YALE-NEW HAVEN HOSPITAL	TITLE: SEBIA ASSIST OPERATION		DEPT OF LAB MEDICINE CLINICAL IMMUNOLOGY Policy and Procedure Manual
			DOCUMENT # IMM -198
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WRITTEN BY: Voula J. Golfis	**EFFECTIVE DATE:** November 16, 2012	**REVISION:** NEW	**SUPERCEDES:** NEW

I. INTENDED USE:

The SEBIA ASSIST prepares and dilutes samples for agarose gel electrophoresis using the SEBIA HYDRASIS system. The ASSIST will make sample dilutions for immunofixation techniques performed on serum. In addition, it will apply the diluted samples on the applicators. Dilutions are performed using pre-programmed dilutions or dilutions can be programmed by entering the dilution ratio or the specified concentration.

II. SAMPLE REQUIREMENTS:

The Assist is validated for serum IFE. The sample volume must be superior or equal to 250 µL. Do not use the Assist for urine IFE samples.

III. REAGENTS:

1. Clinical Laboratory Reagent Water (CLRW).
   -Add fresh CLRW daily

2. IFE Diluent (from Hydragel 4 IF or 9 IF kits)
   - Diluent is ready to use.
   - Store at room temperature
   - Stable until the expiration date on the diluent vial labels.

3. Saline 0.9% (Use Irrigation Saline obtained from the pharmacy)
   - Ready for use
   - Store at room temperature
   - Saline is replaced monthly

IV. MAINTENANCE:

A. Daily Maintenance

1. Remove the humidity chamber / applicator tray from the refrigerator and allow it to come to room temperature.
2. Turn on the ASSIST using the toggle switch on the bottom right side of the instrument.

3. The ASSIST will take approximately 45 seconds to perform self checks
4. Lift lid
5. Replace the Clinical Laboratory Reagent Water (CLRW) & empty the waste container daily
6. Prime the needle
    a. From the main menu, press 2 PRIMING
    b. Press 1 PRIME
    c. Use the default setting of 3 priming cycles
    d. Close Lid
    e. Press GO ▶ to start the priming sequence

7. Clean the needle
    a. In the homepage of the priming menu, press 4, NEEDLE CLEANING on the keyboard.
    b. The following message is displayed: CLEAN THE SAMPLE PROBE WITH ALCOHOL AND PRESS "STOP" WHEN YOU HAVE FINISHED"
    c. Press STOP ■ at the end of the process

B. Monthly

Follow the instructions indicated below to prevent dirt building up inside the rinse container.

DECONTAMINATION OF THE WASTE CONTAINER

1. Prepare a sodium Hypochlorite solution (2 to 3% chlorine) by diluting 250 mL 9.6% chlorine concentration solution with cold water to 1 liter. **CAUTION: Store the working chlorinated solution at room temperature in a closed container. It is stable for 3 months. Avoid storage in sunlight, close to heat and ignition source, and to acids and ammonia.**
2. After each drainage, pour 5 mL of the diluted sodium hypochlorite solution in the waste container.
3. Clean the waste container cap with the diluted sodium hypochlorite solution and rinse it with distilled or deionized water. Refer to § 6.6 ELIMINATION OF WASTE PRODUCTS.

Caution: The waste container contains biological fluids. Handle with care.

CLEANING THE RINSE CONTAINER:

1. Prepare a sodium hypochlorite solution (0.3% chlorine) by diluting 135 mL 2 to 3% chlorine sodium hypochlorite solution in 1 liter of cold water.
2. Empty the container and clean it using the 0.3% chlorine bleach solution.

3. Rinse the container thoroughly with distilled or deionized water.
4. Fill the container or deionized water before putting it back to its place.

CLEANING THE FEEDBACK MIRROR OF THE BARCODE READER

Clean the feedback mirror with a cloth soaked in 70° alcohol.

CLEANING THE ACCIDENTALLY SOILED COMPONENTS

Clean with a cloth soaked in 70° alcohol the humidity chamber walls accidentally soiled, then let them dry.

CAUTION: Do not use bleach to clean the humidity chamber. Never soak the sponge with alcohol or bleach. Contact the SEBIA Technical Department to replace the sponge in case of contamination by a biological fluid.

CLEANING THE SYSTEM'S EXTERNAL COMPONENTS

1. Switch the instrument off.
2. Clean the outside areas, the sample rack slides, the sample racks, the cup holder, the antisera adapter, the housing well and the washing well of the sample probe with a cloth impregnated with
3. 0.3% chlorine sodium hypochlorite solution.

