HCO₃, BE and sO₂. The G3+ is similar to the CG4+, except that lactate is not measured.

B-Responsibilities

- The Point of Care Testing site staff.
- The Point of Care testing site coordinator .
- The laboratory medical director.

C-Policy

-Properly trained and certified physicians, nurses or qualified technical personnel may perform point of care testing outside the laboratory, under the authority and licensure of the laboratory medical director.

Principle

***Sodium, Potassium, Ionized Calcium, pH, and pCO₂**

These analytes are measured potentiometrically by ion-selective electrode. Concentrations are calculated from the measured potential through the Nernst equation.

-**Sodium and potassium** test results are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea.

-**Ionized calcium** is the biologically active fraction of calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, and neuromuscular transmission and in muscle contraction. Measurements of ionized calcium may be particularly useful under these clinical conditions: transfusion of citrated blood, liver transplantation, open-heart surgery, neonatal hypocalcaemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

- **pH** is an index of the acidity or alkalinity of the blood.

-**pCO₂**, along with **pH**, is used to assess acid-base balance. pCO₂ is the respiratory component of acid-base balance. pCO₂ represents the balance between cellular production of CO₂ and ventilatory removal of CO₂. Causes of primary respiratory acidosis (increase in pCO₂) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary metabolic acidosis are ketoacidosis, lactate acidosis and diarrhea. Causes of primary respiratory alkalosis (decrease in pCO₂) are hypoxia due to chronic heart failure, edema and neurological disorders, and mechanical hyperventilation. Causes of primary metabolic alkalosis are vomiting and antacid treatment.

- **pO₂**, a measurement of the pressure of oxygen dissolved in the blood, is measured Ampere-metrically. The oxygen permeates through a gas permeable membrane from the sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

Decreased pO₂ may be caused by ventilation problems or by alteration in the flow of blood within the heart or lungs.

- **Glucose** is measured ampere-metrically. Hydrogen peroxide, produced by the oxidation of glucose, is oxidized at an electrode to produce an electric current proportional to the glucose concentration. Glucose is the primary source of energy for the body and the only source of energy for brain tissue. Measurements of blood glucose levels are important for identification of both hypo- and hyperglycemia, as well as for managing patient treatment to maintain glucose within designated limits.

-**Lactate** is measured ampere-metrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide. The liberated hydrogen peroxide is oxidized by the platinum electrode to produce a current that is proportional to the sample concentration.

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock and hypovolemia; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease.

(The i-STAT will not be used for Hematocrit and/or hemoglobin determinations .

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D-Procedure

I-Specimen Collection

***Suitable Specimens for Cartridges for Blood Gases, Electrolytes, and Chemistries:**

- Fresh whole blood collected in a plain capillary collection tube or capillary collection tube balanced with heparin
- Fresh whole blood collected in a collection tube with lithium or sodium heparin. Fill tube to capacity
- Fresh whole blood collected in a plain plastic syringe or in a blood gas syringe.

***Criteria for Specimen Rejection:**

- Evidence of clotting
- Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin
- Syringe for pH, PCO₂ and PO₂ with air bubbles in sample
- Incompletely filled vacuum tube for the measurement of ionized calcium
- Other sample types such as urine, CSF and pleural fluid

***NOTE: Avoid the Following Circumstances**

- Drawing a specimen from an arm with an I.V
- Stasis (tourniquet left on longer than one minute before venipuncture)
- Extra muscle activity (fist pumping)
- Hemolysis (alcohol left over puncture site or a traumatic draw)
- Icing before filling cartridge
- Time delays before filling cartridge
- Exposing the sample to air when measuring pH, PCO₂ and PO₂

II-Reagent Storage Requirements

- On receipt of new cartridges, Perform liquid QC on the cartridges and document results on the Record QC Documentation Log.

A. Refrigerated cartridges

- Store at 2 - 8 C .Do not allow cartridges to freeze.
- Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Do not use after expiration date.
- Verify that the refrigerator did not exceed the limits of 2 to 8°C (35 to 46°F).
- Record the temperature of refrigerator on temperature log sheet.
- Cartridges must remain in pouches until time of use. Do not use cartridge if pouch has been punctured.
- Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one minute .

***Remedial Action:**

- If the temperature is outside the range of 2 to 8°C, quarantine the cartridges in the storage refrigerator.
- Notify the Site Coordinator of the temperature failure.
- DO NOT USE the cartridges from this refrigerator.

***B. Room temperature cartridges:**

- Cartridges at room temperature 18 to 30°C are good for 2 months. Mark the room temperature expiration date on each cartridge.
- Do not return cartridges to the refrigerator once they have been at room temperature.
- Record the daily room temperature on temperature log sheet
- Return any cartridges that are beyond the 2 month room temperature stability to the site coordinator for tracking purposes.

***C. i-STAT Aqueous Liquid Controls, Levels 1, 2 and 3**

- Store at 2 to 8 C.
- Do not use after expiration date on box and ampoules.
- Aqueous liquid controls used for oxygen measurement must stand at room temperature a minimum of 4 hours before use. Controls used for all other analytes must equilibrate for 30 minutes at room

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temperature.

-Record date and time removed from refrigeration. Aqueous liquid controls expire 5 days after removal from refrigeration

III-Quality Control

Prior to performing quality control, determine if additional preparation is required

i-STAT Aqueous Liquid Controls: (For CG6+, CG4)

1. Aqueous liquid controls require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampoule for 4 hours. If not, equilibrate the ampoule for approximately 30 minutes at room temperature.
2. Hold the ampoule at the top, bottom (with forefinger and thumb), and shake 15-20 times (about 10 seconds) to mix the solution. Tap the ampoule to restore the liquid to the bottom of the ampoule.
3. Open the ampoule by snapping off the tip. Protect fingers with gauze or use an ampoule breaker.
4. Immediately transfer control to syringe as follows: Use a clean 3 mL syringe. Replace attached needle with a 19-gauge blunt tip needle.
5. Aspirate the control from the ampoule into the syringe. Be careful that air is not drawn in with the liquid. Expel one or two drops of liquid before filling the cartridge. If desired, you may detach the blunt tip needle before filling the cartridge.
6. Immediately transfer the solution into a cartridge.
7. Immediately seal the cartridge and insert it into an analyzer.
8. Do not use the solution left in a syringe or ampoule for additional testing of cartridges that contain sensors for ionized calcium, pH, PCO₂, or PO₂. Open a new ampoule.

Running the controls:

1. Put on gloves.
2. Press the On/Off key
3. Press the Menu key
4. Press 3 to select Quality Tests.

NOTE: *Always remember to analyze control materials in the Control pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration Menu. Do not analyze controls under the Patient Test pathway. This must be done before inserting the test cartridge into the analyzer. The analyzer allows 15 minutes to insert the cartridge after the last keystroke*

5. Press 1 to select Control.
6. Press "Scan" to scan Operator ID
7. Press "Scan" to scan Control Lot number
8. Press "Scan" to scan the cartridge lot number from the box or manually enter the number using the keypad and press Enter.
9. Fill cartridge with the control (see below). Insert cartridge.
10. Enter 1 for i-STAT Level 1. Enter 2 for i-STAT Level 2.
11. Results will appear. At the bottom of one of the result pages, you will see 1- Test Options Select 1.
12. You will now have the following options:
 - 1- Next level
 - 2- Repeat level
 - 3- History

Using these options will allow you to continue your Quality Control testing without having to start again at the top of the QC menu.

***Control Evaluation:**

1. Document results on the Record of QC Documentation Log and compare results to the ranges to determine acceptability.
2. The operator performing the quality controls is responsible for evaluating the controls and performing any necessary corrective actions. If the results are out of range, corrective action must be documented on the Record of QC Documentation Log.

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3. If all results are within expected ranges, use the cartridges as needed. Transmit the results when finished.

4. The result statistics will be reviewed monthly by the Medical director.

***Quality Control Corrective Action:**

1. If any liquid control result is unacceptable, patient testing can not be performed until the problem has been resolved. Use another analyzer or send the specimen to the Clinical Laboratory.

2. Repeat any out of range control, verifying that the control procedure above has been followed carefully.

3. Document all the results and corrective actions on the Record of QC Documentation Log.

4. If new control solutions fail a second time, analyzer, control solutions and cartridges should be pulled from use and the POCT program notified ([10075](#))

. An investigation will be done to determine the cause of failure.

IV-Testing Procedure

1. Follow hand hygiene protocol and put on gloves.

2. Turn the analyzer on and press 2 for i-STAT Cartridge.

3. Scan or enter the operator ID and patient's ID. Repeat if prompted.

4. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.

5. Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well and dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.

6. Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)

7. Insert the cartridge into the cartridge port until it clicks into place.

8. Select tests to be reported.

9. Enter additional parameters on the Chart page if required:

-Choose the number corresponding to the type of sample used when prompted at the Sample Type field.

-Patient temperature can be entered as degrees Centigrade or Fahrenheit

- FIO2 can be entered as the numbers of liters or as a percentage of oxygen a patient is receiving

- Press the → key to return to the results page

10. View results shown on the analyzer's display screen.

11. Remove the cartridge after "Cartridge Locked" message disappears. The analyzer is ready for the next test.

12. Remove gloves and perform hand hygiene.

V-Documentation

Dock meter after each test performed to transmit results. During network downtime, results are held in analyzer until they can be transmitted to patients' electronic medical record

VI-Reference Ranges

The tested ranges are those ranges that were tested during functional sensitivity and linearity testing.

TEST	Reference Range	Critical Value Range	Analytical Range
Calcium	ionized 1.14 - 1.30 mmol/L	<0.8 or >1.54 mmol/L	L 0.25 – 2.50
PCO2 (arterial, venous, mix, capillary) mmHg	Art: 14D, 35 - 42 Art: 0 30 - 35 Ven: 38 - 50 Mix: 35 - 50 Cap: 35 - 42	<20 or >75 mmHg, first only (within past 24 hours)	5 - 130
pH (arterial, venous, mix, capillary)	Art: 7.35 - 7.45 Ven: 7.30 - 7.40	<7.10 or >7.59 units, first only	6.5 - 8.2

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	Mix: 7.32 – 7.45 Cap: 7.35 – 7.45	(within past 24 hours)	
PO2 (arterial, venous, mix, capillary) mmHg	Art: 0-14 D: 60 - 80 Art: >14 D: 80 - 100 Mix: 40 - 90 Ven: 35 - 50 Cap: 45 - 60	<40 mmHg	5 - 800
Glucose (Adult)	70-100 mg/dL	<50 or >400	20 - 700
Potassium	*Adult: 3.4 - 4.8 mmol/L *<1 mo: 4.0 - 5.6 mmol/L	<2.8 or >6.0 mmol/L	2 - 9
Sodium	135 - 145 mmol/L	<120 or >160 mmol/L	100 - 180
Lactate	0.5- 2.2 mmol/L	None	0.30 - 20.0
TCO2 (calculated)	*Adult: 23.0 – 31.9 mmol/L *14 days-1 yr: 22.0 – 27.0mmol/L *<14 days: 19.0 – 22.0 mmol/L	<11.0 or >40.0	5 - 50
HCO3 (calculated)	*> 1 year: 24 - 30 mmol/L *14 days-1 yr: 22 - 27 mmol/L *0 - 14 days: 19 - 22 mmol/L	None	1.0 - 85.0
BE (calculated)	None	None (-	(-30) - (+30)
SO2 (calculated)	None	None	0 - 100

VII-Troubleshooting

***A. Analyzer:**

1. **No display:** Either if the display screen remains blank, after a cartridge has been properly inserted or after the On/Off key has been pressed, the batteries should be replaced.
 2. **Cartridge Locked:** Cartridge Locked appears on the screen during the testing cycle to indicate that the cartridge or simulator is locked in the analyzer and should not be removed. **A cartridge or simulator must be removed only after the Cartridge Locked prompt disappears from the screen.** Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the Cartridge Locked prompt will remain on the screen. If this occurs, wait until the analyzer deactivates (display screen blank) and press the On/Off key. The analyzer will try to reset. **If the Cartridge Locked prompt does not disappear, do not attempt to remove the cartridge.** Contact the Point of Care Testing program: (10057)
 3. **Low Battery:** Recharge battery in Downloader/Recharge or swap with extra rechargeable battery.
 4. **Electronic simulator fail** will appear if the analyzer has not successfully completed the electronic simulator Test.
 5. **CLEW expiring, Upgrade required,** Point of Care Testing would need to perform a software update.
 6. **Messages and Quality Check Codes:** If a problem is detected during a testing cycle, the cycle will be stopped and a message box will appear on the screen. The messages will identify the code number. Refer to i-STAT's technical bulletin(s) to determine the meaning of the code number and the suggested action. If the analyzer deactivates before the detected problem is addressed, the message box will reappear the next time the On/Off key is pressed. Document all problems on the Instrument Corrective Action Log and notify Point of Care Testing.(10057).
 - Temperature out of Range error message:** The analyzer must be moved to an area where the temperature is between 18-30° C. Equilibration can take up to 30 minutes.
 - Other error messages:** Point of Care Testing.(10057)
 7. **i-STAT Dropped:** Run simulator prior to patient testing.
 8. **Power Outage or Disaster scenario:** Adaptors are available from the POCT program to allow i-STAT to run on regular 9V batteries. Contact the POCT program for assistance.
- B. Cartridge: *** Instead of Results:**

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1. Test the patient specimen with a new cartridge. If *** reappears, send the sample to the Clinical Laboratory for analysis. The sample may contain a substance that interferes with the test.
2. If *** are obtained for the same test performed on an additional (different) patient, contact Point of Care Testing for assistance.

Technical support may be contacted 24 hours x 7 days at 0501117506.

VIII-Alternative method

Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory service Manual.

E- Forms

QC documentation log.

Point of Care Testing patient result log book.

Temperature monitoring of fridge .

Temperature monitoring of room temperature.



SECTION II.6– I stat Troponin

A-Purpose :

The i-STAT cTnI test is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I (cTnI) in whole blood or plasma samples. Cardiac troponin I measurements can be used as an aid in the diagnosis and treatment of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality. Elevated levels of cardiac-specific troponins convey prognostic information beyond that supplied by the patient's clinical signs and symptoms, the ECG at presentation, and the pre-discharge exercise test.

The ability of cTnI to be measured at the low-end of the concentration range allows therapeutic intervention to be considered at any elevation above the normal range. Whole blood comes into contact with a sensor containing troponin-specific antibody and an enzyme conjugate specific to a separate portion of the cTnI molecule.

The cTnI within the patient's sample becomes labeled with the conjugate and captured onto the electro-chemical sensor. A wash phase results in an enzymatic cleaving of the antibody/antigen/antibody sandwich, releasing a detectable electrochemical product.

B-Responsibilities

- All The Point of Care Testing site staff.
- The Point of Care testing site coordinator.
- The laboratory medical director.

C-Policy

Properly trained and certified physicians, nurses or qualified technical personnel may perform testing of Troponin by Istat procedure outside the laboratory, under the authority and licensure of the laboratory medical director.

D-Procedure

I-Specimen Collection

***Suitable Specimens for Troponin I/cTnI**

- Fresh heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin. Collection tubes must be filled at least half full.
- Non heparinized whole blood samples tested within **one minute** of patient draw collected into a plastic syringe or plastic evacuated tube containing no additives.

***Criteria for Specimen Rejection**

- Evidence of clotting
- The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause a decreased cTnI result.
- Other sample types such as urine, CSF, and pleural fluid
- Capillary tubes and direct skin punctures (e.g. finger sticks) should not be used with the cTnI cartridge
- Samples should not be used unless the blood collection tube is filled at least half full

***NOTE: Avoid the Following Circumstances**

- Drawing a specimen from an arm with an I.V
- Stasis (tourniquet left on longer than one minute before venipuncture)
- Extra muscle activity (fist pumping)
- Hemolysis (alcohol left over puncture site or a traumatic draw)
- Icing before filling cartridge
- Time delays before filling cartridge

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II-Reagent Storage Requirements

***Verification of Cartridge Storage Conditions during Shipment**

- On receipt of new cartridges, Perform liquid QC on the cartridges and document results on the Record of QC Documentation Log.

***A. Refrigerated cartridges**

- Store at 2 - 8 C.
- Do not allow cartridges to freeze.
- Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Do not use after expiration date.
- Verify that the refrigerator did not exceed the limits of 2° to 8°C .
- Record the temperature of refrigerator on temperature log sheet.
- Cartridges must remain in pouches until time of use. Do not use cartridge if pouch has been punctured.
- Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

***Remedial Action:**

- If the temperature is outside the range of 2° to 8°C, quarantine the cartridges in the storage refrigerator.
- Notify the Site Coordinator of the temperature failure.
- DO NOT USE the cartridges from this refrigerator.

***B. Room temperature cartridges:**

- Cartridges at room temperature 18° to 30°C are good for 14 days. Mark the room temperature expiration date on each cartridge.
- Do not return cartridges to the refrigerator once they have been at room temperature.
- Record the daily room temperature on temperature log sheet
- Return any cartridges that are beyond the 14-day room temperature stability to the site coordinator for tracking purposes.

***C. i-STAT Cardiac Marker Controls Levels 1, 2, and 3:**

- Capped and stored at 2-8°C
- . Do not freeze

III-Quality Control

***Prior to performing quality control, determine if additional preparation is required.**

***Liquid Control preparation:**

cTnI Control Level 1, 2, or Level 3

1. Remove vial from freezer and thaw at room temperature (18-30°C) for 15 minutes.
2. Thoroughly mix by gently swirling the bottle. Avoid foaming of the sample.

***Running the controls:**

- . Put on gloves.
- . Press the On/Off key
- . Press the Menu key
- . Press 3 to select Quality Tests.

NOTE: Always remember to analyze control materials in the Control pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration Menu. Do not analyze controls under the Patient Test pathway. This must be done before inserting the test cartridge into the analyzer. The analyzer allows 15 minutes to insert the cartridge after the last keystroke.

- . Press 1 to select Control.
- . Press "Scan" to scan Operator ID
- . Press "Scan" to scan Control Lot number
- . Press "Scan" to scan the cartridge lot number from the box or manually enter the number using the keypad and press Enter.
- . Dispense a drop of sample **directly from the vial into the i-STAT cTnI cartridge** and seal the cartridge. Insert cartridge.

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- . Enter 1 for i-STAT Level 1. Enter 2 for i-STAT Level 2, etc.
- . Results will appear. At the bottom of one of the result pages, you will see 1- Test Options
- . Select 1.
- . You will now have the following options:
 - Next level
 - Repeat level
 - History

Using these options will allow you to continue your Quality Control testing without having to start again at the top of the QC menu.

***Control Evaluation:**

- . Document results on the Record of QC Documentation Log and compare results to the ranges to determine acceptability.
- . The operator performing the quality controls is responsible for evaluating the controls and performing any necessary corrective actions. If the results are out of range, corrective action must be documented on the Record of QC Documentation Log.
- . If all results are within expected ranges, use the cartridges as needed. Transmit the results when finished.
- . The result statistics will be reviewed monthly by the Medical director.

***Quality Control Corrective Action:**

1. If any liquid control result is unacceptable, patient testing can not be performed until the problem has been resolved. Use another analyzer or send the specimen to the Clinical Laboratory.
 2. Repeat any out of range control, verifying that the control procedure above has been followed carefully.
 3. Document all the results and corrective actions on Record of QC Documentation Log
 4. If new control solutions fail a second time, analyzer, control solutions and cartridges should be pulled from use and the POCT program notified (10057)
- . An investigation will be done to determine the cause of failure

V-Testing Procedure

1. Follow hand hygiene and put on gloves.
 2. Turn the analyzer on and press 2 for i-STAT Cartridge.
 3. Scan or enter the operator ID and patient ID. Repeat if prompted.
 4. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
 5. Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well and dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.
 6. Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
 7. Insert the cartridge into the cartridge port until it clicks into place.
 8. Select tests to be reported.
 9. Enter additional parameters on the Chart page if required:
 - Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
- Patient temperature can be entered as degrees Centigrade .
10. Press the → key to return to the results page.
 11. View results shown on the analyzer's display screen.
 12. Remove the cartridge after "Cartridge Locked" message disappears. The analyzer is ready for the next test.
 13. Remove gloves and perform hand hygiene

VI-Documentation

Dock meter after each test performed to transmit results. During network downtime, results are held in analyzer until they can be transmitted to patients' electronic medical record

VII-Reference Ranges

The tested ranges are those ranges that were tested during functional sensitivity and linearity testing.

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TEST	Reference Range	Critical Value Range	Analytical Range
Troponine	Negative	Borderline or positive samples reflex to the core laboratory for additional testing	0.00-50.00

VIII. Troubleshooting

A. Analyzer:

1. **No display:** Either if the display screen remains blank, after a cartridge has been properly inserted or after the On/Off key has been pressed, the batteries should be replaced.
2. **Cartridge Locked:** Cartridge Locked appears on the screen during the testing cycle to indicate that the cartridge or simulator is locked in the analyzer and should not be removed. **A cartridge or simulator must be removed only after the Cartridge Locked prompt disappears from the screen.** Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the Cartridge Locked prompt will remain on the screen. If this occurs, wait until the analyzer deactivates (display screen blank) and press the On/Off key. The analyzer will try to reset. **If the Cartridge Locked prompt does not disappear, do not attempt to remove the cartridge.** Contact the Point of Care Testing program: (10057)
3. **Low Battery:** Recharge battery in Downloader/Recharge or swap with extra rechargeable battery.
4. **Electronic simulator fail** will appear if the analyzer has not successfully completed the electronic simulator test. (10057).
5. **CLEW expiring, Upgrade required,** Point of Care Testing would need to perform a software update.
6. **Messages and Quality Check Codes:** If a problem is detected during a testing cycle, the cycle will be stopped and a message box will appear on the screen. The messages will identify the code number. Refer to i-STAT's technical bulletin(s) to determine the meaning of the code number and the suggested action. If the analyzer deactivates before the detected problem is addressed, the message box will reappear the next time the On/Off key is pressed. Document all problems on the Instrument Corrective Action Log and notify Point of Care Testing.
 - **Temperature out of Range error message:** The analyzer must be moved to an area where the temperature is between 18-30° C. Equilibration can take up to 30 minutes.
 - **Other error messages:** (10057)w
7. **i-STAT Dropped:** Run simulator prior to patient testing.
8. **Power Outage or Disaster scenario:** Adaptors are available from the POCT program to allow i-STAT to run on regular 9V batteries. Contact the POCT program for assistance.

