Wake Forest Baptist Medical Center	**InoqulA Specimen Processor** **MB-73**	**Dept:**	Cl Micro
		Effective Date:	8/27/18
		Revised Date:	01/15/19
		Contact:	Microbiology Manager
Name & Title: Dr. Gregory Pomper		**Date:**	
Signature:			

1) General Procedure Statement:

a. **Purpose:** This procedure is to serve as a guide for trained personnel in the Clinical Microbiology Laboratory to perform the test described herein. This procedure should be used in conjunction with proper training and only by qualified technologists.

b. **Responsible Department/Scope:**
   i. Procedure owner/implementer: Dr. Elizabeth Palavecino.
   ii. Procedure prepared by: Christy Hernandez, MT(ASCP)
   iii. Who performs procedure: Clinical Microbiology Laboratory personnel.

2) Procedure:

Intended use of the InoqulA+ system

The BD Kiestra™ InoqulA+™ is an in vitro diagnostic device system which is intended to automate specimen processing according to user-defined procedures and protocols. In Fully Automated (FA) mode, this includes opening and closing sample container(s), barcoding, inoculating and streaking plated media, and inoculating tubes and slides. In Semi-Automated (SA) mode, dishes are automatically selected, barcoded, streaked in a pre-configured pattern while the user manually inoculates dishes, tubes and slides. An optional biosafety cabinet on the SA module provides personnel, product, and environmental protection.The InoqulA+ is indicated for use in the clinical laboratory. A standalone InoqulA+ system includes:

- SorterA-BarcodA
- FA module
- SA module

The InoqulA+ consists of:

- SorterA: stores and sorts dishes with media for sample inoculation.
- BarcodA: applies barcode labels to dishes for sample traceability.
- FA module, where fully automated processing of liquid samples occurs: including agitation of sample container, decapping and recapping, automated pipette based inoculation, and bead insertion.
- SA module, where manual sample inoculation and spreading occurs for all sample types.

The SorterA consists of boxes where prepared media is stored until sample processing is initiated. The prepared media can be loaded into the SorterA boxes individually or as a stack of up to 17 dishes. The SorterA is available in multiple sizes and configurations, and the total number of dishes that can be stored depends on the number of installed boxes. After the user loads the dish stacks, the SorterA module controls the conveyor belts and destacker(s), so that the correct dishes are transported to the BarcodA.
Placement of the barcode is always on the side of the dish base. After the barcode label is applied, the dish is ready for processing.

During fully automated (FA) processing, dishes are automatically supplied by the SorterA-BarcodA depending on the required analysis. The InoqulA+ agitates the sample, uncaps the sample, aspirates sample material from the container, and inoculates the sample onto dishes, broth tubes, and/or slides. Following inoculation, dishes are transported to the spreader where the inoculum is spread over the agar surface, using a magnetically controlled bead.

During semi-automated (SA) processing, inoculation is performed manually and inoculum spreading onto dishes is automated. After the user scans a sample's barcode, dishes are automatically selected and barcoded by the SorterA-BarcodA, the InoqulA+ adds a bead (or two beads if using bi-plates) to all dishes and transports them to the inoculation position. The user inoculates the dish(es) and any broth tubes or slides, then the InoqulA+ spreads the inoculum on the dishes using the magnetically controlled bead.

Up to five dishes can be spread simultaneously according to preset streaking patterns. Following inoculation and spreading, dishes are sorted and stacked in the correct output stacker. The stackers automatically sort and stack dishes according to selected conditions (e.g., O_2 or CO_2 incubation, or medium type).

System Startup

1. Turn on the InoqulA+.
2. Press the reset buttons. When the system is powered, the blue light turns off. If the light does not turn off, the BarcodA hood or the FA front cover is likely not closed.
3. If your InoqulA is equipped with an optional Biological Safety Cabinet (BSC), the BSC should be turned on and should remain closed while the system is in operation.
4. Turn on the BSC.
5. Press the blower button. The indicator below the button illuminates and an audible alarm sounds. When the proper blower speed is reached, the alarm shuts off.
6. Press the fluorescent light button to illuminate the work area.
7. Turn on the SorterA-BarcodA computer (and the monitor, if it does not turn on automatically with the computer).
8. Wait for the computer to complete mapping the drives.
9. Turn on the InoqulA computer. The touchscreen monitor starts up automatically.
10. On the SorterA-BarcodA monitor, double-click the **BarcodA** icon. The SorterA-BarcodA monitor is not a touchscreen; make selections using the keyboard or mouse.

11 Log in with your username and password and click **OK**.

12 On the InoqulA touchscreen, double-tap the **InoqulA** icon using the stylus.

13 Log in with your username and password and tap **OK**. There are two methods for logging in:

- Use either the virtual or physical keyboard to enter your username and password.
- Use the handheld barcode scanner to scan your personal barcode (if the system has been configured for scanning personal barcodes).

