HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Controlling the Quality of Test Methods		
Applies To:	All laboratory staff		
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1. PURPOSE:

1.1 Monitor performance; identify problems regarding quality control of test method and initiate corrective action if needed.

2. DEFINITONS:

2.1 The quality control (QC) : Processor system for monitoring the quality of laboratory testing, and the accuracy and precision of results, Routinely collect and analyze data from every test run or procedure and allows for immediate corrective action.

3. POLICY:

3.1 The laboratory must have a site-specific, written QC plan which clearly defines procedures for monitoring analytic performance; this program ensures the consistent identification, documentation, and resolution of QC issues.

4. PROCEDURE:

4.1 The laboratory shall use quality control product which is a patient-like material ideally made from human serum, urine or spinal fluid. A control product can be a liquid or freeze-dried (lyophilized) material and is composed of one or more constituents of known concentration. Control products should be tested in the same manner and by the same laboratory personnel testing patient samples.

4.2 The laboratory must test normal and abnormal controls (two or more controls levels) for each test at daily work manner at the start of morning shift to monitor the analytical process. If some changes occurred which could potentially affect the test stability, controls should be assayed more frequently.

4.3 The QC materials must be prepared (if needed), handled and stored according to manufacturer instruction

4.4 QC materials must be handled and tested in the same manner and by the same laboratory personnel testing patients' samples.

4.5 The analyses concentrations in the control solutions should reflect the values at which clinical medical decisions are made and not coincide with the calibration points.

4.6 The laboratory should establish local tolerance limits of controls results.

4.7 For qualitative tests (widal , brucella , CRP, ASOT, RF), do positive and negative controls with each run.

4.8 Both random and systemic error must be detected if present utilizing Levey-Jennings Chart and apply Westgard Rules on daily process.

4.9 Patient values will be reported only when Quality Control values are within the stated acceptable limits:

4.9.1 Each section of the laboratory will have a corrective action procedure to be followed when control values do not fall within the expected range and following Westgard Rules.

4.9.2 Quality control acceptable ranges must be established for all quantitative testing (at least 20 QC data), manufacture range will be used as baseline ranges.

4.9.3 Westgard Rules followed for rejection criteria:

4.9.3.1 One control value outside the ±2SD): warning

4.9.3.2 One control is greater than ±3SD of test mean): rejection

4.9.3.3 Two controls; normal and abnormal; are greater than ±2SD of test mean.): rejection

4.9.3.4 One control is greater than ±2SD from test mean for two consecutive days: rejection

4.9.4 All controls subject for rejection must be documented using the corrective action report form.

4.9.5 Patient tests should be run only if the quality controls both the normal and abnormal values are within the stated acceptable limits.

4.9.6 Tests using positive/negative controls only must have appropriate reactions on both positive and negative controls before patient values are reported.

4.10 Patient values will be reported only when Quality Control values are within the stated acceptable limits:

4.11 In case of QC role violation, corrective action must be taken and documented to assure that the error has been resolved.

4.12 Corrective action protocol:

4.12.1 The corrective actions used in any laboratory can be based on the following corrective action protocol suggested by the National Committee for Clinical Laboratory Standards (NCCLS): a generic protocol for corrective actions:

4.12.1.1 Check all maintenance and calibration records.

4.12.1.2 Check reagents, consumables ad QC materials validity and status.

4.12.1.3 Check which types of errors based on Westgard Rules.

4.12.1.4 Reanalyse the same control immediately.

4.12.1.5 Repeat the test using a fresh vial of control.

4.12.1.6 Repeat the test using a new control from a different lot if it is applicable.

4.12.1.7 Perform maintenance and rerun the control.

4.12.1.8 Recalibrate and rerun the control.

4.12.1.9 Consult a supervisor and troubleshoot.

4.13 The laboratory quality control system must conform to the manufacturer's instructions.

4.14 For staining procedures, gram stains require both Gram positive and Gram-negative control organisms to be used once per week and with each change of a lot number of any component in the stain procedure. Other stains require daily or day of use QC, using a positive reacting organism and a negative, which could include the patient sample.

5. MATERIALS AND EQUIPMENT:

5.1 QC material

5.2 Quality Control Log Sheet

5.3 Quality Control Corrective Action Form

6. RESPONSIBILITIES:

6.1 It is the responsibility of the medical technologists or technicians in charge to:

6.1.1 Perform and document the performance of quality control procedures with every patient procedure performed as stated in this policy and procedure and in the section procedure manuals.

6.1.2 Perform and document the performance of preventive maintenance on all laboratory instruments and equipment as states in this policy and procedure and in the section procedure manuals.

6.1.3 Perform and document all miscellaneous quality control procedures as stated in this policy and procedure.

6.2 It is the responsibility of the section heads to ensure that the quality control of their sections are performed and documented.

7. APPENDICES:

7.1 Quality Control Corrective Action Form

8. REFERENCES:

8.1 National Institute of Health; Good Clinical Laboratory Practice Standards; DAIDS Guidelines for Good Clinical Laboratory Practice Standards; Approved guidelines-final version 3.0,09 July, 2013.

8.2 Henry's Clinical Diagnosis and Management by Laboratory Methods, 21st 2007.

9. APPROVALS:

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Appendices 7.1 Quality Control Corrective Action Form

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

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

QUALITY CONTROL CORRECTIVE ACTION FORM

INSTRUMENT:		**SECTION:**	
ANALYTE:			
QC OPERATOR:			
DATE:			

CORRECTIVE ACTION TAKEN:

- ☐ Check if there is air bubble or precipitation of the reagent, incorrect preparation.
- ☐ Check for improper mixed/ dissolved QC reagent.
- ☐ Check pipettes, probes for tips/clot/ misalignment/ improper washing, leakage, crystallization, scratches.
- ☐ Check reagent lot number.
- ☐ Check reagent expire date (open and shelf life).
- ☐ Check for debris in sample tubing, cells, probes.
- ☐ Check maintenance or change major part.
- ☐ Check machine temperature, ambient temperature, system pressure.
- ☐ Check for contamination particles or fungal contamination.
- ☐ Check pipette calibration and accuracy.
- ☐ Check water system supply.
- ☐ Check calibration, inaccurate, incorrect values.

ACTION TAKEN:

- ☐ Run internal quality control.
- ☐ Run with new fresh QC vial.
- ☐ Run/ re-run calibration.
- ☐ Use backup instrument.
- ☐ Call company Engineer/ Biomed. and notify the supervisor.

COMMENT:

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QC Correction Done By:	
QC Reviewed By:	