B. Cartridge: * Instead of Results:**

1. Test the patient specimen with a new cartridge. If *** reappears, send the sample to the Clinical Laboratory for analysis. The sample may contain a substance that interferes with the test.
2. If *** are obtained for the same test performed on an additional (different) patient, contact Point of Care Testing for assistance: (10057). (This problem may have been caused by improper cartridge storage).

Technical support may be contacted 24 hours x 7 days at 0501117506.

IX Alternative method

Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory service guide .

E-Forms

- QC documentation log .
- Point of Care Testing patient result log book
- Temperature monitoring of fridge.
- Temperature monitoring of room temperature

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SECTION III.1 - Point of Care Testing Application

The committee will review the request along with any additional data/research supplied by the requesting department in support of the request

A-Requestor Details

Name of requestor/title :
Phone number
Email address
Department

B- POCT Details

Test requested:

Preferred Device:

Preferred Manufacturer:

Test site

Inpatients

Outpatients

Inpatients & Outpatients

Is this :

a new service

Yes

No

Replaces a lab test? Which test.....

Replaces a POCT test? Which test.....

Purpose of test:

Is this test available through the lab?

Yes

No

What is the desired turnaround time if performed in the lab?

Briefly explain why the lab cannot fulfill your needs

.....
If POCT was successful how quickly would the results be reviewed for clinical decision making?

Estimate the number of tests _____

What level of staff would perform the test and how many would need to be trained?

.....
Personnel responsible for implementation and training?

.....
Briefly describe the patient care benefits/outcomes and potential cost savings. (Consider: QC, reagents, interface, maintenance, testing time LAB involvement. Also provide evidence and attach cost analysis comparing POCT to lab testing costs)

.....
.....
.....

C-Departmental Considerations

A successful POCT plan requires a commitment from the department to meet all regulatory requirements and a dedicated member of staff to work with the POCT team from initial set up to the daily running of the device.

Are you willing to release staff required for initial set up, implementation, daily QC, daily maintenance, EQA, regular training and POCT liaising?

.....

POINT of CARE PROGRAM MANUAL

.....
.....
Do you have adequate storage/refrigerator space for the reagents/calibrates/QC material? (Both room temperature and refrigerator storage must be temperature monitored)
.....
.....
.....

D- Signatures

Requestor's signature.....
date:.....

Departmental Director's signature.....
date:.....

The POCT committee will review the information provided
 Approve/ Not approve .

If approved, the following criteria will be evaluated by the POCT department in conjunction with the requesting department:

- Device requirements
 - o Number of devices requested
 - o Specimen type and volume needed
 - o Interface
 - o QC/EQA schemes
- Cost comparison
 - o Initial cost
 - o Reagents
- Method comparison & verification (POCT against lab)
- Training
 - o What is the initial training?
 - o How is competency assessed?
 - o Are audit days/training days included in the overall training ?
- o Are they used elsewhere in the KFGH
- o Data management
- o Ease of use
- o Maintenance
- o Annual service cost
- o QC o Interface
- o When is re-training required?
- o Education requirements?

POINT of CARE PROGRAM MANUAL

SECTION III.2 - Coordinator Job description

1.0 POSITION SUMMARY:

Serves as a POCT coordinator between lab and user location.

2.0 POSITION ACCOUNTABILITY:

Essential job responsibilities/ functions to include but not limited to:

- 2.1 Responsible for oversight of POCT for all the hospital.
- 2.2 With lab medical director establishes methodology , communicate purchasing of equipment , ensure availability of procurement.
- 2.3 Recognizes, identifies and resolves problems and issues that arise without direct supervision and then report to Lab Medical Director.
- 2.4 Participate as an active member of the laboratory staff to improve the overall operation and efficiency of POCT.
- 2.5 Monitor quality control data by signing sheets available in all location.
- 2.6 The staff should be committed and implement the safety rules and regulations included in lab safety manual in the outside services.
- 2.7 Enforce compliance to quality control measures and their documentation.
- 2.8 Monitor QC charts at least twice a month.
- 2.9 Ensure compliance to corrective action of control failure.
- 2.10 Monitor and follow unscheduled maintenance of all equipment subject to repair and ensure availability of backup instrument in all locations.
- 2.11 Train all users practically for instrument use ,troubleshooting and daily maintenance .
- 2.12 Forward all data and information to laboratory medical director.
- 2.13 Prepare annual reports for POCT.
- 2.14 In case of establishing connectivity he/she will be responsible for issuing user passwords and lock out based on an approval from medical director.
- 2.15 Communicate with medical supply to ensure availability of tests strips , backup instruments ,statistics from all location to request annual procurements .
- 2.16 Ensure that all procurement are available and all POCT and controls are available at all times by follow up and direct purchase in case of procurements cut or shortage.
- 2.17 Complies and completes the processes of filing and documentation of all laboratory procedures including log book for instruments maintenance , calibration ,QC charts , troubleshoots , inventory filing.
- 2.18 Maintains his/her technical competency by joining continued biomedical education programs , joining technical courses , teaching lectures and seminar.
- 2.19 Read, follow, and implement POCT policies and procedures.
- 2.20 Monitor the adherence of POCT users to test procedures according to manufacturer's instruction either manually or automated .
- 2.21 Maintain and make minor adjustment to POCT equipment e.g. calibrating , alignment.

3.0 POSITION QUALIFICATION :

3.1 EDUCATION:

- 3.1.1 Bachelor of Medical Technology or Science.
- 3.1.2. With intermediate university degree in health sciences or equivalent.

3.2 EXPERIENCE:

Under graduate training is a must.

3.3 EXPERTISE AND SKILLS:

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- 3.3.1. Professional knowledge of concepts, principles, practices, methodology including routine, complex and frequently requested analysis.
- 3.3.1 Knowledge of quality control principles sufficient to maintain and advise on action relative to quality control concepts and correlation of laboratory results.
- 3.3.2 Knowledge and understanding of instrument technology sufficient to monitor mechanical and technical operation and locate and correct malfunction.
- 3.3.3 Skill in interpersonal relationships important for this position since the customer is the priority and must be attended all their needs.
- 3.3.4 B.B Knowledge of Privacy of patient record is and integral part of the position and privacy of individuals must be protected to the fullest.
- 3.3.5 Ability to work easily and with a friendly manner to the customers and easily handle the patient's complaints and arguments.

4.0 WORKING CONDITION:

- 4.1 Official working hours from 7:30 Am to 4:30 pm (Sunday to Thursday).
- 4.2 The work is performed primarily in the laboratories of the KFH. The work is performed in a clinical laboratory setting thus providing a moderate risk or discomfort from working with infectious material, chemicals and electrical equipment. The employee is frequently exposed to communicable diseases.
- 4.3 Safety precautions for employees such as blood withdrawing for screening of various diseases such as hepatitis, etc. must required immunizations, du to temperature variations within the laboratory are present.
- 4.4 Could work in any of the three shift Covering the 24 hours work according to needs.



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SECTION III.3 -Coordinator Competency

Job Title: _____ Supervised by: _____
 Prepared by: _____ Approved by: _____
 Date: _____ Date: _____

Job Summary: Operates, calibrates and troubleshoots all machines and equipment's in the point of care services , participates in the Quality Assurance Program, To improve performance and ensure high quality care for patients and ensure that employees are competent to performed assigned tests.

DUTIES AND RESPONSIBILITIES:

E = Exceeds All Expectations = 2
 M = Meets Expectations = 1
 P = Partially Meets Expectations = 0

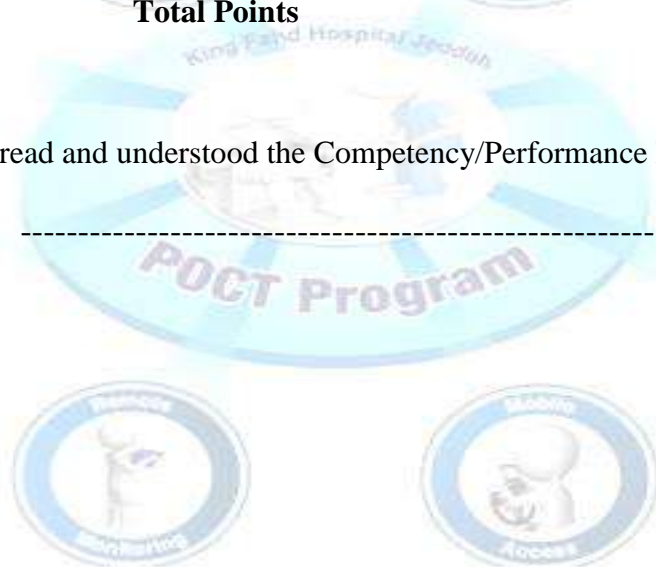
Demonstrates Competency in the Following Areas:

	<u>E</u>	<u>M</u>	<u>P</u>
Direct observation of employee or Medical Staff performing test for Proper waive testing	2	1	0
Direct observation of employee or Medical Staff performing test for Proper instrument use (Non –waived)	2	1	0
Compliance with QC policy and procedures.	2	1	0
Compliance with Proficiency testing policy and procedures.	2	1	0
Patient/specimen identification.	2	1	0
Specimen procurement and handling.	2	1	0
Testing of sample.	2	1	0
Documenting and reporting of results.	2	1	0
Knowledge of factors that influence test results.	2	1	0
Troubleshooting ability.	2	1	0
Enters all the necessary data in the computer and generates a	2	1	0
Maintains a clean environment as per hospital policy and procedure.	2	1	0
Uses independent judgment and specialized knowledge to issue non-verified results to physicians and/or nursing personnel.	2	1	0
Trains and teach new staff members.	2	1	0
Records all inventory of reagent supplies and initiates ordering of supplies when low.	2	1	0
Able to perform proficiency testing & contribute in corrective action	2	1	0
Organizes reviews and audits workload statistics.	2	1	0
Maintains a safe work environment/color discrimination test	2	1	0

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<u>Professional Requirement:</u>	<u>E</u>	<u>M</u>	<u>P</u>
Completes training program of POCT requirements.	2	1	0
Maintains regulatory requirements.	2	1	0
Maintains patient confidentiality at all times.	2	1	0
Reports to POCT services on time and as scheduled, completes work within designated time.	2	1	0
Wears POCT member card while on duty.	2	1	0
Actively participates in quality improvement and patient safety	2	1	0
Demonstrates respect for laws and customs of the Kingdom of Saudi Arabia and the patients served.	2	1	0
Communicates the mission, ethics and goals of the hospitals..	2	1	0
Total Points			

I have received, read and understood the Competency/Performance Evaluation above.