When running in SA mode, the InoqulA+ is started after pressing Add samples to batch in the Batch Prepare tab.

When start conditions are not met, this is shown in a yellow panel on the lower right of the screen.

When all start conditions are met, the Start FA [F2] button in the upper left of the screen becomes enabled.

Emergency Stop

Using the emergency stop

1 Press the red emergency stop button. The electricity and air pressure to all connected equipment is deactivatedReadA Compact. The computer system continues to operate.

2 All systems must be restarted after an emergency stop.

Restarting after an emergency stop

1 Determine the cause of the emergency stop.

2 Resolve the cause of the emergency stop and ensure that any other hazardous conditions or blockages that may prevent the equipment from functioning properly have been eliminated.

3 Ensure that all FA processing sample containers and broth tubes have been capped and replaced into the appropriate racks. If applicable, replace slides in the appropriate slide rack positions.

4 Release the emergency stop by turning the button clockwise. The button pops out and a green ring becomes visible.

5 Press the reset button; the light turns off.

6 Remove and discard any dishes from the dish scan position.

7 Tap **Reset Error** from the InoqulA main menu and then tap **Start FA [F2]** to restart operation.

8 Click **Reset error(s) [F5]** from the BarcodA main menu and then click **Start [F2]** to restart operation.

Preparation for Processing (BarcodA)

Prepare dishes

Allow any dishes that are stored refrigerated to come to room temperature before use. Once removed from their storage location, BD Kiestra recommends maintaining dishes with the lids upright so that moisture does not form on the lids.

Fill the SorterA boxes with dishes

1. View the active SorterA configuration field to identify which medium is needed for each SorterA box.
2. Place a stack of dishes on the sensor in the SorterA box.
   In the configuration field, the corresponding box changes from gray to yellow, indicating the sensor recognized that dishes were added.
   Ensure that the height of the dish stack is just under the cover of the SorterA box, so the cover won't rest on the stacks.
3. If batch or lot numbers need to be scanned, follow the steps described in the following section.
4. Place additional stacks until the box is full (no space is required between stacks).
5. Repeat steps 2–4 for all required SorterA boxes.
6. Close the protective covers over the SorterA boxes.

Verifying the carbon and label rolls

Before starting operation, check the supply of labels in the BarcodA printer. The number of labels used is shown on the right side of the BarcodA main window, in the Labels used from roll field. Once the counter approaches 6500, change the label and carbon rolls.

1. Click **Help** from the main menu and then **Printer Wizard**.
   - Follow the steps described in the Printer Wizard to change the label and carbon rolls and for cleaning instructions.
   - Click the **[►]** arrow at the bottom of the window to advance to the next step.
   - Click the **[◄]** arrow at the bottom of the window to return to the previous step.
2. Click **Close.**
3. Click OK. The label counter resets to zero.
4. Close the BarcodA hood.

Operation (BarcodA)

1. Press the blue reset button if necessary.
2. Click **Start [F2]**.
3. Click **OK** in the Machine will be initialized field.
   The SorterA-BarcodA starts transporting dishes after it receives requests. Dishes are requested by the InoqulA+ system. Dish requests are chronologically stored in a worklist until the dish has been delivered.
4. During operation, the status of the requests is continually updated and presented on the display:

- True – indicates that the dishes have been transported to the next component.
- False – indicates that the request has been recreated.

Preparing for fully automated operation

1. Turn on the BSC.
2. Ensure that the SorterA-BarcodA contains enough dishes with the required culture media.
3. The number of labels used is shown on the right side of the BarcodA software window in the Labels Used From Roll field. When the counter approaches 6,500, replace the BarcodA printer label and carbon rolls.
4. Replace the InoqulA desktop printer label and carbon rolls if necessary.
5. Obtain all liquid sample containers for processing and place into sample container racks.
6. Place the sample container racks in the rack holder and enter the rack codes into the InoqulA software.
7. Obtain broth tubes required for inoculation and place into broth tube racks.
8. Place the broth tube racks in the rack holder and enter the rack codes into the InoqulA software.
9. Fill the pipet tip racks if necessary, and reset the tip counter in the InoqulA software.
10. Empty the pipet tip waste container if necessary. Ensure that the cap has been removed from the container before starting operation.
11. Obtain slides if required. Label the slides with labels from the desktop printer.
12. Place slides in a slide rack with the sample ring and barcode label facing up. Place the slide rack in the slide preparation module and enter the slide identification codes into the InoqulA software.
13. Fill the beads in the bead dispenser if necessary.
14. Empty the bead disposal containers if necessary.
15. The shifter cover is connected to the printer cover and the bead disposal drawer. To enable changing the printer label roll or emptying the bead disposal containers during processing, click **Unlock printer cover and bead disposal drawer** under System Menu.

