BIOGENIX

SOP FOR HEPATITIS B SURFACE ANTIBODIES

	NAME	DESIGNATION	SIGNATURE	DATE
Prepared by	MS. PREETY RAHEJA	QUALITY MANAGER		30/06/2020
Reviewed by	Dr Bhagyashree Thakre	Deputy Lab Director		01/07/2020
Approved by	Dr Sally Abdulla Ibrahim	Lab Director		01/07/2020

1. TABLE OF CONTENT

2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3. REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

4. PURPOSE

The Alinity i Anti-HBs assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of antibody to Hepatitis B surface antigen (anti-HBs) in human serum and plasma on the Alinity i analyzer.

5. TEST PRINCIPLE

This assay is a two-step immunoassay for the quantitative determination of anti-HBs in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample and recombinant HBsAg (rHBsAg) coated paramagnetic microparticles are combined and incubated. The anti-HBs present in the sample binds to the rHBsAg coated microparticles. The mixture is washed. Recombinant HBsAg acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of anti-HBs in the sample and the RLUs detected by the system optics.

6. PERFORMANCE CHARACTERISTICS

6.1. This test is verified with (accuracy and precision)

6.2. Precision

Complex precision: Precision evaluation experiments evaluate the degree to which repeated measurements show the same result under a specified set of conditions.

Run 3 levels of QC (negative, positive +, Positive 2+) five times for five days.

6.3. Linearity

Linearity studies is performed as in order to determine linear reportable range. Calibrators is tested in the same manner as patient samples. Testing is performed in triplicate

6.4. Comparison

A set of 25 patients' samples already processed on the using Alinity i of another laboratory are processed to do comparison studies.

6.5. For detailed reports Please refer to method verification file.

7. TYPE OF SAMPLE/CONTAINER/ADDITIVE/PATIENT PREPARATION

7.1. SAMPLE TYPE

Specimen Types	Collection Tubes
Serum	Serum Serum separator
Plasma	Dipotassium EDTA Sodium citrate ACD CPDA-1 Lithium heparin Sodium heparin

- **Specimen storage conditions:**

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum/Plasma	2 to 8°C	14 days	Specimens may be stored on or off the clot or red blood cells.

If testing is delayed more than 14 days, remove serum or plasma from the clot, serum separator, or red blood cells and store frozen (-20°C or colder).

7.2. HANDLING OF SPECIMENS:

7.2.1. Centrifuge serum samples after complete clot formation (3500rpm/15minutes)

7.2.2. Ensure the patients' samples are at ambient temperature (20-25°C) before measurement.

7.2.3. For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation

7.3. SAMPLE ACCEPTANCE AND REJECTION CRITERIA

Do not use:

7.3.1. Pooled specimens.

7.3.2. Grossly hemolyzed specimens.

7.3.3. Heat-inactivated specimens.

7.3.4. Inspect all samples for bubbles.

7.3.5. Improper labeling.

7.3.6. Insufficient quantity.

7.3.7. Obvious microbial contamination.

7.3.8. Body fluids other than human serum and plasma.

For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.

To prevent cross contamination, use of disposable pipettes or pipette tips is recommended

8. PATIENT PREPARATION

N.A.

9. REQUIRED EQUIPMENT AND REAGENT

9.1.1. Alinity i Anti-HBs assay file

9.1.2. 07P8901 Alinity i Anti-HBs Calibrators

9.1.3. 07P8910 Alinity i Anti-HBs Controls or other control material

9.1.4. 07P8942 Alinity i Anti-HBs Specimen Diluent

9.1.5. Alinity Trigger Solution

9.1.6. Alinity Pre-Trigger Solution

9.1.7. Alinity i-series Concentrated Wash Buffer

9.1.8. Probe conditioning solution

9.1.9. Sample Cups

9.1.10. Reaction Vessels

9.1.11. Printer paper

9.1.12. D/W

10. ENVIRONMENT & SAFETY CONTROL

10.1. Temperature/ humidity.

10.2. In vitro diagnostic uses: Exercise the standard precautions required for handling all laboratory reagents.

10.3. Disposal of all waste material in accordance with Procedure for Waste Management.

10.4. Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).

10.5. For environmental and safety precautions for using reagent for Alinity i refer to MSDS.

11. CALIBRATION

11.1. CALIBRATION FREQUENCY

11.1.1. A reagent kit with a new lot number is used.

11.1.2. Daily quality control results are outside of statistically- based quality control limits used to monitor and control system performance, as described in the Quality Control Procedures section of this package insert.

11.1.3. If statistically- based quality control limits are not available, then the calibration should not exceed a 30-day limit for recalibration frequency.

11.2. TRACEABILITY

The calibrators are manufactured by dilution and tested against internal standards.

The internal standards are standardized to the anti-Hepatitis B immunoglobulin World Health Organization (WHO) 2nd International Reference Preparation, 2008 (code 07/164) at each concentration level.