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COMPETENCY/PERFORMANCE EVALUATION CONTINUATION

Staff Member: -----

Job Title: _____

Performance Evaluation Score:

$\frac{\text{\# of total points achieved}}{\text{\# of questions x 2}} \times 100 = \underline{\hspace{2cm}} \%$

80 – 100% - exceeds standards

50 – 79% - meets standards

0 – 49% - needs improvement

POCT coordinator's Comments:

Recommended Goals / Actions:

Staff Member's Comments:

Actions Recommended by coordinator's

Staff Member's Signature

Date

coordinator's Signature

Date

Administrative Signature

Date

POINT of CARE PROGRAM MANUAL

SECTION III.4 - Proficiency Testing Tracking Form

Survey: PT Provide-----
 Shipment date..... Date received
 Type of sample Whole blood Lyophilized plasma Other

Condition of sample

Sample	Satisfactory	If unsatisfactory, please explain

- If reconstitution required, record:
- Date _____ Diluent _____ Amount _____ Initials _____
- Date specimens tested: _____
- Samples handled, processed, and tested in same manner as routine tests? _____
(attestation statement signed?)
- Results recorded on PT report forms by _____ (initials) _____
- Results on PT report form reviewed & checked by (initials) _____
- Copy of PT report made (retain copy at ward) _____
- PT report sent to PT Program/Regulatory Agency: (date & initials) _____
- Method: Entered on website, fax, e-mail, _____ (circle)

- *Review of results from PT Program:
- Date received in lab _____
- Date reviewed by medical director _____
- Reviewed/completed PT evaluation report filed in lab records
(date & initials) _____

POINT of CARE PROGRAM MANUAL

SECTION III -5 Investigation of Unsatisfactory Proficiency Testing Results

N.B

- Not all errors can be identified with one particular tool.
- Laboratories should consider the unique factors for each test system and expand its investigation when indicated.

1. General

- | | | |
|---|-------|------|
| A. Did more than one challenge in this event fail? | • Yes | • No |
| B. Did more than one analyte fail? | • Yes | • No |
| C. Are there previous trends/unacceptable results for this test? | • Yes | • No |
| D. Do the SDIs show a bias in the current event or from event to event? | • Yes | • No |
| E. Was there low consensus for the analyte or sample? | • Yes | • No |
| F. Were there <10 participants in the event peer group? | • Yes | • No |

G. Provide the scores from the three prior events (most recent first):

Year Event Score
 201 _____
 201 _____
 201 _____

2. Administrative

- | | | |
|---|-------|------|
| A. Was the PT kit ordered on time? | • Yes | • No |
| B. Were results submitted to the PT provider? | • Yes | • No |
| C. Were results submitted to the PT provider <i>on time</i> ? | • Yes | • No |
| D. Did the PT provider receive the results? | • Yes | • No |
| E. Other _____ | | |

3. Clerical

- | | | |
|--|-------|-------|
| A. Were results transcribed correctly? | • Yes | • No |
| B. Was the correct method code selected? | • Yes | • No |
| C. Was the correct reagent code selected? | • Yes | • No |
| D. Was the correct instrument code selected? | • Yes | • N/A |
| E. Was unit conversion performed correctly, if applicable? | • Yes | • N/A |
| F. Other _____ | • Yes | • No |

4. Methodological & Technical (problems attributable to either the test system or POCT personnel actions)

A. Problem with proficiency testing material

- | | | |
|--|-------|------|
| 1. Was the kit received without delays in transport? | • Yes | • No |
| 2. Did the kit arrive at the appropriate temperature? | • Yes | • No |
| 3. Were proper storage conditions maintained? | • Yes | • No |
| 4. Were the samples prepared per the PT provider instructions? | • Yes | • No |
| 5. Other _____ | | |

B. Instrument maintenance

- | | | | |
|---|-------|------|-------|
| I. Were there any problems with routine instrument maintenance? | • Yes | • No | • N/A |
| II. Was there any unscheduled maintenance? | | | |

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- | | | | |
|--|-------|------|-------|
| 1. Was there service or repair by a service rep? | • Yes | • No | • N/A |
| 2. Were any major parts replaced? | • Yes | • No | • N/A |
| 3. Other _____ | | | |

C. Calibration or calibration verification

- | | | | |
|--|-------|------|-------|
| 1. Did the instrument have successful calibrations or calibration verifications? | • Yes | • No | • N/A |
| 2. Was calibration or calibration verification performed when it was due? | • Yes | • No | |
| 3. Date of last calibration before PT testing: _____ | • N/A | | |
| 4. Date of last calibration verification before PT testing: _____ | • N/A | | |
| 5. Was PT result within the linear range of instrument? | • Yes | • No | |
| 6. Other _____ | | | |

D. Quality control and reagents

- | | | | |
|---|-------|------|-------|
| 1 Prepared at recommended temperatures with proper reconstitution volumes, diluents, etc. • | • Yes | • No | • N/A |
| 2 At the manufacturer suggested intervals and according to POCT policy. | | | |
| 3. Was there unacceptable QC on the day of PT testing? | • Yes | • No | |
| 4. Was there unacceptable QC during the month previous to the day of testing? | • Yes | • No | |
| 5. Was there unacceptable QC during the month following the day of testing? | • Yes | • No | |
| 6. Were any shifts or trends identified? | • Yes | • No | |
| 7. Date of last lot change in QC material before PT testing: _____ | • N/A | | |
| 9 . Date of last lot change in reagents before PT testing: _____ | • N/A | | |

5. Evaluation of Patient Results

- A. Determine if patient results could have been affected by the error since the last successful PT event.
- B. If results could be affected, conduct an evaluation for potential adverse patient outcomes.
- C. If the potential for adverse patient outcomes is identified, notify the patient's physicians (REF. Amendment result reporting policy).

6. Plan of Action Review

- | | | |
|---|-------|------|
| A. Are policies and procedures written in a manner to prevent recurrence? | • Yes | • No |
| B. Are systems and processes designed to prevent recurrence? | • Yes | • No |
| C. Are personnel trained and competent on the above (items 6A & 6B)? | • Yes | • No |
| D. Is there ongoing oversight in place to prevent recurrence? | • Yes | • No |

Testing personnel:

Signature of SIT POCT coordinator	_____	Date _____
Signature of POCT coordinator	_____	Date _____
Signature of Quality Supervisor/	_____	Date _____
Signature of Medical Laboratory Director	_____	Date _____

Retain this record for at least two years.

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SECTION III.7 – Room Temperature Monitoring

Ward-----

Month/Year _____

IMPORTANT REMINDERS

- **Temperature acceptance between 18-30 C.**
- **Don't work on POCT when temperature exceed the above value**
- **Corrective action is taken when temperature exceed the above value**

Date	Room Temperature	Nurse ID	Remark/Action taken
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			

****Signature of

- POCT site coordinator-----

POCT coordinator-----

-Laboratory Medical Director -----



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SECTION III.8- Fridge Temperature Monitoring

Ward----- Fridge control No.----- Month/Year _____

IMPORTANT REMINDERS

- Temperature acceptance between 2-8 C.
- Don't use POCT reagents when temperature exceed the above value and notify POCT coordinator (EXT .10057).
- Corrective action is taken when temperature exceed the above value .

Date	8 am	Nurse ID	4pm	Nurse ID	12am	Nurse ID	Remark/Action taken
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							

****Signature of POCT site coordinator-----

POCT coordinator----- -Laboratory Medical Director -----

.....

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SECTION III.9 - Safety Competency

DUTIES AND RESPONSIBILITIES:

E= Exceeds all expectations = 2

M= Meets Expectations = 1

P= Partially Meets Expectations = 0

STAFF NAME	
Ward /Department	

REQUIRMENTS	E	M	P	COMMENTS
WASTE DISPOSAL PROCEDURES				
What items go into:				
-Yellow basket				
-Rigid yellow container				
-Yellow gallon.				
-Red basket				
-Black basket				
SAFETY REQUIRMENTS				
What are the general hazards when you are doing the P.O.C.T?				
What are the general safety precautions?				
The nurse is committed to apply safety & IC precautions (PPE, Hand hygiene).				
ACCIDENTS				
What should you do if you accidently prick yourself?				
How do you deal with the biological?				
COPLIANCE WITH SAFETY & IC RULES				

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The nurse is committed to wearing personal protection tools.				
The nurse is committed to disinfecting the device and cleaning it after each patient?				
The nurse is committed to changing the gloves after each patient?				
TOTAL POINTS				

PERFORMANCE EVALUATION SCORE:

_____ %

- * 80-100% EXCEEDS STANDARDS.
- * 50-79% MEETS STANDARDS.
- * 0-49% NEEDS IMPROVEMENT

	NAME	SIGNATURE	DATE
Employee			
POCT Sit Coordinator			
POCT Coordinator			
Lab & Blood Bank Medical Director			










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SECTION III.10 - Risk Assessment form

Employee Name:		Section:	
Lab ID :		Date:	

Have you got a copy of the Lab MATERIAL SAFETY DATA SHEET (MSDS) for all substance in your Lab?	YES	NO
Do you know the meaning of all risk and safety signs ?	YES	NO

Classified the Lab chemicals according to the risk and safety signs and write bellow the appropriate sign the name of chemical belong to:

 corrosive	 flammable	 harmful irritant	 lung hazard	 Toxic
 Biological	 oxidizing	 explosive	 dangerous environment	

Do you know how to deal with all substance spills in your lab?	Yes	No
Do you know how and where you should store each substance in your lab?	YES	NO

Employee Name:	Signature:
Prepare by Chemical Safety Officer Name:	Signature:
Review and approved by Medical Director:	Signature:

Lab-Adm-Ipp-form(45)

POINT of CARE PROGRAM MANUAL

SECTION III.11 - Ishihara's Test

PLATE #	RESPONSE/ANSWER	CORRECT RESPONSE
PLATE 1		
PLATE 2		
PLATE 3		
PLATE 4		
PLATE 5		
PLATE 6		
PLATE 7		
PLATE 8		
PLATE 9		
PLATE 10		
PLATE 11		

NAME: ID

DATE:

POCT Coordinator.....