Placing sample containers in sample container racks

1. Place the sample container barcode label lengthwise so that when holding the container in a vertical position, the barcode lines are horizontal.

2. Place the labeled sample containers in the sample racks appropriate for the sample containers' diameter.

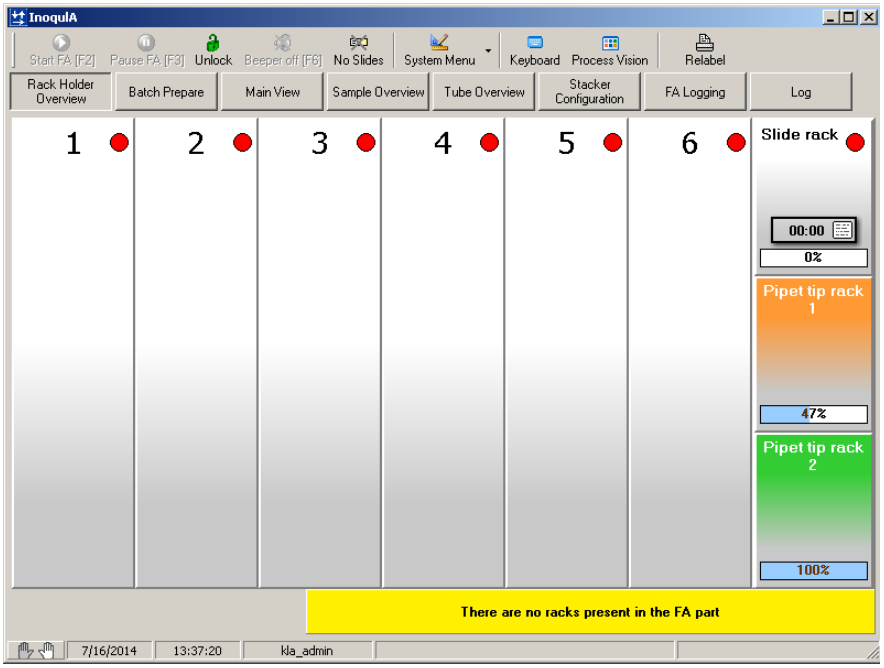
Sample container racks are barcoded to identify the type of rack. Be sure to use the appropriate rack, as the InoqulA software processes the rack according to the barcode information.

3 Fill racks starting with row A, number 1. After completely filling row A, continue with row B, number 1, etc.

4 Do not leave any spaces between sample containers.

Placing sample container racks in the rack holder

1 Tap **Rack Holder Overview** from the main menu.



2 If no sample container racks have been placed in the rack holder:

- The display does not show any information in the rack positions, and a red dot (indicating “empty”) is present for each rack.
- The message “There are no racks present in the FA part” appears on the bottom of the display.

3 Open the hood and front cover of the rack holder.

4 Place the sample racks in the rack holder. Sample racks may be placed in any rack holder position; however, racks containing sample containers are typically placed on the left side. If only one rack is being processed, place the rack in position 5 for optimal operation.

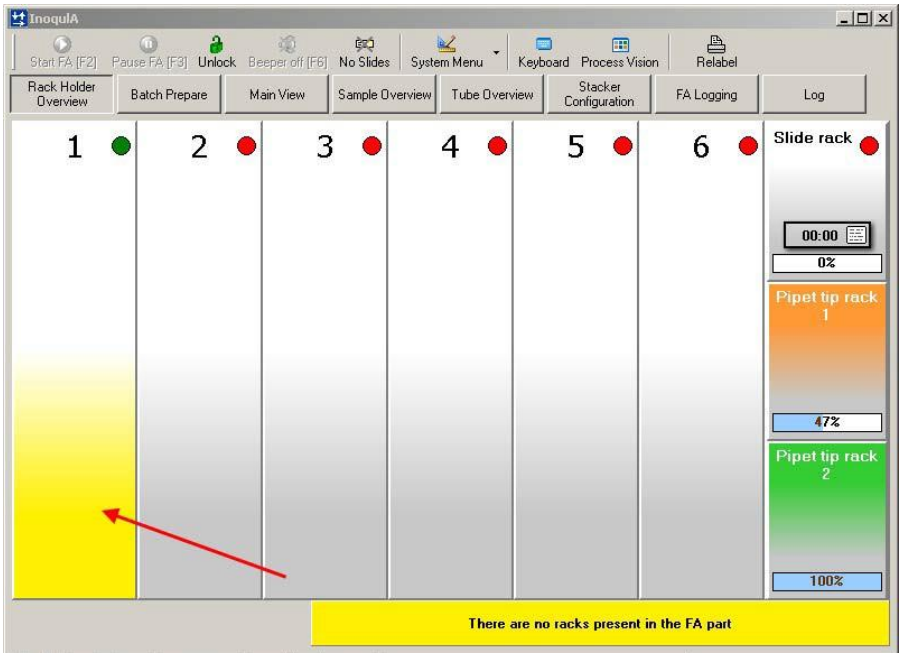
5 Ensure that the rack legs are positioned on the blue sensor in the rack holder. Click the rack firmly into position.

