FastPack® IP System

Procedure Manual

qualigen
DIAGNOSTICS

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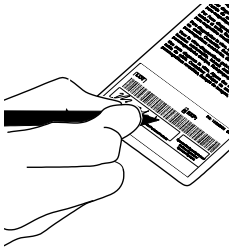
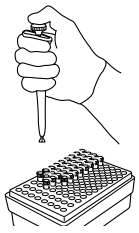
FastSteps For FastPack® IP

1. Identify

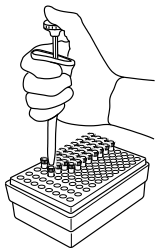


Write the Patient's Name/ID # and the operator's initials on the FastPack® IP label.

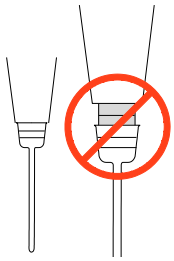
2. Attach Tip



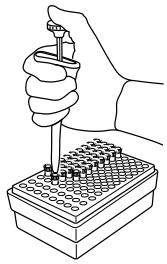
Press and hold the pipette plunger down completely so that the metal grippers are extended and open.



While holding the plunger down, firmly press the pipette into the pipette tip until it snaps in place, then release the plunger.

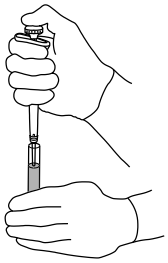


Be sure the pipette tip is seated properly on the end of the pipette.



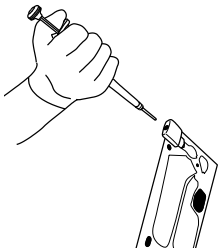
Verify that the pipette tip is properly seated by gently pressing the plunger down to the first "stop" and releasing.

3. Withdraw

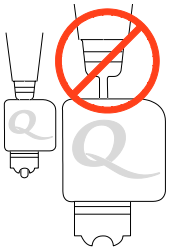


Gently press the pipette plunger down to first "stop" and hold. Place pipette tip into sample tube; withdraw sample by slowly releasing plunger. Confirm there are no air bubbles in the sample.

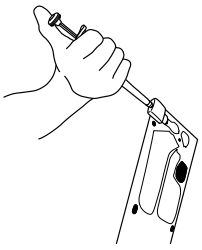
4. Inject



With your finger off the pipette plunger, fully insert the filled pipette tip into the FastPack® IP Injection Port. It should fit tightly.



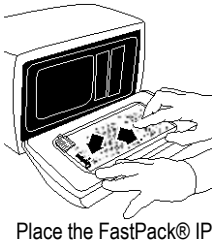
Be sure the pipette tip is seated properly into the injection port.



In one continuous motion, quickly press the pipette plunger all the way down. This action will simultaneously inject the sample into the FastPack® IP and eject the pipette tip.

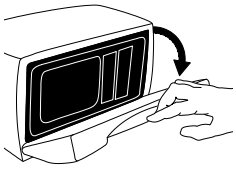
5. Run

Be certain not to unseat pipette tip from injection port. The tip acts as a plug to seal the sample in the FastPack® IP. If you observe a leak, properly dispose of the pack and begin with a new FastPack® IP.

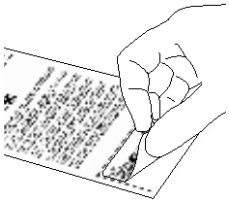


Place the FastPack® IP on the door of the analyzer. Align the pins on the door with the holes in the FastPack® IP. Close the analyzer door.

Press the blue Start button on the analyzer.



Open analyzer door when the test is complete. Remove FastPack® IP and print the results on the attached label.



Peel off the label and place it in the patient record.

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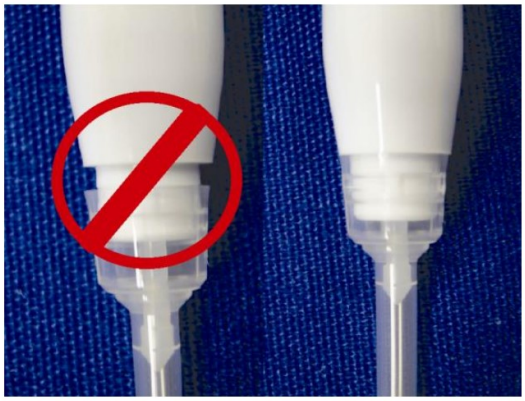
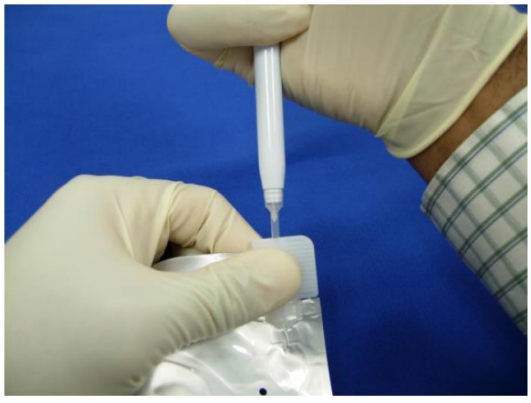
Do not pull the piston out from the capillary (pipette tip) after injecting sample. Sample will leak from the FastPack and lead to incorrect results.

Pipette tip improperly seated into the injection port

Pipette tip properly seated into the injection port



IMPROPERLY vs. PROPERLY seated pipette tip on the pipette

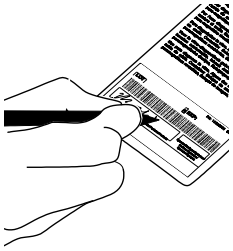


Inserting the filled pipette tip into the injection port

Metal tip extended to grip the pipette piston

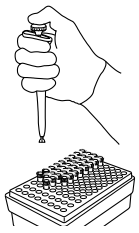
FastSteps For Vitamin D & SHBG

1. Identify

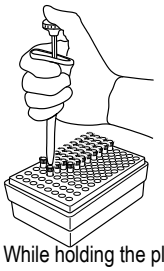


Write the Patient's Name/ID # and the operator's initials on the FastPack® IP label.

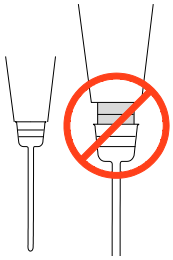
2. Attach Tip



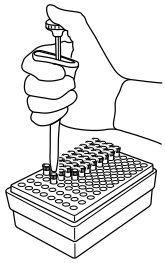
Press and hold pipette plunger down completely so that the metal grippers are extended and open.



While holding the plunger down, firmly press the pipette into the pipette tip until it snaps in place, then release the plunger.

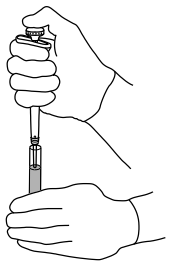


Be sure the pipette tip is seated properly on the end of the pipette.



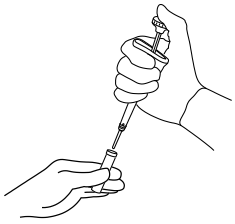
Verify that the pipette tip is properly seated by gently pressing the plunger down to the first "stop" and releasing.

3. Withdraw

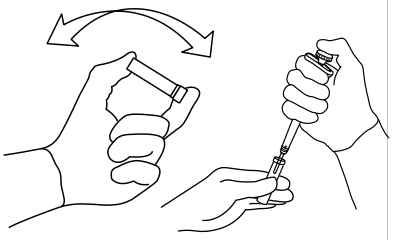


Gently press pipette plunger down to first "stop" and hold. Place pipette tip into sample tube; withdraw sample by slowly releasing plunger. Confirm there are no air bubbles in sample.

4. Mix



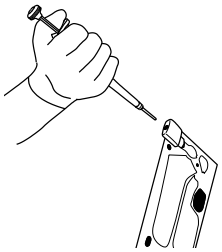
Eject sample into Pretreatment Buffer vial (Vitamin D), or SHBG Sample Diluent vial (SHBG) by pressing down on pipette plunger to first stop. Replace screw cap tightly onto vial. **This step is required for ALL types of runs: patient samples, QC, calibration, verifiers, proficiency tests, etc.**



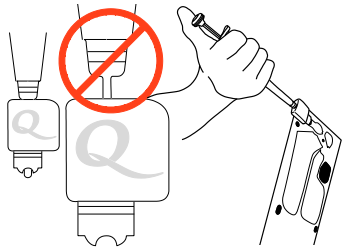
Mix the sample and buffer thoroughly by inverting the buffer tube at least 3 times.

Withdraw the mixed sample from the buffer tube using the same pipette tip as before and following the same technique as in Step 3 above.

5. Inject



With your finger off the pipette plunger, fully insert the filled pipette tip into the FastPack® IP Injection Port. It should fit tightly.

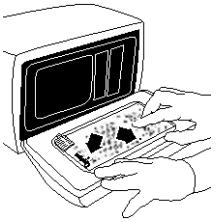


Be sure the pipette tip is seated properly into the injection port.

In one continuous motion, quickly press the pipette plunger all the way down. This action will simultaneously inject the sample into the FastPack® IP and eject the pipette tip.

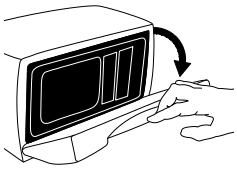
6. Run

Be certain not to unseat pipette tip from injection port. The tip acts as a plug to seal the sample in the FastPack® IP. If you observe a leak, properly dispose of the pack and begin with a new FastPack® IP.

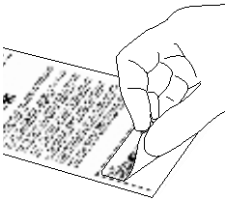


Place the FastPack® IP on the door of the analyzer. Align the pins on the door with the holes in the FastPack® IP. Close the analyzer door.

Press the blue Start button on the analyzer.



Open analyzer door when the test is complete. Remove FastPack® IP and print the results on the attached label.



Peel off the label and place it in the patient record.

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Welcome

The FastPack® IP System provides lab-quality immunoassay performance in a design ideal for the physician's office or small laboratory. The small system utilizes advanced technology to provide an immediate result, yet it is very simple to use.

The FastPack® IP System includes the FastPack® IP Analyzer and External Printer. The FastPack® IP System requires a disposable single-use FastPack® IP for each test. The operator simply loads the sample into the FastPack® IP, places the FastPack® IP in the Analyzer, and presses the start button. When the test is complete, the Analyzer displays the result.

The FastPack® IP System is for *in vitro* diagnostic use only.

This manual contains all of the information needed to operate and care for the FastPack® IP System. **Please read this entire manual before you begin operation.**

For information on the performance of FastPack® IP tests, please refer to the current direction insert posted on the Qualigen, Inc. website at www.qualigeninc.com.

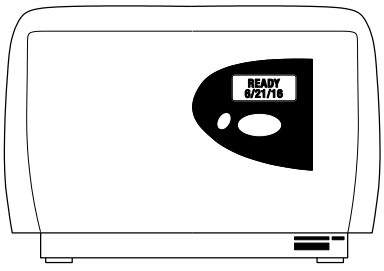
If you have questions or concerns about the FastPack® IP System, please contact your local distributor or call Qualigen, Inc. Toll Free: 1-877-770-6127.

What the FastPack® IP System Does

The FastPack® IP System performs immunoassays on serum and plasma samples. Refer to the Principle of Operation for a detailed description.

Immunoassay tests help physicians diagnose and monitor a range of disease states.

About This Manual

Action	Instrument	Information	Illustration
This column represents your action.	This column shows what the analyzer displays.	This column provides additional information about the action.	
Press the BLUE button.	"**Ready**"	This is the "Ready Mode" of the instrument, i.e., the analyzer is ready to perform a test.	

Safety Features

Electrical

The FastPack® IP Analyzer must be connected to a properly grounded outlet.

Nemko Mark Label

The application of the Nemko mark denotes that the FastPack® IP System meets all requirements for electrical safety and is approved for use in the field.

Other Symbols

All symbols discussed on this page can be found on the inside door plate of the FastPack® IP Analyzer.

Biomedical Label

This symbol indicates the area in the analyzer that may contain potentially infectious human serum or blood products. Healthcare personnel should always wear disposable gloves when handling blood products. Adhere to state and federal infection control guidelines. All blood specimens should be handled at the Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories," 1988.

Attention Label

Attention: Important information that must be read is located both in the Procedure Manual as well as in the directional inserts for all assays performed on the FastPack® IP System.

CE Mark Label

This label signifies that the FastPack®
IP System conforms with all applicable health, safety and environmental protection standards of the European Union.

IVD Label

The FastPack® IP System is an *In vitro* diagnostic medical device.

