



HEALTH HOLDING

HAFAER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Serology)		
Document:	Internal Policy and Procedure		
Title:	Hepatitis B Surface Antigen		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

- 1.1 This standard operating procedure (SOP) describes the procedure for carrying out Hepatitis B surface Antigen (HBsAg) test in the laboratory.

2. DEFINITONS:

- 2.1 Hepatitis B surface antigen (HBsAg) is a blood test ordered to determine if someone is infected with the hepatitis B virus. Thus, Monolisa HBsAg ULTR Assay is a one-step enzyme immunoassay technique used for the detection of the surface antigen Hepatitis B virus (HBsAg) in the human serum/plasma.

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 This HBsAg test method is an enzyme immunoassay based on the principle of the "sandwich" type using monoclonal antibodies and polyclonal antibodies selected for their ability to bind themselves to the various subtypes of HBsAg and the most part of variant HBV strains.

4.2 Sample and Reagents preparation:

- 4.2.1 Bring reagents and specimens to room temperature.
4.2.2 Carefully establish the sample distribution and identification plan.
4.2.3 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.
4.2.4 Prepare the conjugate R6+R7 working solution, and Substrate solution.
4.2.4.1 Gently tap the vial of the lyophilized conjugate on the work-bench to remove any substance from the rubber cap.
4.2.4.2 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.
4.2.4.3 Dilute 1:11 the chromogen in the substrate Buffer. Stability is for 6 hours in the dark once prepared.
4.2.5 Take out from the protective packing the support frame and the necessary number of strips (R1). Put the unused strips back in their packing and reclose it.
4.2.6 Insert the racks and the plates into EVOLIS machine. Run the machine.
4.2.7 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 Samples with ratio values lower than 1 are considered to be negative by the Monolisa™HBs Ag ULTRA.
- 4.3.2 Samples with ratio values equal to or greater than 1 are considered to be initially positive by the Monolisa™HBs Ag ULTRA.
 - 4.3.2.1 Calculation:
 - 4.3.2.1.1 Cut OFF: Average OD value of OD R3 + 0.050.
 - 4.3.2.1.2 Sample ratio = OD sample / Cut-off value.

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.

5. MATERIAL AND EQUIPMENT:

- 5.1 Refer to the Monolisa HBs Ag ULTRA 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.

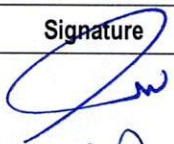





7. APPENDICES:

- 7.1 N/A

8. REFERENCES:

- 8.1 Monolisa™HBs Ag ULTRA kit
- 8.2 Clinical Diagnosis & Management by Laboratory Methods 18th ed by John Bernard Henry.

9. APPROVALS:

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