6 On the InoqulA display, a green dot indicates where a rack has been placed, and the rack position has a yellow background.

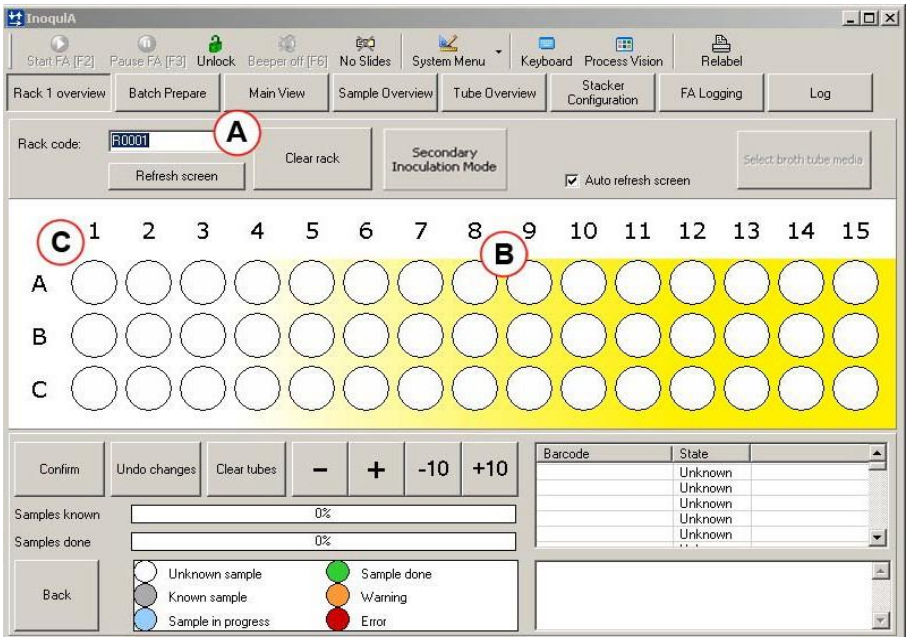
Defining sample container racks in the InoqulA software

1 Tap **Rack Holder Overview** from the main menu if it has not already been selected.

2 Tap on the rack to be identified. Rack holders that contain a rack have a green dot and a yellow background.



3 The Rack Overview detail display shows the rack status. Changes to the rack are entered using this display.



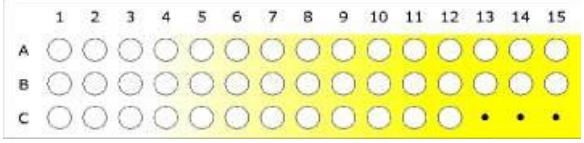
3 If any existing rack information needs to be deleted, tap **Clear rack**. The information in the Rack code field (A) resets.

4 Use the hand scanner to scan the barcode of the sample container rack placed in the selected rack holder, or type the rack barcode number in the field and tap **Enter**.

5 The barcode appears in the Rack code field (A). A sample rack graphic is displayed (B). The letters and numbers correspond to the sample container rack rows and columns (C). New racks default to a full rack of sample containers (all locations are represented by a white circle).

6 Compare the display to the sample rack and verify that the number of sample containers match. White circles indicate a sample container is present in that location, small black dots indicate no sample container is present in that location.

- Tap the **–** or **+** buttons to change the number of sample containers.
- Tap the **–10** or **+10** buttons to change the number of sample containers in units of ten.



7 If necessary, tap **Undo changes** to undo any changes that are made. The settings are deleted, and you exit the Rack Overview display.

8 If you need to edit the rack after tapping Undo changes, tap **Edit rack** and enter changes.

9 If necessary, tap **Clear tubes** to reuse a sample rack with new sample containers.

Sample rack barcodes are linked to the diameter of the sample containers. When a particular sample rack and barcode are reused, the InoqulA software must be updated with data for the new sample containers.

