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ROUTINE PREVENTIVE MAINTENANCE

TOTAL SERVICE CALL

The Total Service Call procedure should be performed each time a Field Service Engineer (FSE) has worked on a COMMANDER® FPC. The Total Service Call is a general checkout, and assumes you have verified the problem worked on was resolved. This manual addresses the FPC. If service is provided on a COMMANDER System, then the checkout should include reader verification. A Total Service Call consists of the following sequential procedures:

- ❒ **Visually inspect the instrument.**
- ❒ **Check and replace all tubing as necessary.**
- ❒ **Verify that the Sample Syringe is secured against the block section. Refer to the Installation Guide in this manual if the syringe is loose.**
- ❒ **If any of the following is replaced:**
  - = Sample Syringe
  - = Diluent Syringe
  - = Sample Tubing
  - = Diluent Valve
  - = Nozzle Assembly
  - = Syringe Plunger or Plunger Tip

= the following procedures are required.

- ❒ Leak Test
- ❒ Tip Threshold Test
- ❒ 1:41 Dilution Verification

- ❒ **Perform a Leak Test (refer to Diagnostics Section of this manual).**
- ❒ **Perform the Instrument Lubrication Procedure (refer to page 4A-5).**
- ❒ **Perform an XYZ Alignment if necessary.**
- ❒ **Run an assay setup as follows:**
  - = Use a minimum of 20 tubes.
  - = Two tubes should be without water.
  - = Remove two of the disposable tips from the tip rack.
- ❒ **Verify that the assay is dispensed correctly. It should give pipetting errors on the two empty tubes and bypass the missing disposable tips.**
- ❒ **Perform the ABC PRISM Cleaning Procedure, if needed.**

PREVENTIVE MAINTENANCE CHECKLIST

- ❒ **Clean and Decontaminate Instrument**
  - ❒ Check and Replace as Necessary:
  - ❒ Sample Tubing
  - ❒ Diluent Tubing
  - ❒ Diluent Valve
  - ❒ Diluent Filter
  - ❒ Sample & Diluent Syringes
  - ❒ ABC Lens
- ❒ **Instrument Lubrication:**
  - ❒ X-Axis
  - ❒ Y-Axis
  - ❒ Z-Axis
  - ❒ Pump Assembly
- ❒ **Origin Sensor Verification:**
  - ❒ X-Origin
  - ❒ Y-Origin
  - ❒ Z-Origin
  - ❒ Diluent Syringe Origin
  - ❒ Sample Syringe Origin
- ❒ **Alignments and Checks:**
  - ❒ XYZ Alignments
  - ❒ SDH Adjustment
  - ❒ Tip Rack Z-Height Adjustment
  - ❒ Tip Wipe-Off Adjustment
- ❒ **Perform The Following Voltage Check:**
  - ❒ F-Link +5V Supply
- ❒ **Perform The Following Diagnostics:**
  - ❒ Leak Test
  - ❒ ABC (If Applicable)
  - ❒ Sensor Module (If Applicable)
  - ❒ Hand Bar Code Reader
  - ❒ RS-232 Port
  - ❒ Printer
- ❒ **Perform The Following:**
  - ❒ Tip Threshold
  - ❒ 1:41 Dilution Verification
  - ❒ Run An Assay
- ❒ **International Only:**
  - ❒ Perform Cable Inspection
- ❒ **Cable Tension**
  - ❒ Check Adjustment (refer to page 4A-8)

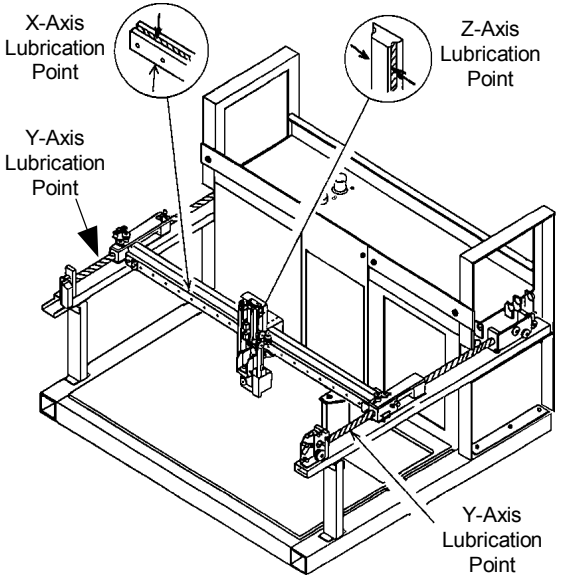


Figure 4A-1. XYZ Lubrication Points

INSTRUMENT LUBRICATION

Instrument Lubrication consists of four (4) procedures:

1. = X-Axis Lubrication
2. = Y-Axis Lubrication
3. = Z-Axis Lubrication
4. = Pump Assembly Lubrication

X-AXIS LUBRICATION

1. = Disconnect the AC Power Cord from the outlet.
2. = Remove the Right Arm End Cover by removing the two (2) mounting screws.
3. = Remove the Right Arm Internal Cover by removing the four (4) mounting screws, lowering the cover, and then taking it out. BE EXTREMELY CAREFUL TO NOT CATCH A METAL CABLE WHILE REMOVING THE COVER.
4. = Remove the Right Arm External Cover by removing the two (2) remaining mounting screws. Slide the cover forward and lift up while twisting the bottom of the cover to the right. BE EXTREMELY CAREFUL TO NOT CATCH A METAL CABLE WHILE REMOVING THE COVER.

5. Remove the X-Axis Assembly Top Cover by removing the two (2) mounting screws. To remove the cover, place the Z-Axis Assembly all the way to one side and carefully slide the cover out from the opposite direction. BE EXTREMELY CAREFUL TO NOT CATCH A METAL CABLE WHILE REMOVING THE COVER.

6. Remove the X-Axis Assembly Front Cover by removing the two (2) mounting screws. To remove the cover, place the Z-Axis Assembly all the way to one side and carefully slide the cover out from the opposite direction. BE EXTREMELY CAREFUL TO NOT CATCH A METAL CABLE WHILE REMOVING THE COVER.

7. Clean existing grease from both X-Axis Guide Bars using a soft, lint-free cloth and alcohol (isopropyl) as needed.

8. Apply a little grease (Super Lube® Grease P/N 14233-001) with a brush into the slot on both sides of the X-Axis Guide Bars as shown in (Figure 4A-1).

9. Distribute the grease evenly by moving the X-Axis Assembly to the left and right.

10. Replace the covers by performing steps 1-6 in reverse order.

Y-AXIS LUBRICATION

1. Disconnect the AC Power Cord from the outlet.

2. Remove the Right Arm End Cover by removing the two (2) mounting screws.

3. Remove the Right Arm Internal Cover by removing the four (4) mounting screws, lowering the cover, and taking it off. BE EXTREMELY CAREFUL TO NOT CATCH A METAL CABLE WHILE REMOVING THE COVER.

4. Remove the Right Arm External Cover by removing the two (2) remaining mounting screws. Slide the cover forward and lift up while twisting the bottom of the cover to the right. BE EXTREMELY CAREFUL TO NOT CATCH A METAL CABLE WHILE REMOVING THE COVER.

5. Remove the Left Arm End Cover by removing the two (2) mounting screws.

6. Remove the Left Arm Internal Cover by removing the four (4) mounting screws, lowering the cover, and then taking it out. BE EXTREMELY CAREFUL TO NOT CATCH A METAL CABLE WHILE REMOVING THE COVER.

7. Remove the Left Arm External Cover by removing the two (2) remaining mounting screws. Slide the cover forward and lift up while twisting the bottom of the cover to the right. BE EXTREMELY CAREFUL TO NOT CATCH A METAL CABLE WHILE REMOVING THE COVER.

8. Clean existing grease from both Y-Axis Guide Bars using a soft, lint-free cloth and alcohol as needed.

9. Apply a thin coating of Super Lube® Grease (P/N 14233-001) with a brush onto the Right Side Y-Axis Guide Rod as shown in Figure 4A-1. Repeat the application to the Left Side Y-Axis Guide Rod. Distribute the grease evenly by moving the Y-Axis Assembly to the front and back a few times.

10. Replace the covers by reversing the order of steps 1-8.

Z-AXIS LUBRICATION

1. Disconnect the AC Power Cord from the outlet.

2. Remove the Z-Axis Assembly Front Cover by removing the top screw and loosening the three (3) side screws (one in the front, left side, and right side).

3. Clean existing grease from both Z-Axis Guide Bars using a soft, lint-free cloth and alcohol as needed.

4. Apply a thin coating of Super Lube® Grease (P/N 14233-001) with a brush into the slot on both sides of the Z-Axis Guide Bars as shown in Figure 4A-1.

5. Distribute the grease evenly by moving the Nozzle Assembly up and down.

6. Replace the covers by reversing the order of step 2.

PUMP ASSEMBLY LUBRICATION

1. Remove the Pump Assembly as described in Section 5, Component Replacement of this manual.

2. Remove the two (2) Side Panels.

3. Clean existing grease from each Smooth Shaft and Screw Drive Shaft using a soft, lint-free cloth and alcohol as needed.

4. Apply a thin coating of grease with a brush onto both smooth

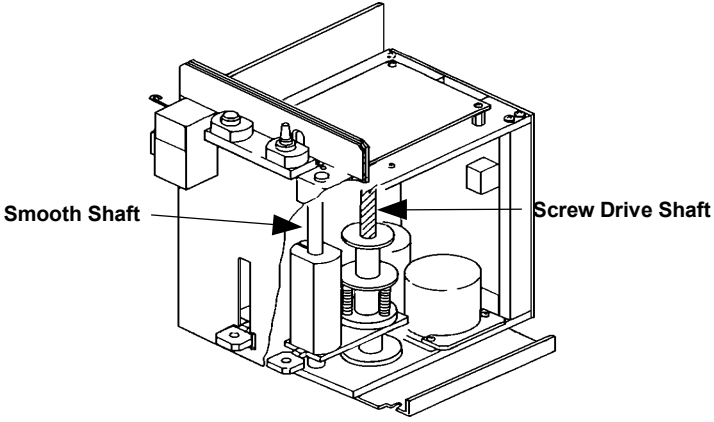


Figure 4A-2. Pump Assembly Lubrication Points

shafts and screw drive shafts. Distribute the grease evenly by turning the motor shaft to move the syringe drive up and down (refer to Figure 4A-2).

PROPER PIPETTING VERIFICATION

The following procedures for verification of proper pipetting are recommended:

1. = Leak Test.
2. = Tip Threshold Test.
3. = 1:41 Dilution Verification.

These tests should be performed at the following times:

- = Upon installation
- = After replacement of any of the following:
  - = Tip Nozzle
  - = Tubing
  - = Syringes (pre-lubricated, syringe plunger tips are not replaceable)
  - = Syringe Plunger or Plunger Tip

TIP THRESHOLD

Use this function to set the reference point for liquid level sensing and volume verification during installation. The Pipettor will automatically pick up 5 pipette tips and aspirate air, followed by a series of pipette tips to aspirate distilled/deionized water. Use a 100 ml bottle containing at least 25 ml of distilled/deionized water in the D1 position.

NOTE:
Do not execute Tip Threshold until Leak Test passes.

FPC CABLE TENSION CHECK/ADJUSTMENT PROCEDURE

Tools Required

- = Phillips Screwdriver
- = 7 mm open-end wrench or small adjustable wrench
- = 3 mm Allen Wrench
- = FPC Cable Tension Gauge

Disassembly

1. Turn the power off.
2. Remove the Pause Switch Mounting Panel by removing two screws. (Refer to Figure 4A-3).
3. Remove the Left External Cover by removing four screws.
4. Remove the Right End Cover by removing two screws.
5. Remove the Right External Cover by removing four screws. Refer to Figure 4A-3.

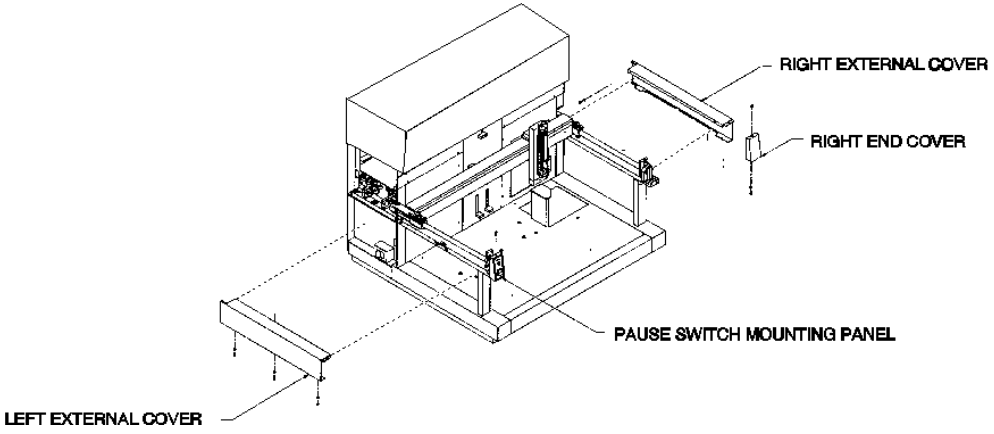


Figure 4A-3. Right External Cover

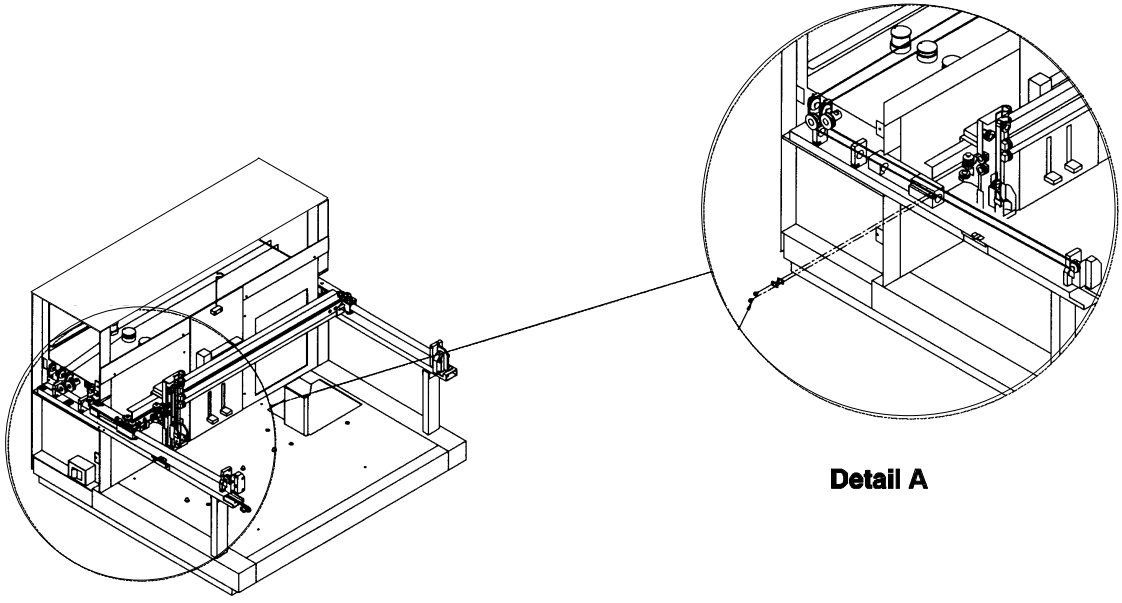


Figure 4A-4. Left Idle Pulley Assembly

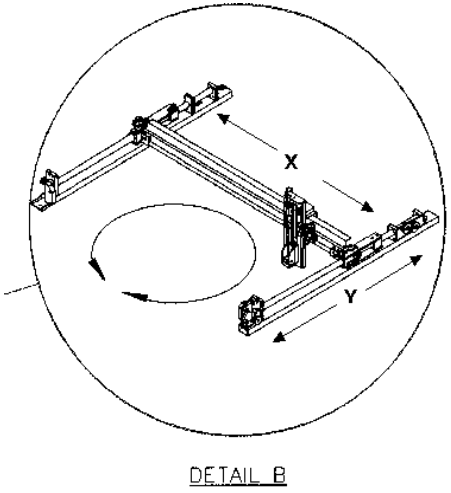


Figure 4A-5. Rotate the Assemblies

6. Loosen two screws holding the Y-Axis Cable Clamp at least three full turns to release Y cable from Left Idle Pulley Assembly (refer to Figure 4A-4).

7. Prepare FPC Cable for tension measurement:
While holding the Z-Axis Assembly, move it and the X-Axis Assembly in both the “X” and “Y” directions to simulate plotting a circle (refer to Figure 4A-5). Rotate the assemblies three times, both clockwise and counterclockwise. Avoid hitting the mechanical stops.

8. Move the Z-Axis Head Assembly to the “home” position (the left, rear corner of FPC with nozzle raised).

9. Lower and raise the Nozzle Assembly three times. Return it to the fully-raised position.

Tension Verification

To measure Z-cable tension, perform the following procedure:

1. Place the tension gauge shoulder screw in the Z MIN position on the gauge.

2. Identify the right side of the Z-cable (refer to Figure 4A-6).

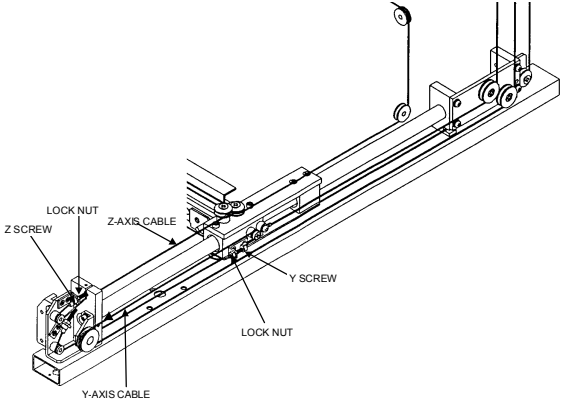


Figure 4A-6. Z and X-Axis Cables

3. Place the tension gauge on the right side of the Z-cable (refer to Figure 4A-7).

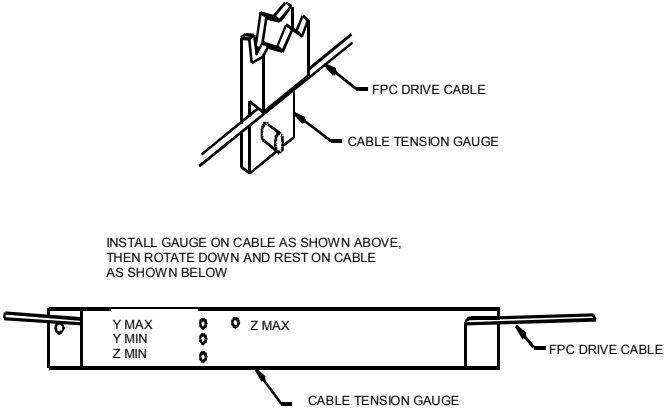


Figure 4A-7. Tension Gauge

NOTE:
If the cable tension is well above the minimum specification, the tension gauge will not balance on the cable. If this happens, the Z-cable tension does not need to be adjusted.

4. If the Z-cable touches the tension gauge (refer to Figure 4A-8), the cable tension is at, or below, the minimum specification. Adjust the cable tension as described in the Re-tension section on the next page. If the Z-cable is not touching the tension gauge, tension is above the minimum specification. No adjustment is required.

Measure Y-Cable Tension:

1. Place the tension gauge shoulder screw in the Y MIN position on the gauge.

2. Identify the right side of the Y-cable (refer to Figure 4A-6).

3. Place the tension gauge on the right side Y-cable (refer to Figure 4A-7).

NOTE:
If the cable tension is well above the minimum specification, the tension gauge will not balance on the cable. If this happens, the Y-cable tension does not need to be adjusted.

4. If the Y-cable touches the tension gauge (refer to Figure 4A-8), the cable tension is at, or below, the minimum specification.

5. Adjust the cable tension as described in the Re-tension section. If the Z-cable is not touching the tension gauge, tension is above the minimum specification. No adjustment is required.

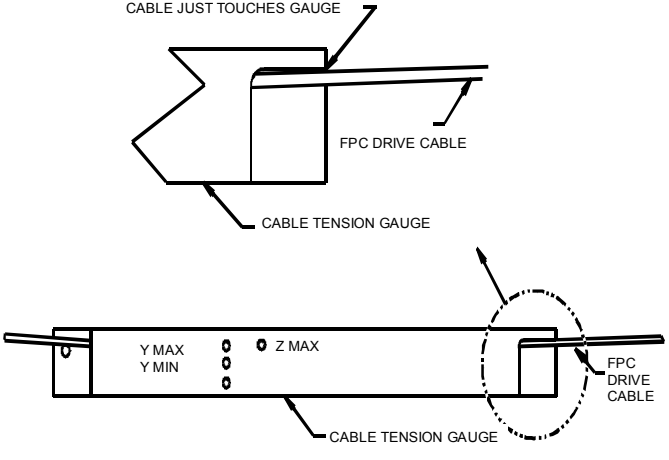


Figure 4A-8. Adjust Cable Tension

Re-Tension

To adjust Z-cable tension, perform the following procedure:

1. Place the tension gauge shoulder screw in the Z MAX position on the gauge.
2. Place the tension gauge on the right side of the Z-cable (refer to Figures 4A-6 and 4A-7).
3. Loosen the Z-cable adjusting screw lock nut using a 7 mm wrench.
4. Tighten the Z-cable tension adjusting screw using a 3 mm Allen wrench until the gauge just lifts off the cable (refer to Figure 4A-8). No further adjustment is required.

NOTE:
If there is not enough adjustment in the tension adjusting screw to lift the tension gauge off the cable, maximum cable tension is not obtained. This condition is normal.

5. Tighten the Z-cable adjusting screw lock nut.

To adjust Y-cable tension, perform the following procedure:

1. Place the tension gauge shoulder screw in the Y MAX position on the gauge.
2. Place the tension gauge on the right side of the Y-cable (refer to Figures 4A-6 and 4A-7).
3. Loosen the Y-cable adjusting screw lock nut.
4. Tighten the Y-cable tension adjusting screw until the gauge just lifts off the cable (refer to Figure 4A-7). No further adjustment is required.

NOTE:
If there is not enough adjustment in the tension adjusting screw to lift the tension gauge off the cable, maximum cable tension is not obtained. This condition is normal.

5. Tighten the Y-cable adjusting screw lock nut.

Reassemble The FPC

1. Pull the X-Axis Assembly fully forward (towards the operator) and against the stops.
2. While holding the X-Axis Assembly against the front stops, tighten two screws holding the Y-Axis Cable Clamp (Figure 4A-4, Detail A) to lock cable to Left Side Pulley Assembly.
3. Reverse steps 2 through 5 of the Disassembly instructions (Page 4A-9 of this section) to install the sheet metal covers.

Checkout

1. = Perform the FPC Alignment procedure specified in the Alignments and Calibrations section of this manual.

2. = Perform Total Call.

DILUTION VERIFICATION (DILUTOR D1)

Purpose

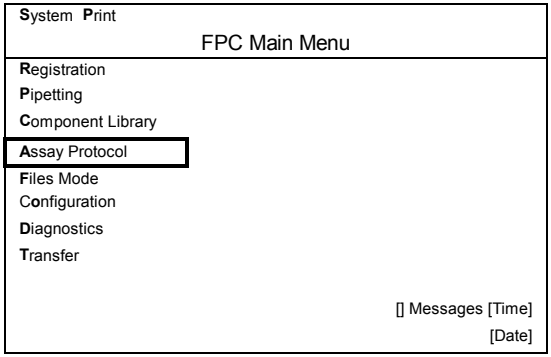
The following procedure may be used to verify the accuracy and precision of the volumes dispensed by the COMMANDER® FPC. The verification procedure makes use of the dyes provided in the Diluter Calibration Kit from MLA.

Description

Measurement of results should be done with an Abbott QUANTUM™ II Analyzer or equivalent. You may be required to perform the following dilution verification procedure or an equivalent developed by Abbott Laboratories. **The following procedure is only for 1:41 (5:200) dilution.** This procedure requires the use of the Range #2 dye from the MLA Kit.

Create a New Assay

1. = Select **Assay Protocol** from the Main Menu.



2. Select **Assay HCV-2.0 PPC D1** as a template.

System Print View Delete Create Disk Panel

Assay Protocols

001 AUSZYME MONO PPC a	002 AUSZYME MONO QT a	003 AUSZYME MONO QNB a
004 CORZYME PPC a	005 CORZYME QT a	006 CORZYME QNB a
007 -A-HIVAB-1 PPC a	008 -A-HIVAB-1 QT a	009 -A-HIVAB-1 QNB a
010 -A-HIVAB-1-2 PPC a	011 -A-HIVAB-1-2 QT a	012 -A-HIVAB-1-2 QNB a
✓013 HTLV-1 PPC D0 a	014 HTLV-I PPC D1 a	015 HTLV-I QT D0 a
016 HTLV-I QNB D0 a	017 HTLV-I QT D1 a	018 HTLV-I QNB D1 a
019 A-HCV 2.0 PPC D0 a	020 A-HCV 2.0 PPC D1	021 A-HCV 2.0 QT D0 a

3. Press the **Space Bar** to select an assay.

4. Select **F5** (or Alt + **C**reate) and press ↵**Enter**.

5. Assign any Assay Number that is currently not used by the customer and enter it into the Assay Code field (for example, Assay Code Number 200.)

6. Enter the Assay Name “dilver” (dilver stands for *dilution verification*).

System Print Save Delete Insert NextSec PreSec

Create Assay Protocol From Template

General Information

Assay Code:	200	Analyzer Test Number: 78
Assay Name:	dilver	Extra Sample Volume: 20 µl
Date:	08/07/92	Extra Air Volume: 0 µl
Destination Type:	60 Well Tray	Print Map: No
Source Return Volume:	100 µl	Tech ID: _ _ _ _ _

7. Select **F6** (or Alt + **N**extSec) and press ↵**Enter**.

System Print Save Delete Insert NextSec PreSec

Create Assay Protocol From Template

Pipetting Section: #3

Source Material:	Unknown	Touch-off Direction: Vertical
Source Location:	Unknown	Touch-off Value: 5.0 mm
Destination Volume:	5.0 µl	Dispense Height: 0.0 mm
Destination Loc.:	Next Address	Diluent Volume: 200 µl
No. of Replicates:	3	Diluent Source: Dilutor
Pipetting Sequence:	Diluted	Dil. Dispense Option: Post
Pipetting Direction:	Horizontal	Mandatory Flag: Yes
New Tip Required:	Optimize	Error Handling: Unknown
Source Pickup Height:	0 mm	

8. = Arrow down to **No. of Replicates**, type in the number **3**, and press ↵**Enter**.

9. = Save this new assay by selecting **F3** and press ↵**Enter**.

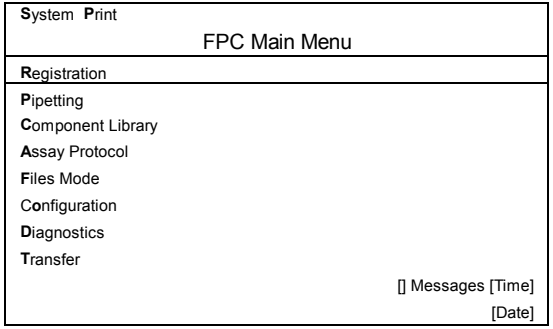
10. Press the **Esc** key to return to the Main Menu.

Sample Registration

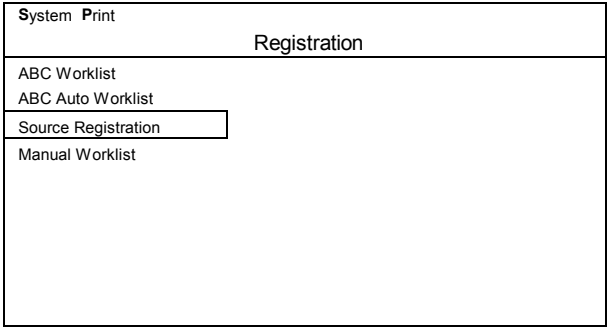
NOTE
ABC users, go to page 4a-19 for pipetting mode. Sensor Module users follow the procedure below.

The following steps explain how to register a sample rack with the Sensor Module.

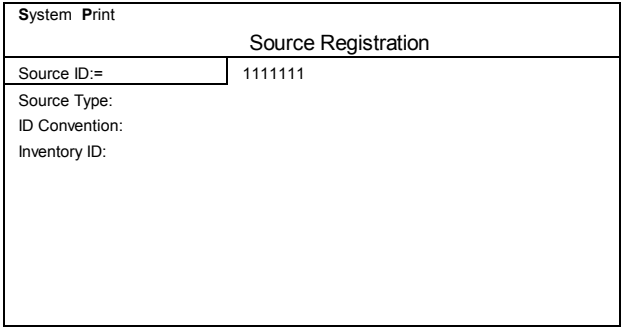
1. = Select **Registration** from the Main Menu and press ↵**Enter**.



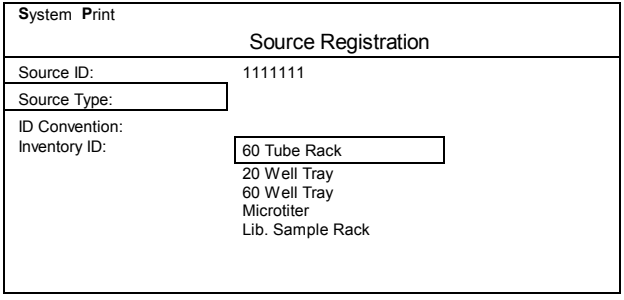
2. = Select **Source Registration** and press ↵**Enter.**



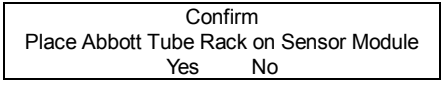
3. = Enter the ID of the Service rack and press ↵**Enter.**



4. Press ↵**Enter** to select this Source Type: 60 Tube Rack.

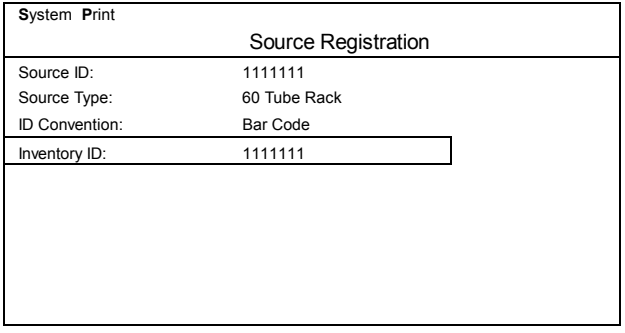


5. Select **ID Convention** and select **Bar Code** and press ↵**Enter**.

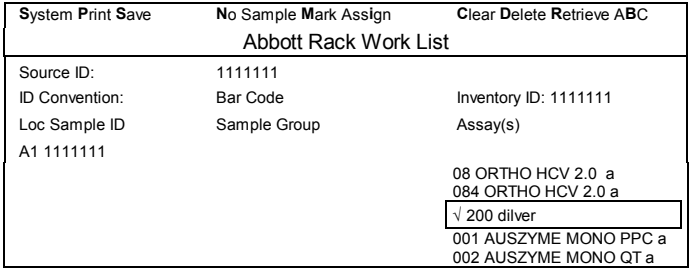


Confirm placement of the tube rack. Select **Yes** and press ↵**Enter**.

6. Select **Inventory ID,** enter the value, and press ↵**Enter**



Abbott Rack Work List Procedure

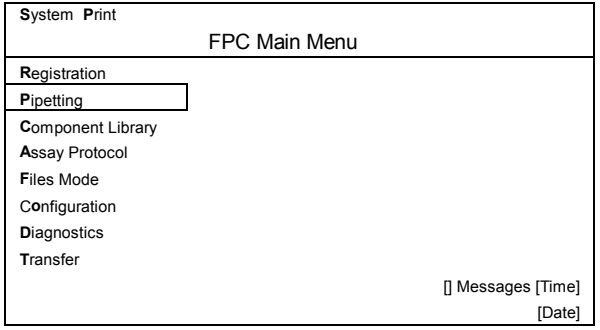


1. Read the ID Number on the Sample Tube and place the tube in the A-1 location in the rack.
2. Arrow down in the Assay Menu to select **200 dilver**.
3. Press the **Space Bar** to select Assay.
4. Press ↵**Enter**.
5. Select **F3** (or Alt + **S**ave) and press ↵**Enter**.
6. Press the **Esc** key to return to the Main Menu.

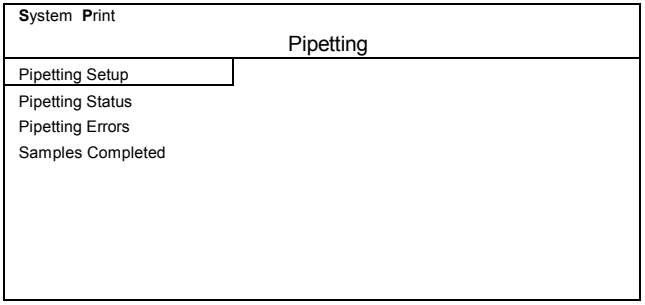
Pipetting Mode

The following steps explain how to begin pipetting:

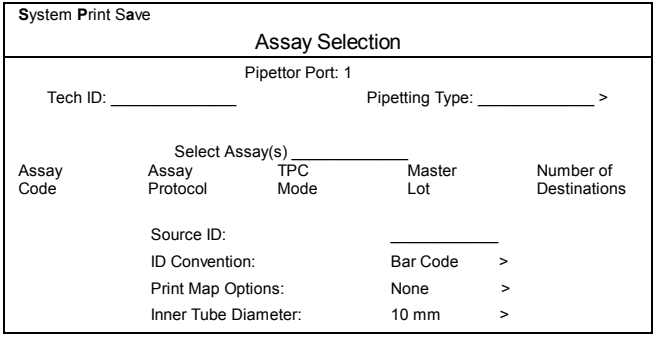
1. Select **Pipetting** from the FPC Main Menu and press ↵**Enter**.



2. Select **Pipetting Setup** and press ↵**Enter**.



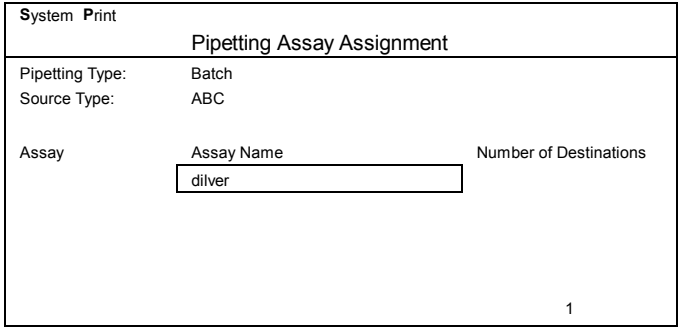
3. Enter the requested information, select **F3** (or Alt + **S**ave), and press ↵**Enter**.



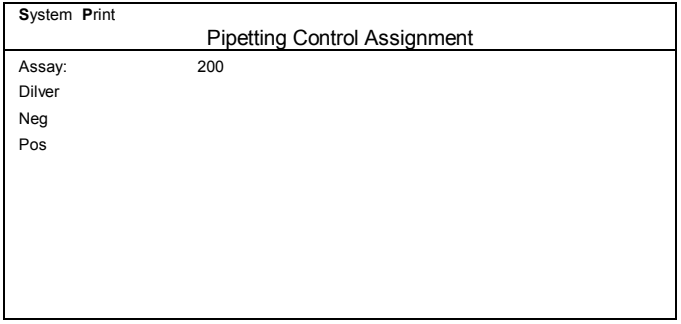
4. Select **dilver** Assay**.**

5. Press ↵**Enter**.

6. Select **F3** (or Alt + **S**ave) and press ↵**Enter**.

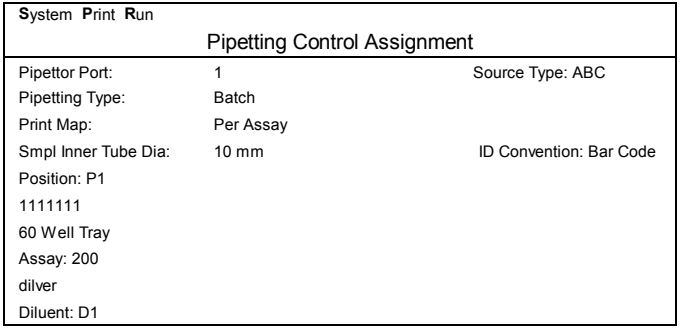


7. Press the **Space Bar** to deselect controls selected by the assay for destination.



8. Select **F3** (or Alt + **S**ave) and press ↵**Enter**.

9. Enter the **Tray ID**.



10. Select **F3** (or Alt + **R**un) and press ↵**Enter**.

Confirm
Place the following objects on the platform:
Position P1: 1111111
Diluent: D1
Yes No

11. Place a 100 ml bottle of deionized water in position D1.

12. Select **10** and press ↵**Enter**.

Prime Pipettor 1	
Enter Number of cycles to prime	10
Yes No	

13. Select **Yes** and press ↵**Enter**.

14. When pipetting is complete, remove the tray from the FPC platform.

15. Manually pipette the 1:41 (5:200) dilution from wells A1, A2, and A3 of the tray into a single, clean, dry cuvette as supplied in the MLA Kit.

16. Cap the cuvette with the rubber stopper to prevent evaporation.

NOTE
The glass cuvette tube from the MLA Kits can be reused if it is cleaned and dried prior to use.

17. This completes dilution preparation.

Absorbance Reading

The absorbance readings require an Abbott QUANTUM™ II Spectrophotometer.

1. Turn the QUANTUM™ II Power Switch to the on position. The power switch is located on the rear of the unit. Wait for the Abbott logo to appear on the display. It should appear within two (2) seconds.

2. If the monitor displays an error code, refer to the Operator's Manual for additional information.

3. Press the **LAMP** key to enable the keyboard. A three minute warm-up period is necessary before the **READY** light comes on.

4. Enter the Date in European Format according to the example below:

   DATE 20. 09. 96. Then press ↵**Enter**.
   d. m. yr.
   Each numerical entry must be followed by a period. 2 digits are required for each entry.

5. Enter the time in 24 Hour Format according to the example below:

   TIME 14. 36. 32. Then press **↵Enter**.
   hr.min.sec.
   Each numerical entry must be followed by a period. Two digits are required for each entry.

6. Enter the filter type:

   FILTER 492. 600. Then press **↵Enter.**
   Peak Side
   Band Band
   Each numerical entry must be followed by a period.

7. Wait for the **READY** light to come on. Then press **MODE 0** followed by the **RUN** key.

8. Place the black metal Elevation QUANTUM™ II Insert into the QUANTUM™ II Read Well (refer to Figure 4A-9).

9. When the **BLANK** and **READY** lights are on, insert the MLA "Zero Standard" to perform the instrument "blank" readings.

10. Insert the A, B, and C standard dye solutions (sealed) provided with the MLA Diluter Calibration Kit and take the absorbance readings.

11. Insert each sample vial and obtain readings.

12. After completing the absorbance readings, remove the insert with the removal magnet supplied with the FPC. Clean the cuvettes with distilled water.

13. Air dry the cuvettes and store them in a clean environment.

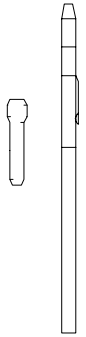


Figure 4A-9. QUANTUM™ II Insert and Magnet

Data Analysis

The following steps explain how to plot the absorbance readings for the known standards and determine the dilution for the sample:

1. Use only the "Calibration Curve for Range 2 1/17 to 1/80 Ratio" graph paper.

1. Plot the A standard by locating the absorbance reading obtained from the A standard on the Y-Axis. Locate and mark this value on the vertical line labeled A.

2. Repeat step 2 for the B standard. Draw a line connecting the points plotted on the A line and B line.

3. Repeat step 2 for the C standard. Draw a line connecting the points plotted on the B line and C line.

4. Find the absorbance for the Range 2 dilution on the Y-Axis, and draw a horizontal line across the graph. Locate the point where this line intersects the lines drawn in steps 2, 3, and 4. Draw a vertical line from the intersection point to the X-Axis. Read the dilution. The acceptable range for a 1:41 dilution is from 1:37 to 1:45.

Example

Below is an example of how to calculate the dilution after you have pipetted on the FPC and have the following absorbance values:

A Standard = 0.200 C Standard = 0.800

B Standard = 0.520 Range 2 Dilution 1:41 (5:200)=0.240

1. Plot the A standard on the vertical A line, the B standard on the B line, and the C standard on the C line. Using a straight edge, connect the A standard point and the B standard point. Then connect the B standard point to the C standard point. DO NOT connect all three points by a single best-fit line (refer to Figure 4A-10).

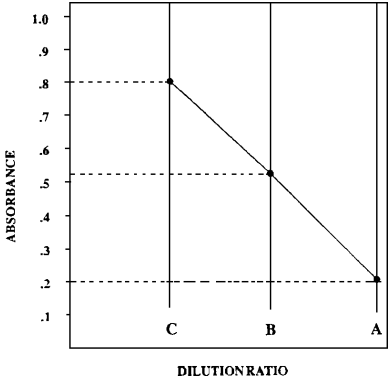


Figure 4A-10. Dilution Ratio Calculation

2. Find the Range 2 absorbance reading (0.240) and locate this point on the Y Axis (absorbance) and draw a horizontal line from this point across the paper. Draw a vertical line from the point that your line crosses the Standard Curve to the horizontal axis (Dilution) and read the dilution from the point it crosses the Horizontal Axis (refer to Figure 4A-11).

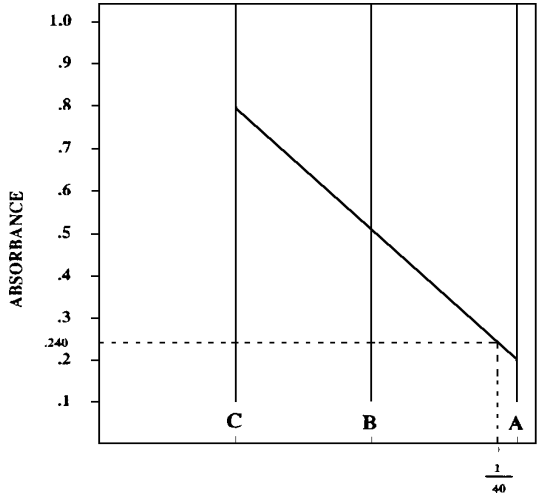


Figure 4A-11. Absorbance Reading

DILUTION VERIFICATION (DILUTOR D0)

The Dilution Verification Procedure may be used to verify the accuracy and precision of the volumes dispensed in the range of 5-µl and dilution ratios, and should be run whenever a change has been made in the sample/diluent delivery system (tubing/syringes). Measurement of results should be done with an Abbott Quantum II analyzer or equivalent.

NOTE:
Medical Laboratories Automation, Inc., 500 Nuber Avenue, Mt. Vernon, NY 10550., M.L.A Diluter Calibration Kit Catalog No. 9086.

The 1:41 Dilution Verification Procedure is recommended to verify proper pipetting because it is the most stringent pipetting sequence performed on the FPC. When the 1:41 Dilution Verification Procedure falls within the acceptable specifications, Pipettor operation will have been verified.

Dilution Verification Procedure

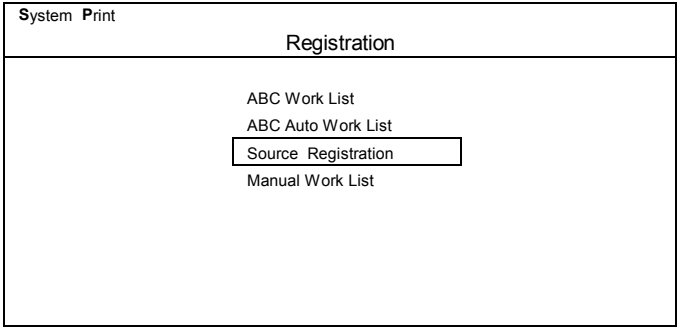
Instrument Preparation

1. Select the Range for the specific dilution ratio and corresponding dye 1, 2, or 3. Dye # 2 will be used for this procedure.
2. Place Dye # 2 into sample tube.
3. Prepare D0 position with distilled/deionized water for dilution.
4. Verify the 1:41 Dil Verify Assay Protocol has been loaded on the system. If the assay protocol does not exist, follow the directions in the FPC Operations Manual, Section 5, Assay Protocols, “Installing Assay Protocols from Diskette.”

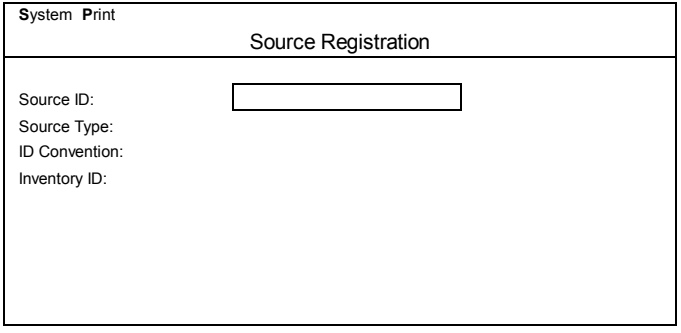
Registration

If you are using a Sensor Module:

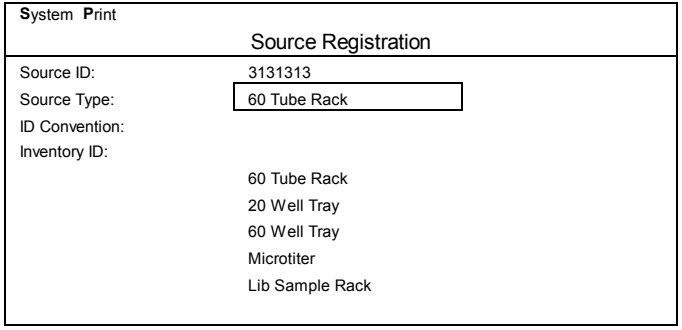
1. Place the 60 tube rack with a bar code label in the sensor module.
2. Pipetting in a non-ABC environment requires the registration of the source to enter Sample IDs.
3. Select Registration for the FPC Main Menu.
4. Select Source Registration



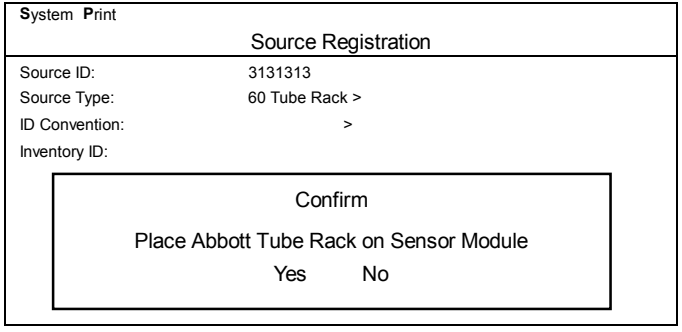
5. Scan the bar code label on the sample rack with the Bar Code Reader. If necessary, you can manually enter the ID followed by ↵**Enter**.



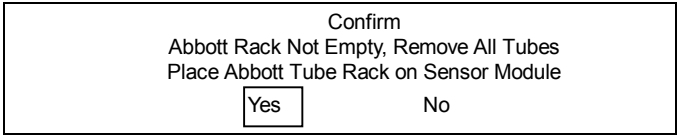
6. Select 60 Tube Rack as the source type module .



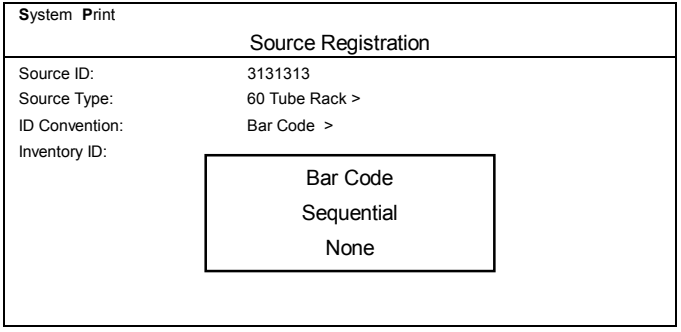
The System prompts you to place the rack on the sensor



7. When the confirm screen appears place the 60 tube rack in the sensor module and select YES.



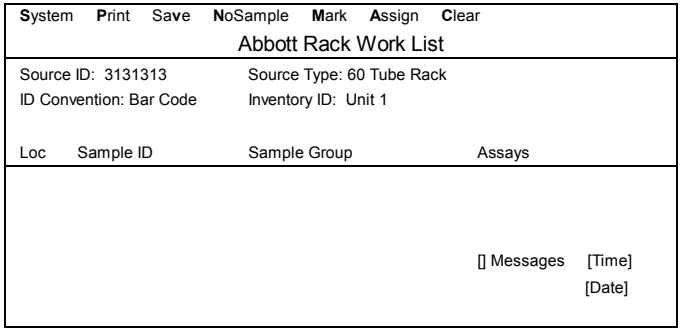
8. A pop-up screen displays ID convention options.



Select Bar code followed by ↵**Enter**.

9. Select the ID convention being used. The screen displays it and prompts for an inventory ID. Press ↵**Enter** to skip.

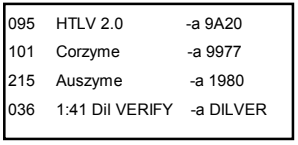
The computer Records your entry.



10. Scan the bar code for the first tube or manually enter it from the Keyboard. It will appear on the screen under “Sample ID”

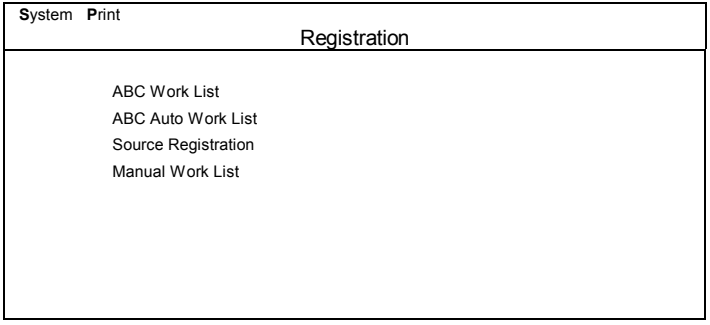
11. Place the tube in the source rack. The sample ID location (Loc) will appear on the screen.

12. A pop-up screen provides available assays.



13. To make a selection, use the **Arrow** keys to highlight to the assay and press the **Space Bar** to select it with a check mark (√).