SCORE:

COMMENTS:

PASS FAIL

POINT of CARE PROGRAM MANUAL

SECTION III .12 - QC Urine Dipstick – Chem 10



King Fahad General Hospital
Department Of Laboratory and Blood Bank
Point Of Care Testing (POCT) Program

URINE DIPSTICK QC LOG
Multistix-10SG

QC Frequency:

- Once Weekly
- When opening new bottle

Site/Ward: _____ **Month/Year:** _____

Date	Time	Nurse Initials	Bottle or Room NO.	Level 1 Normal Control (N)		Level 2 Abnormal Control (A)		Dipstick	Glucose (30 sec)	Ketone (40 sec)	Protein (60 sec)
				Lot*	Exp. Date	Lot*	Exp. Date				

POCT SIT Coordinator Review:

POCT Coordinator Review:

Medical Director Review:

LAB -APP-ADM-F (59)

POINT of CARE PROGRAM MANUAL

SECTION III.13 - Patient Log for Urine Test

Ward-----

Month/Year _____

-Lot Number _____

Expiration Date _____

IMPORTANT TEST REMINDERS

- **Timing is critical. follow procedures exactly.**
- **For negative results, indicate with a “-” or “N”; do not leave space blank.**
- **Control lot numbers must be documented.**

Date	Patient ID & Name	Glucose	Bilirubin	Ketones	Specific Gravity	Blood	pH	Protein	Urobilinogen	Nitrites	Leukocytes	Action: 1. C&S sent to lab 2. UA sent to lab 3. RX given 4. No action	Signature

1-C/S: culture & sensitivity 2- UA : urgent examination 3- RX: treatment prescription

****Signature of Head nurse -----

POINT of CARE PROGRAM MANUAL

SECTION III.14 – Urine Analysis Training & Competency Record

A- At the completion of training session, the trainee should be able to complete these tasks and successfully conduct Urine Analysis testing

Checked items	MET	Un-MET	Remark
1. Describes purpose of test			
2. Demonstrates hand hygiene protocol and wears gloves			
3. Uses two identifiers on sample and/or scans barcode for patient identification			
4. Demonstrates proper technique when dipping and removing test strip from urine sample			
5. Demonstrates correct technique when blotting test strip prior to placing on test table.			
6. Correctly places the test strip on instrument within the 8 second time frame.			
7. Reports the result in the appropriate log or record			
8. Discards used strip in proper container and wipes table clean of residue.			
9. Successfully runs two levels of controls each day of patient testing			
10. Ensures QC bottles are labeled with expiration date (i.e. after 20 dips or 90 days once opened)			
11. Understands QC pass or fail and steps to take			
12. Takes appropriate action if QC results are out of range. (repeats test/or contacts POCT program).			
*All skills parameters must be “met” in order to become an authorized user of this product			

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B-Learning assessment test

*1- Reagent strips must be submerged in the sample for 2 minutes in order for the leukocyte result to be valid.

- a) True
- b) False

*2. The reagent strip should be drawn along the edge of the urine container and then blotted, pad side up, to remove excess urine before placing strip on bottle .

- a) True
- b) False

*3. Use 10% bleach to clean the test strip bottle after every sample.

- a) True
- b) False

4. Urine controls can be used immediately after removal from the refrigerator.

- a) True
- b) False

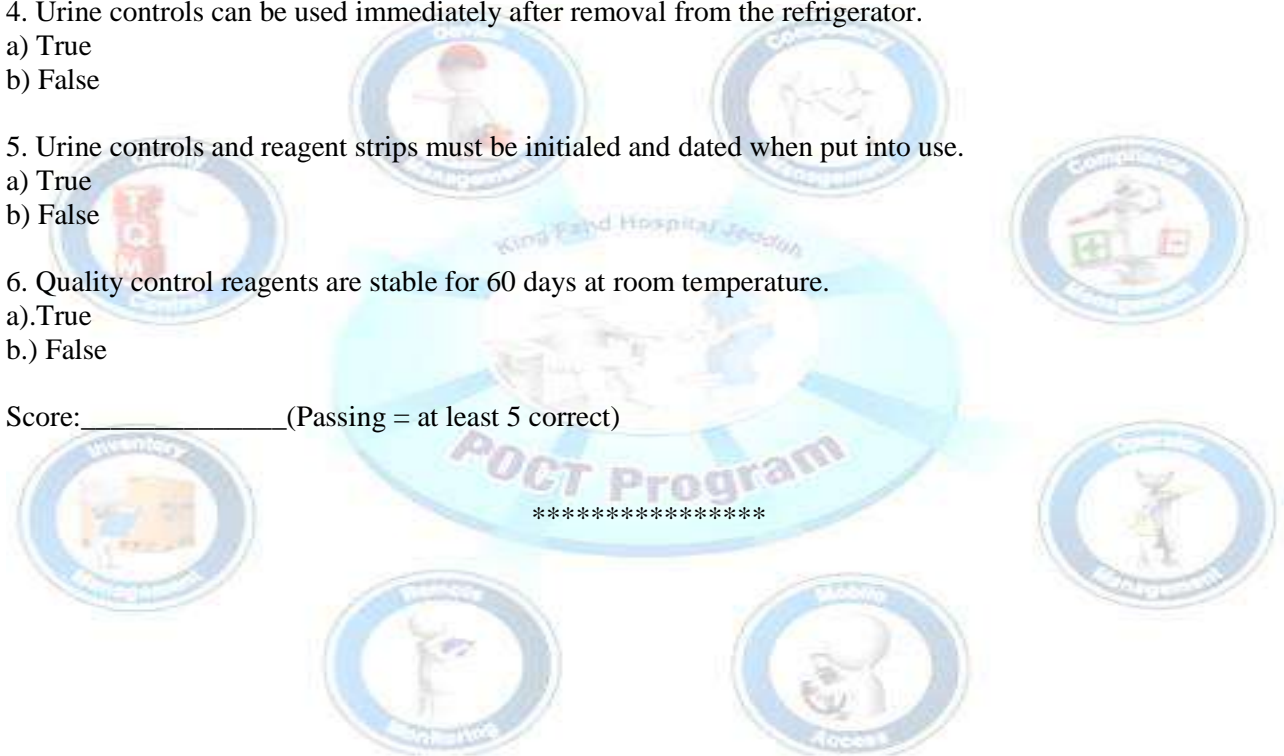
5. Urine controls and reagent strips must be initialed and dated when put into use.

- a) True
- b) False

6. Quality control reagents are stable for 60 days at room temperature.

- a) True
- b) False

Score: _____ (Passing = at least 5 correct)



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SECTION III.16 - Glucometer Maintenance Check list

Ward: _____

Month/Year: _____

Device No. : _____

#	Menu	Days																														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Cleaning Glucometer Monitor																															
2	Performing Quality Control Check																															
	Nurse Sign																															
Periodically (If Needed)																																
3	Changing Battery	Changed By: _____															Date & Sign: _____															

Head Nurse: _____

POCT Coordinator: _____

Date & Signature: _____

Date & Signature: _____

POINT of CARE PROGRAM MANUAL

SECTION III.18- Glucose meter Initial Training & Competency Assessment

A- At the completion of training session, the trainee should be able to complete these tasks and successfully conduct glucose Meter testing(

Checked items	MET	Un-MET	Remark
1. Describes purpose of test			
2. Demonstrates hand hygiene protocol and wears gloves			
3. Uses two identifiers on sample and/or scans barcode for patient identification .			
4-Dates expiry date on QC bottles (???)&strips (???)when opened			
5-Explains proper finger stick technique – no milking and wipe away first drop prior to sampling			
6-Inserts test strip into the meter and applies sample			
7-. Reports the result in the appropriate log or record			
8-Recognizes action range symbols and meter testing range			
9. Discards used strip in proper container and wipes table clean of residue. Describes how to clean and disinfect meter			
10-Understands meter charging requirement and extra battery swap			
11- Understands QC frequency (2 levels/24 hrs) and what to do for failure			
12- Takes appropriate action if QC results are out of range. (repeats test/or contacts POCT program).			
13-Knows POCT glucose procedure is found through Lab Handbook			
*All skills parameters must be “met” in order to become an authorized user of this product			

POINT of CARE PROGRAM MANUAL

B-Learning assessment test

*1. You do not need to check two patient identifiers prior to running a test.

T _____ F-----

*2. Strips and QC expire after how long once opened?

- a) Strips, 30 days, QC, 30 days
- b) Strips, 180 days, QC, 90 days
- c) Strips, 90 days, QC, 180 days
- d) They never expire.

*3. What's the first thing you must do when opening a new set of controls or a new vial of strips?

- a) Test a patient
- b) Date them
- c) Call the POC Program
- d) You don't need to do anything.

*4. Which patient identifier and method of entry is preferred ?

- a) Scanned from the patient's wrist band or patient label
- b) MRN, manually entered into the meter.

Score: _____ (Passing = at least 3 correct)

Name: _____

Employee ID#: _____

Care Unit: _____

Date of Training: _____

Other: _____

Training Status:

- New/Initial
- Recertification

Trainer Signature

(Trainer signature indicates trainee has successfully completed the program and scored 80% or better on the quiz)

******Retain as part of permanent record*

POINT of CARE PROGRAM MANUAL

SECTION III.19 - Daily Qc of Blood gases

Site/Ward: _____ Month/Year: _____
 Machine control NO:..... Lot NO:

Day	Morning Shift			Evening Shift			Night Shift			4 Levels				
	Qualichech 5 ⁺	autocheck 5 ⁺	ID POCT /User	Qualichech 5 ⁺	autocheck 5 ⁺	ID POCT /User	Qualichech 5 ⁺	autocheck 5 ⁺	ID POCT /User					ID POCT /User
1														
2														
3														
4														
5														
6														
7														
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30														

POCT Sit Coordinator POCT Coordinator
 Laboratory medical director

POINT of CARE PROGRAM MANUAL

SECTION III.20 - Competency Check List For Blood Gases Sampling

Checked items	MET	Un-MET	Remark
1. Describes purpose of the procedure & Explain and discuss the procedure with the patient. /If possible			
2-Check the concentration of oxygen the patient is breathing and body temperature at time of sampling. -Check the patient's current coagulation screen, platelet count, medical history and prescription chart for anticoagulation therapy.			
3. Uses two identifiers on sample and/or scans barcode for patient identification .			
4- proper Preparing trolley with its contents			
5- Demonstrates hand hygiene protocol and wears gloves			
6- Perform the modified Allen test			
7-Proper disinfection for the puncture sit			
8-Proper preparing &using of ABG syringe .			
9-Expel any air bubbles from the syringe, and cap the arterial syringe			
10- deal with the sample within 10minute or but in ice up to 30mnutes till analysis			
11. Dispose of equipment safely			
12Label with patient's identification at the patient's bedside.			
13-Check puncture site and apply a clean, sterile gauze dressing. Secure with tape.			
14-Clearly document rationale for procedure in patient's notes and verbally communicate arterial analysis findings to relevant ordering doctor			
15--Knows POCT blood gases procedure is found through Lab Handbook			
*All skills parameters must be “met” in order to become an authorized user to handle this procedure			

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SECTION III.21 - I-stat Qc & Maintenance check list

I-STAT QC and MAINTENANCE CHECKLIST											
Ward Site:		Month/Year:		Lot No:		Device No.:					
ELECTRONIC SIMULATOR EVERY 8 HORS: if pass continue to quality control. if fail displayed repeat contact POCT coordinator.											
Liquid Quality Control must be performed:											
On every month.											
On every new lot number and every new shipment of cartridges.											
If any results are outside the expected ranges:											
Record the QC failure in the i-STAT QC sheet and contact the POCT coordinator Ext:2758											
For NURSING Use	Simulator	Nurs Name/ID	Simulator	Nurs Name/ID	Simulator	Nurs Name/ID	for POCT Coordinator	Tech, ID			
	1										
	2										
	3										
	4										
	5										
	6										
	7										
	8										
	9										
	10										
	11										
	12										
	13										
	14										
	15										
	16										
	17										
	18										
	19										
	20										
	21										
	22										
	23										
	24										
	25										
	26										
	27										
	28										
	29										
	30										
31											
Head of Nurse :		POCT Coordinator :		Medical director :							
signature :		signature :		signature :							
POCT Cordinator Ext :2758											
Mentenance Biomed mobile : 0546141423 _ Ext: 1756											

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SECTION III.22 - I-stat Competency Check List

Ward----- Name:-----Position:-----
 Unit / Ward:----- Trainer: Date of Completion:-----

1	PROCEDURE	Met	Not MET
	A-Operator has read the i-STAT1 Manual (POCT) B-Knowledge of i-STAT System Components		
2	Operator & Patient Identification		
	A-Operator ID & ongoing competency requirements (Level 1 or Level 3 Aqueous QC or [1] Patient Test Monthly; to include [1] each of a Level 1 and Level 3 Aqueous QC Quarterly.) B-Patient ID – as per clinical program (Patient name –MRN)		
3	SUPPLIES - EQC, AQC & CARTRIDGE		
	Cartridge is at room temperature 5 minutes prior to use. Confirms: <ul style="list-style-type: none"> • Cartridge room temperature Expiry date – by cartridge type. • Cartridge Fridge Expiry date. • Cartridge Lot # with QC chart. • Quality Control room temperature Expiry Date. • Quality Control Fridge Expiry date. Cartridge handling - to avoid sensor contamination, cartridge damage		
4	QUALITY CONTROL – Electronic & Aqueous		
	Successfully performs Electronic Simulator QC. Successfully performs Aqueous QC Level ((Daily, q 8 hrs when in use (1 & Level 3.		
5	PATIENT TESTING		
	Review proper collection procedure & cartridge fill of patient sample. (Performs unknown patient sample in duplicate to demonstrate consistency in patient sample handling & testing		
6	RESULT REPORTING		
	A-Review results - analytical measuring ranges, critical values Repeating a patient test - analysis on the i-STAT1 B-Reporting of critical results as per the POCT program. C-Reporting of results for the Simultaneous Draw D-Transmit test results at the Central Data Station. (Weekly at a minimum E-Review a result stored in the analyzer		
7	TROUBLESHOOTING		
	.Review of “trouble guide” & Error Codes Protocol for instrument troubleshooting and instrument replacement		
8	MAINTENANCE		
	.A-External cleaning of the analyzer - B-Battery replacement of the analyzer – (<8.0 Volts – iSTAT1 batteries from Abbott only		

POCT sit coordinator.....POCT coordinatorlaboratory medical director

POINT of CARE PROGRAM MANUAL

SECTION III .23- I-stat Competency written Exam

Operator Name: _____ Employee ID: _____

Title _____ Date _____

Competency type: 6-month (during the first year for CG4+, CG8+, PT/INR,)

Annual (For all cartridges)

1. What is the room temperature storage expiration for PT/INR, cartridges?
 - 5 days
 - 14 days
 - 2 months
2. To prevent blood from clotting in the syringe, what should be done before filling PT/INR cartridges?
 - Shake the syringe vigorously for 20 sec
 - Use only heparinized syringes
 - Expel a few drops from the syringe, then immediately fill the cartridge
3. Once a single cartridge is removed from the refrigerator, how long before it can be used?
 - 1 hour
 - 5 minutes
 - 30 minutes
4. Which key should be pressed to back light the display when working in dimly lit areas?
 - “.” Key
 - Right arrow key
 - “0” key
5. If “***” appears on the analyzer screen:
 - Turn analyzer off and on
 - Draw fresh sample and repeat
 - Wait until “***” disappears from screen
6. If “Analyzer Error/Use Electronic Simulator” appears on the screen:
 - Remove analyzer from use/contact POCT program
 - Turn analyzer off and on
 - Wait 10 minutes and try again
7. Cartridge may be removed at any time during a test
 - True
 - False
8. For PT/INR testing: The thumb should be used for finger stick sampling.
 - True
 - False
9. The analyzer may be moved during a test
 - True
 - False
10. The analyzer stays on for 15 minutes when this is displayed:
 - Cartridge Lot Number
 - Insert Cartridge
 - Main Menu

Score _____

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SECTION III .24 - Checklist for Site Compliance

A. Site Director

1. Leadership

- Is familiar with relevant JC standards as they apply to the site
- Ensures a system is in place to document orders or protocols for testing patients
- Annually reviews site specific protocols and procedures
- Ensures the sites are enrolled in a proficiency-testing program and documents results review, if required
- Recommends, approves and implements remedial action plans when necessary

2. Orientation, Training, and Education

- Provides initial orientation to staff
- Ensures that staff can describe their roles and responsibilities relative to safety.

B. Site Coordinators

1. Assessing Competence

- Provides initial training, orientation and competency to staff for each POC test they perform
- Ensures that during the first year (**new hire or new operator to test method**), each staff member's competence is evaluated and documented at six months for non-waived tests
- Each staff member's competency is evaluated and documented on an **annual basis within 365 days of the initial training**

Acceptable methods to document competency for waived testing:

- a. Written quiz
- c. Monitoring QC performance
- b. Direct observation
- d. Performance of a test on a blind specimen

Acceptable methods to document competency for non-waived testing:

- a. Direct observation of patient testing
- b. Monitoring, recording, and reporting of test results
- c. Review of quality control and/or proficiency tests
- d. Direct observation of performance of instrument maintenance
- e. Testing previously analyzed specimens, internal blind testing samples
- f. Problem-solving skills as appropriate to the job

2. Documentation

- Ensures that current test and quality control procedures are available for each test performed and that site specific protocols are reviewed and signed by the Site Director annually
- Investigates and takes remedial action for deficiencies identified through quality control measures
- Retains all the records for 4 years per MA DPH

3. Reagents

- Ensures that the reagents are stored at required temperature as suggested by manufacturer
- Ensures that the reagents are dated and initialed when first opened.
- Ensures that any expired reagents or cartridges are discarded
- Ensures that the temperature log sheets are reviewed and corrective action documented as needed

4. Proficiency testing

- Tests proficiency samples as requested by POCT program and ensures that documents are signed by site director and maintained (non-waived sites only)

5. Running QC

- Ensures that appropriate levels and frequency of QC performed, specific to the instrument in use
- Ensures that appropriate levels and frequency of electronic quality control is performed, as required
- Ensures that appropriate levels and frequency of QC performed for non instrument-based testing.

C. Operators

- Read and become knowledgeable with all testing policies/procedures performed at the site

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- Run the liquid QC for the appropriate analyzers at the expected frequency
- Verify the reagents or cartridges for in date prior to use and discard any expired ones
- Maintain the inventory adequately and store the inventory according to the manufacturer requirement
- Ensure that any reagents or controls with expiration dates that change upon opening are dated
- Ensure that the analyzers are downloaded and results transmitted after each patient and QC test performed
- If a transmission error occurs, notify the POCT Coordinators or the site coordinator within 24 hours for resolution
- Check **two patient identifiers** when scanning barcode for patient ID to ensure correct patient
- Perform the proficiency testing (for non-waived testing)

Contact us: 10057



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SECTION III.25 - Quality Assurance Monitor Report

-Site: Date: _____

-Title of Report: _____

-Type of Monitor: Accuracy Efficiency Timeliness
(Check all that apply) Appropriateness Safety Effectiveness

-Aspect of Care: Hi Volume Hi Risk to patient Problem Prone

-Project Leader: _____

-Disciplines Involved: _____

-Project Dates: : _____

-Description: _____

-Reason for Performing Monitor: _____

-Acceptable Limits: _____

-Data Source: _____

-Analysis of Data: _____

-Conclusion of Analysis: _____

-Action to Be Taken: _____

-Assessment of Actions Taken (Improvement): _____

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SECTION III .26 - Point Of Care Site Inspection Check List

Date ----- Location ----- Staff involved -----		
Approved test menu -----		
O Test materials found that are not on menu ? items found ----- -		
Tracer performance? o Y or o N patient MRN ----- patient name ----- -----		
Indicator	Compliance Yes –No or N/A	Finding
Quality control /proficiency testing		
Appropriate QC frequency for each test		
Appropriate QC documentation for each test		
Remedial action documented for QC failures		
Monthly review for non-waived test		
QC reagent properly dated and stored		
Proficiency testing available /appropriately reviewed		
Remedial action documented for failures		
6-month correlation performed		

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SECTION III .27 - Unscheduled Maintenance Of Instruments

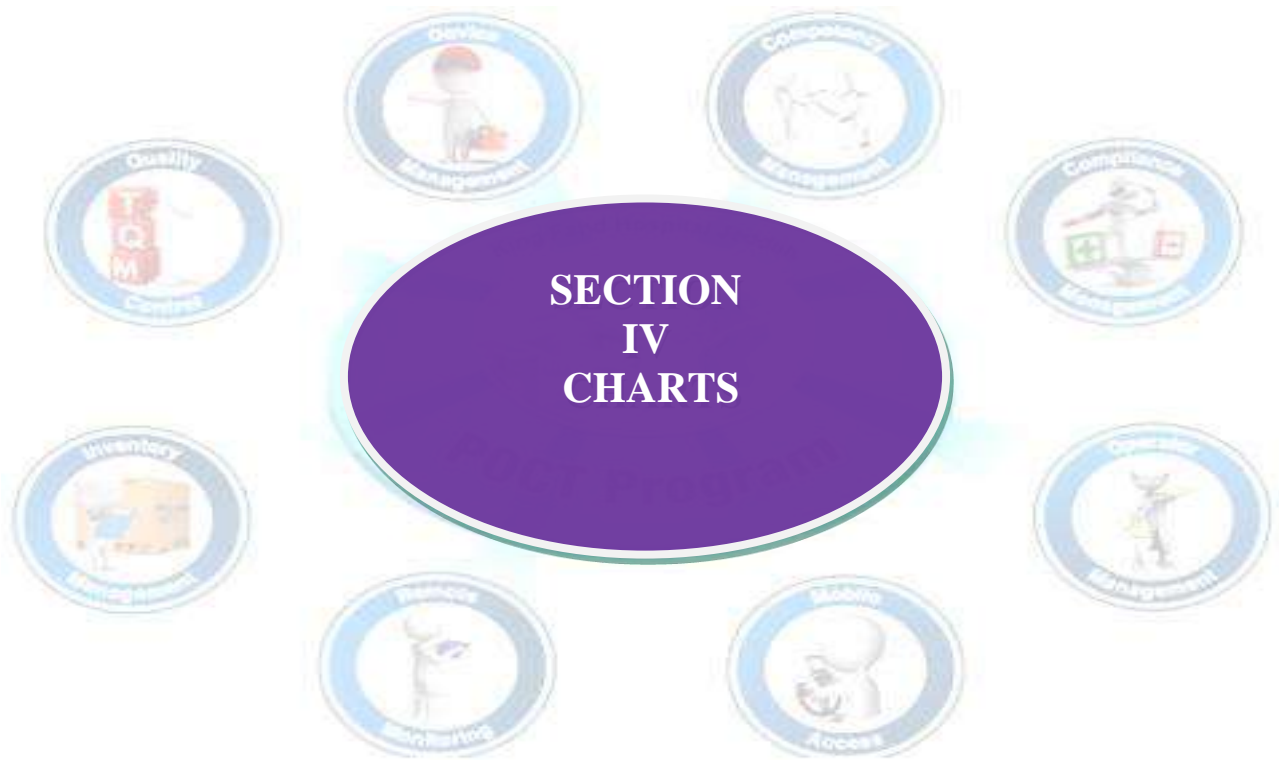
Ward :