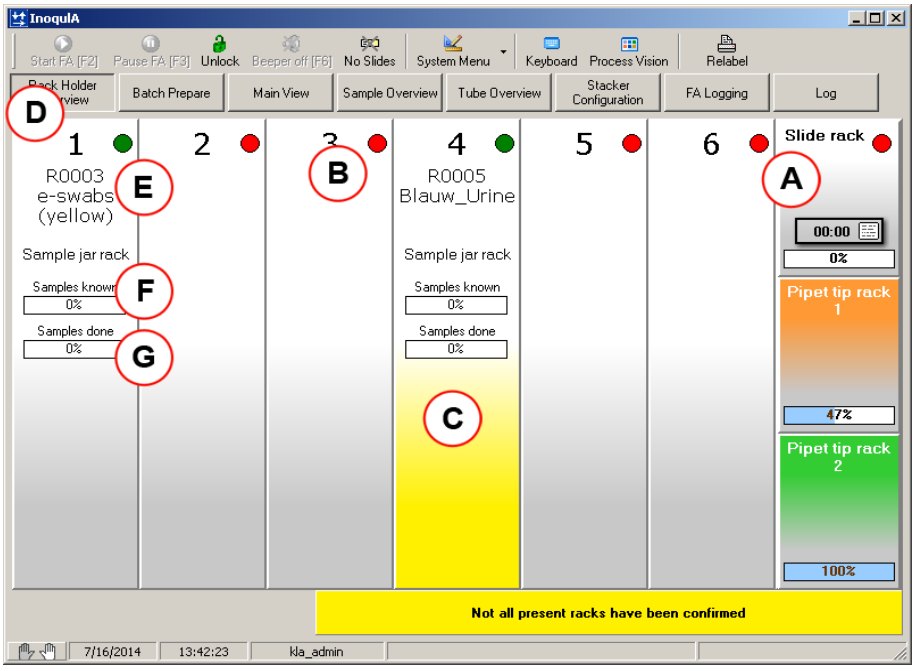
10 When you are finished, tap **Confirm**. The rack data is stored and the Rack Holder Overview display appears. Or, tap **Back** to return to the Rack Holder Overview display without confirming.

11 Repeat steps 2–11 for each sample container rack until the display matches the racks.

Verifying the status of sample containers and sample container racks

After all sample container racks have been entered into the InoqulA software, verify the status of the racks using the procedure below. Once sample processing begins, status information is presented.

1 Tap **Rack Holder Overview** from the main menu.

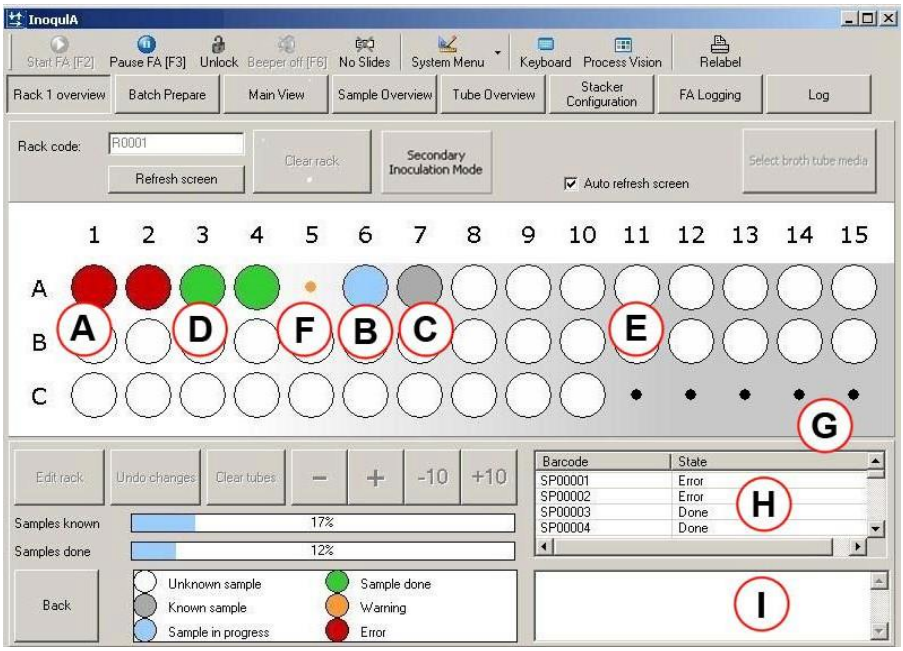


The six rack holder positions are presented across the display (A).

- Rack holder positions with no rack have a red dot (B).
- Rack holder positions with a rack have a green dot.
- Rack holder positions with a rack that has not yet been entered or confirmed in the InoqulA software have a yellow background (C).

- Rack holder positions with a rack that has been entered and confirmed in the InoqulA software have a green dot along with information about processing status (D).
- The code for each rack is shown as well as the rack type (sample container rack or broth tube rack) (E).
- The Samples known field (F) displays the percentage of samples that have been automatically scanned. When this field is at 0%, only the rack has been identified in the InoqulA software. The system has not yet started scanning any of the sample containers.
- The Samples done field (G) displays the percentage of samples that have been processed.

2 From the Rack Holder Overview display, tap on the desired sample container rack to view detailed information about processing status and individual sample containers. The Rack Overview detail display for that sample container rack appears.



3 The display shows the sample containers in the rack and their status. Each sample container is represented by a circle.