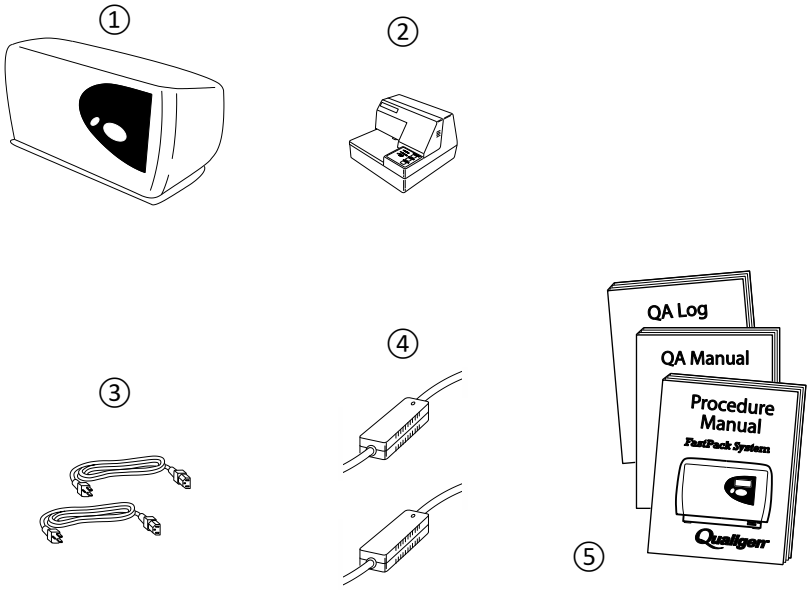
Serious Injury

Any serious incident that has occurred in relation to this device shall be reported to Qualigen Diagnostics and the competent authority in which the user and/or the patient is established.

Setting Up the FastPack® IP System

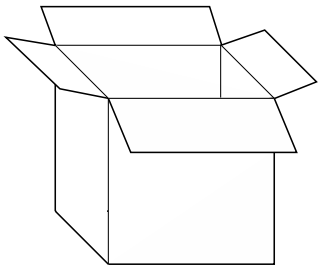
What is Included

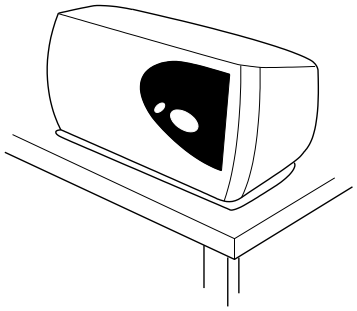
1. FastPack® IP Analyzer
2. External Printer
3. AC Power Cords (2)
4. Desktop Power Supply (2)
5. Procedure Manual
   QA Manual (US Only)
   QA Log (US Only)



FastPack® IP System Set Up

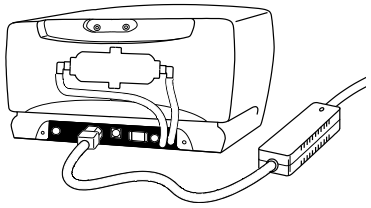
Unpacking the FastPack® IP System

Action	Instrument	Information	Illustration
Remove all components of the FastPack® IP System from their boxes.		Keep shipping boxes and internal packaging in case units have to be returned.	

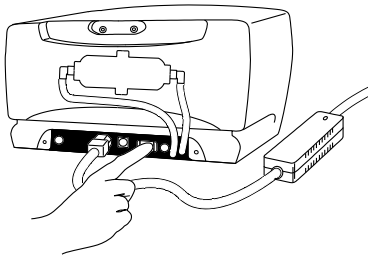
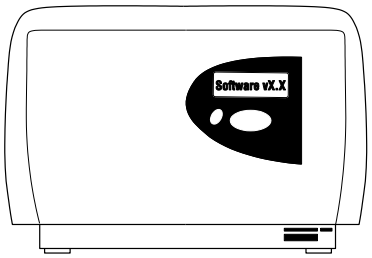
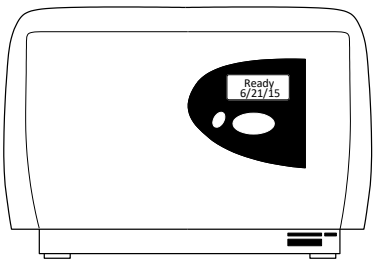
Place analyzer on countertop.		Analyzer is designed to be set on a table top.	

FastPack® IP System Set Up

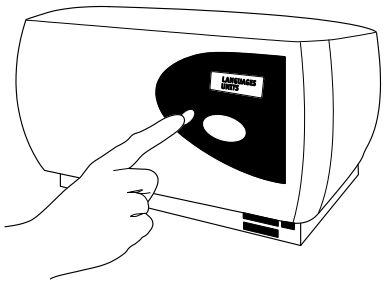
Getting Power to the FastPack® IP System

Action	Instrument	Information	Illustration
Plug Desktop Power Supply into the analyzer. Plug AC Power Cord into Desktop Power Supply.			

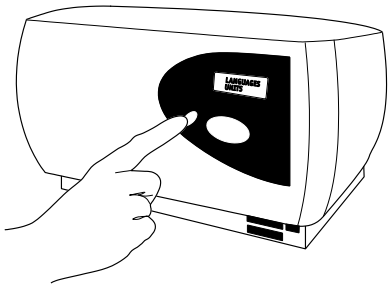
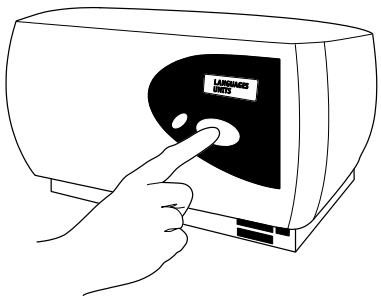
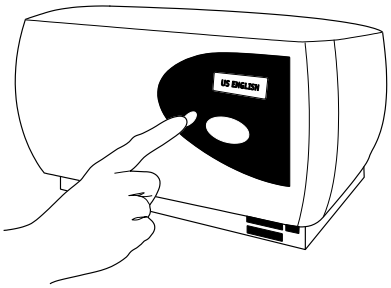
Turning ON the System Analyzer

Plug AC Power Cord into the wall socket. Turn analyzer on using power button located on back of unit. **Attention:** Leave analyzer on at all times.		Power Supply operates with input voltage of 100 240±10% VAC and 50/60 Hz.	
	"**Software vX.X**" "**Ready 06/21/20**"	The analyzer will beep once and display the internal software version for 5 seconds. Analyzer will now perform a self-diagnostic check and it will not function until operating temperature is reached. It takes 40- 60 minutes to reach operating temperature. During this time the display will show two sets of temperature readings. The analyzer will beep twice and display "Ready" when operating temperature is reached.	 

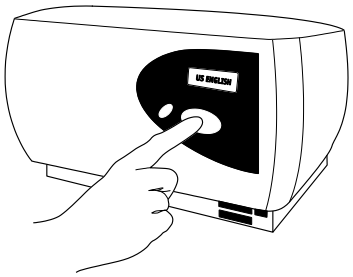
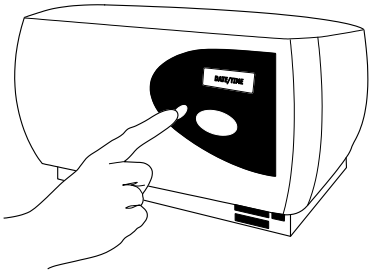
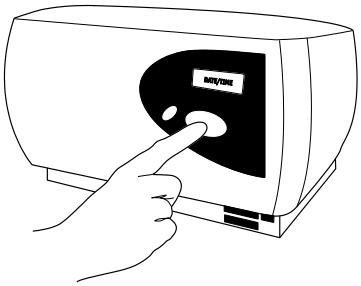
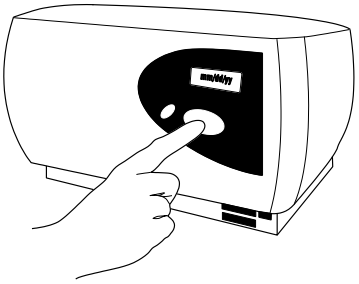
Set Up Menu

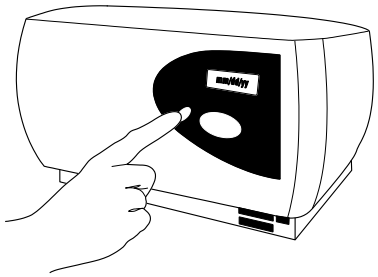
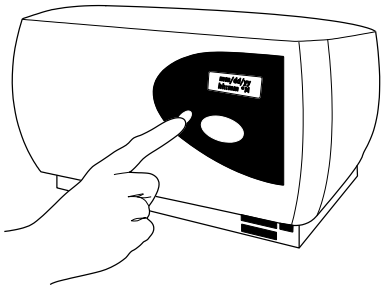
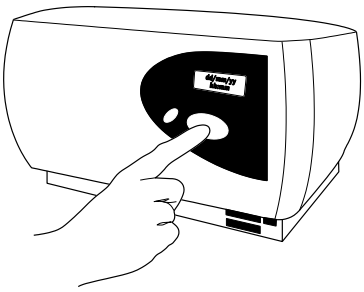
Action	Instrument	Information	Illustration
Enter the Set Up Menu for the analyzer by pressing the RED button.		This mode is not accessible when a test is in progress.	

Language Units

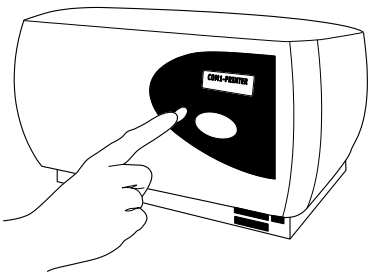
Scroll to "Languages Units" by pressing the RED button.	"**Languages Units**"		
Press the BLUE button to select the "Languages Units" menu category.			
Scroll through the language options by repeatedly pressing the RED button.	**English 1** **English 2** **Espanol** **Portugues** **Italiano** **Deutsch** **Francais** **Nederlands** **Swedish**	The analyzer allows the selection from nine languages and units: English 1 English 2 Spanish Portuguese Italian German French Dutch Swedish	

FastPack IP System Set Up

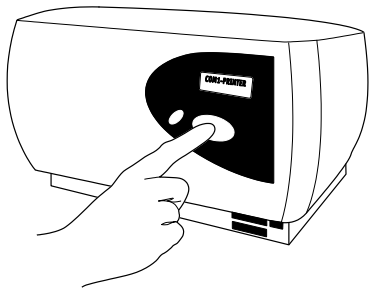
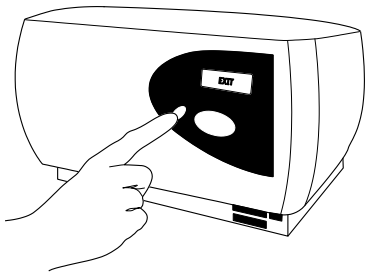
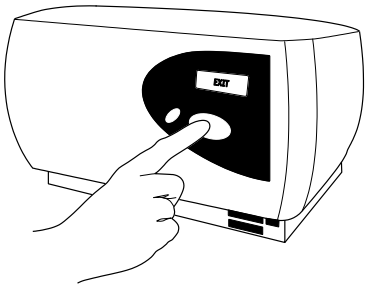
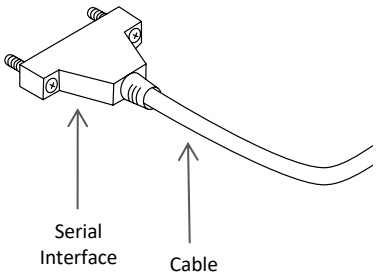
Action	Instrument	Information	Illustration
Select your language by pressing the BLUE button.		Testosterone units will display as “ng/dL” when English 1 is selected.	
Setting Date and Time			
Scroll to “Date/Time” by pressing the RED button.	“**Date/Time**”		
Press the BLUE button to select “Date/Time” menu category.			
If date is correct, press the BLUE button to accept this date.	“**mm/dd/yy**”	The analyzer has an internal clock that allows it to print the date for each test result. To maintain optimum quality control, it is important this is set correctly.	