CAUTION: Do not use a 3% chlorine sodium hypochlorite solution older than 3 months.

C. Yearly Care

Contact the SEBIA Technical Department for the annual overhaul of the system.

V. PREPARATION OF SERUM IFE DILUTIONS AND APPLICATORS:

1. Load the IFE sample diluent and saline. The diluent is placed in position A and the saline is placed in position B
2. Label 3 18-well applicators with the Gel Letter and sample numbers, i.e. Gel A, 1-3
3. Load the applicators into the humidity chamber / applicator tray. For the first position, insert the left side of the applicator first. Press both ends to ensure that each applicator is properly seated
4. Place the humidity chamber / applicator tray on the system
5. Remove the sample racks & dilution racks from the system
6. Load the patients in Rack 1 with the barcodes facing left

7. Load a microcup in racks 2 & 3 for each patient (for dilutions)
8. Program the samples
    a. Double click on the PHORESIS icon
    b. User/password is ADM/SEBIA
    c. Worklist
    d. Worklist by Table
    e. On the bottom tool bar, make sure the program is Hydragel IF/Bence Jones
        a. Click on the HYDRAPLUS/ASSIST button to connect PC to ASSIST and open the barcode loading program
        b. When the blue arrow turns green and starts to move upwards, Rack 1 can be loaded
7. Place Rack 1 on the system and slowly slide forward to read barcodes
8. Place the dilution racks on the system
9. Click on Send barcodes to worklist*
10. On the ASSIST menu, press 1, SELECT PROGRAM
11. Enter the appropriate program number or use the arrows to move the cursor to the correct program (& IFx 9)
12. Confirm the sample number that is on each applicator
13. Press Enter
14. Select No for Dynamic Mask
15. An asterisk indicates that the sample is programmed
16. Close lid and press GO
17. When the dilutions are ready, the system will indicates if any samples were missed

* The following message appears when the HYDRAPLUS recognizes an empty space on the rack: "Some barcodes coming from the HYDRAPLUS and not downloaded in the worklist have been found. These new barcodes will be added into the worklist."

VI. TROUBLESHOOTING:

Refer to the Troubleshooting Shooting Guide (Doc# 198-A) for error messages and troubleshooting solutions.

If the problem cannot be solved contact SEBIA technical service for assistance.

VII. INSTRUMENT VALIDATION:

Precision:

Intrarun Precision: Intra-assay performance was evaluated by testing of 2 specimens, a Normal and an Abnormal, 4 times on a single run. All the results were in agreement.

Interrun Precision: Inter-assay performance was evaluated by testing 2 specimens, a Normal and an Abnormal, on 3 separate runs. All the results were in agreement.

Carryover Studies: Carryover studies were evaluated by running a total of 9 aliquots, alternating normal and abnormal specimens. The results indicate that there is no carryover using this sample preparation process.

Correlation: 18 specimens were tested on two separate runs using the Sebia Assist. Results are in agreement with original run.

VIII. REFERENCE:

Sebia, Assist Training Manual. Release 4.50. 2010/06

IX. APPENDIX:

198-A	Sebia Assist Troubleshooting Guide
198-B	Sebia Assist Training Checklist
198-C	Sebia Assist Quiz
198-M	Sebia Assist Maintenance Chart

Sebia Assist Trouble Shooting Guide Doc 198-A

ERROR MESSAGE	PROBABLE CAUSES	SOLUTIONS
WASTE CONTAINER FULL	The waste container is full.	Empty the waste container. Pour 5 mL of diluted sodium hypochlorite solution. See § 6.1. DECONTAMINATION OF THE WASTE CONTAINER. Restart the system. If the problem continues, contact the Technical Department.
RINSE CONTAINER EMPTY	The rinse container is empty.	Fill the container with distilled or deionized water, then run a priming cycle and restart the system. If the problem continues, contact the Technical Department.
NO LIQUID DETECTION	There is a drop of fluid on the tip of the sample probe. The sample probe's fluid capacity sensor is not working.	Clean the tip of the probe with alcohol. Restart the system. If the problem continues contact the Technical Department.
CLOSE LID	The cover is open.	Close the cover. Restart the system. If the problem continues, contact the Technical Department.
MOTOR BLOCKED 1	The arm rotational motion is blocked.	Make sure there is no obstruction and then restart the system. If the problem continues, contact the Technical Department.
MOTOR BLOCKED 2	The arm motion is blocked.	Make sure there is no obstruction and then restart the system. If the problem continues, contact the Technical Department.
LIFT STILL ON SENSOR	The sample probe up and down motion is blocked.	Restart the system. If the problem continues, contact the Technical Department.
LIFT STILL ON SENSOR BEFORE MOVE M1/M2	Home position sensor or lift motor malfunction.	Restart the system. If the problem continues, contact the Technical Department.