14. When finished registering samples, select **F3** SAVE from the Menu Bar to save the work list.

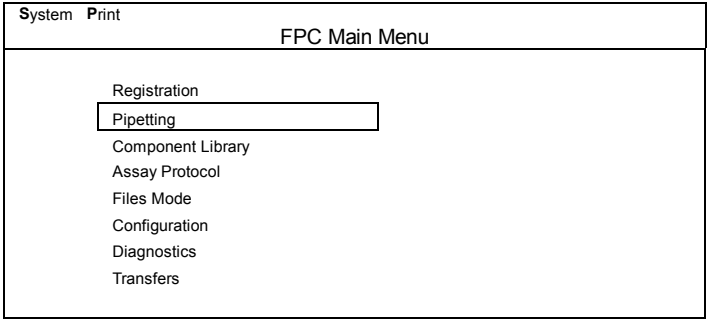


15. To exit from Registration, Press **Esc** to return to the FPC Main Menu.

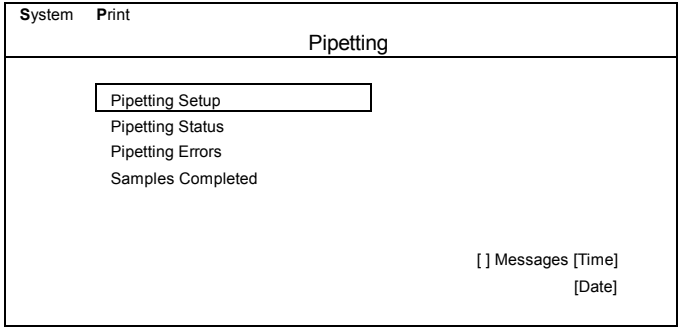
Pipetting (Sensor Module)

If you are using a Sensor Module:

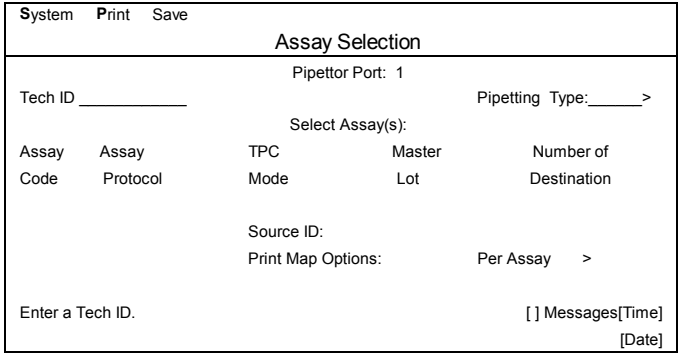
1. Select Pipetting from the FPC Main Menu. The screen displays:



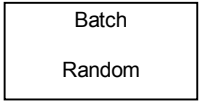
2. Select Pipetting Setup and press the ↵**Enter** key.



The System next displays a screen with some or all of the following information:



3. Type in ID and Press ↵**Enter**.
4. Press the **Space Bar** and a pop-up screen displays:



Select Batch and Press ↵**Enter**.

5. Select 1:41 Dil Verify using the **Arrow** keys to highlight your selection.

031	CORZYME PPC	-a	9977
032	CORZYME QT	-a	9977
033	HTLV I PPC D0	-a	9A20
034	HTLV 1 QT D0	-a	9A20
035	RBC Antisera	-a	ANTI
√036	1:41 DIL VERIFY	-a	DILVER
038	FPIA Cal	-a	FCAL
039	FPIA Mode 2	-a	FMOD
040	Forward Typing	-a	FORT
041	MEIA QualMode1	-a	MODE

Press **Space Bar** and a check mark appears next to the assay.

Press ↵**Enter**

The screen displays the following:

System **P**rint Save

Assay Selection

Pipettor Port: 1

Tech ID _____ Pipetting Type: Batch>

Select Assay(s):

Assay Code	Assay Protocol	TPC Mode	Master Lot	Number of Destinations
036	1:41 DIL VERIFY-a	Off		1

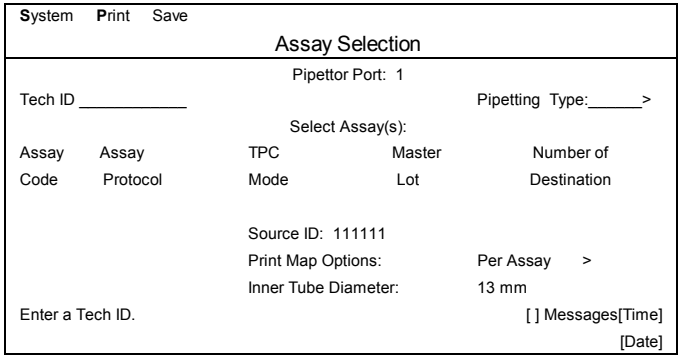
Source ID:

Print Map Options: Per Assay >

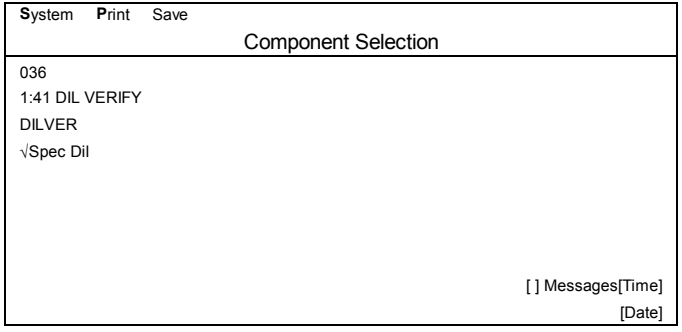
Enter a Tech ID. [ ] Messages[Time]

[Date]

6. Highlight the Source ID field and scan (or type in ID) the bar code on the Registered Source (TUBE RACK) and press ↵**Enter**.

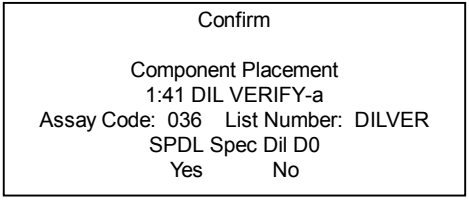


7. Select **F3** Save and Press ↵**Enter**.

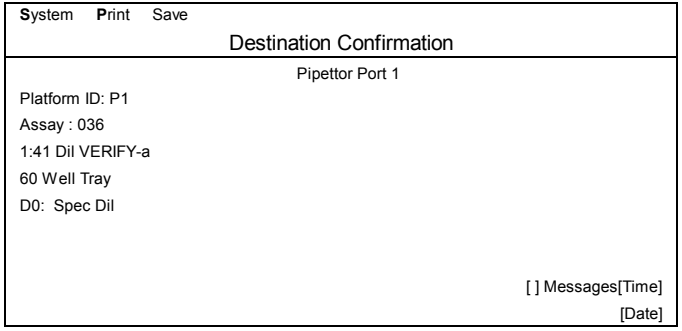


8. Insure that all components selected are correct.

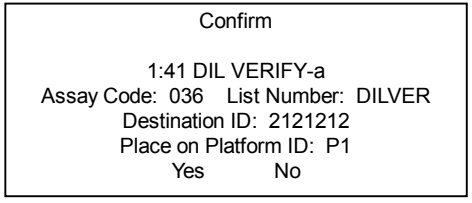
9. Select Save **F3** Key and press ↵**Enter**.



10. Select Yes and press the ↵**Enter** key.

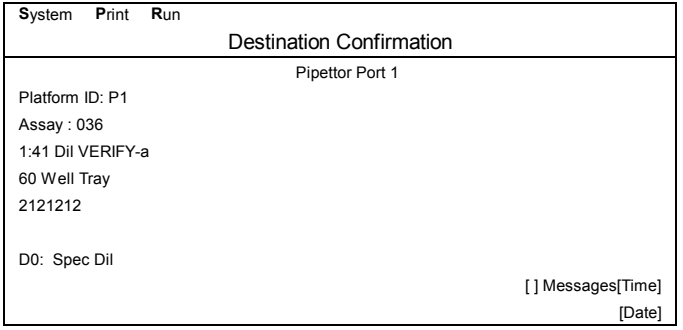


11. Scan bar code label for the 60 well tray.



12. Select Yes and Press ↵**Enter**.

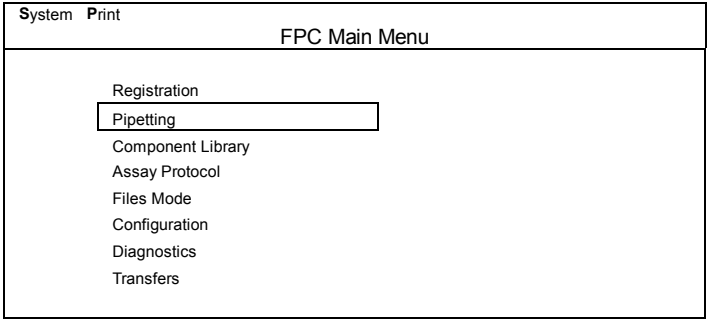
13. Select Run **F3** and Press ↵**Enter** to start the pipetting.



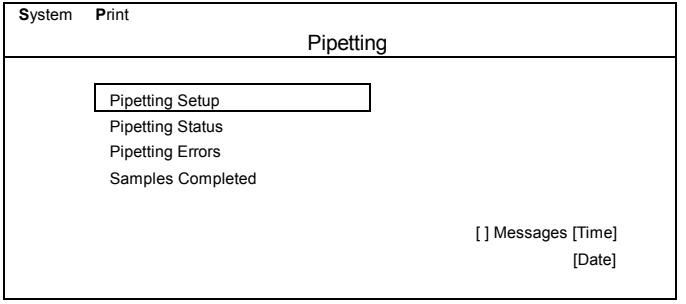
Pipetting (ABC)

If you are using an **ABC**.

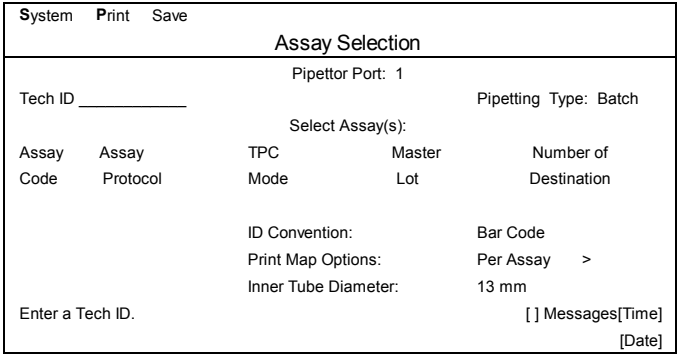
1. Select Pipetting from the FPC Main Menu.



2. Select Pipetting Setup from the Pipetting Menu.



The System next displays a screen with some or all of the following information:



3. If required, scan your TECH ID or enter it from the Keyboard and press ↵**Enter**.

4. If you wish to change the displayed pipetting type, press the **Space Bar** .

   A pop-up Screen Displays:

Batch
Random

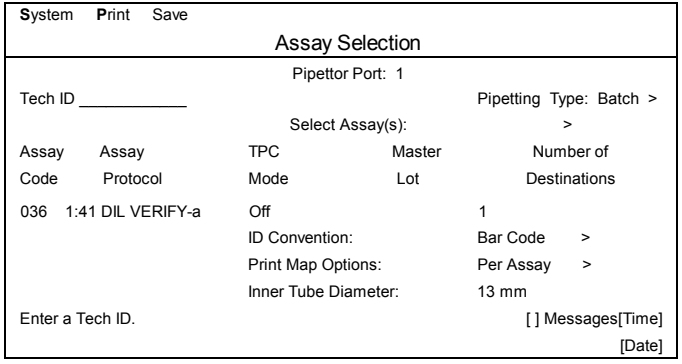
5. Select Batch and press ↵**Enter**.