Year/month

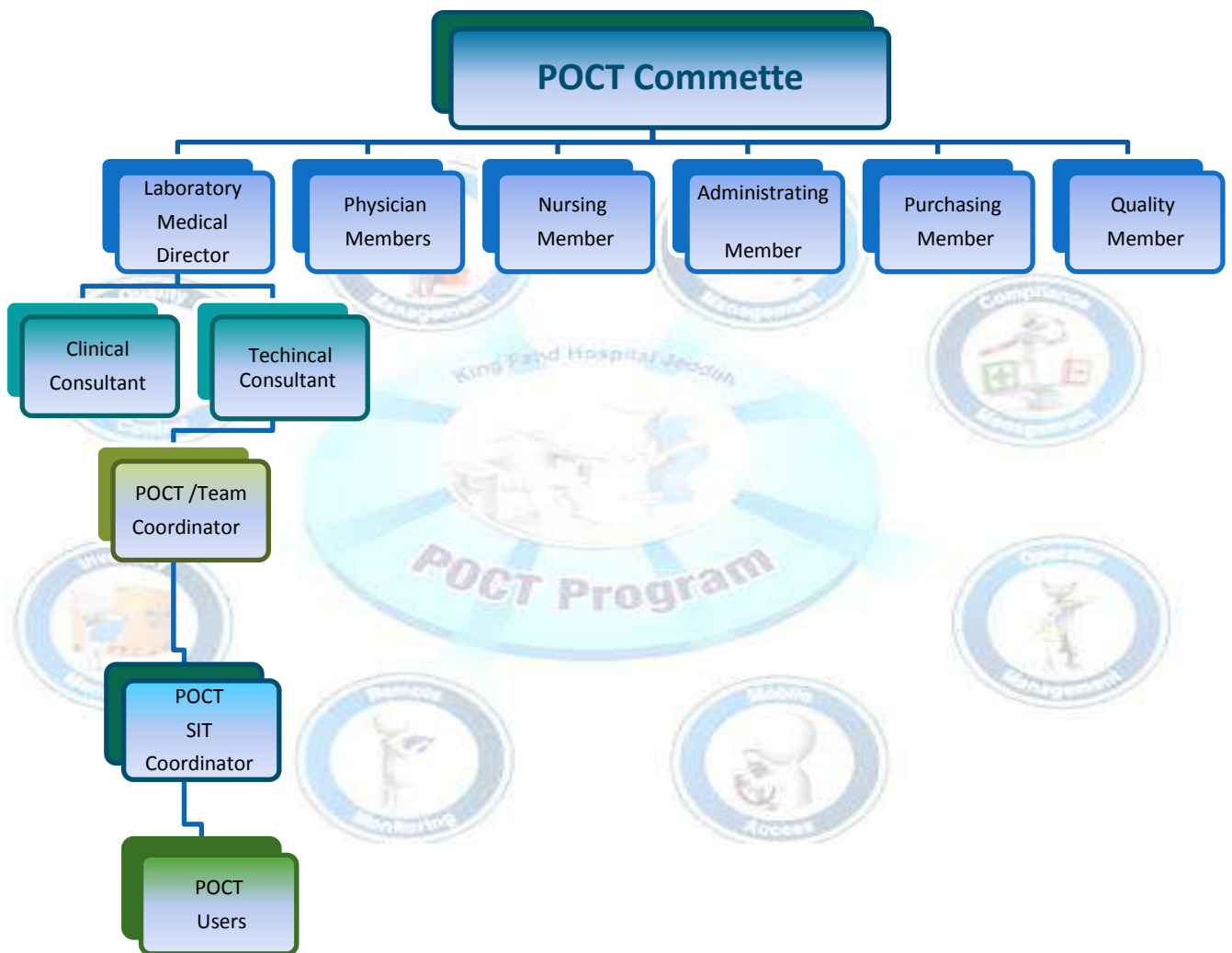
Date	Device Problem	Did You Call BioMed/ POCT Coordinator		Action Taken during Maintenance or Fixation Period	POCT user Signature
		Yes	No		

POCT site Coordinator.....
 POCT Coordinator
 Laboratory Medical Director.....

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SECTION IV .1 – Organization Chart



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SECTION IV.2 – Allowable Limits of Performance

TEST or Analyte	Acceptable Performance
Alanine aminotransferase	Target value +/-12%
Albumin	Target value +/-6%
Alkaline phosphatase	Target value +/-12%
Amylase	Target value +/-10%
Aspartate aminotransferase	Target value +/-12%
Bicarbonate	Target value +/-10%
Bilirubin, total	Target value +/-12%
Blood gases pO ₂	Target value +/- 3SD
Blood gases pCO ₂	Target value +/-8%
Blood gases PH	Target value +/-0.04
Calcium ,total	Target value +/- 4%
Chloride	Target value +/- 3%
Cholesterol ,Total	Target value +/-6%
Creatinine kinase	Target value +/-12%
Creatinine	Target value +/- 8%
Glucose	Target value +/- 8%
HDLcholesterol	Target value +/-12%
Lactate Dehydrogenase (LDH)	Target value +/-8%
Magnesium	Target value +/-8%
Potassium	Target value +/-5%
Sodium	Target value +/- 2%
Total Protein	Target value +/-5%
Triglycerides	Target value +/-12%
Troponin I	Target value +/-20%
Troponin T(Qualitative)	Target value <50ng/L Negative
Troponin T(Quantitative)	Target value +/-20%
Urea	Target value +/-12%
HbA1C	Target value +/-5%

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SECTION IV .3 – Reference & Critical Ranges

Reference range implies the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system's results have been shown to be valid. The following table contains the Reference Ranges (for adults) and Reportable Ranges applicable to the POCT system

ANALYTE	UNIT	REFERENCE RANGE		REPORTABLE RANGE	NOTES
		(arterial)	(venous)		
Sodium	mmol/L	136-146		100-180	
Potassium	mmol/L	3.2-5.0		2.0-9.0	
Chloride	mmol-L	95-110		65-140	
Urea	Mmol/L	(M) 3.0 – 7.5 (F) 2.5 – 6.5		1 – 50	
Glucose(fasting)	mmol/L	3.0 – 5.4		1.1 – 38.9	
Creatinine	µmol/L	(M) 60 – 110 (F) 45 – 90		18 – 17.68	
Ionized Calcium	mmol/L	1.12-1.30		2.50-0.25	Sample must be collected into a BALANCED HEPARIN tube or syringe
pH		7.35-7.45	7.32-7.43	6.50 – 8.20	
pCO ₂	mmHg	35-48	32-45	5 – 130	
pO ₂	mmHg	83-108		5-800	
tCO ₂ *	mmol/L	19-24		5-50	Measured on CHEM8+cartridge
Hematocrit	Fraction	(M) 0.40 – 0.54 (F) 0.36 – 0.44		0.10 – 0.75	
Lactate	mmol/L	0.5-2.0		0.30 – 20.00	
HCO ₃ [*]	mmol/L	22-28	23-30	1.0 – 85.0	
BE*	mmol/L	(-2)-(+2)		(-30) – (+30)	
Anion Gap*	mmol/L	12-20		(-10) – (+99)	
sO ₂ *	%	95-100		0 - 100	
Hb*	g/L	M 13.0-18.0 M 12.0-17.0	F 11.5-16.5 F 115 – 16.5	34 – 255	
Prothrombin Time/PT	INR	3.5-2.5 mechanical heart valve most other conditions 2-3		0.8-8.0	

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URINE:

Color: NR straw-yellow	Appearance: NR Clear-Hazy
Urobilinogen : NR Up to 1 mg/dl	Nitrites: NR negative
Blood : NR Negative	Ketone : NR Negative
Specific Gravity: NR 1.010-1.030	Leukocytes: NR Negative
Protein: NR Negative-Trace	pH : NR 4.5-8.0
Bilirubin: NR Negative	Glucose : NR Negative

Critical Results

-Critical Result: a result so abnormal that it would have an immediate effect on the management of a patient

-Procedure : a critical result is immediately notified to the treating clinician

ANALYTE (units)	ADULT		CHILDREN		NEONATES	
	Low	high	Low	high	Low	high
Sodium (mmol/L)	125	160				
Potassium (mmol/L)	2.5	6.0				
TCO2 (mmol/L)	10	40				
(Ionized Calcium mmol/L)	0.78	1.58				
pH	7.21	7.6				
PCO2 (mmHg)	20	70				
pO2 (mmHg)	43	-				
Urea (MMol/L)	-	50.0				
Glucose (mmol/L)	2.0	30.0	2.0	15.0	2.0	15.0
Creatinine (umol/L)	-	400				
Hematocrit	0.30	0.60			0.30	0.70
Lactate	0.4	5.0				
Prothrombin Time/PT		4.5				
Troponin I/cTnI		0.08				

*****Qualifications**

.Haematocrit must be confirmed with a fresh sample. Sample mixing may be an issue

-Creatinine critical range does not apply to end stage renal disease patients under the care of a renal physician.

-PO2 range applies to arterial samples.

SECTION IV .4 – Scenario of Critical Result Reporting

***Hello, This is (Nurse ., Name And ID Number #####) , calling From (ward...)**

I have A POCT critical Result For Patient (*) , With MRN (#####).**

***The Critical Result For (Name Test).**

***The Result is (Xxxx).**

***Please Repeat Back To Me The Result I have given To You .**

***May I Have Your Name .**

***Thank You For Your Help) .**



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SECTION IV .5 – Documentation Papers

- All required information must be recorded or verified for test kits, reagents, QC products, etc. (i.e. lot number, expiration date, date opened as applicable)
- **Reminder:** All refrigerators that are used for the storage of any reagents, QCs, etc. must be checked daily and temperatures logged. If they fall outside the posted range (i.e. 2 - 8°C), remedial action must be taken and documented. Minimum and maximum temperatures must be documented after a site is closed for holidays or weekends.
- Site test menu must be approved by the medical director of the laboratories prior to implementation.
- For new requests, submit POCT application form to POCT committee.
**The POCT program with questions or concerns: Ext 10057.