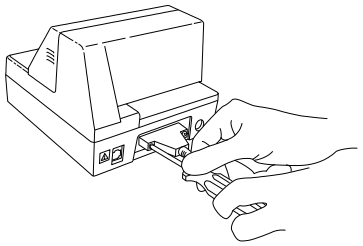
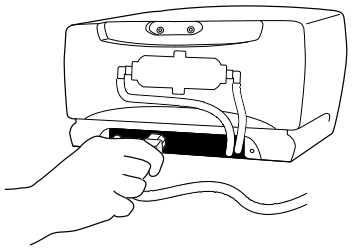
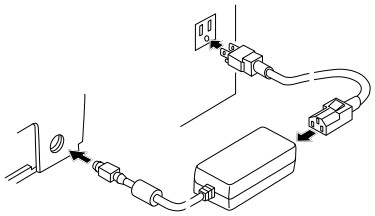
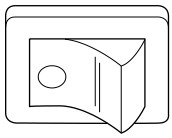
Action	Instrument	Information	Illustration
If date is incorrect, press RED button to change this date.			
Scroll to the correct date and time digit with the RED button. Approve each date/time digit and move ahead to the next digit by pressing the BLUE button.	"**mm/dd/yy hh:mm *M**" or "**dd/mm/yy hh:mm**"	If English 2 or a European language has been chosen, date is in Day/Month/Year format and time is in 24 hour format. If English 1 is chosen, date is in Month/Day/Year format and time is in 12 hour format. See Troubleshooting if a date or time error occurs.	 

Setting Analyzer for External Printer Use

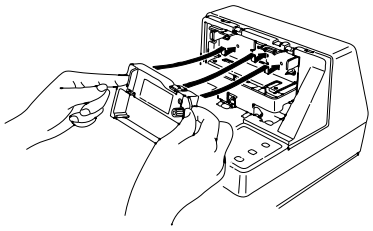
Press red button several times until you see "Result=printer Tap blue to chng". On USB equipped models, scroll the screen will display "Printer Output ON, Tap blue to chng"	"**Result=printer Tap blue to chng**" OR "**Printer Output ON Tap blue to chng**"	If the display shows "Result=printer Tap blue to chng" the system is already configured for an external printer. Tapping blue button will change it to be configured for output to an external computer. On USB equipped models tapping blue will stop output to the Printer.	

FastPack® IP System Set Up

Action	Instrument	Information	Illustration
If applicable, press the BLUE button to configure analyzer to send result to printer.	"**Result=printer"** OR "**Printer On**"		
Scroll to "Exit" by pressing the RED button.	"**Exit**"		
Select "EXIT" by pressing the BLUE button.			
Connecting the External Printer			
		Further instruction and illustration can be found in the External Printer User's Manual.	

Action	Instrument	Information	Illustration
Connect the large end of the Serial Printer Cable to the rear of the external printer with a screwdriver, or tighten screws by hand.		Analyzer should be turned on and in “Ready” position.	
Connect the other end of the Serial Printer Cable to the analyzer at the port labeled COM1.			
Plug the Desktop Power Supply into the back of the External Printer. Plug the AC Power Cord into the Desktop Power Supply. Plug the AC Power Cord into the wall socket.		External Printer operates with input voltage of 100 240±10% VAC and 50/60 Hz.	
Press the Printer’s ON switch located on the left side.			

FastPack® IP System Set Up

Action	Instrument	Information	Illustration
Remove the printer cover. Unwrap and insert the printer ribbon cartridge into the printer.		Follow all instructions found in the printer manual.	
		You are now ready to calibrate the analyzer! You can only run a FastPack® IP on the analyzer if it has been calibrated for that test.	

Calibrating the FastPack® IP System

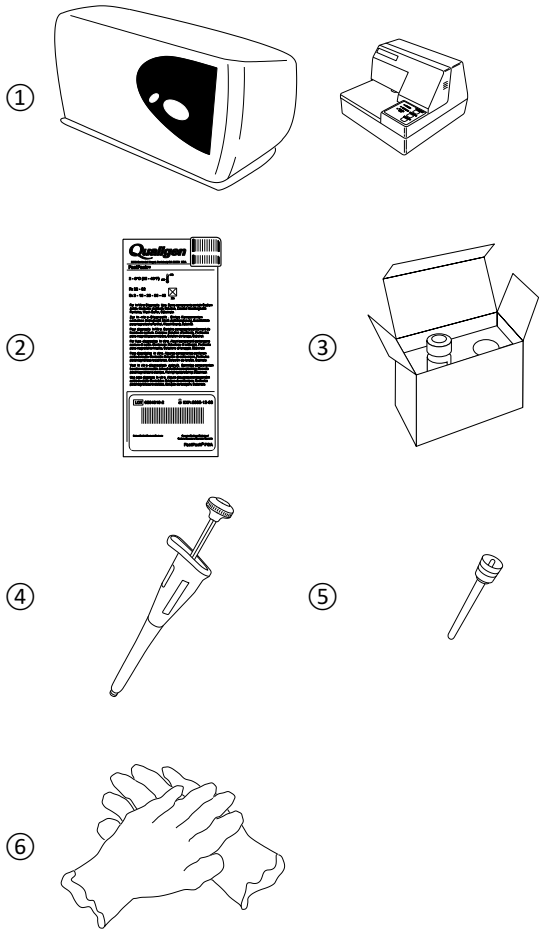
When to Calibrate

Calibration ensures that each individual analyzer results are identical to all other analyzer results, and to the master curve established by the manufacturer.

Additional information about calibration can also be found in the Direction Insert for each FastPack® IP product as well as in the "A Word About Calibration" section found in the procedure manual.

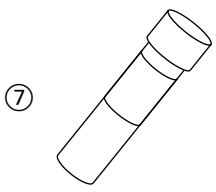
What You Need

1. FastPack® IP System
2. FastPack® IP
3. FastPack® IP Calibration Kit
   a. Calibration Card
   b. Vial of Calibrator (1)
4. Pipette
   * Use 25 µL pipette for hCG.
5. Pipette Tips (available from Qualigen)
6. Medical Gloves – used to avoid contact with biohazard materials such as human blood, etc.

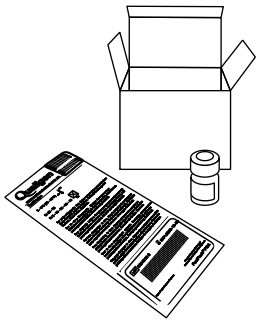
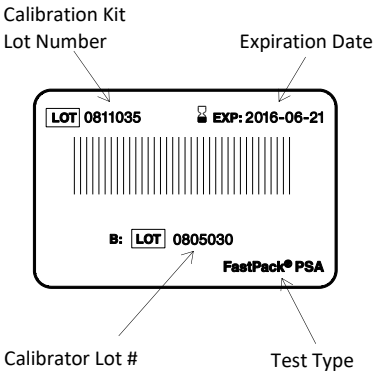
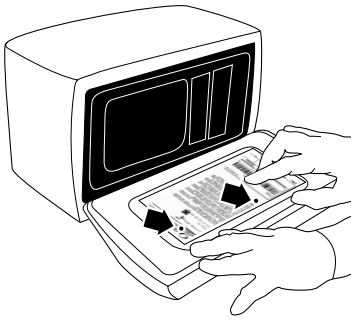
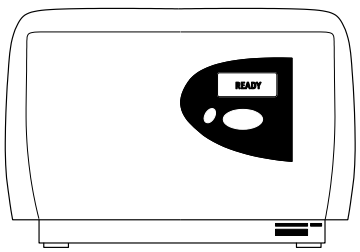


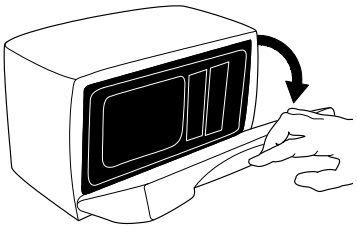
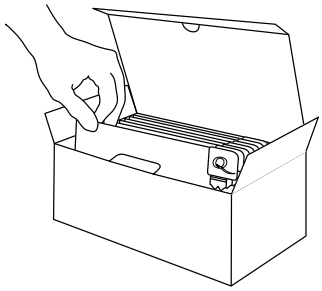
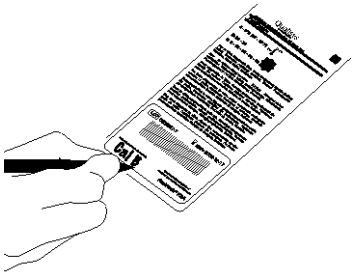
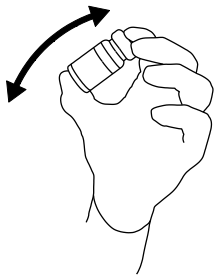
FOR FASTPACK® IP VITAMIN D and SHBG

7. Pretreatment Buffer (Vitamin D) OR Sample Diluent (SHBG)

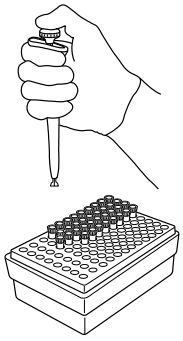
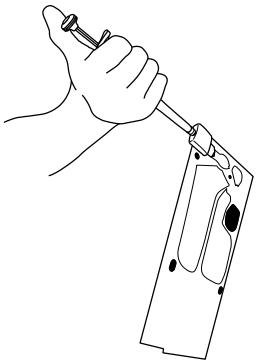
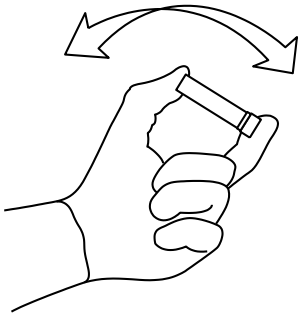


Calibration Procedure

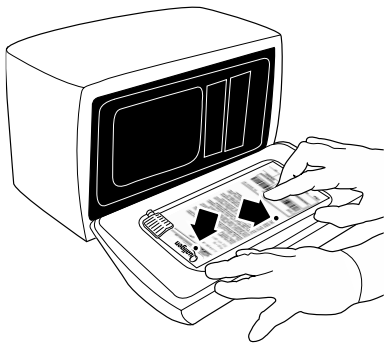
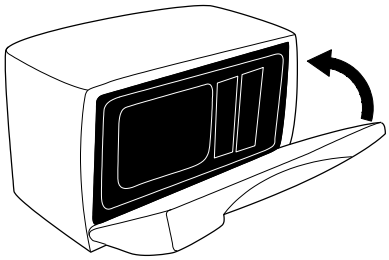
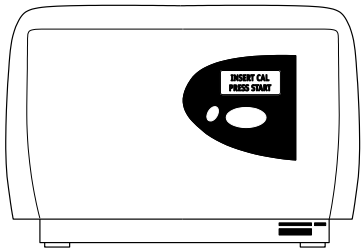
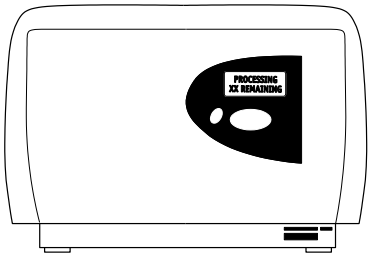
Action	Instrument	Information	Illustration
Open the FastPack® IP Calibration Kit. Remove contents.		Be sure to refer to the Direction Insert for the test type being calibrated.	
		The calibrator vial lot number should match the lot number on the calibrator card.	
Place "Calibration card" on the door. Align the pins on the door with the holes in the FastPack® IP.		The analyzer will read the bar code on this card to perform the calibration. If the calibrator has expired, the analyzer will not operate.	
Press the BLUE button.	"**Ready**"	The door will lock, and the analyzer will read the calibration card. This will take about 30 seconds.	

Action	Instrument	Information	Illustration
Open the analyzer door. Remove the calibration card. Store card in Calibration Kit.	"**Remove Cal Card, Run Cal Pack**"		
Remove the FastPack® IP from its box. Check to make sure it is the correct test type.		Always keep FastPack® IP stored in the refrigerator, in the position indicated on the box, at 2-8°C (36-46°F) prior to use. FastPacks® can be taken directly from the refrigerator and used in the analyzer.	
Write "CAL 1 or CAL 2" along with the operator's initials on the peel-off FastPack® IP label.			
Invert the calibrator vial 6-8 times before opening.		Follow this procedure each time you run a sample.	

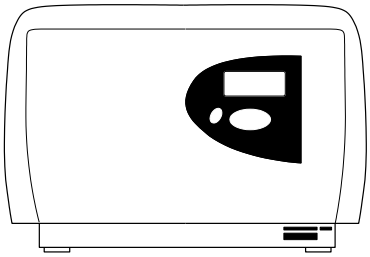
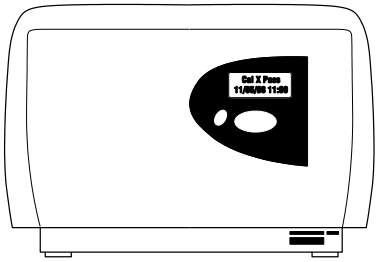
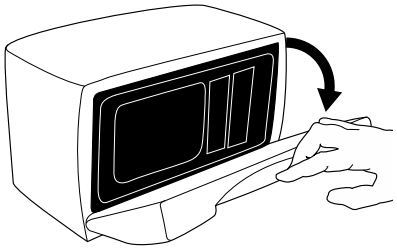
Calibration Procedure

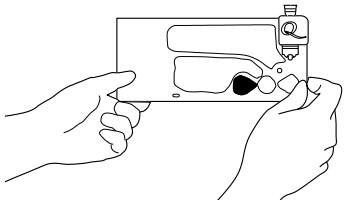
Action	Instrument	Information	Illustration
Closely follow FastStep 2 from your FastSteps Guide.		Use only Qualigen recommended pipette tips. The tips are available through your local distributor or Qualigen. Be sure that the pipette operates smoothly and does not stick. It is very important that the tip is properly seated on the pipette. If it is not, there is a high likely hood of short sampling which will directly affect calibration results.	
Closely follow FastSteps 3 through 4 from your FastSteps Guide.		Use serum, plasma, calibrators or controls only. Always wear gloves when handling samples. It is very important that the pipette tip is firmly placed in the injection port. If any sample leaking is detected, immediately dispose of the FastPack® IP and begin again with a new FastPack® IP and sample.	
Vitamin D and SHBG Users ONLY! Sample Pretreatment OR SHBG Dilution			
Eject the calibrator sample into the pre-treatment buffer OR Sample Diluent tube by pressing down on the pipette plunger to the first stop. Replace the screw cap tightly onto the buffer tube.		**Each patient sample, calibrator or control must be thoroughly mixed with the FastPack® Pre-treatment buffer (Vit D) or Sample Diluent (SHBG) before running a FastPack® IP Vitamin D assay or an SHBG assay.**	
Invert the buffer tube at least 3 times to thoroughly mix together the sample and buffer. Follow the FastSteps for Vitamin D and SHBG steps 4 and 5 to complete sample delivery to the FastPack® IP.			

Calibration Procedure - Continued

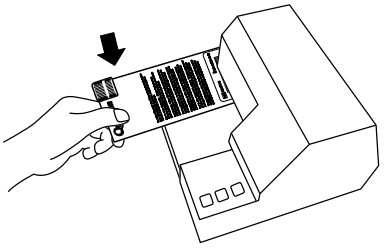
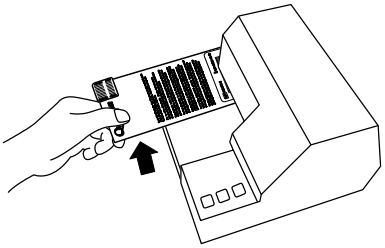
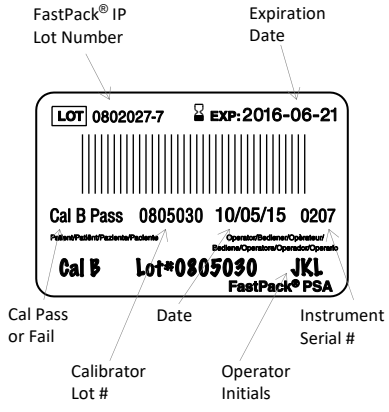
Action	Instrument	Information	Illustration
Open analyzer door. Place FastPack® IP on the door. Align the pins on the door with the holes in the FastPack® IP.	"**Remove Cal Card, Run Cal Pack**"	It is only possible to align the FastPack® IP in one direction.	
Close the analyzer door.		If the door is not closed, the analyzer will not run.	
Press the BLUE button.	"**Remove Cal Card, Run Cal Pack**"	The door will lock and the analyzer will run the test.	
	"**Processing XX remaining**"	The screen will display test status and time remaining.	

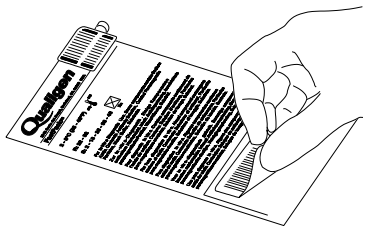
Calibration Procedure

Action	Instrument	Information	Illustration
		When calibration is complete, analyzer will beep.	
The display will confirm whether calibration passed or failed, and display date and time.	"**Cal X Pass 06/21/20 11:00**" or "**Cal X Fail 06/21/20 11:00**" or "**Cal Fail 06/21/20 11:00**" "**Insert FP in Printer**"	The result will remain displayed for one minute after the door is opened. See Troubleshooting if calibration fails.	
Open the analyzer door.		Analyzer will start beeping and display "Insert FastPack® in Printer" until result is printed.	

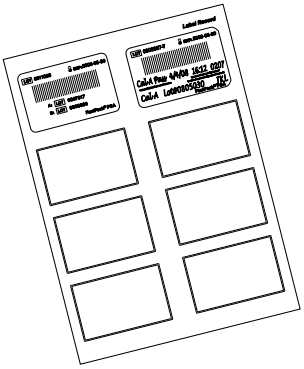
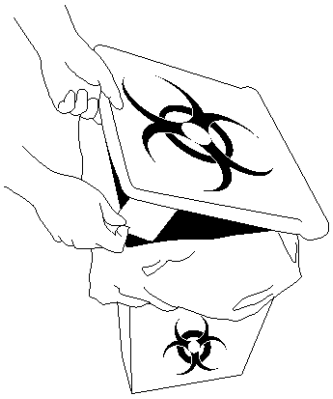
Remove and inspect the FastPack® IP. Check the inside of the analyzer door for fluid. If there is fluid on the FastPack® IP or analyzer, disregard the result and properly dispose of the pack. Implement the Cleaning Procedure.		Ensure that all chambers have burst. Fluid should easily flow between all chambers. Observe that most of the fluid in the FastPack® IP is yellow. If there is no yellow fluid, disregard the result and rerun a FastPack® IP.	

Calibration Procedure

Action	Instrument	Information	Illustration
Slip the FastPack® IP into the external printer from the **left side** with the label side up and the label facing towards the rear of the external printer.		Printer will print and release the FastPack® IP automatically. It is important to insert the FastPack® IP from the left side of the printer to avoid tangling or twisting the printer ribbon.	
Remove the FastPack® IP from the **left side** of the external printer.		It is important to remove the FastPack® IP from the left side of the printer to avoid tangling or twisting the printer ribbon.	
Find the result printed on the FastPack® IP peel-off label. Calibrator Pass/Fail Calibration Lot # Date of Test Instrument Serial#		All the necessary information for Quality Control is now included on the peel off label.	

Peel off the label.			

Calibration Procedure

Action	Instrument	Information	Illustration
Place the printed Calibration label on a Label Record in the appropriate assay section of your Quality Assurance Log.		Important calibration information is now included in your Quality Assurance Log.	
Discard the FastPack® IP into a Biohazards container.			

Repeat the Calibration Procedure. All calibrations require that **TWO (2)** calibrations be run with the calibrator. All calibrations must **"PASS"** for a successful calibration. See the Calibration Process Tree on Page 20 which illustrates the messages shown on the analyzer display. See Direction Insert for the test being calibrated.		**Discard all expired calibrator material, in stoppered vials, into a Biohazard container.** Order a new Calibration Kit from your local distributor or Qualigen, Inc.	

A Word about Calibration

Purpose

The purpose of this section is to concisely define how and when calibrators are run for the various assays used in the FastPack® IP System.

General Procedure

The calibration kit contains a calibration card and 1 vial of calibrator. The calibration card is used to communicate to the analyzer that the next test run will be a calibration. Please follow these steps carefully:

Preparing a FastPack® IP with a Calibrator Sample

1. Remove a FastPack® IP from the kit and write CAL 1 or CAL 2 and the operator's initials on the peel-off-label.
2. Gently invert the calibrator vial several times before drawing a sample from it. Inverting this vial should be done each time you draw a sample.
3. Fill a FastPack® IP with the calibrator sample following the instructions found in your FastSteps guide.

Preparing to Calibrate your Analyzer

1. Take the calibration card from the calibration kit.
2. Place the calibrator card in your analyzer by aligning the holes in the card with the pins in the analyzer door.
3. Press the BLUE button.
4. The analyzer will read the calibration card information (~30 sec).

5. The analyzer should read “Remove Cal Card, Run Cal Pack”.
6. Remove the calibration card.

Running the Calibrator FastPack® IP

1. Place the, calibrator filled, FastPack® IP into the analyzer and push the BLUE button.
2. The analyzer will process this pack and when complete, will display “Cal X Pass”.
3. Remove the processed FastPack® IP from the analyzer and place in the printer.
4. Place the printed label onto the Label Record in the appropriate assay section of your Quality Assurance Log.
5. Repeat the Calibration Procedure (The analyzer will display an alert when calibration is required. See the Calibration Process Tree on Page 20 which illustrates the messages shown on the analyzer display.).
6. Place the calibration card back into the Calibration Kit for storage.

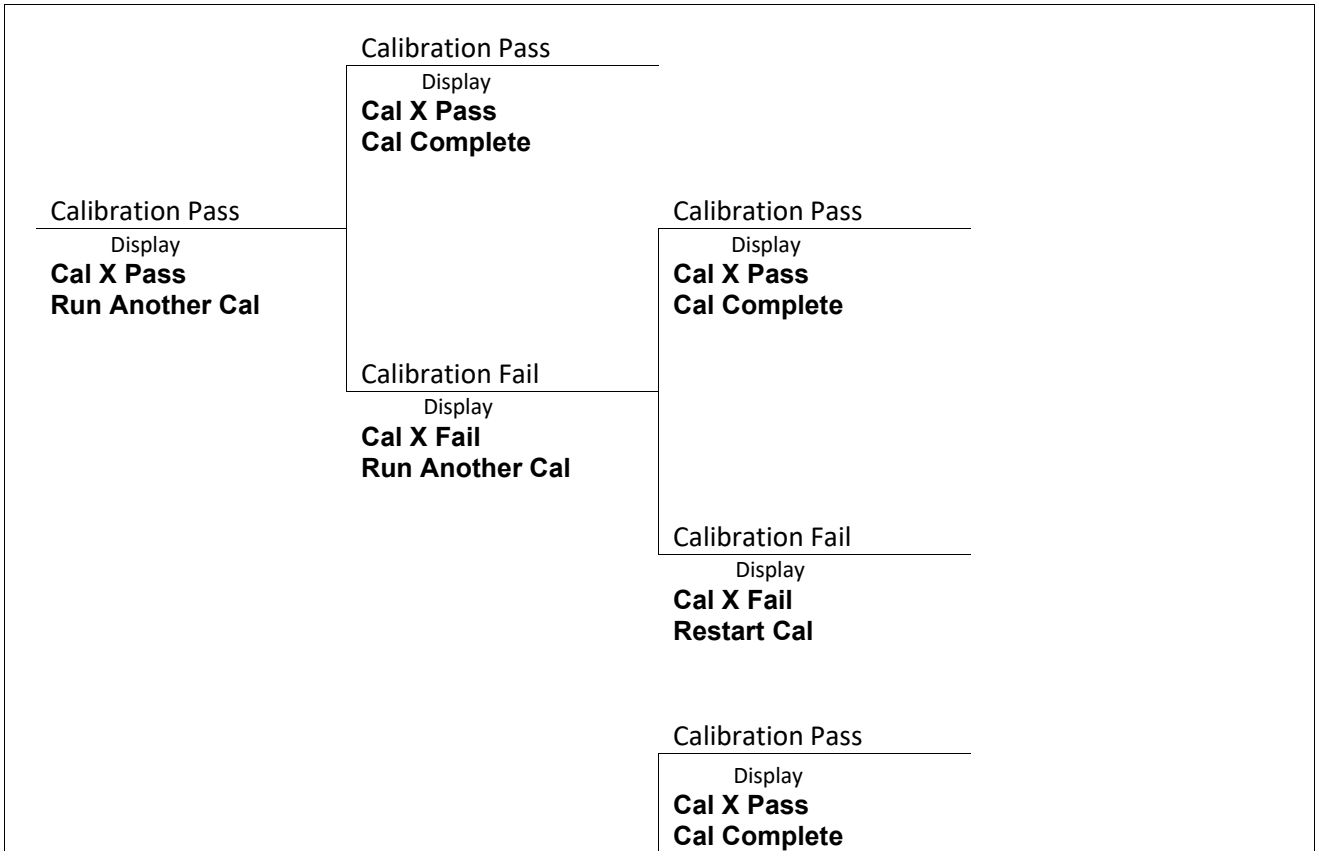
When is Calibration Required?

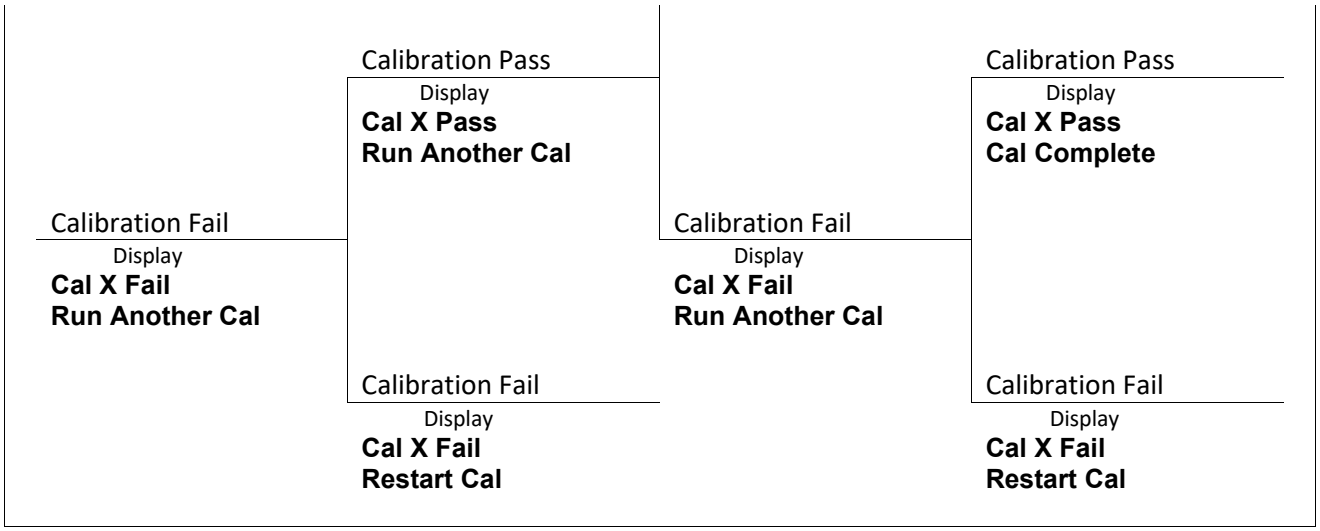
The analyzer display will prompt you automatically when a calibration is due. This prompt will occur for two reasons:

1. **When Attempting to Use New Lots of FastPacks or Calibrators**
2. **When it’s Time to Recalibrate**
   - Calibration expires every **31 days** for the following assays: Vitamin D, PSA, hCG, αGST
   - Calibration expires every **29 days** for SHBG.
   - Calibration expires every **15 days** for the following assays: TSH, Free T4, Testo

When either of these two scenarios occurs, run ***two calibrations.***

FastPack® IP System Analyzer Calibration Process Tree




Calibration Pass
Display
Cal X Pass
Run Another Cal
Calibration Fail
Display
Cal X Fail
Run Another Cal
Calibration Fail
Display
Cal X Fail
Restart Cal
Calibration Fail
Display
Cal X Fail
Run Another Cal
Calibration Pass
Display
Cal X Pass
Cal Complete
Calibration Fail
Display
Cal X Fail
Restart Cal

Control Testing

When to Control Test

Control testing ensures that you are running the test correctly and that your FastPack® IP System is working properly.

When control testing is performed, two control levels must be used. Qualigen recommends that users run controls whenever:

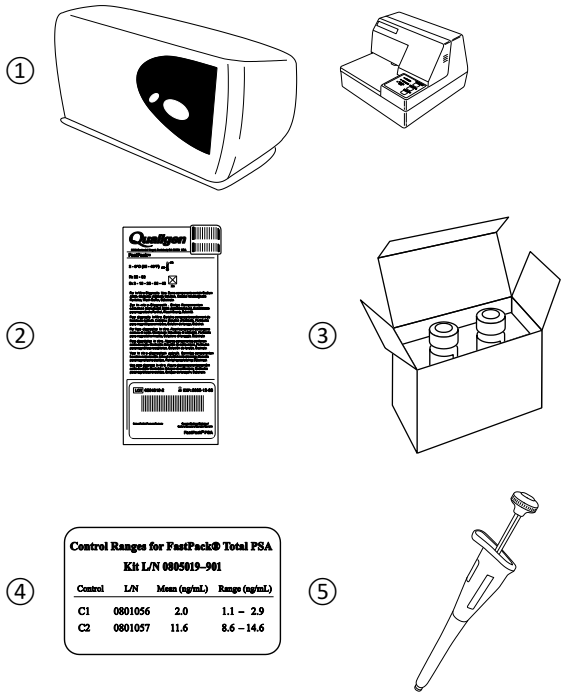
- Patient testing is performed.*
- A calibration is performed.
- Repair maintenance is performed.
- Improper storage or handling of FastPacks® is suspected.
- Questionable patient results are obtained.

Users should follow proper state and federal quality control guidelines.

** Review the Individualized Quality Control Plan (IQCP) Guidelines implemented by CMS. These guidelines are based on individual risk factors involved in the performance of each test run in your laboratory. IQCP is voluntary and provides laboratories with flexibility in customizing QC policies and procedures based on the unique aspects and test systems found in your laboratory and may allow for the reduction in the frequency of control testing required.*

Visit www.qualigeninc.com for additional regulatory information.

What You Need



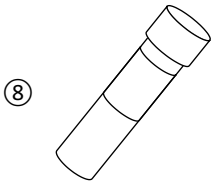
1. FastPack® IP System
2. FastPack® IP
3. FastPack® IP Control Kit
    - Control Vials (2)
4. Control Range Card
5. Pipette
   Use 25 µL pipette for hCG.
6. Pipette Tips
7. Medical Gloves – used to avoid contact with biohazard materials such as human blood, etc.

⑥ 

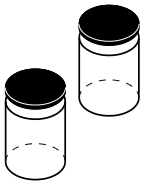
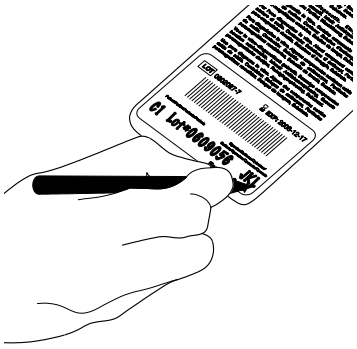
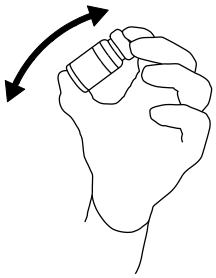
⑦ 

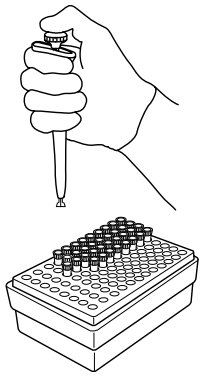
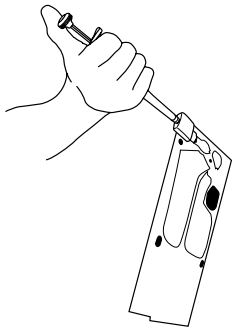
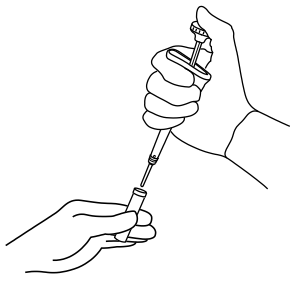
*

8. Pretreatment Buffer (Vitamin D) OR
   Sample Diluent (SHBG)

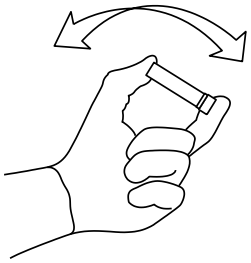


Control Testing Procedure

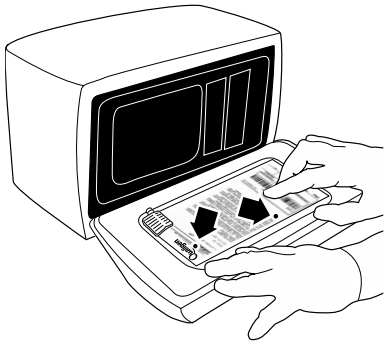
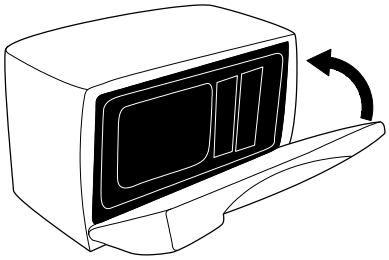
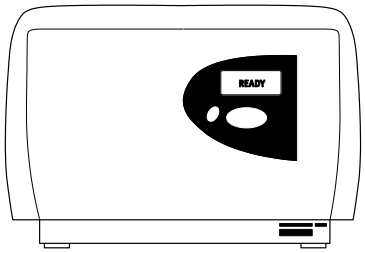
Action	Instrument	Information	Illustration
Open the FastPack® IP Control Kit. Remove contents.		Keep the Control Range Card in a place easily retrieved for reference; possibly in your Quality Assurance Log.	
Write “CX”, depending upon the Control Vial used and lot number, and the operator’s initials on the peel-off FastPack® IP label.		E.g., C1 for Control Level 1 or C2 for Control Level 2.	
Invert Control Vial 6-8 times before opening.			

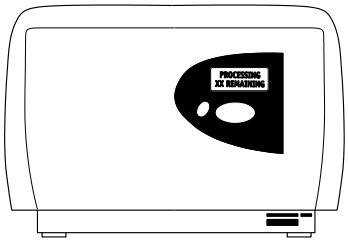
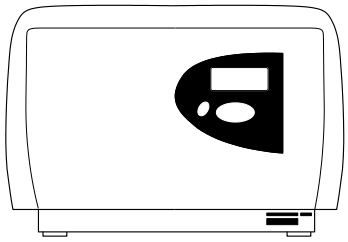
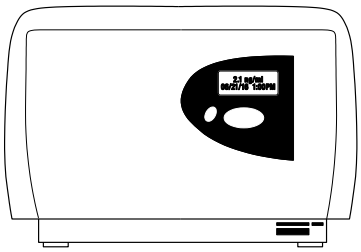
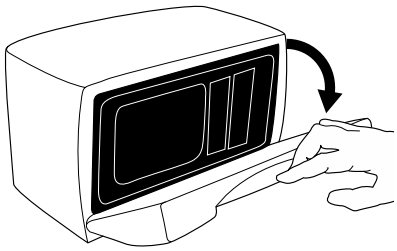
Action	Instrument	Information	Illustration
Closely follow FastStep 2 from your FastSteps Guide.		Utilize only Qualigen recommended pipette tips. The tips are available through your local distributor or Qualigen. Be sure that the pipette operates smoothly and does not stick. It is very important that the tip is properly seated on the pipette. If it is not, there is a high probability of short sampling which will directly affect control results.	
Closely follow FastSteps 3 and 4 from your FastSteps Guide.		Use serum, plasma, calibrators or controls only. Always wear gloves when handling samples. It is very important that the pipette tip is firmly placed in the injection port. If any sample leaking is detected, dispose of the FastPack® IP and begin again with a new FastPack® IP and sample.	
FastPack® IP Vitamin D and SHBG			
Eject the control sample into the pre-treatment buffer tube by pressing down on the pipette plunger to the first stop. Replace the screw cap tightly onto the buffer tube.		**Each patient sample, calibrator or control must be thoroughly mixed with the FastPack® Pre-treatment buffer before running a FastPack® IP Vitamin D assay.**	

Control Testing Procedure

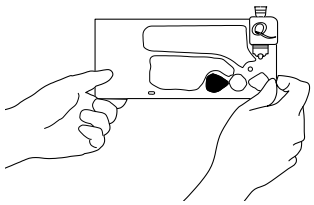
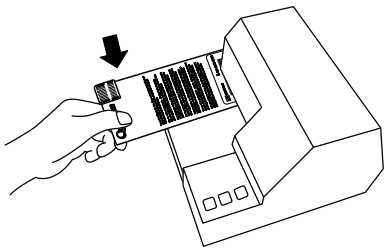
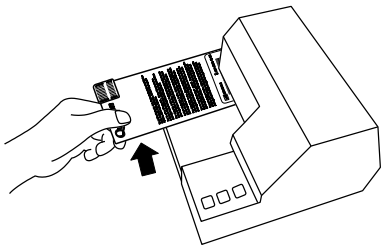
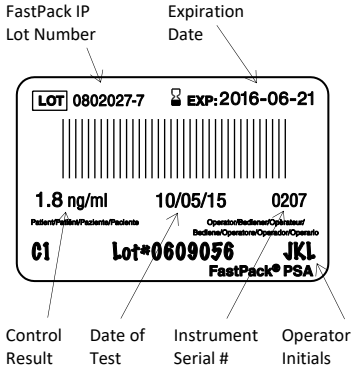
Action	Instrument	Information	Illustration
Invert the buffer tube at least 3 times to thoroughly mix together the sample and buffer. The act of mixing the sample and buffer releases the vitamin D present, therefore making it available for the assay. Follow the FastSteps for Vitamin D and SHBG steps 4 and 5 to complete sample delivery to the FastPack® IP.			

Control Testing Procedure - Continued

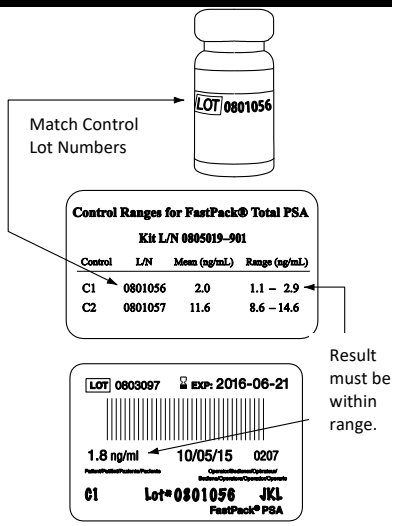
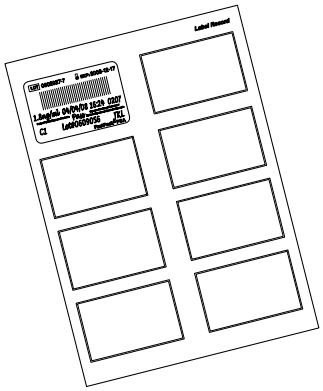
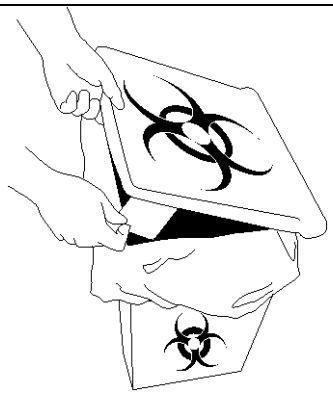
Open analyzer door. Place FastPack® IP on the door. Align the pins on the door with the holes in the FastPack® IP.	"**Ready**"	It is only possible to align the FastPack® IP in one direction.	
Close analyzer door.		If the door is not closed, the analyzer will not run.	
Press the BLUE button.	"**Ready**"	The door will lock and the analyzer will run the test.	

Action	Instrument	Information	Illustration
	"**Processing XX remaining**"	The screen will display test status and time remaining.	
		When test is complete, analyzer will beep.	
	Example: "**2.1 ng/mL 06/21/20 1:00PM**" or "**2.1 ng/mL 21/06/20 13:00**"	The analyzer will provide the test result on the display. The result will remain displayed for one minute after the door is opened or until another test is run. When a new test is run, the previous test result is erased from the analyzer memory and display.	
Open the analyzer door.	"**Insert FastPack IP in Printer**"	Analyzer will start beeping and display "Insert FastPack® in Printer" until result is printed.	

Control Testing Procedure

Action	Instrument	Information	Illustration
Remove and inspect the FastPack® IP. Check the inside of the Analyzer door for fluid. If there is fluid on the FastPack® IP or Analyzer, disregard the result and properly dispose of the pack. Implement the cleaning procedure.		Ensure that all chambers have burst. Fluid should easily flow between all chambers. Observe that most of the fluid in the FastPack® IP is yellow. If there is no yellow fluid, disregard the result and rerun FastPack® IP.	
Slip the FastPack® IP into the external printer from the **left side** with the label side up and the label facing towards the rear of the external printer.		Printer will print and release the FastPack® IP automatically. It is important to insert the FastPack® IP from the left side of the printer to avoid tangling or twisting the printer ribbon.	
Remove the FastPack® IP from the **left side** of the external printer.		It is important to remove the FastPack® IP from the left side of the printer to avoid tangling or twisting the printer ribbon.	
Find the result printed on the FastPack® IP peel-off label. Control Result Units Date of Test Instrument Serial#		All the necessary information for Quality Control is now included on the peel-off label.	**FastPack® IP Label after Printing** 

Control Testing Procedure

Action	Instrument	Information	Illustration
Match each control lot number from the Control Range Card with the lot number on the control vials. If each of these lot numbers match, then verify that the result printed on the FastPack® IP is within range for the appropriate control.		If a control is outside of the acceptable range, repeat the test. If the retest is still outside of the acceptable range, call Qualigen System Support at 877-770-6127.	
Apply the Control Label onto the Label Record in the appropriate assay section of your Quality Assurance Log.		Important control information is now included in your Quality Assurance Log.	
Discard the used FastPack® IP into a Biohazard container.			
The FastPack® IP analyzer requires testing with two levels of controls. Repeat the control procedure as needed.		**Discard both control vials when one vial is empty or when the control kit has expired into a Biohazard container.** Order a new control kit from your local distributor or Qualigen, Inc.	

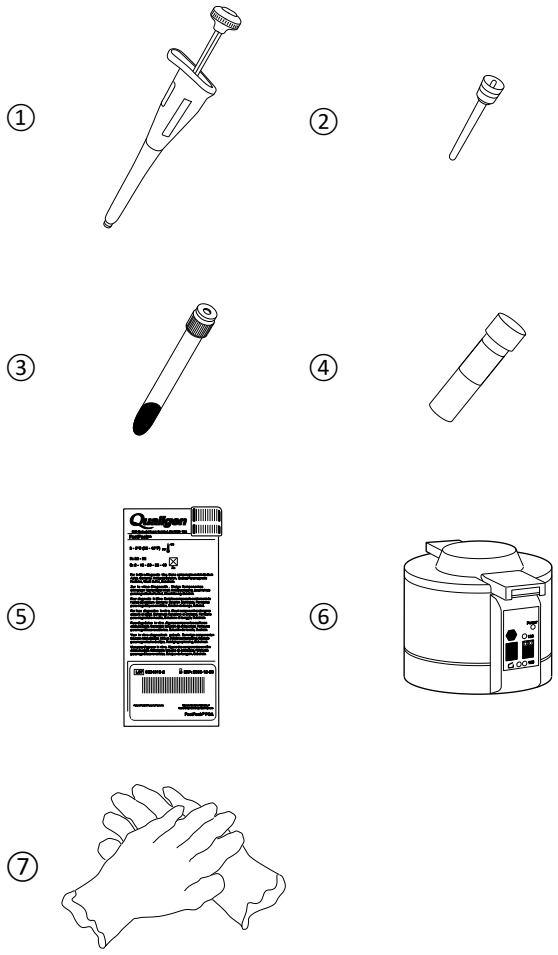
Sample Dilution - hCG

When to Dilute an hCG Sample

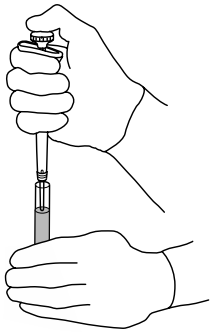
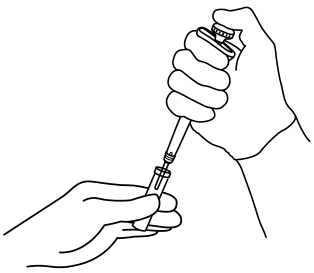
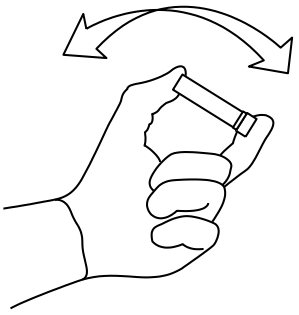
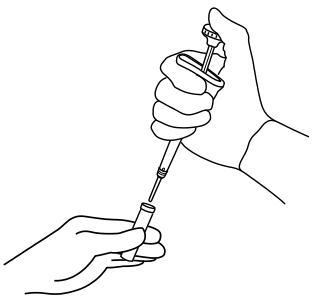
Samples can be accurately measured for hCG if it is within the analytic range of 1. 8 – 1000 mIU/mL. However, in some instances, the analyte level in patient samples may exceed the assay range of 1000 mIU/mL. In these cases, the assay must be run again using a diluted sample in order to determine the actual quantitative hCG concentration.

What You Need

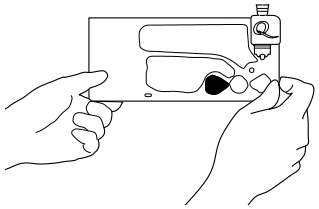
1. 25 µL Pipette
2. Pipette Tips
3. Patient Sample
4. FastPack® hCG Sample Diluent Kit
5. FastPack IP for hCG
6. Microcentrifuge
7. Medical Gloves – used to avoid contact with biohazard materials such as human blood, etc.



Diluting an hCG Sample

Action	Instrument	Information	Illustration
Using a NEW pipette tip, draw a fresh 25 µL patient sample		It is IMPORTANT to use a new unused pipette tip in order to create an accurate dilution.	
Add this sample to a Sample Diluent tube.			
Replace the cap and gently mix by inverting the tube back and forth several times.		This will create a 1:100 diluted sample.	
Using a NEW pipette tip, draw a 25 µL sample from the mixture in the Sample Diluent tube.		It is IMPORTANT to use a new unused pipette tip in order to maintain an accurate dilution.	

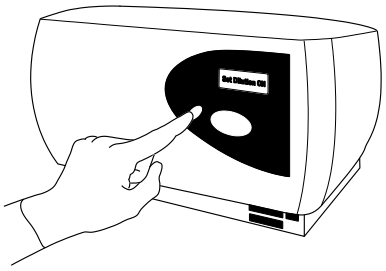
Diluting an hCG Sample

Action	Instrument	Information	Illustration
Place this sample into a fresh FastPack® IP.		This is now your 1:100 diluted patient sample that you will run through the FastPack® IP System analyzer. To create a 1:10,000 diluted sample, repeat the above steps using your 1:100 diluted sample as your patient sample.	

Setting hCG Dilution Mode

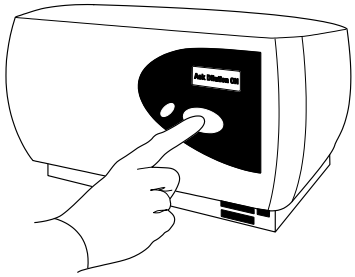
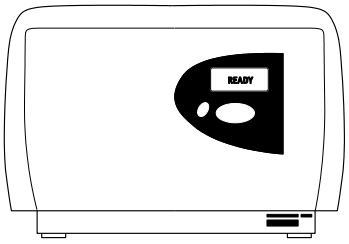
This mode enables the analyzer to calculate and output results for hCG samples that have been diluted prior to testing. This affects hCG tests only. The analyzer outputs the calculated result based on the operator-selected dilution factor. A "D" or "X:" will be printed to the left of the result if a sample was tested in Dilution Mode. "D" indicates that a sample was tested at a 1/100 dilution; "X" indicates that a sample was tested at a 1/10,000 dilution. "D" or "X" will likewise appear on the second character row of the analyzer screen under the same testing conditions. With Dilution Mode disabled, the analyzer will immediately initiate an hCG test with no dilution prompts, and results will be output with no dilution correction, and no indication that the tested sample had been diluted.

Enable Dilution Mode - hCG

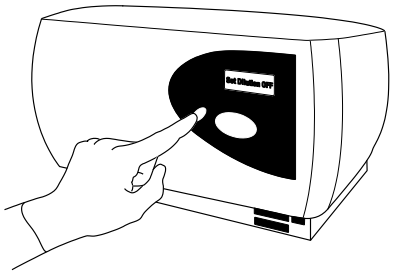
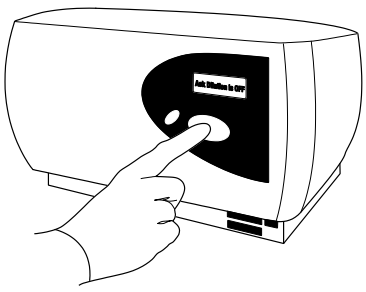
Action	Instrument	Information	Illustration
Press RED button several times to scroll through the menu till you see "Dilution disabld"	"**Dilution disabld**"		

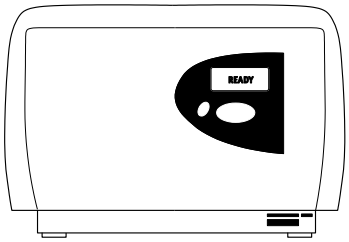
Setting hCG Dilution Mode

Enable hCG Dilution Mode – hCG - Continued

Action	Instrument	Information	Illustration
Press the BLUE button to change the mode to enable hCG Dilution mode.	"**Dilution enabled**"	This action enables the hCG Dilution Mode.	
	"**Ready**"	The analyzer display will return to the "Ready" screen	

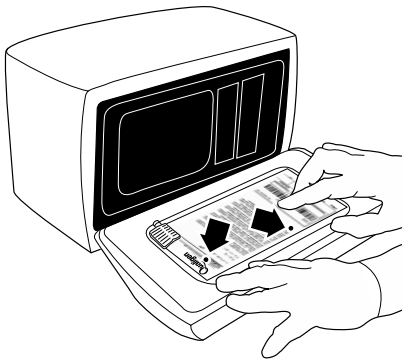
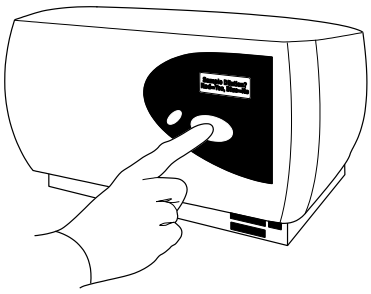
Disable hCG Dilution Mode - hCG

Press RED button several times to scroll through the menu till you see "Dilution enabld"	"**Dilution enabld**"		
Press BLUE button	"**Dilution disabld** "	This action disables the dilution mode.	

Action	Instrument	Information	Illustration
	"**Ready**"	The analyzer display will return to the "Ready" screen	

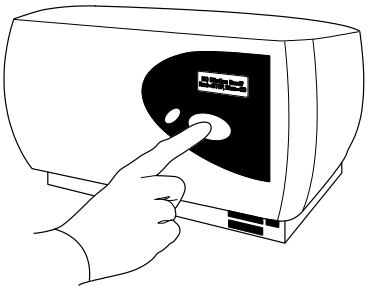
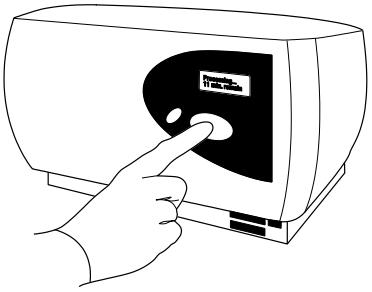
Testing with the FastPack® IP System in hCG Dilution Mode

Testing a Neat Sample in hCG Dilution Mode

Action	Instrument	Information	Illustration
Insert the sample filled FastPack® IP into the analyzer.			
Press the BLUE button.	"**Sample Dilution? Red=Yes, Blue=No**"	This prompt is questioning whether or not the current test sample is diluted. To test a neat sample, respond with "No". A "Yes" response indicates test sample is diluted.	

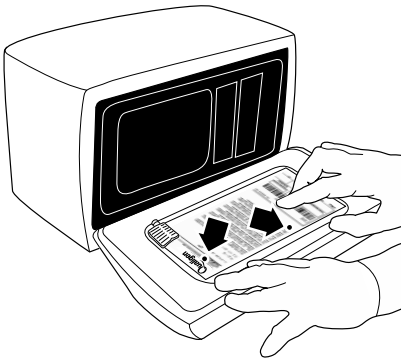
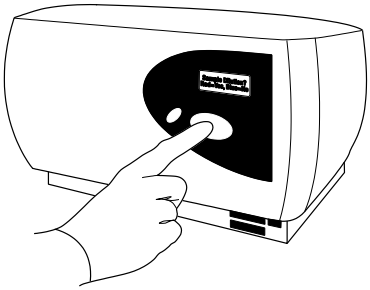
Testing in hCG Dilution Mode

Testing a Neat Sample in Dilution Mode - Continued

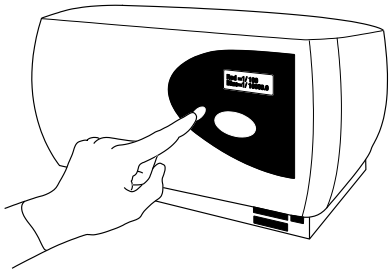
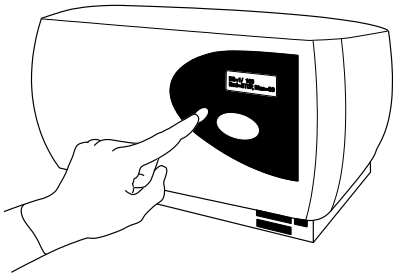
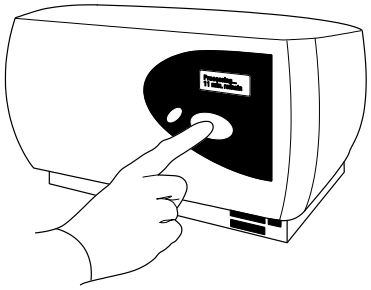
Action	Instrument	Information	Illustration
Press the BLUE button.	"**NO Dilution Used Red=STOP, Blue=GO**"	This prompt is asking for confirmation that you are testing a neat sample.	
Press the BLUE button.	**"Processing… 11 min. remain"**	The test is initiated.	

Testing an hCG 1/100 Diluted Sample in hCG Dilution Mode

To learn more about hCG sample dilution, go to www.qualigeninc.com/hcgdilution.

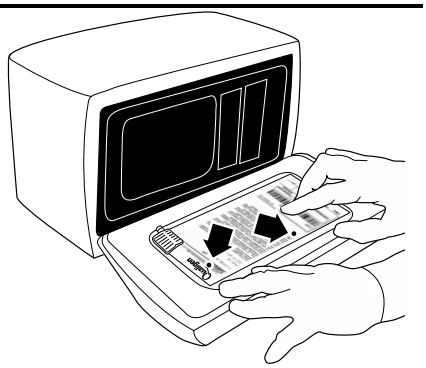
Insert the sample filled FastPack® IP into the analyzer.		NOTE: In this scenario, the sample will have been diluted 1/100 prior to filling into the FastPack®.	
Press the BLUE button.	"**Sample Dilution? Red=Yes, Blue=No**"	This prompt is questioning whether or not the current test sample is diluted. To test a diluted sample, respond with "Yes". A "No" response indicates a neat sample is to be tested.	

Testing an hCG 1/100 Diluted Sample in hCG Dilution Mode - Continued

Action	Instrument	Information	Illustration
Press the RED button.	"**Red=1/ 100 Blue=1/10000.0**"	This prompt is asking for the dilution factor of the sample.	
Press the RED button.	"**Dil=1/ 100 Red=STOP,Blue=GO**"	This prompt is asking for confirmation.	
Press the BLUE button.	"**Processing… 11 min. remain**"	The test is initiated.	

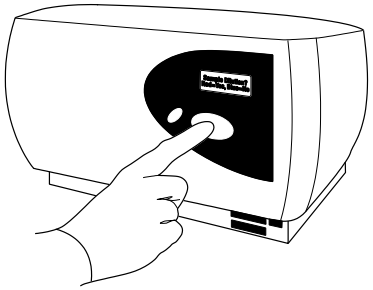
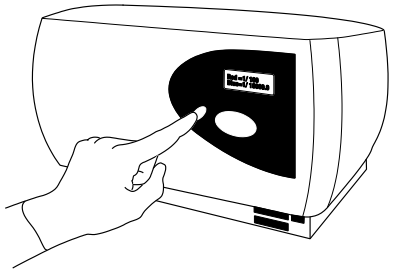
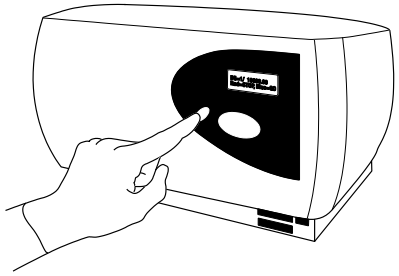
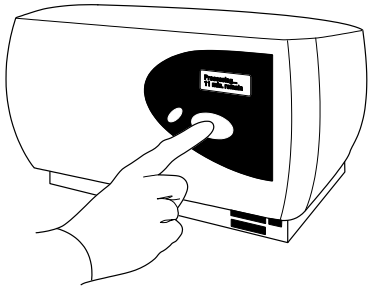
Testing an hCG 1/10000 Diluted Sample in hCG Dilution Mode

To learn more about hCG sample dilution, go to www.qualigeninc.com/hcgdilution.

Insert the sample filled FastPack® IP into the analyzer.		NOTE: In this scenario, the sample will have been diluted 1/10000 prior to filling into the FastPack®.	

Testing in hCG Dilution Mode

Testing an hCG 1/10000 Diluted Sample in hCG Dilution Mode - Continued

Action	Instrument	Information	Illustration
Press the BLUE button.	"**Sample Dilution? Red=Yes, Blue=No**"	This prompt is questioning whether or not the current test sample is diluted. To test a diluted sample, respond with "Yes". A "No" response indicates a neat sample is to be tested.	
Press the RED button.	"**Red=1/ 100 Blue=1/10000.0**"	This prompt is asking for the dilution factor of the sample.	
Press the BLUE button.	"**Dil=1/10000.0 Red=STOP, Blue=GO**"	This prompt is asking for confirmation.	
Press the BLUE button.	"**Processing… 11 min. remain**"	The test is initiated.	

WHO International Standard

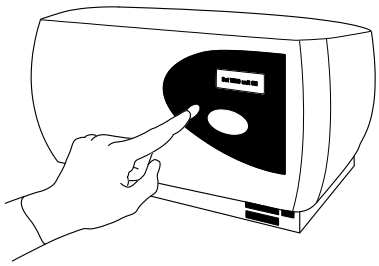
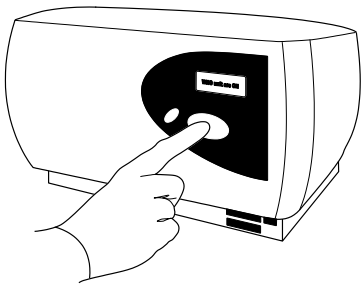
The World Health Organization (WHO) has established International Biological Reference Preparations to serve as reference sources for defining biological activity expressed in an internationally agreed upon unit of measure. The FastPack® IP System provides the user the option of displaying results for Total PSA based on the WHO standard.

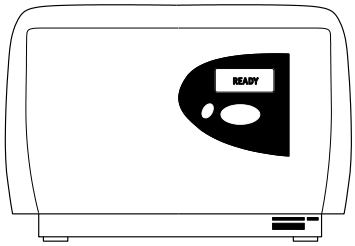
WHO International Unit Mode

This mode enables the analyzer to output WHO standardized Total PSA results as an alternative to the default Hybritech standardized results. No other tests are affected. An uppercase "W" will appear in the second character row of the analyzer display when the WHO Unit Mode is enabled. The uppercase "W" will also appear to the left of the result when results are printed in this same mode. There are no additional steps required for using the WHO unit mode aside from enabling or disabling this mode. To learn more about WHO standardization and Hybritech standardization, go to www.qualigeninc.com/WHO.

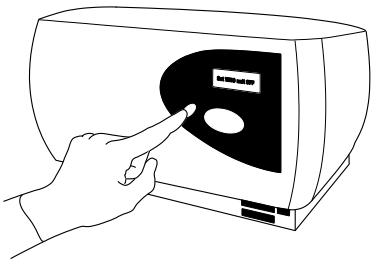
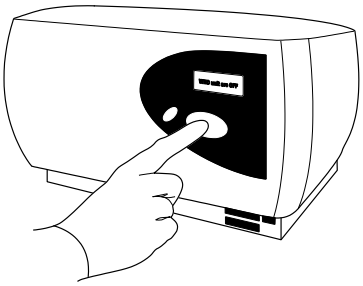
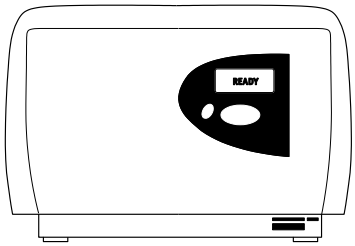
Enable WHO Unit Mode – Total PSA

WHO Unit Mode

Action	Instrument	Information	Illustration
Press the RED button several times until the display reads "PSA=Hybritech".			
Press the BLUE button.	**"PSA=WHO Unit"**	This action enables the WHO unit MODE.	

	"**Ready**"	The analyzer display will return to the "Ready" screen.	

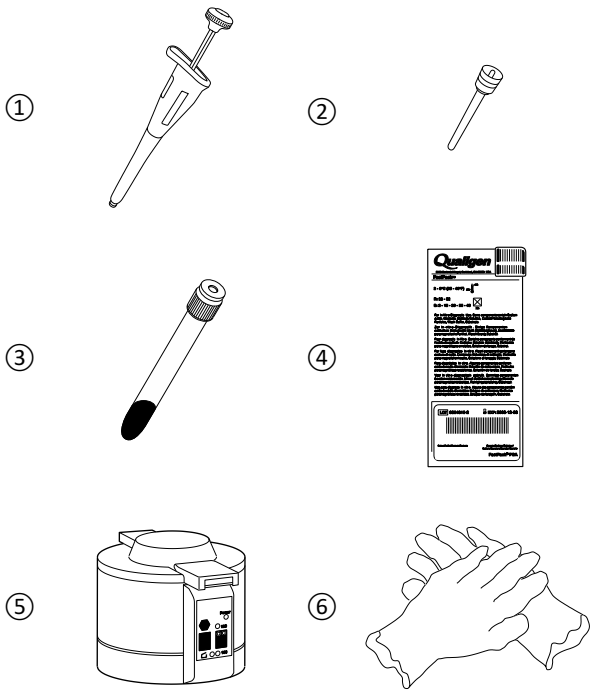
Disable WHO Unit Mode – Total PSA
WHO Unit Mode

Action	Instrument	Information	Illustration
Press the RED button several times until the display reads "PSA=WHO Unit".			
Press the BLUE button.	"**PSA=Hybritech**"	This action reverts the analyzer back to outputting PSA results in Hybritech standardized results.	
	"**Ready**"	The analyzer display will return to the "Ready" screen.	