- Green indicates that the sample container has been processed (D).
- Blue indicates that the sample container is currently being processed (B).
- Gray indicates that the sample container has been scanned (C).
- Red indicates that an error has occurred for that sample (A). Click on the red circle to view the cause of the error, shown in the box on the right side of the display (I).
- White indicates that a sample container has been placed in the rack, but is not yet scanned (E).

- Orange indicates a warning has occurred for that sample (F). Click on the orange dot to view the cause of the warning, shown in the box on the right side of the display (H).
- A small black dot indicates that the rack does not contain a sample container in that location (G).
- A blue ring appears around the circle for the sample container when it is selected, and detailed information appears on the right side of the display (H). This information includes sample barcode and status.
- When a specific barcode is selected, the position of the sample container in the rack is displayed with a blue outline.

Labeling broth tubes

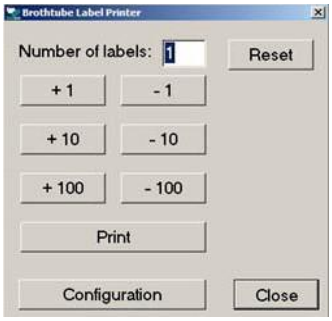
Broth tubes must be labeled with a unique barcode before being placed in a rack. After inoculating the tubes, the barcode is linked to the corresponding sample.

Generate and print barcodes with the Brothtube Label Printer application.

1 Minimize the InoqulA application by tapping the **–** button on the upper right of the display.

2 Double-tap the Brothtube Label Printer icon.

3 In the **Number of labels** field, enter the number of barcode labels needed for broth tubes. Tap the **+1**, **–1**, **+10**, **–10**, **+100**, and **–100** buttons to increase or decrease the number of labels to the correct amount.



4 When the correct number of labels has been selected, tap **Print**.
The desktop printer prints the requested number of barcode labels. Tear off the labels from the roll. For printers with a cutting option, the printer can also be set to automatically cut each label.

5 Close the Brothtube Label Printer window by tapping **Close**. Maximize the InoqulA application.

Follow the same procedure to place broth tubes in the rack holder, identify tubes in the InoqulA software, and verify the status of tubes and racks as you would for samples and sample racks (pages 5-10).

Before operation of the InoqulA, check that there are sufficient pipet tips and beads. Follow the BD quick guide to replenish these supplies or to empty the pipet tip waste.

Starting fully automated processing

1. Close the hood and front cover of the rack holder.
2. Press any reset buttons that are lit (blue button).
3. Tap **Rack Holder Overview** from the main menu if it has not already been selected.
4. Tap **Start FA [F2]** from the main menu.

Pausing operation

During operation, it is not possible to open the hood and front cover. If you need to open the hood and front cover or want to pause the system for another reason, tap **Pause FA [F3]** on the Rack Holder Overview display.

After tapping Pause FA [F3], the system finishes the last dish or sample it was processing. If the system is in the middle of an inoculation, it discards the pipet tip and returns all tubes and/or slides to their original rack position. Then the system stops and the hood and front cover can be opened.

To resume operation, tap **Start FA [F2]**.

Viewing a completed batch

1. Once processing is complete:
   - No new carriers are being transported.
   - There are no dishes along any point of the transport system.
   - All inoculated dishes have been sorted into the stackers.
   - The InoqulA software pauses.
2. Tap **Rack Holder Overview** from the main menu if it has not already been selected. The samples counter shows 100% complete for all sample container racks. Additionally, the rack graphics change color.
   - Green indicates that the entire rack has been processed without errors.

- Red indicates that an error has occurred with one or more sample containers in the rack.

3 View the detailed information displays for sample containers and broth tubes. Any sample containers that were not successfully completed must be reprocessed.

4 Discard any broth tubes marked with an error.

End of run cleanup

1 Open the hood and front cover of the rack holder.

2 Remove all racks.

3 Store sample containers in bucket to be discarded 48 hours after receipt.

4 Transport the stacks of inoculated dishes and broths to the appropriate incubators.

5 Leave the pipet tip racks in the rack holder unless they are empty. Replace if necessary.

Semi-Automated Sample Processing

Preparing for SA processing

1 Turn on the BSC.

2 Ensure that the SorterA-BarcodA contains enough dishes with the required culture medium.

3 The number of labels used is shown on the right side of the BarcodA software window, in the Labels Used From Roll field. When the counter approaches 6,500, change the BarcodA printer label and carbon rolls.

4 Replace the InoqulA+ desktop printer label/carbon rolls if necessary.

5 Obtain the sample containers for processing.

6 Obtain broth tubes required for inoculation.

7 Add slides to the slide dispenser if necessary. Replace the cover over the slides.

8 Fill the beads in the bead dispenser if necessary.

9 Empty the bead disposal containers if necessary.

Setting left- and right-handedness

During semi-automated processing (SA processing), the system considers the position (left-handed or right-handed) from which to inoculate a sample, and uses LED lights under the dish to indicate where to inoculate. If the user is right-handed, the left LED indicators will be lit; if the user is left-handed, the right LED indicators will be lit.

