HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Control of Deviations and Exceptions Policy		
Applies To:	All laboratory and Blood Bank Staff		
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1. PURPOSE:

1.1 To provide guidelines of to control the deviations and exceptions to laboratory and procedures.

2. DEFINITONS:

2.1 A deviation is defined as an unexpected / unapproved departure from the policy's procedures that was approved by laboratory administration.

2.2 Exception is defined as the enrolment of a specific patient / specimen that does not meet the criteria of an approved procedure.

3. POLICY:

3.1 It is our laboratory policy to control deviations and exception to approved policies and procedures in the laboratory, monitor and document them.

4. PROCEDURE:

4.1 All laboratory staff should follow the laboratory policies and procedures all times.

4.2 Deviations and exception warranted by clinical situations or special circumstances should be justified, pre-approved, and documented case-by-case basis.

4.3 Deviations and exceptions must be approved for only one implementation event by the Lab Director.

4.4 Exceptions may pertain to specimen quality and to the analytic process. Examples but not limited to:

- 4.4.1 A sample that was not transported under optimal conditions. A decision may be made to process the sample and to proceed with subsequent testing if the specimen is precious and cannot be re-obtained.
- 4.4.2 If a Precious specimen is leaking, still must be processed as CSF sample, or intra operative specimen ,histopathology specimen .
- 4.4.3 Using expired reagents in case of reagent shortage.
- 4.4.4 Releasing of incompletely tested blood and blood components.

4.5 In all cases of deviation and exceptions, the concerned department in-charge staff should be informed to rectify the error and confirm that the error cannot be corrected, and the result/service should be proceeded.

4.6 The deviation/exception should be documented in the deviation and exception form and approved by the laboratory director.

4.7 The physician responsible for the patient should be informed about the deviation/exception and the possible effects that may alter the patient results/service.

5. MATERIALS AND EQUIPMENT:

5.1 Deviation and Exception form

6. RESPONSIBILITIES:

6.1 All laboratory staff
6.2 Section head/section supervisor
6.3 Laboratory director

7. APPENDICES:

7.1 Deviation and exception form

8. REFERENCES:

8.1 National Standards for Clinical Laboratories and Blood Bank

9. APPROVALS:

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Appendices 7.1 Deviation and Exception Form

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

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

DEVIATION AND EXCEPTION FORM

DEVIATION/EXCEPTION:
PATIENT NAME: **MRN:** **DEPARTMENT:** **PHYSICIAN NAME:**
DATE: **TIME:**
ACTION DONE:
DONE BY: **SIGNATURE:** **STAMP:**
SECTION SUPERVISOR:
SECTION HEAD:
PHYSICIAN INFORMED: **DATE:** **TIME:**
LAB QUALITY ASSURANCE OFFICER:
LAB DIRECTOR APPROVAL: