HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Multidisciplinary Policy and Procedure		
Title:	Point of Care Testing Policy		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To ensure the Accuracy and Reliability of the results obtained from Point of Care Testing (POCT) Equipment used outside the Laboratory in order to contribute to optimal patient care.

1.2 This is intended to mainly provide certain laboratory results in the minimum possible Turn Around Time to help diagnosis and prognosis without compromising quality.

2. DEFINITONS:

2.1 Point of Care Testing (POCT) is defined as any diagnostic testing that is performed at or near the site of patient care units by non-laboratory healthcare professionals like ward staff. It is accomplished through the use of transportable, portable, and hand held instruments e.g., Blood Glucometer, Arterial blood gas instrument, Cardiac Reader, and Bleeding time and clotting time measuring gadgets.

3. POLICY:

3.1 Point of care Testing is performed by non-Laboratory Health Care Professionals like Nurses under the Laboratory supervision.

3.2 A list of all Point of Care Testing equipment approved by medical director is available in the office laboratory director and nursing Directress, which is updated physically and in the records every six months and submitted to the medical director's office.

3.3 A detailed training Program and quality control management program is established for all POCT users along with their responsibility.

4. PROCEDURE:

4.1 **A detailed training Program and quality control management program is established for all POCT users along with their responsibility.**

4.2 POCT equipment's are placed in the clinical areas with agreement between the Laboratory Director and Nursing Directress and Heads of concerned Departments with the approval of the Medical Director.

4.3 **Safety:**

- 4.3.1 All POCT testing is undertaken in a way that does not put the patient or any POCT users at additional risk.
- 4.3.2 Proper infection control measures are practiced and Safety policies strictly adhered to.
- 4.3.3 Staffs operating POCT devices are aware of the biohazards of patient samples, the chemical hazards of reagents and the physical or electrical hazards of operating the devices.
- 4.3.4 Appropriate personal protective equipment such as gloves, gowns, face shields or masks, and eye protection are provided and used accordingly.

4.4 **Training :**

- 4.4.1 Accurate and precise test results obtained during POCT depend upon the POCT user consistently following and successfully adhering to the test procedures.
- 4.4.2 All staff operating a POCT devices receive training from.

4.4.2.1 The company application specialist at the time of installation of the equipment supported by written (up-to-date) operator's manual.
4.4.2.2 Laboratory POCT Coordinator.
4.4.2.3 Nurse In-charge in their Department.

4.4.3 POCT Training document is kept in respective nursing staff personal file.

4.4.4 Only staff whose training has been established and documented can use POCT device.

4.5 **Patient identification and sample collection:**

4.5.1 POCT users always positively identify the patient according to the standards.

4.5.2 All materials and equipment needed for the POCT sample collection are placed within safe and easy reach.

4.5.3 For the Blood Collection Procedures of :

4.5.3.1 ABG Testing: to follow the Standard Operative Procedure manual near the ABG machine.

4.5.3.2 Glucometer: to follow the user manual of the Glucometer provided by the manufacturer

4.6 **Operating POCT Device:**

4.6.1 Cleaning and maintenance:

The purpose of maintenance is to ensure that the POCT device is at optimal working condition and ensure the good quality of the result obtained. Maintenance should be performed by POCT users in coordination with Bio-Medical engineer on daily/ weekly basis and documented in the log sheet which should be near the POCT Device. The actions done in maintenance include, but are not limited to:

4.6.1.1 Cleaning (to the extent permitted to the operator).

4.6.1.2 Minor trouble shooting (Following the alarm messages if any and to follow corrective actions).

4.6.1.3 Changing of batteries, tubes and other consumable parts.

4.6.1.4 Checks for damaged or worn components, and protective measures.

All the above steps performed are documented on a daily basis.

4.6.2 Calibration:

The purpose of Calibration is to obtain accurate results from the POCT device. It is done according to the manufacturer's instructions by the nurse in-charge or by the staff assigned by him / her.

4.6.3 Quality control check is performed by the in charge nurse or assignee and recorded before the device / instrument is used for patient sample processing.

4.6.4 Sample processing: Process Samples as per the guidelines in the operator manual or SOP manuals provided for the POCT devices.

4.7 **Documentation and Result Reporting:**

4.7.1 The standard of reporting for POCT results is similar to that of laboratory testing.

4.7.2 POCT results are reported with sufficient detail like Department, patient demographics for identification purpose, time and date of blood collection, time and date of performing the POC Testing, the result, and name and signature of the POCT performing Staff.