Left- or right-handedness can be saved in the user's profile. When a user logs in to the InoqulA software, the system settings are shown at the bottom of the display. The hand icon that is colored white indicates which handedness is applied.

If you need to change the hand for inoculation, tap the hand icon.

Defining a sample batch in the InoqulA Software

1 Tap **Batch Prepare** from the main menu.

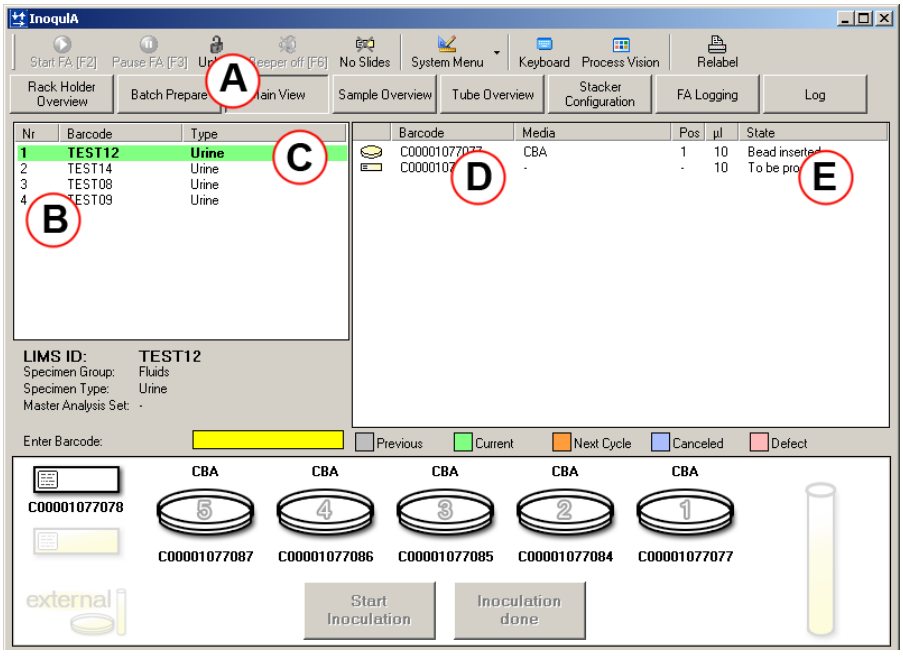
2 Using the hand scanner, start scanning the barcodes of the samples to be processed. The software tracks which analyses and carriers are needed for each sample. Unique system barcodes are generated for each carrier analysis and displayed on the right side of the window. These barcodes are different from the sample's LI(M)S barcode.

Starting semi-automated processing

1 Tap **Add Samples to Batch**. If a dish is required, it is sent from the SorterA-BarcodA with a unique barcode label. After the bead(s) has (have) been added, the dish is transported to the buffer position to await the request for inoculation.

2 Tap **Main View** from the main menu if it is not already selected.

The Main View (A) shows the created batch (B) with an overview of all analyses to be performed on the current sample (C). The analyses for the current sample are categorized by slides, dishes, and broth tubes as shown by the graphics to the left of the system barcode (D).



Check the status (E) of each analysis.

- Gray indicates that the analysis has been completed.
- Green indicates that the carrier is currently being processed.
- White indicates that the carrier is ready for future processing.
- Blue indicates that the analysis has been canceled by the user.
- Pink indicates a defective dish or that the dish was contaminated, as determined by the user.
- Orange indicates the dishes in the next set to be transported into the inoculation position.

The software displays the LI(M)S ID code of the sample for which carriers are ready for inoculation.

3 Scan the barcode of the sample with the corresponding LI(M)S ID.

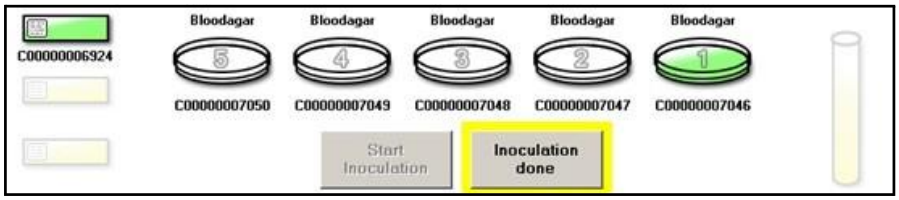
4 Dishes are transported in sets of up to five from the buffer position to the inoculation position. The five dishes may not all be required for the current sample.

5 Inspect the agar in the dishes. A dish might be unsuitable for inoculation if it is dried out, contains an air bubble, or is contaminated. This dish can be rejected and the system will automatically request and transport a new one.

