BIOGENIX

SOP FOR OPERATING & MAINTENANCE OF ALLINITY I

	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 purpose of this SOP is to Provide complete instructions for the use and maintenance of the Alinity I

5. TEST PRINCIPLE

Methodology: **Chemiluminescent Microparticles Immunoassay (CMIA)**

Paramagnetic microparticles coated with capture molecules (antigens, antibodies, or viral particles) that are specific for the analyte being measured.

5.1 The sample and the paramagnetic microparticles coated with capture molecules are dispensed into the reaction vessel (RV). The vortexmixes the reaction mixture.

5.2 The reaction mixture incubates. The analyte in the sample binds to the capture molecules on the paramagnetic microparticles and forms an immune complex

5.3 A magnet attracts the paramagnetic microparticles (which are bound to the specific analyte) to a wall of the RV. The wash zone assembly washes the reaction mixture to remove unbound materials

5.4 The pipettor dispenses a chemiluminescent, acridinium-labeled conjugate into the RV. The conjugate binds to the immune complex to complete the reaction mixture. The reaction mixture incubates.

5.5 The wash zone assembly washes the reaction mixture to remove unbound materials.

5.6 Pre Trigger Creates an acidic environment to prevent the early release of energy (light emission)

5.7 The Trigger Solution creates an alkaline environment that, with the exposure to peroxide in the Pre-Trigger Solution, causes the acridinium dye to undergo an oxidative reaction. The oxidative reaction causes a chemiluminescent reaction to occur. N-methylacridone forms and releases energy (light emission) as N-methylacridone returns to its ground state. The CMIA optical system measures the chemiluminescent emission (activated read) over a predefined timeperiod to determine a result.

5.8 The optical system on the processing module directs the chemiluminescent emission from the reaction vessel (RV) to the optics. The i-series module uses an optical measurement to obtain relative light unit (RLU) readings and then converts them to assay-specific analyte concentration units or qualitative interpretations for index (cutoff) assays

6. PERFORMANCE CHARACTERISTICS

6.1 Test run on Alinity i verified with precision, comparison, linearity, reportable range and accuracy, wherever applicable

6.2 Refer to verification record.

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

7.1. SAMPLE TYPE

7.1.1. Serum

7.1.2. Specimen should be free from any fibrin clot.

7.2. HANDLING OF SPECIMENS

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

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

7.3. SAMPLE ACCEPTANCE AND REJECTION CRITERIA

7.3.1. Pooled
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

8. PATIENT PREPARATION

8.1. TYPE OF CONTAINER

8.1.1. Vacutainer for serum (yellow top, red top)

8.1.2. Vacutainer for plasma (Purple top /Green top/Blue Top)

9. REQUIRED EQUIPMENT AND REAGENT

9.1.1. Trigger
9.1.2. Pre Trigger
9.1.3. Probe conditioning solution
9.1.4. Concentrated Wash Buffer
9.1.5. Sample Cups
9.1.6. Reaction Vessels
9.1.7. Control
9.1.8. Calibration
9.1.9. Printer paper
9.1.10. Distilled Water
9.1.11. Reagent from Abbott
9.1.12. Sample rack
9.1.13. Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

10. ENVIRONMENT & SAFETY CONTROL

10.1. Temperature.
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

Every reagent specific information for calibration of the particular reagent lot.

11.1. CALIBRATION FREQUENCY

10.1.1 Calibration must be performed once per reagent lot.
10.1.2 As required: e.g. quality control findings outside the defined limits.
10.1.3 Calibration stability is expired

11.2. TRACEABILITY

Refer to sops for each test.

11.3. CONTENTS

Refer to sops for each test

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

Refer to sops for each test

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 run unless IQC result is acceptable /refer to Procedure for Ensuring Quality Of Examination Results

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. Start up the machine:

13.1.1. Turn on the SCM (system control module) main power.

13.1.2. Turn on the CPU.

13.1.3. Wait for the Log On screen to display on the monitor, press Log on and enter username and password.

13.1.4. Power on the main power breaker of the processing module to turn on the power.

13.1.5. Move the SCM power switch upward to power on the RSM and the SCM bar code scanner

13.1.6. First machine shows offline mode, wait until it shows stopped status on both RSM and alinity.

13.1.7. To transition the instrument statuses to Idle, select stopped and press start then machine will be on Idle mode.

13.2. PROCEDURE FOR CALIBRATION OF REAGENT:

13.2.1. Follow standard protective precautions such as gloves, lab coat

13.2.2. Check daily and weekly maintenances if pending do first before you start run calibration or control or patient sample.

13.2.3. Upload reagent

13.2.4. Alinity i Calibration requires no preparation prior to use.

13.2.5. Allow calibrator to come to room temperature.

13.2.6. Be sure machine on running mode.

13.2.7. On the menu bar, tap Orders.

13.2.8. On the orders screen, tap create order.

13.2.9. On the create order, press on calibration tab.

13.2.10. Verify that the correct calibrator details have been entered into the calibration order.

13.2.11. Mix bottle five times by gentle inversion.

13.2.12. Open bottle, place drops (for amount refer to kit insert for each test) of each calibrator in a separate sample cup, and place in the assigned positions.

13.2.13. Cap bottle tightly and return to refrigerated storage immediately after use.

13.2.14. Select rack number and starting position then under assays, select assay panel to calibrate and put calibrator on labeled Alinity sample cup.