6. The next pop-up screen displays:

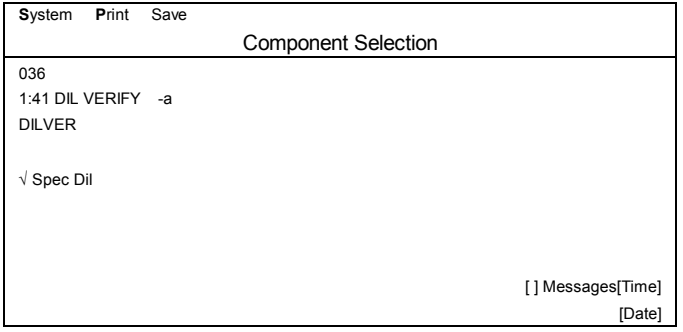
031	CORZYME PPC	-a 9977
032	CORZYME QT	-a 9977
033	HTLV I PPC D0	-a 9A20
034	HTLV 1 QT D0	-a 9A20
035	RBC Antisera	-a ANTI
√036	1:41 DIL VERIFY	-a DILVER
037	FPIA Cal	-a FCAL
038	FPIA Mode 2	-a FMOD
039	Forward Typing	-a FORT
040	MEIA QualMode1	-a MODE

7. Use the **Arrow** keys to highlight 1:41 Dil Verify and then press **Space Bar**. A check mark will appear next to the assay you have selected. Press ↵**Enter**

The System screen displays:



8. Select Save **F3** key and Press ↵**Enter**.

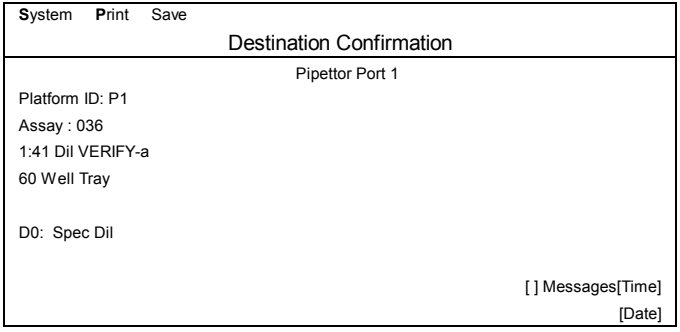


9. Ensure that all components selected are correct. Use the A**rrow** keys to highlight the field, then press the **Space Bar** to select or deselect.

Confirm
Component Placement 1:41 DIL VERIFY-a Assay Code: 036 List Number: DILVER SPDL Spec Dil D0 Yes No

10. Select Yes and then press ↵**Enter**.

11. Select **F3** Save and then press the ↵**Enter** key.



12. Scan the Bar Code label for the Well Tray

13. Select Save **F3** Key and press ↵**Enter**.

14. Enter Prime Cycle of 10 at the prompt.

15. Select Run **F3** key and press ↵**Enter** to start the pipetting.

Transferring Sample to Cuvettes or Glass Tubes

1. Manually pipette the dye mixer from three wells (for example, A1, A2, A3) into a single clean, dry cuvette as supplied in the MLA Kit or a glass tube (12 x 75).

2. Cap each cuvette or glass tube to prevent evaporation.

Measurement of Results

The absorbance reading requires an Abbott Quantum™ II Spectrophotometer.

1. Turn the Quantum II Power Switch to the ON position. The power switch is located on the rear of the System. Wait for the Abbott logo to appear on the display.

2. If an Error Code is displayed, refer to the Quantum II Operator's Manual.

3. Press the LAMP key to enable the Keyboard. A three minute warm-up period is necessary before the READY light comes on.

4. Enter the Date in the European format according to the example below.

NOTE:
Each numerical entry must be followed by a period.
All entry must be two digit.

DAY. MONTH. YEAR.
DATE 20. 09. 96.

5. Press the ↵**Enter** key.
6. Enter the time in 24-Hour format according to the example below:

NOTE:
Each numerical entry must be followed by a period.
All entry must be two digit.

HOUR. MINUTE. SECOND.
TIME 14. 36. 32.

7. Press ↵**Enter** key.
8. Enter the Filter type:

- **PEAK BAND 492 mm**
- **SIDE BAND 600 mm**

NOTE:
Entry Must be followed by a period

FILTER 492. 600.

9. Press ↵**Enter** key.
10. Wait for the READY light to come on. Then press **MODE 0** key followed by the **RUN** key.
11. Place the black metal elevation Quantum™ II Insert into the read well of the Quantum.

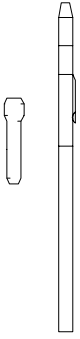


Figure 4A-12: QUANTUM™ II Insert & Magnet

12. When the BLANK and READY lights are ON, the instrument is in Start status.

13. The first four absorbance reading will be taken from the standards provided with the MLA Diluter Calibration Kit.
    - Zero Standard (The zero standard is used as the Blank reading for the instrument.)
    - A Standard
    - B Standard
    - C Standard

14. Insert each of the standards above into the Quantum™ read well for an absorbance reading.

15. Insert the cuvette with the dilution into the Quantum read well for an absorbance reading.

Data Analysis

The following steps explain how to plot the absorbance reading for the known standards and determine the dilution for the sample:

1. Use only the "Calibration Curve for the **Range 2** ratio **"1\17 to 1\80**" graph paper.

2. Plot the "A" Standard by locating the absorbance reading obtained for the "A" Standard on the Y-Axis. Locate and mark this value on the vertical line labeled "A".

3. Repeat Step 2 for the "B" standard. Draw a line connecting the points plotted on the "A" line and "B" line.

4. Repeat Step 3 for the “C” standard. Draw a line connecting the point plotted on the “B” line and “C” line.

5. Find the absorbance for the Range 2 dilution on the Y-Axis and draw a horizontal line across the graph.

Locate the point where this line intersects the lines drawn in 2, 3, and 4. Draw a vertical line from the intersection point to the X-Axis. Read the dilution ratio.

NOTE

The acceptable range for a 1:41 dilution is 1:37 to 1:45 ratio.

EXAMPLE:

Below is an example of how to calculate the dilution after you have pipetted on the FPC and have the following absorbance values:

A standard = 0.200 C standard = 0.800

B standard = 0.520 Range 2 Dilution 1:41 (5:200) = 0.240

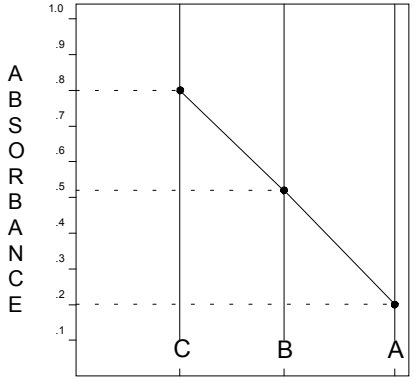


Figure 4-13: Dilution Ratio Calculation

1. Plot the A standard on the vertical A line, the B standard on the B line, and the C standard on the C line. Using a straight edge, connect the A standard point and the B standard point. Then connect the B standard point to the C standard point. Do NOT connect all three points by a single best-fit line (refer to Figure 4-13).

2. Find the Range 2 absorbance reading (0.240) and locate this point on the Y-Axis (absorbance) and draw a horizontal line

from this point across the paper. Draw a vertical line from the point that your line crosses the Standard Curve to the horizontal axis (dilution) and read the dilution from the point it crosses the horizontal axis (refer to Figure 4-14).

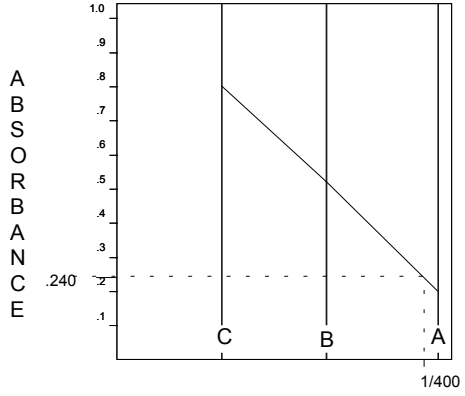


Figure 4-14. Absorbance Reading

ASSAY PROCEDURES

FPC Version 2 with ABC Pipetting

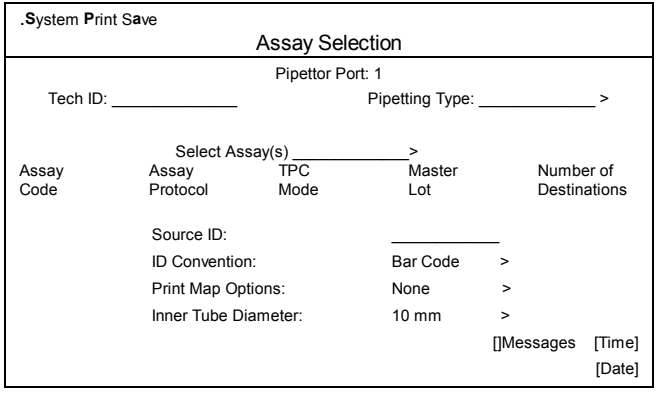
When you are pipetting the assay on each sample in a batch run using the ABC, the registration procedures are not necessary.

ABC System Preparation

1. Use 20 sample tubes with bar code labels and MEIA buffer.
2. Load the tubes into the ABC carriers.
3. Place the End of Batch Plug after the last sample tube.
   - Select **Pipetting** from the FPC Main Menu.
   - Select **Pipetting Setup** from the Pipetting Menu.

NOTE:
If you have two FPC Units, the screen requires a choice. Pipettors are designated "available" or "busy". Only "available" pipettors can be selected. Highlight an "available" pipettor and press ↵Enter.

- The screen will display the following:



a. Pipettor Port: This is for information only and is displayed if you have more than one FPC.

b. Pipetting Type: Press the **Space Bar** for the Menu. Highlight the **Batch** option and press **↵Enter**.

4. The screen next displays a pop-up menu with a list of assays available for pipetting.

5. Select the following assays for your pipetting sequences:
   - Corzyme PPC -a
   - Auszyme Mono PPC -a
   - HTLV-I PPC D0 -a

6. Use the **Up** and **Down** keys to highlight each assay, then press the **Space Bar**. A check mark appears next to the assay, indicating that you have selected it. Press **↵Enter** when you have selected all assays to be pipetted in this run.