11.3. CONTENTS

The calibrator Kit contain six levels of calibrators A, B, C, D, E, F with different concentrations

11.4. CALIBRATOR STORAGE & STABILITY

11.4.1. Keep Alinity Calibrator upright at 2 to 8°C.

11.4.2. Unopened calibrator is stable until the expiration date when stored at 2 - 8°.

11.4.3. Opened calibrator is stable until the expiration date when handled as directed and stored at 2 to 8°C

12. QUALITY CONTROL

12.1. QC MATERIALS

3 levels of QC supplied by the manufacturer will be run daily before running patients' samples:

12.1.1. Negative

12.1.2. Positive 1+

12.1.3. Positive 2 +

12.2. FREQUENCY OF RUNNING INTERNAL QC

12.2.1. Every 24 hours when the test is in use.

12.2.2. On Opening of new reagent kit.

12.2.3. After every calibration.

12.2.4. Patient samples are not processed unless IQC result is acceptable /refer to Procedure for Ensuring Quality Of Examination Results

12.2.5. Refer to General SOP/for Allinity startup, running control, calibrating, and machine shut down procedures

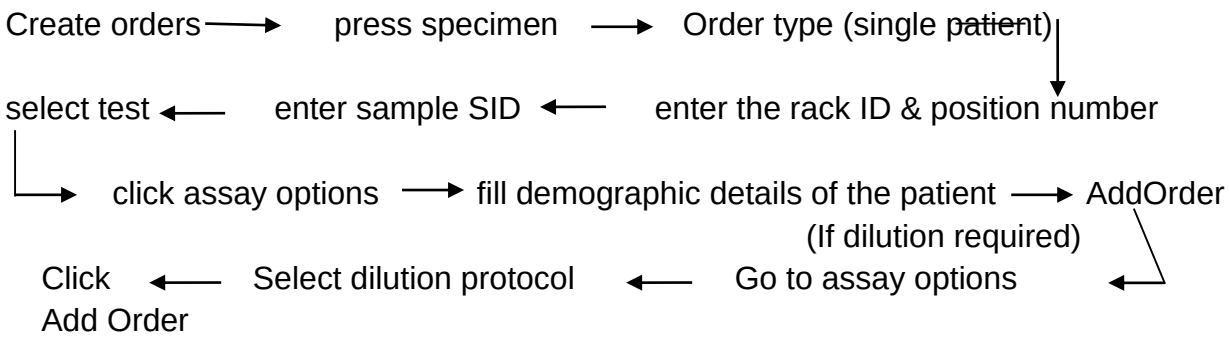
12.3. EXTERNAL QC

12.3.1. We are enrolled in CAP PT program

12.3.2. Refer to PT/INTER LAB COMPARISON record file

13. PROCEDURE

13.1. Follow standard Personnel Protective equipment's precautions.
13.2. Check the request for Routine or urgent, Confirm the label on the tube and bar-coded sticker with accompanying requisition form.
13.3. Prepare the sample as per our Procedure For Sample Handling, Preparation And Storage
13.4. Take the Request form and check all the Demographic details and Test order in LIS;
13.5. Check the sample for Barcode;
13.6. Check for the daily and weekly maintenance, if pending perform it first and then proceed for the test;
13.7. Check for all consumables and reagent needed before processing the sample.
13.8. After checking the validity of controls and calibrators process samples using LIS or manual entry
13.9. LIS method: Take sample carrier, position the tube by barcode facing outside, machine will automatically take the rack and start to run the test.
13.10. If LIS is not working or any problem with LIS we process samples manually, place the tube in appropriate sample carrier , in main menu:



13.11. Place the rack in the sample loading area
13.12. Machine will automatically start performing the tests
13.13. After some time it will give results.
13.14. If barcoded samples are used, the rack ID and position number are not required.
13.15. In case of Bar-coded Batch, select bar-coded batch, scan the first SID then the last SID, name the batch, select assay then Add Order

14. INTERFERENCE

14.1. This study was performed on the Alinity i System.

Potentially Interfering Endogenous Substances

14.2. No qualitative performance differences were observed between experimental controls and 23 nonreactive or 23 spiked reactive specimens tested with elevated levels of triglycerides, bilirubin, or hemoglobin.

14.3. No qualitative performance differences were observed between experimental controls and 21 nonreactive or 20 spiked reactive specimens tested with elevated levels of protein.

Potentially Interfering Substance	Interferent Level
Triglycerides	≤ 3000 mg/dL
Bilirubin	≤ 20 mg/dL
Hemoglobin	≤ 500 mg/dL
Protein	≤ 12 g/dL

15. CALCULATION

The Alinity i Anti-HBs assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, X-weighted) to generate a calibration and results.

16. BIOLOGICAL REFERENCE INTERVALS

Based on the World Health Organization recommendation, an Anti-HBs concentration ≥ 10 mIU/mL is regarded as being protective against Hepatitis B viral infection.

17. DILUTIONS

N.A

18. CRITICAL VALUE

N.A

19. LABORATORY CLINICAL INTERPRETATION

19.1. Result evaluation:

- Result of the patient evaluated according to provisional diagnosis of the patient and the type of the sample.

19.2. Result confirmation:

- Result is confirmed by revising the patient identification from the request with the sticker on the sample
- The laboratory technical staff confirms the acceptability of quality control results prior to reporting patient results.
- Patients with previous Laboratory records, check first the latest results before releasing the current results.
- Confirm and repeat any High / low result.
- Review the results for any Flags on the system.

20. POTENTIAL SOURCES OF VARIATION

20.1. PERSONAL:

- Competency of staff.

20.2. MACHINE /EQUIPMENT:

- Centrifuge
- Maintenance
- PPM
- Pipette

20.3. REAGENT:

- Stability of reagent and expiry date
  Temperature of refrigerator

21. REFERENCES

21.1. User Manual for Allinity.

21.2. Kit insert of Anti HBs reagent

21.3. Insert of Anti HBs Calibrator

BIOGENIX

Abu Dhabi, UAE

Call: 0466 XXX XX
Fax: 046XXX XXX

name@biogenix.com

Thank You