Test	QC	Frequency	QC Results Record	Record Patient Results	Reagents	External QC Product	Special Issues
Glucometry	<ul style="list-style-type: none"> • 2 Levels (liquid) -RT -Expire 90 days after opening 	Each 24hr of patient testing		Patient Record (electronic or paper)			
Hemocue Hgb	<ul style="list-style-type: none"> • Internal • External (2 levels) 	<ul style="list-style-type: none"> -Every 8 hours automated -Each 24hr of patient/Donor testing 	Download after each test, reviewed monthly by POCT program	Patient/ Donor Record- electronic	Hemocue microcuvettes	N/A	Only Pathology approved micr-ocuvette and QC lot numbers may be used
i-STAT ACTk i-STAT PT/INR	<ul style="list-style-type: none"> • Internal • External simulator • Liquid QC (2 levels) 	<ul style="list-style-type: none"> Every 8 hours automated Every 6 months Once per month per lot of cartridge and each new shipment 	Download after each test, reviewed monthly by POCT program	Patient Record- electronic	ACT kaolin & PT/INR cartridges- RT 14 days (date each cartridge) or Frig until Mfgr expiration date ACTk: PS#329023 PT/INR: PS#118473	<ul style="list-style-type: none"> i-STAT ACT Level 1 PS#:141622 i-STAT ACT Level 2 PS#:141623 i-STAT PT/INR Level 1 PS#:137158 i-STAT PT/INR Level 2 PS#:137159 	
i-STAT blood gases, electrolytes, lactate	<ul style="list-style-type: none"> • Internal • External simulator • Liquid QC (3 levels) 	<ul style="list-style-type: none"> Every 8 hours automated Every 6 months Once per month per lot of cartridge and each new shipment 	Download after each test, reviewed monthly by POCT program	Patient Record- electronic	<ul style="list-style-type: none"> G3+,CG8+, CG4+ cartridges -RT 2 months (date each cartridge) or Frig until Mfgr expiration date G3+: PS#218460 	<ul style="list-style-type: none"> i-STAT Blood Gas QC level 1 PS#62741 i-STAT Blood Gas QC level 2 PS#163167 i-STAT Blood Gas QC level 3 PS#218509 Frig storage until Mfgr. expiration date. Date for 	

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					CG8+: PS#101554 CG4+: PS#162960	RT storage. Leave at RT for 4 hours prior to use or RT storage up to 5 days	
	<ul style="list-style-type: none"> • Internal • External simulator • Liquid QC (2 levels) 	<p>Every 8 hours automated</p> <p>Every 6 months</p> <p>Once per month per lot of cartridge and each new shipment</p>	Download after each test, reviewed monthly by POCT program	Patient Record-electronic	<p>Creatinine cartridges - RT 14 days (date each cartridge) or Frig until Mfgr expiration date</p> <p>PS#: 163684</p>	<p>iSTAT Level 1 PS#:62741</p> <p>iSTAT Level 3 PS# 218509</p> <p>Frig storage until Mfgr. expiration date</p>	
Urine dipstick by Clinitek STATUS	2 Levels (liquid) Frig until Mfgr. Exp. date or 6 months RT	<p>Each day of patient testing</p> <p>Each new bottle of strips</p>	<p>QC log</p> <p>Lab log</p>	Patient Record (electronic or paper)	<p>Multistix 8 SG Bayer PS#028143</p> <p>RT storage-date bottle once QC done</p>	<p>Sentry Urine Dipstick Controls</p> <p>Date when opened-Frig until Mfgr. Exp. date or 6 months RT (PCS obtains QC from POC, GRJ239)</p> <p>Fisher Scientific #23-029375</p>	Only Pathology approved lot numbers may be used

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SECTION IV .6 – Temperature Rang

Reagent	Unopened	Opened Temp	Room	Opened Refrigerator	Notes
GLUCOS					
Glucose Reagent Strips	Manufacturer Expiration when stored at: 4-30 °C	Manufacturer Expiration when stored at: 4-30 °C			Do not freeze or refrigerate No direct heat or sunlight
H&L Controls	Manufacturer Expiration when stored at: 4-30 °C	Expiration: 90 days or manufacture date Whichever date comes first! Store: 4-30 °C			Do not freeze or refrigerate No direct heat or sunlight
Glucose Calibration Verification	Manufacturers Expiration when stored at: 2-30 °C			Store: 2-8 °C Expiration date: 90 days	Avoid freezing and temp > 30 °C
Urine dip stick					
MultiStix 10	Manufacturer Expiration Date when stored at: 15-30 °C	Manufacturer Expiration Date when stored at: 15-30 °C			Do not freeze or refrigerate No direct heat or sunlight
Urine H&L Controls	Manufacturers Expiration Store: 2-8 °C	Expiration in 30 days or manufacturers. Whichever date comes first! Store: 15-30 °C		Manufacturers Expiration Store: 2-8 °C	Do not freeze or refrigerate No direct heat or sunlight
Istat Stat					
Cartridges	*Store at 2 - 8 C .Do not allow cartridges to freeze. Manufacturers Expiration *If store at room temperature : 18 to 30°C for 2 months Mark the room temperature expiration			*five minutes at room temperature *An entire box of cartridges should stand at room temperature for one minute	
Aquaous Control ampule	Store at 2 - 8 C .Do not allow cartridges to freeze -Can stay up to 5 days in room temperature after removal from refrigerator				-For oxygen control stany for 4 hours befor used in room temperature. -Other stay 30miutes at room temperature befor use

SECTION IV .7 – Ten Commandments Of Phlebotomy





The Ten Commandments of Phlebotomy

I

Thou shalt protect thyself from injury


Using gloves, needle disposal units and proper technique can significantly minimize your risk of becoming one of the estimated ONE MILLION health care workers who will experience an accidental needle stick this year. Thousands will contract some form of hepatitis. Fifty to sixty of them will acquire HIV injury.



II

Thou shalt identify thy patients


This means referring to an identifying bracelet affixed to the patient or asking the patient to state his or her name. When this is not possible, have the patient's family or caregiver identify the patient and document the verifier. No other methods are acceptable.



III

Thou shalt collect specimens Only from an acceptable site

Antecubital and hand veins are acceptable, unless their use is precluded by intravenous infusions, injury or mastectomy. Any other site should be approached with great trepidation. Should an injury occur, your puncture site had better be defensible in court.




IV

Thou shalt glorify the medial vein

the medial vein is the vein of choice for four reasons:

- 1) It's more stationary;
- 2) puncturing it is less painful to puncture;
- 3) it's usually closer to the surface of the skin; and
- 4) it isn't nestled among nerves or arteries.


Keep the basilic vein as a last resort. Most nerve injuries and arterial nicks, result from misguided punctures into this vein.



V

Thou shalt Puncture the skin at about a Fifteen-degree angle


Most textbooks agree on a Fifteen to Thirty-degree angle of insertion. Injure a patient while puncturing at a greater angle and you will have a difficult time convincing the jury that you are immune from the prevailing standards.



VI

Thou shalt stretch the skin at the puncture site.


This accomplishes two functions: it anchors the vein and minimize the pain of the puncture. Your patients will thank you for considering their suffering.



VII

Thou shalt invert tubes containing anticoagulant Immediately after collection


A high percentage of blood specimens rejected by testing labs are due to clots in lavender or blue-top tubes. A couple of quick but gentle inversion of tubes with additives after collection gives the ideal specimen for testing and most often preventing a second puncture.



VIII

Thou shalt label specimen at the bedside.


This means complete identification, not just temporary identifiers to help you when you find time to label them more completely later. Find time NOW: Patients have died as a result of mislabeled specimens.



IX

Thou shalt know when to quit


Not everyone can draw blood from every patient. Even those who elevate phlebotomy to an art form can have difficulty from time to time. After two failed attempts, consider sending in someone else. That's professionalism: It may also be the answer to your patient's prayers.



X

Thou shalt treat all patients as if they are family

In health care center, the only peace many patients experience is that which you bring them by your kind words, gentle technique and your smiles. Regardless of what you might think, you have been assigned to health care by higher authorities because of the comfort you can offer the sick and the injured.

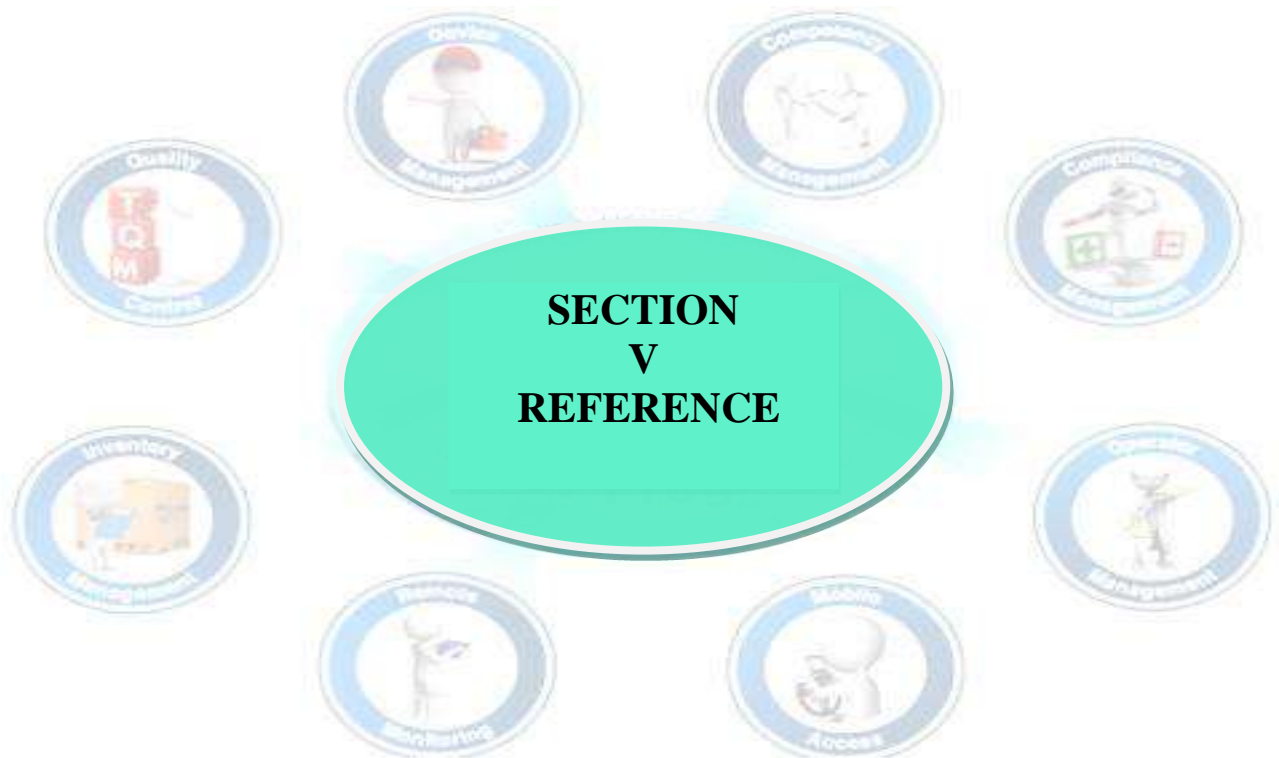


Laboratory & Blood Bank Department King Fahd Hospital Jeddah

ing Press Jeddah

Dr. Fathia Fathy

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