13.2.15. Load rack on machine.

13.2.16. Machine automatically start take the rack and run calibration.

13.2.17. The rack ID and the starting position are not required if the calibration uses bar-coded samples.

13.3. When to request a calibration:

Most calibrations are scheduled to run automatically for any new lot of reagent, but you may need to request a calibration:

13.3.1. If you change the test definition,

13.3.2. Troubleshooting for out of control situation

13.3.3. If control measurements are outside the specified range

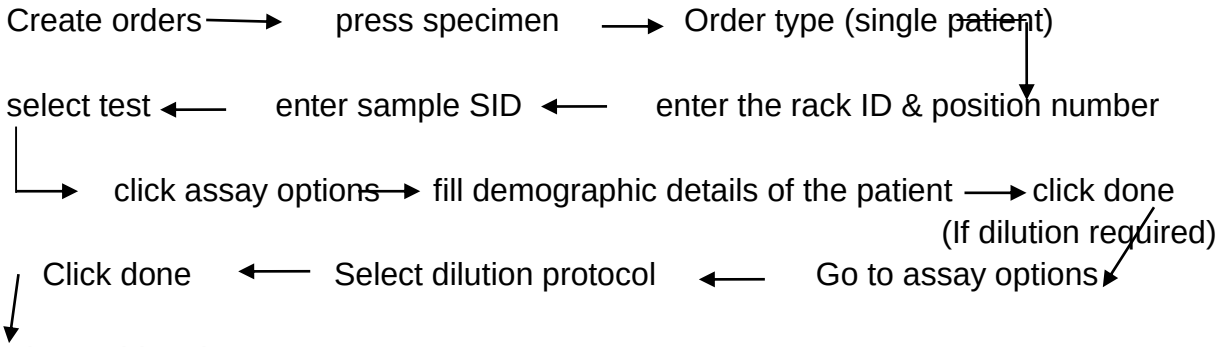
13.4. PROCEDURE FOR PROCESSING THE CONTROL:

13.4.1. Follow standard protective precautions such as gloves, lab coat.

13.4.2. Check daily and weekly maintenances if pending do first before you start run calibration or control or patient sample
13.4.3. Upload reagent
13.4.4. After validating the calibration, QC materials can be processed
13.4.5. Alinity Controls requires no preparation prior to use.
13.4.6. Verify that the correct control details have been entered into the control order.
13.4.7. Allow control to come to room temperature.
13.4.8. Mix bottle five times by gentle inversion.
13.4.9. Open bottle, place drops (for amount refer to kit insert for each test) of each control in a separate sample cup, and place in the assigned positions.
13.4.10. Cap bottle tightly and return to refrigerated storage immediately after use.
13.4.11. On the menu bar, tap orders then tap create Orders.
13.4.12. Press control tab.
13.4.13. Scan rack.
13.4.14. Select position then select control to be run, check the lot number of the control and put control in labeled Alinity sample cups.
13.4.15. Load the rack on the machine
13.4.16. Machine automatically start take the rack and run control.

13.5. PROCEDURE FOR PROCESSING SAMPLE:

13.5.1. Follow standard Personnel Protective equipment precautions.
13.5.2. Check the request for Routine or urgent, Confirm the label on the tube and bar-coded sticker with accompanying requisition form.
13.5.3. Prepare the sample as per our Procedure for Sample Handling, Preparation and Storage
13.5.4. Take the Request form and check all the Demographic details and Test order in LIS;
13.5.5. Check the sample for Barcode;
13.5.6. Check for the daily and weekly maintenance, if pending perform it first and then proceed for the test;
13.5.7. Check for all consumables and reagent needed before processing the sample.
13.5.8. After checking the validity of controls and calibrators process samples using LIS or manual entry
13.5.9. LIS method: Take Alinity *i* sample rack, position the tube by barcode facing outside, machine will automatically take the rack and start to run the test.
13.5.10. If LIS is not working or any problem with LIS we process samples manually, place the tube in appropriate Alinity *i* sample rack , in main menu:



Add Order

13.5.11. Place the rack in the sample loading area
13.5.12. Machine will automatically start performing the tests
13.5.13. After sometime it will give results.
13.5.14. If barcoded samples are used, the rack ID and position number are not required.
13.5.15. 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.

13.6. Shut down procedure:

13.6.1. RSM and Alinity mode can be IDLE, stopped, offline or warming.
13.6.2. From main screen press shut down, when confirmation message is displayed, tap Yes.
13.6.3. The user interface computer powers off when the system software completes the shutdown.
13.6.4. Move the RSM and processing module power switch downward
13.6.5. Power off the main power breaker of each Alinity i processing module.

14. INTERFERENCE

Refer to SOPs for each test

15. CALCULATION

15.1. The analyzer automatically calculates the analyte concentration of each sample
15.2. Refer to SOPs for each test

16. BIOLOGICAL REFERENCE INTERVALS

Refer to SOPs for each test

17. DILUTIONS

17.1. Samples with high result concentrations above the measuring range automatically Diluted in the machine.

17.2. Refer to sop for each test

18. CRITICAL VALUE

Refer to sops for each test

19. LABORATORY CLINICAL INTERPRETATION

Refer to sops for each test

20. POTENTIAL SOURCES OF VARIATION

20.1. PERSONAL:

20.1.1. Competency of staff.

20.2. MACHINE /EQUPIMENT:

20.2.1. Centrifuge

20.2.2. Maintenance

20.2.3. PPM

20.3. REAGENT:

20.3.1. Stability of reagent and expiry date

20.3.2. Temperature of refrigerator

21. REFERENCES

21.1. User Manual for Alinity i.

BIOGENIX

Abu Dhabi, UAE

Call: 0466 XXX XX
Fax: 046XXX XXX

name@biogenix.com

Thank You