HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Serology)		
Document:	Internal Policy and Procedure		
Title:	Human Immunodeficiency Virus		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To establish a standardized operating procedure for Human Immunodeficiency Virus (HIV) testing.

2. DEFINITONS:

2.1 HIV tests detect HIV type 1 and 2 that cause AIDS, a virus inducing infectious disease characterized by strongly depressed immunity. It is used to screen blood and blood products that will be used for transfusion, and to test people at risk for developing AIDS (eg, IV drug users, sexual partners of HIV-infected persons, and infants born to HIV-infected women, etc).

3. POLICY:

3.1 Positive results should be retested in duplicate before final interpretation.
3.2 Another sample is requested if retested samples are positive and new samples are retested.
3.3 Positive retested samples are sent to Dammam Regional lab for confirmatory test.
3.4 Samples sent to Dammam with all done results and patient national ID.

4. PROCEDURE:

4.1 **Principle:**
- 4.1.1 HIV test method is an enzyme immunoassay based on the principle of the sandwich technique for the detection of HIV antigen and of the various antibodies associated with HIV-1 and/or HIV-2 virus in human serum or plasma.

4.2 **Sample and Reagents preparation:**
- 4.2.1 Bring all the reagents and samples to room temperature for 30 minutes before use.
- 4.2.2 Carefully establish the sample distribution and identification plan.
- 4.2.3 Take the required number of strips from sealed antigen coated microplate, and the remaining strips must be kept at 2-80C with a silica gel (desiccant) in an aluminium pouch.
- 4.2.4 Prepare the diluted washing solution. Dilute 1:20 in distilled water to obtain the ready-for-use washing solution. Prepare 800 ml for one plate of 12 strips.
- 4.2.5 Prepare conjugate R7a R7b 2 working solution:
  - 4.2.5.1 Gently tap the vial of the lyophilized conjugate on the work-bench to remove any substance from the rubber cap.
  - 4.2.5.2 Carefully remove the cap and pour the content of a conjugate diluents vial into the lyophilized conjugate vial. Put the cap on and let stand for 10 minutes while gently shaking and inverting from time to time to ease dissolution.
- 4.2.6 Prepare the Substrate solution:
  - 4.2.4.1 Dilute 1:11 the chromogen in the substrate Buffer. Stability is for 6 hours in the dark once prepared.
- 4.2.7 Insert the racks and the plates into EVOLIS machine.
- 4.2.8 Run the machine.

4.2.9 Check for agreement between the spectrophotometric reading and visual readings and against the plate and sample distribution and identification plan.

4.3 **Interpretation of the results:**

4.3.1 Non-reactive HIV test results occur during the acute stage of disease when antigen or antibodies are not sufficiently developed to be detected (very low titre).

4.3.2 The variability of HIV-1 and HIV-2 allows the possibility of false negative reactions.

4.3.3 Some icteric, hyper lipemic, or hyper hemolyzed samples may affect the spectrophotometric method for verifying the conjugate 1 deposition.

4.3.3.1 Calculation:

4.3.3.1.1 Cut OFF: Average OD value of Negative Control / 3

4.3.3.1.2 POSITIVE: OD value = or 〉 Cut Off value
NEGATIVE: OD value 〈 Cut Off value
OD R3 < 0.170
OD R4 > 0.9
OD R5 > 0.9

4.4 **Results reporting:**

4.4.1 Negative results are stamped with NEGATIVE stamp.

4.4.2 Positive results are stamped with REACTIVE stamp.

4.4.3 Confirmed positive results are stamped with POSITIVE stamp.

4.5 **Quality Control:**

Use positive (R4) and negative (R3) control in each run of test to validate the assay.

5. MATERIAL AND EQUIPMENT:

5.1 Refer to the Genscreen™ ULTRA HIV Ag-Ab kit Pamphlet

6. RESPONSIBILITIES:

6.1 All trained laboratory personnel on the serology section.

6.2 The final report must be signed by section supervisor and approved by lab pathologist.

7. APPENDICES:

7.1 Genscreen™ ULTRA HIV Ag-Ab Pamphlet

8. REFERENCES:

8.1 Genscreen™ ULTRA HIV Ag-Ab Pamphlet

8.2 Clinical Diagnosis & Management by Laboratory Methods 18th ed by John Bernard Henry

9. APPROVALS:

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