7. Type the number of destinations (trays, carousels, etc.) for each assay you select. Choose "1 " tray for each assay (a total of 3).

8. Press **F3** and **↵Enter** (or Alt + **S**ave) when finished. If the assays you have chosen require controls, calibrators, etc., the screen displays them. All controls are selected by default and are shown "checked". Use all controls for the three assays chosen.

   Place the controls for the assay in the specified position of the Control Bottle Rack.

NOTE:
Fill the Control Bottles with MEIA Buffer.

9. Press **F3** and **↵Enter** (or Alt + **S**ave) when finished. The screen displays confirmation of the data you have entered and tells you how to place destinations on the platform positions for the run.

10. The cursor highlights P1, the first destination. Scan the bar code on the destination (tray) with the hand-held reader or manually type the ID followed by **↵Enter**.

11. Place the destinations in the specified location on the tray platforms.

12. When you have completed placement for the first destination, select **Yes**. The System moves to the next destination. Follow the same procedure until you have placed destinations for the remaining two assays in this pipetting run.

13. Empty the Tip Bin and ensure there are enough pipette tips in the Tip Rack.

14. Select **Run** from the Menu bar (or **F3** + **↵Enter**). If a diluted assay was chosen, select **5** when prompted for the number of cycles to prime.

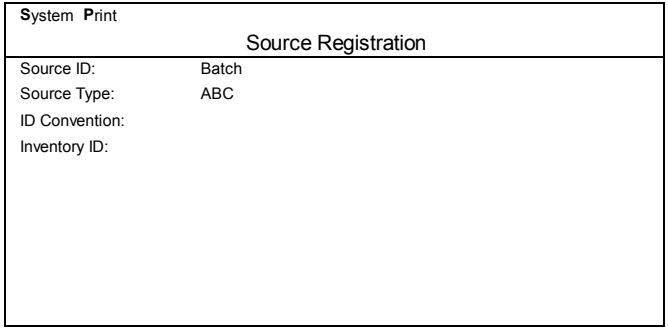
15. The pipetting procedure begins as specified by each assay protocol and proceeds automatically,

FPC Sensor Module Registration

NOTE:
Prepare 10 sample tubes with bar code labels and MEIA Buffer.

1. Select **Registration** from the FPC Main Menu.

2. Select **Source Registration**. The screen displays:



3. Scan the bar code label on the Sample Rack with the Bar Code Reader. If necessary, you can manually enter the ID followed by **↵Enter**.

4. If the Source Type needs to be entered or changed, press the **Space Bar** to display the pop-up screen listing source type options.
    - Select **60 Tube Rack** as the source type. The System prompts you to place the Rack in the Sensor Module.
    - Place the Rack and select **Yes**. If the Rack is not empty, you will be asked to remove all tubes.
    - Remove the Rack, empty it, and reposition it on the Sensor Module. Select **Yes**.

5. If the ID Convention needs to be entered or changed, press the **Space Bar** to display the pop-up screen listing ID Convention options:

Bar Code Sequential None

6. Select the ID Convention being used. The screen displays it and prompts you for an Inventory ID. Type up to 16 characters followed by ↵**Enter** or press ↵**Enter** alone to skip. The computer records your entry.

7. Scan the bar code for the first tube ID or manually enter it with the Keyboard. It appears on the screen under “Sample ID”.

8. Place the tube in the rack. The location registers on the screen and the System prompts for selection of assays.

9. Select the following assays for each sample:
    - Corzyme PPC -a
    - Auszyme Mono PPC -a
    - HTLV-I PPC D0 -a

10. Use the **Up** and **Down Arrow** keys to highlight each assay, then press the **Space Bar**. A check mark appears next to the assay, indicating that you have selected it. Press ↵**Enter** when all selections have been made.

11. Read 9 more tubes (for a total of 10), place them in the Sample Rack, and assign the 3 assays listed in step 9.

12. When you have finished registering samples, press **F3** (or Alt + ↵**Enter**) to save the work list.

13. To exit from Registration, press **Esc** to return to the FPC Main Menu.

Pipetting (Non-ABC)

1. Select **Pipetting** from the FPC Main Menu.

2. Select **Pipetting Setup** from the Pipetting Menu.

NOTE:
If you have two FPC Units, the screen requires a choice. Pipettors are designated "available" or "busy". Only "available" pipettors can be selected. Highlight an "available" pipettor and press ↵Enter.

3. The screen will display the following:

System Print Save

Assay Selection

Pipettor Port: 1

Tech ID: _____ Pipetting Type: _____ >

Select Assay(s) _____>

Assay Code	Assay Protocol	TPC Mode	Master Lot	Number of Destinations

Source ID: _____

ID Convention: Bar Code >

Print Map Options: None >

Inner Tube Diameter: 10 mm

[]Messages [Time]

[Date]

a. Pipettor Port: This is for information only and displays if there is more than one FPC.

b. Pipetting Type: Press the **Space Bar** for the Menu. Highlight the **Batch** option and press ↵**Enter**.

c. Source ID: Scan the bar code on the source with the hand-held reader or manually type the ID followed by ↵**Enter**.

d. Source Type: Displays the type of the source requested.

4. The screen next displays a pop-up menu with a list of assays available for pipetting.

5. Select the following assays for your pipetting sequences:

- Corzyme PPC -a
- Auszyme Mono PPC -a
- HTLV-I PPC D0 -a

6. Use the **Up** and **Down Arrow** keys to highlight each assay, then press the **Space Bar**. A check mark appears next to the assay, indicating that it is selected. Press ↵**Enter** when you have selected all assays to be pipetted in this run.

7. Type the number of destinations (trays, carousels, etc.) for each selected assay. Choose a tray for each assay (for a total of three.)

8. Press **F3** and **↵Enter** (or Alt + **S**ave) when finished. If the assays you have chosen require controls, calibrators, etc., the screen displays them. All controls are selected by default and are shown "checked". Use all controls for the three assays chosen. Place the controls for the assay in the specified position of the Control Bottle Rack.

NOTE:
Fill the Control Bottles with MEIA buffer.

9. Press **F3** and **↵Enter** (or Alt + **S**ave) when finished. The screen displays a confirmation of the data you have entered and tells you how to place destinations on the platform positions for the run.

10. The cursor highlights P1, the first destination. Scan the bar code on the destination (tray) with the hand-held reader or manually type the ID followed by **↵Enter**.

11. Place the destinations in the specified location on the tray platforms.

12. When you have completed placement for the first destination, select **Yes**. The System moves to the next destination. Follow the same procedure until you have placed destinations for the remaining two assays in this pipetting run.

13. Review the confirmation screen. If there are any required changes to the Print Map, Sample Tube Inner Diameter, or ID Convention, refer to the Operator's Manual, page 5-8.

14. Empty the Tip Bin and ensure there are enough pipette tips in the Tip Rack. Add them as needed.

15. Select **Run** from the Menu bar (or **F3** + **↵Enter**). If a diluent assay was chosen, select **5** when prompted for the number of cycles to prime.

16. The pipetting procedure begins as specified by each assay protocol and proceeds automatically.

ABC PRISM CLEANING PROCEDURE

Before cleaning, inspect the outside prism surface with a bright light source. If significant light scattering from the prism surface is observed or dirt is apparent, perform the following procedure. If the prism is clean, bypass this procedure and complete the cleaning and realigning the reader platform procedure.

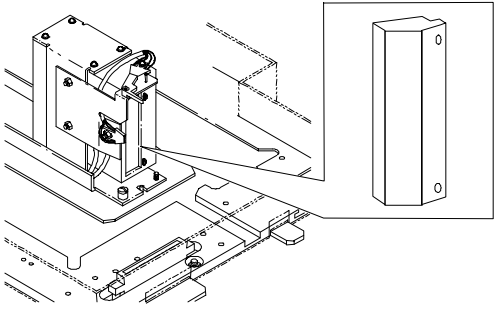


Figure 4A-15. ABC Reader Prism Installation

1. Remove the accessory tube rack behind the reader box by lifting it vertically from the alignment pins.

2. Loosen (do not remove) the three flathead screws attaching the reader to the surface plate.

3. When the reader box can be lifted free from the surface platform, raise it vertically while tilting the front end to contact the plate.

   This process frees the cable and connector beneath the reader box. Unscrew the “multipin”, black-plastic connector counterclockwise until the connector is free.

Note:
It may be necessary to retract some of the wire from the opening in the box to free the connector.

4. Remove the reader box from the ABC. Do not allow the prism to contact other surfaces.

5. Remove the two screws holding the prism in place. Be careful not to scratch the prism or touch the prism surface. See Figure 4A-16.

Note:
The prism lens is made from polished acrylic plastic and highly susceptible to scratching and physical damage if handled improperly. Please use extreme caution when handling the prism.

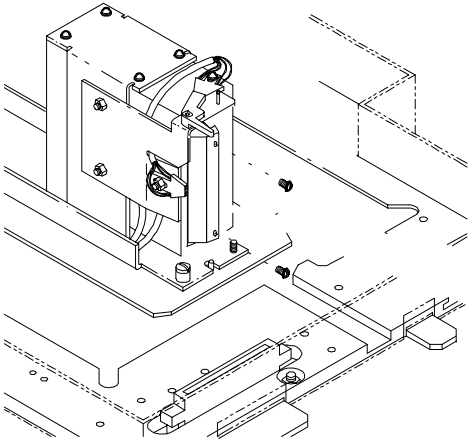


Figure 4A-16. ABC Reader Prism Mounting

6. Remove the prism for cleaning.

7. Remove any dirt or particulates form the prism surface by gently brushing with a lens brush or soft, lint-free cloth. Gently wipe with a lint-free cloth moistened with warm water or acrylic plastic cleaner. Do not scrub.

8. Gently wipe with a dry, lint-free cloth to remove any residual droplets or moisture.

9. Reinspect the prism/window surfaces. If foreign material is still present between the prism and the window, remove the prism as before. Repeat the cleaning procedure. Reinspect before and after installation of the prism.

10. Clean the surface plate and the bottom of the reader box if dirt or crystals are found.

11. Hold or rest the reader box on or above the rear tube carriers while positioning and reconnecting the “multipin” black-plastic connector. Several turns are required to attach the connector securely. Return the remaining excess cable into the reader box while holding the reader near the connector.

12. Realign the reader box over the rear and front alignment pins. Lower the box into position. Tighten the three flathead screws while holding the reader box securely on the alignment pins. Replace the accessory tube rack.

Note:
For ABC alignment see the Automatic Bar Code Reader Service Manual, ABC Alignment Procedure.

NOTES