4.7.3 POCT results are permanently filed in patient's medical record.

4.7.4 Any critical results are subjected to repeat check and confirmed before reporting following the set protocol.

4.7.5 The result records distinguish between POCT results and those from the Laboratory.

4.7.6 The POCT results are entered in the log sheet.

4.8 **Quality Control Program:**

4.8.1 Measurement of QC Solutions at regular intervals is followed for all POCT devices that are generating results on which a clinical decision is made.

4.8.2 QC measurement is used to detect any malfunction/ error in the POCT Device and ensure that the device. Is meeting the clinical and technical specifications required for the test?

4.8.3 It is done:

4.8.3.1 Daily once as a part of daily QC program.

4.8.3.2 When obtaining abnormal result that does not match the clinical findings in the patients.

4.8.3.3 When changing Consumables / Reagents.

4.8.3.4 After Calibrating the POCT Device.

4.8.3.5 After major maintenance work is performed and the device / instrument are restarted.

4.8.4 QC results should be reviewed and evaluated by the operator performing the test and in case of Glucometer. QC results are recorded in QC log sheet and in case of ABG machine the printed QC results are filed.

4.8.5 QC records are kept in the testing site for 2 years.

4.8.6 Quality Control Guidelines:

4.8.6.1 If QC results are within the expected range, POCT user can proceed to perform patient testing.

4.8.6.2 If QC results fail to be in the expected range, POCT user should NOT perform patient testing and must take the required corrective actions and resolve the problem according to the protocol.

4.8.6.3 The expiration date should be checked on the QC solutions, test kits, test strips or any reagent or consumables being used.

4.8.6.4 QC test should be repeated with the same material for the second time before deriving conclusion.

4.8.6.5 If repeat QC passes, patient testing is performed after recording QC results and documents all actions taken in the QC log sheet.

4.8.6.6 If repeat QC is still out of the expected range, it should be repeated using fresh QC vials, test strips, test kit or reagents.

4.8.6.7 If second repeat QC fails, patient testing is NOT being performed on the POCT Device, but the blood sample is processed on another device, and the Bio-Medical Engineer and POCT coordinator are informed for corrective action to be taken.

4.8.7 Competency assessment:

4.8.7.1 The competency of a trained staff is evaluated by the Nursing Director, Ward nurse in-charge and the Laboratory POCT Coordinator and is be documented using appendix.

4.8.7.2 The Point Of Care Site Nurse In-charge ensures that training and competence validation is in place for the respective sites.

4.8.7.3 POCT users are revalidated at an interval of every two years.

5. MATERIALS AND EQUIPMENT:

5.1 **List of POCT devises in hospital Departments.**
5.2 **Training and competency assessment record for Glucometer.**
5.3 **Training and competency assessment record for ABG machine.**
5.4 **Daily maintenance and QC Log Sheet of Glucometer.**
5.5 **Daily maintenance and QC Log Sheet of ABG machine**
5.6 **POCT Result Log Sheet of Glucometer**

6. RESPONSIBILITIES:

6.1 **Laboratory POCT Coordinator is responsible for:**

6.1.1 Monitoring POCT sites to ensure the Quality of POCT in coordination with Nurse In-charge in POCT site.

6.1.2 Training and competency assessment of POCT users in coordination with Nurse Director and Nurses In-charge in each POCT site.

6.1.3 Maintaining monthly records of the review to ensure compliance with the requirements of the POCT Policy.

6.1.4 Troubleshooting test system problems/failures in coordination with Bio-Medical Department.

6.2 **The Nurse in-charge in the Point of Care site takes up the responsibility of:**

6.2.1 Ensuring that all ward staff including shift staff and new staff on-site received training to use POCT Device and make training Schedules for the untrained staff.

6.2.2 Coordination With the Laboratory Store In-charge to provide the required supplies of Reagents, consumables.

6.2.3 Ensuring that quality control and daily maintenance is done daily.

6.2.4 The maintenance and troubleshooting of malfunctions and error in POCT devices' performance with the help of the Laboratory POCT coordinator and Biomedical Department

6.2.5 Competency assessment of POCT users in coordination with Laboratory POCT Coordinator and Nursing Director.

6.3 **The POCT users are responsible for:**

6.3.1 Strictly adhering to patient Identification Policy, critical value policy, and safety / infection control precautions.

6.3.2 Performing POCT according to the Standard Operative Procedure manual and Operator's manual of the POCT device.

6.3.3 Adhering QC protocol at each testing site each day before patient testing

6.3.4 Maintaining records and documentation according to the policy.

6.3.5 Checking the stocks of reagents and consumables of the POCT devices and coordinating with POCT site in charge to procure the same from medical supply department

6.3.6 Checking the expiry date and proper storage of materials/consumables.

6.4 Guidelines describing the process of acquiring POCT devices/methods:

6.4.1 The executive committee is responsible for discussing requests for approval of new point of care test or device.

6.4.2 This preliminary step in the procurement is to ensure the following criteria has been considered:

6.4.2.1 Is there a clinical need?

6.4.2.2 How does it benefit the patient?

6.4.2.3 Has it been discussed with the laboratory?

6.4.2.4 Can laboratory medicine and blood bank department offer a solution to meet the need?

6.4.2.5 Is it cost effective?

7. APPENDICES:

7.1 Glucometer QC Sheet

7.2 ABG QC Sheet

7.3 Request for Approval of New Point of Care Test or Device

8. REFERENCES:

8.1 Westgard, Westgard Quality Corporation, www.westgard.com.

8.2 Kaplan, Szabo, Clinical Chemistry: Interpretation and Technique.

8.3 Tietz, Textbook of Clinical Chemistry.

8.4 http://en.wikipedia.org/wiki/Glucose_meter.
http://www.webmd.com/lung/arterial-blood-gases.

9. APPROVALS:

	Name	Title	Signature	Date
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Reviewed by:	Mr. Sabah Turayhib Al Harbi	Director of Nursing		January 09, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 13, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025

Appendix 7.1 Glucometer QC Sheet

Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

DAILY GLUCOMETER QUALITY CONTROL SHEET

DEPARTMENT: ..... **MONTH:** ..... **YEAR:** .....

Day	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
Control low result																															
Control high result																															
Sign																															

Quality Control Procedure:

1. Run 2 QC levels every day.
2. Shake control bottle well, then remove the cap and use a tissue to wipe away any solution around the tip before dispensing a drop.
3. Squeeze small drop of solution onto clean nonabsorbent surface.
4. Immediately touch the tip of the test strip to the drop of control solution
5. Compare your result with control ranges on the test strip bottle.
6. If the result is out of range repeat it with the same control, if out again use new control, if again out of range use new strip bottle, if again out of range contact the POCT coordinator or laboratory administrator to do comparison study with lab machines and give the final decision about the machine .

Corrective Action Table:				
Date:	**Problem:**	**Corrective Action:**	**Name:**	**Sign:**

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Appendix 7.2 ABG QC Sheet

Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

ABL - 800 ABG QUALITY CONTROL AND MAINTENANCE SHEET

DEPARTMENT: ..... **MONTH:** ..... **YEAR:** .....

NOTE: QC check should be done every day once before starting to use the ABG for patients.

	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
Clean Machine Surface:																															
Clean Aspirator with Alcohol Swab:																															
Check Consumables:																															
Remove Waste Container (if full):																															
Rinse																															
Check Calibration: Point 1 / Point 2																															
Run QC: (write the No. of QC)																															
Name:																															
Signature:																															

QUALITY CONTROL PROCEDURE:

1. Run 2 QC levels every day.
2. Break the QC vial.
3. Lift the aspirator lid and immediately introduce QC vial to the sample aspirator
4. In the screen, press QC botton and press start.
5. The QC result will come automatically, if the QC results fall in the expected range, proceed to patient samples.
6. If QC result is out of the range, repeat QC with another vial.
7. If QC result is still out of the range, calibrate 1 point, 2 point and repeat the QC.
8. If QC result is still out of the range, call Bio – MED to check the ABG machine.
9. In steps 7, 8 if the QC result falls within the expected range, record the action taken in the corrective action table and proceed to patient samples.

Corrective Action Table:

DATE	PROBLEM	CORRECTIVE ACTION	NAME	SIGNATURE

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Appendix 7.3 Request for Approval of New Point of Care Test or Device

Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

REQUEST FOR APPROVAL OF NEW POINT OF CARE TEST OR DEVICE

REQUESTED DATE:

TEST REQUESTED:	
NAME OF DEVICE:	
HOW DID YOU LEARN ABOUT THIS TEST? **Contacted by the Seller (Company and Name):** ○ **Journal Article** ○ **Conference** ○ **Recommended by Colleague (Name and Phone)** ○ **Physician Request (Name and Phone)**	
PURPOSE OF INTRODUCING TEST:	
WHERE THIS TEST WILL BE USED:	
ESTIMATE ANNUAL TEST VOLUME:	
ESTIMATE ANNUAL TEST USE:	

REQUESTED BY:

NAME: .....

POSITION: .....

DEPARTMENT: .....

MOBILE NUMBER: .....

EMAIL ADDRESS: .....