ERROR MESSAGE	PROBABLE CAUSES	SOLUTIONS
POSITION ERROR	Relative-movement error. The number of encoder steps detected does not match the number of motor steps.	Restart the system. If the problem continues, contact the Technical Department.
POSITION ERROR 2	Absolute-movement error. The position reached by the motor relative to the encoder steps does not correspond to the theoretical forecast position.	Restart the system. If the problem continues, contact the Technical Department.
MOTOR 1 TIMEOUT	The arm rotation sensor is not detecting the start position. Motor 1 is not stopping within the allocated time.	Restart the system. If the problem continues, contact the Technical Department.
MOTOR 2 TIMEOUT	The telescoping arm sensor is not detecting the start position. Motor 2 is not stopping within the allocated time.	Restart the system. If the problem continues, contact the Technical Department.
MOTOR 3 TIMEOUT	The sample probe up and down motion sensor does not detecting the start position. Motor 3 is not stopping within the allocated time.	Restart the system. If the problem continues, contact the Technical Department.
MOTOR 4 TIMEOUT	The syringe sensor is not detecting the start position. Motor 4 is not stopping within the allocated time.	Restart the system. If the problem continues, contact the Technical Department.
MOTOR 5 TIMEOUT	The lid closing sensor in the humidity chamber is not detecting the start position. Motor 5 is not stopping within the allocated time. Motor 5 remains blocked on the sensor when the cover is opened.	Check that the cover is closed and restart the system. Restart the system. If the problem continues, contact the Technical Department.
MOTOR ERROR – MOTOR BLOCKED	A problem has occurred in the motor unit during operation.	Restart the system. If the problem continues, contact the Technical Department.

ERROR MESSAGE	PROBABLE CAUSES	SOLUTIONS
ERROR DIALOGUE DCN	Link wire cut or disconnected. Problem with sensor card.	Restart the system. If the problem continues, contact the Technical Department.
POWER DRIVER ERROR	The power driver broke down.	Restart the system. If the problem continues, contact the Technical Department.
DYNAMIC MASK DEPOSIT ERROR	No antisera vials or stoppers on antisera vials. Problem with fluid detection.	Place antisera vials in position or remove stoppers. Restart the system. If the problem continues, contact the Technical Department.
I2C DIALOGUE ERROR	Problem of connection with peripheral card.	Restart the system. If the problem continues, contact the Technical Department.
NOT EMPTY WELL ERROR	The well was not emptied during flow-rate reading operation.	Restart the system. If the problem continues, contact the Technical Department.

Sebia Assist Maintenance Log Doc# 198-M

Month:_____ Year: _____

Daily	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Take out chamber																															
Turn the power on																															
Replace the CLRW																															
Empty the Waste																															
Prime the Needle																															
Clean the Needle																															
Initials																															

Monthly	
Decontaminate Waste Container w/ sodium hypochlorite (2-3%) 375 mL to 1 L	
Clean the Rinse Container w/ sodium hypochlorite (0.3%) 135 mL (of 2-3%) to 1 L	
Clean External Components w/ 0.3% soduim hypochlorate	
Clean Barcode Reader Mirror w/ 70% ETOH	
Clean Humidity Chamber Walls w/ 70%ETOH	
Initials	

Yearly	
Sebia authorized service	
Date	

Supervisor's Review	1	2	3	4	5
Date					
Initials					

Sebia Assist Checklist

Doc# IMM 198-B

Initial ☐ 6 Months ☐

YES/NO

1. Has read the Sebia Assist Operation Procedure _____
2. Has passed to Sebia Assist Quiz _____
3. Can perform daily and monthly maintenance. _____
4. Able to load IFE samples for dilution and application _____
5. Able to perform routine troubleshooting. _____

Training Completed _____

Signature _____ Verified By _____

Learning Technologist Teaching Technologist

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November 27, 2012

Signature Approval

Name: SEBIA ASSIST OPERATION PROCEDURE

Document #: IMM 198

Name (Print)	Title	Signature	Date of Review	Revision Page and Section # (Use Procedure Review Log to document staff review)	Issue Date for Training if Applicable	Effective Date for Use
TEODORICO LEE	LAB MANAGER	Teodorico Lee	11/27/12	NEW		11/27/12
BRIAN SMITH	LAB DIRECTOR	B Smith	11/27/12	NEW		11/27/12