6 The carrier status is displayed in the bottom window. Slides are on the left, dishes are in the center, and broth tubes are on the right.

- White indicates carriers for future samples.
- Green indicates carriers to be inoculated for the current sample.
- Gray indicates carriers that have already been inoculated or processed.

The barcode for each sample is shown on the display.



7 Only dishes intended for the current sample are opened automatically. This ensures that other dishes cannot be inoculated.

8 Inoculate the sample onto the dishes where indicated by the LED light. When using bi-plates, there are two lights.

9 If a broth tube is required, the desktop printer prints a label with the correct barcode. Place the label on the broth tube and inoculate the tube. Process the tube in accordance with your laboratory procedures.

10 When inoculation of all carriers is complete, tap **Inoculation done** or press the foot

pedal once. The system closes the inoculated dishes for that sample.

If more than five dishes are needed for a given sample, inoculate the first five at the inoculation position, then tap Inoculation done or press the foot pedal once. The remaining dishes needed for that sample will be provided with the next transport.

11 Repeat the necessary steps 3–11 above for all samples.
Once five dishes have been inoculated, they are moved to the spreader position for automatic spreading according to the preset pattern. Once spreading is complete, the bead is removed from the dish, and the dishes exit via the conveyor belt.

The InoqulA+ sorts the dishes into stackers based on the required incubation environment or other selected condition.

Viewing a completed (SA) batch

1 Tap **Main View** from the main menu if it is not already selected.

2 You can monitor sample processing by retrieving a list of steps performed.

3 The batch is complete when the main view shows that all scanned samples have been inoculated on all requested carriers.

4 Once processing is complete:

- No new carriers are being transported.
- There are no dishes along any point of the transport system.
- All inoculated dishes have been sorted into the stackers.
- The InoqulA software pauses.

System Shutdown

1 Log off of all software on both PCs

2 Shut down the InoqulA PC

3 Shut down the BarcodA PC

4 Turn off the InoqulA

See the InoqulA+ Users Manual (located on the BarcodA computer desktop) for troubleshooting and error messages.

Cleaning Schedule

Follow the schedule for daily, weekly, monthly, and quarterly cleaning. Initial and date the maintenance sheet located at the InoqulA.

Location	Cleaning method			Cleaning Frequency			
	Dry	Wet	Dry then wet	Daily	Weekly	Monthly	Quarterly
InoqulA FA - Drip collection trays		X		X [1]			
InoqulA FA - Leak trays		X		X[1]			
InoqulA FA - Stainless steel surface next to the pipet tip waste container		X		X[1]			
InoqulA FA - Racks + Slide preparation rack		X		X[1]			
InoqulA FA - Rack holder		X		X[1]			
InoqulA FA - Plexiglass cover		X		X[1]			
InoqulA FA - Tube clamp and gripper pads		X		X[1]			
InoqulA SA - Clean the touchscreen(s)		X		X[1]			
InoqulA SA - Slide dispenser		X		X[1]			
InoqulA SA - Work surface		X		X[1]			
InoqulA+ SA - Inside of Bio Safety Cabinet (including safety shield)		X		X[1]			
Mice, Keyboards, LCD monitors, Touchscreens	X	if needed		X[1]			
SorterA BarcodA - Conveyer belts	Vacuum				X		
SorterA - Plexiglass components		X			X		
SorterA - Sensors	Brush				X		
BarcodA - Metal bridge (guide) and the recess underneath, suction cup area.	Brush, micro-fiber wipe		X		X		
BarcodA - Sensors	Brush				X		
InoqulA - White and blue conveyer belts	Vacuum				X		

Location	Cleaning method			Cleaning Frequency			
	Dry	Wet	Dry then wet	Daily	Weekly	Monthly	Quarterly
InoqulA - Stackers		X			X		
InoqulA - Lifting and rotating cylinder		X			X		
InoqulA - Scanner + scanner windows	Micro-fiber wipe				X		
InoqulA - Sensors	Brush				X		
InoqulA - Suction cups (all)		X			X		
InoqulA SA - Clamps at spreader area		X			X		
InoqulA FA - Bead dispenser		X				X	
InoqulA FA - Pipet tips racks		X				X	

3) Review/Revision/Implementation:

All procedures must be reviewed at least every 2 years.

- All new and procedures that have major revisions must be signed by the CLIA Laboratory Director.
- All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director.

4) Related Procedures: None

5) References: BD Kiestra InoqulA+ System User's Manual, Dec. 2017

6) Attachments:

InoqulA Maintentance Log Sheet
file:///G:\Lab_Shared\Micro_QC_Sheets\InoqulA%20Maintenance%20Log.xlsx

7) Revised/Reviewed Dates and Signatures: Revised 01/15/19 (CH)

Review/Revision Date	Signature