HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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| **Department:** | Laboratory and Blood Bank (Serology) | | |
| **Document:** | Internal Policy and Procedure | | |
| **Title:** | Hepatitis C 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 HCV test in the laboratory.

## 2. DEFINITONS:

2.1 Hepatitis C Virus, formerly known as non-A, non-B hepatitis, is the most common cause of post-transfusion hepatitis. HCV infection is characterized by presence of antibodies to hepatitis C (Anti-HCV). Levels of anti-HCV remain positive for many years, therefore, a reactive test indicates infection with HCV, or a carrier state but not infectivity or immunity.

## 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 The test for Anti- HCV is based upon the use of a solid phase prepared with purified antigens and detection is with purified goat anti-human IgG. Antibodies to HCV, if present in the samples and control sera that were added to the wells, bind to the antigens fixed on the solid phase and will further bind to peroxidase-labelled antibodies to human IgG that were added after washing. Unbound enzymatic conjugate is removed, and the antigen-antibody complex revealed by adding the substrate. Reaction is then stopped and absorbance read spectrophotometrically. Color intensity is proportional to the quantity of antibody to HCV bound on the solid phase.

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 2-8$^0$C 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 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.
4.2.6 Insert the racks and the plates into EVOLIS machine.
4.2.7 Run the machine.
4.2.8 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 an optical density lower than the cut off value are considered negative (ratio <1) by the Monolisa™ anti-HCV PLUS.

4.3.2 Samples with an optical density greater than the cut off value are considered initially positive (ratio ≥1) by the Monolisa™ anti-HCV PLUS.

4.3.2.1 Calculation:

4.3.2.1.1 Cut OFF: Average OD value of R4* 0.4

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.

4.5 **Quality control:**

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

## 5. MATERIAL AND EQUIPMENT:

5.1 Refer to the Monolisa™ anti-HCV PLUS 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™ anti-HCV PLUS.

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


## 9. APPROVALS:

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