HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Haematology)		
Document:	Internal Policy and Procedure		
Title:	Controls –General Policies		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 Controls shall be used in all analytic procedures where it is practical and technically feasible to do so

2. DEFINITONS:

N/A

3. POLICY:

3.1 All controls are to be run and handled in the same manner in which Patient's specimens are processed for each testing procedure.

4. PROCEDURE:

4.1 Results of controls must be recorded in the appropriate file and reported with the patient results if necessary

4.2 Results of analytic procedures must not be released unless the controls perform as expected and the results of the controls are verified for acceptability.

4.3 The results of the controls exceed tolerance limits for the procedure, documentation of the specific controls (parameter) which is out of range must be written on the designated log sheet. The following steps must then be followed:

4.3.1 Repeat the procedure

4.4 If results of control still exceed limits, check the following

4.4.1 Procedure is as written in manual.

4.4.2 Reagents – expiry dates, contamination

4.4.3 Instrumentation – refer to manufacturer's operator manual for troubleshooting

4.5 If results of controls continue to exceed tolerance limits:-

4.5.1 Notify senior technologist/section supervisor

4.5.2 Hold non-critical specimens until problem can be identified and corrected

4.5.3 Arrange for back-up service for critical specimen

4.6 Controls – Tolerance Limits And Use

4.6.1 Commercial assayed controls used for the C.B.C. Analyzers are intended for the use on analyzers. Once new shipments of controls arrive in the section, they must be checked for integrity and the mean for the controls must be verified before putting them to use. New target values may be established as appropriate as long as the new target values fall within the recovery range supplies by the manufacturer.

4.6.2 Normal Control:

To be used as a reference control for its own analyser. Refer to assay sheet provided with each lot number for expected ranges and instruction for use. This control must be run at least once per shift and whenever the instrument is in use. It is to be included in the daily start-up procedure. All parameters are to be entered in the control files. This is then

printed out at the expiry date of each normal lot before the new lot number values are entered.

4.6.3 Abnormal High And Low Control:
To be used as reference controls for its own analyzer. Refer to assay sheet provided with each lot number for expected ranges and instructions for use. These controls are to be run daily. They are to be included in the start-up procedure each day and entered in the appropriate analyzer control files.

4.7 Note:

4.7.1 At least two levels of controls are to be run per shift. Also, the controls should be run anytime the results or the instruments performance is in question

4.7.2 Controls must be run anytime a new lot number of reagents/diluents are put to use, and after an acceptable background check is performed

4.7.3 Automated blood counts and differential counts: To ensure that results obtained from two different analyzers and/or from two different modes on the same analyzers are in agreement, a daily inter-instrument comparison is performed in the automated hematology between the analyzers. Also, a manual differential is performed on the same specimen to ensure that the manual and automated differential results are also in agreement.

4.7.4 Sickle test positive (AS) and negative (AA) controls shall be used as positive and negative controls for screening test for sickle hemoglobin.
These controls must be included with every batch of test samples. These controls must react as expected. Refer to sickled procedure for the interpretation of results

4.8 Review Of Quality Control Data

4.8.1 Comprehensive quality control records shall be maintained in the section on a daily basis. These records must be reviewed daily by the senior technologist in-charge and/or section supervisor and doctor in charge.

4.8.2 Evidence of such reviewed must be documented at least weekly. On completion of a calendar month all quality control records shall be statistically analyzed and submitted to the doctor in charge for review.

4.8.3 The records shall be filed for a minimum of two years. When results of controls have been shown to exceed tolerance limits evidence of corrective action must be available

4.8.4 Corrective action shall be indicated on daily log sheet and/or maintenance log sheet. Active review of monthly quality control records shall be indicated by the pathologist's and section supervisor's signatures.

5. MATERIAL AND EQUIPMENT:

5.1 Normal Control
5.2 Abnormal High And Low Control

6. RESPONSIBILITIES:

6.1 All Haematology Staff

7. APPENDICES:

N/A

8. REFERENCES:

8.1 CRC Handbook Series in Clinical Laboratory, Science, Section 1: Hematology Volume III, 1980. CRC Press, Inc. Boca Raton, Florida.

9. APPROVALS:

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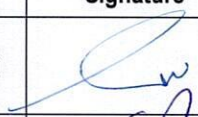
Prepared by:	Dr. Fatma Hassan Ahmed	Clinical Pathologist		January 06, 2025
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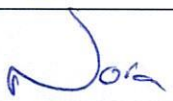
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
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