Sample Collection and Delivery into the FastPack® IP

What You Need

1. Pipette
   * Use 25 µL pipette for hCG.
2. Pipette Tips
3. Sample (patient plasma or serum, calibrator or control)
4. FastPack® IP
5. Centrifuge (required for patient samples only)
6. Medical Gloves – used to avoid contact with biohazard materials such as human blood, etc.



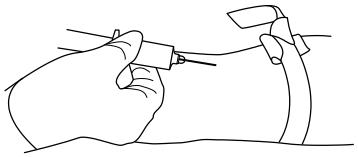
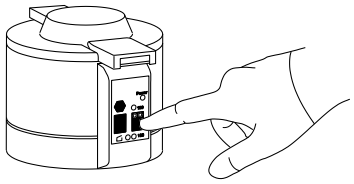
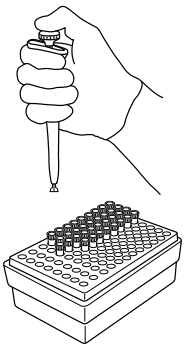
IMPORTANT: FastPack IP Vitamin D and FastPack IP SHBG

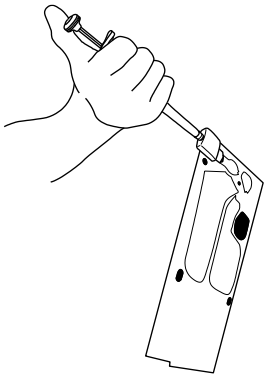
For calibration, controls or running patient samples, you must pre-treat each Vitamin D sample with the FastPack® Pretreatment Buffer, OR dilute each SHBG sample with Sample Diluent.

See the section on:

Sample Collection, Pretreatment and Delivery into the FastPack® IP (Vitamin D Testing and SHBG)

Sample Collection and Delivery

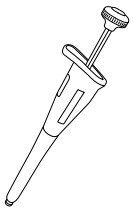
Action	Instrument	Information	Illustration
For patient samples, collect 2-4 mL of blood in a 5 mL tube.		Refer to specific direction insert for sample collection and handling.	
Centrifuge blood collection tube to separate serum or plasma from red blood cells.		Refer to the user manual of your centrifuge for specific usage instructions. Refer to the FastPack® IP Kit Direction Insert for additional information about sample processing and storage.	
Closely follow FastStep 2 from your FastSteps Guide.		Use only Qualigen recommended pipette tips. The tips are available through your local distributor or Qualigen. Be sure that the pipette operates smoothly and does not stick. It is very important that the tip is properly seated on the pipette. If it is not, there is a high likelihood of short sampling which will directly affect patient results.	

Action	Instrument	Information	Illustration
Closely follow FastSteps 3-5 from your FastSteps Guide.		Use serum, plasma, calibrators or controls only. Always wear gloves when handling samples. It is very important that the pipette tip is firmly placed in the injection port. If any sample leaking is detected, immediately dispose of the FastPack® IP and begin again with a new FastPack® IP and sample.	

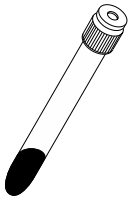
Sample Collection and Delivery into the FastPack® IP (Vitamin D and SHBG Only)

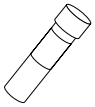
What You Need

1. Pipette (available from Qualigen)
2. Pipette Tips (available from Qualigen)
3. Sample (patient plasma or serum, calibrator or control)
4. FastPack® Pretreatment Buffer (Vitamin D) OR Sample Diluent (SHBG)
5. FastPack® IP for Vitamin D OR SHBG
6. Centrifuge (required for patient samples only)
7. Medical Gloves - used to avoid contact with biohazard materials such as human blood, etc.

① 

② 

③ 

④ 

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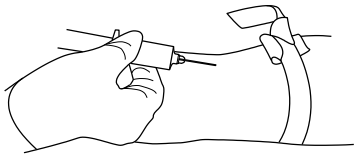
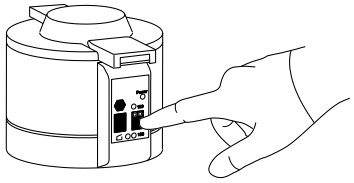
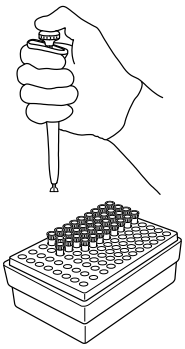
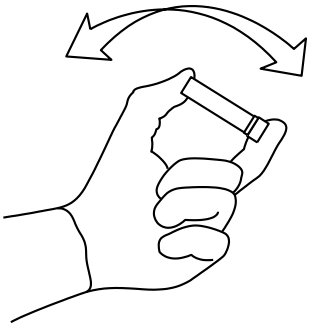
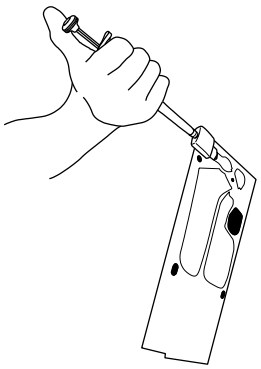
Sample Collection and Delivery – Vitamin D and SHBG Only

Action	Instrument	Information	Illustration
For patient samples, collect 2-4 mL of blood in a 5 mL tube.		Refer to specific direction insert for sample collection and handling.	
Centrifuge blood collection tube to separate serum or plasma from red blood cells.		Refer to the user manual of your centrifuge for specific usage instructions. Refer to the FastPack® IP Kit Direction Insert for additional information about sample processing and storage.	
Closely follow FastStep 2 and 3 from your **FastSteps For Vitamin D and SHBG**.		Use only Qualigen recommended pipette tips. The tips are available through your local distributor or Qualigen. Be sure that the pipette operates smoothly and does not stick. It is very important that the tip is properly seated on the pipette. If it is not, there is a high likelihood of short sampling which will directly affect patient results.	

Sample Collection and Delivery – Vitamin D Only

Action	Instrument	Information	Illustration
Follow step 4 from your **FastSteps for Vitamin D and SHBG**.		When testing for Vitamin D, it is necessary to treat each sample with pre-treatment buffer prior to putting the sample into the FastPack® IP	
Closely follow step 5 and 6 from your **FastSteps for Vitamin D SHBG.**		Use serum, plasma, calibrators or controls only. Always wear gloves when handling samples. It is very important that the pipette tip is firmly placed in the injection port. If any sample leaking is detected, immediately dispose of the FastPack® IP and begin again with a new FastPack® IP and sample	

Running Patient Samples

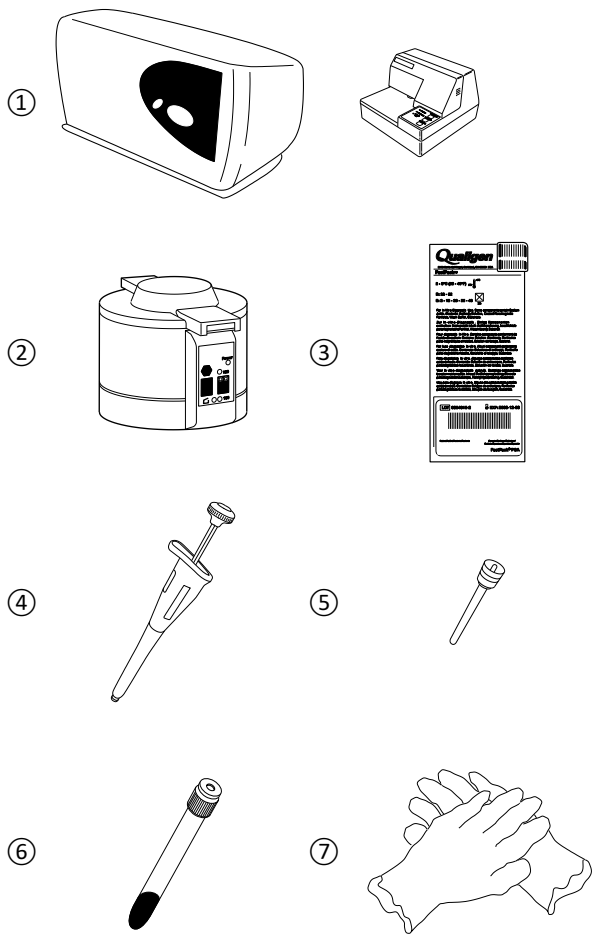
When to Run a FastPack® IP

The FastPack® IP System analyzer is ready to run a FastPack® IP at any time as long as it is turned on, has reached operating temperature and pressure, and has been calibrated. If the analyzer is not at operating temperature, the analyzer will not operate and the BLUE button will not function. Leave the analyzer turned on 24 hours a day so that it will always be at operating temperature.

The analyzer performs a comprehensive Self Diagnostic test every midnight to ensure the system is functioning properly. When the Self Diagnostic test is running, the analyzer door will be locked shut.

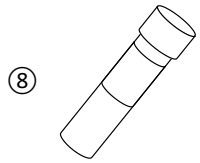
What You Need

1. FastPack® IP System
2. Microcentrifuge (required for patient samples only)
3. FastPack IP (for the specific assay to be tested)
4. Pipette (available from Qualigen)
5. Pipette Tips (available from Qualigen)
6. Patient Sample (serum or plasma depending on the assay)
7. Medical Gloves - used to avoid contact with biohazard materials such as human blood, etc.

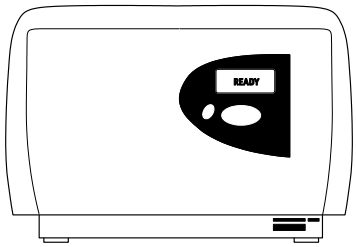
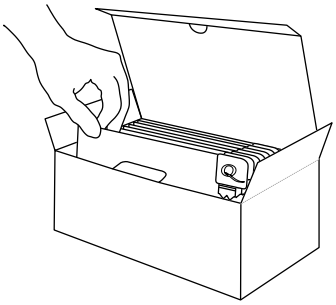
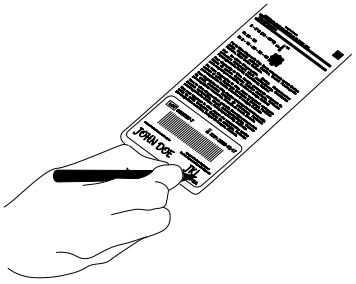


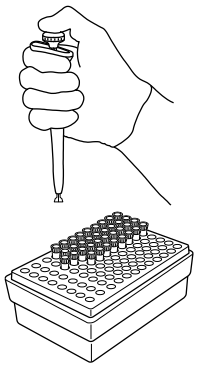
FOR FASTPACK® IP VITAMIN D and SHBG

8. Pretreatment Buffer (Vitamin D) OR Sample Diluent (SHBG)

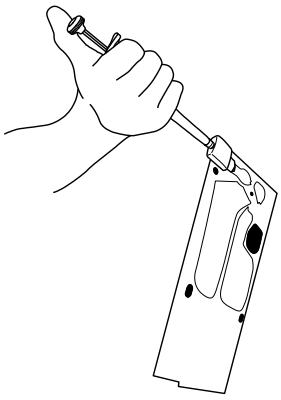


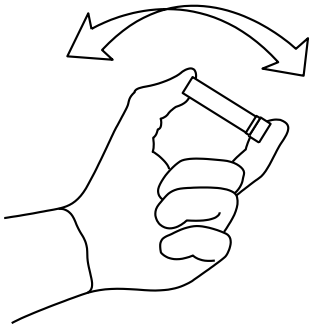
FastPack® IP System Procedure

Action	Instrument	Information	Illustration
Verify that the analyzer is in "Ready" mode.	"**Ready**"		
Remove the FastPack® IP from its box. Check to make sure it is the correct test type. Ensure there are no external fluid leaks or any burst chambers on the FastPack® IP.		Always keep FastPacks® stored in the refrigerator in the upright position indicated on the box, at 2-8°C (36-46°F) prior to use. FastPacks® can be taken directly from the refrigerator and used in the analyzer.	
Write the Patient's Name/ID # and the operator's initials on the peel-off FastPack® IP label.		This information is important for quality control.	

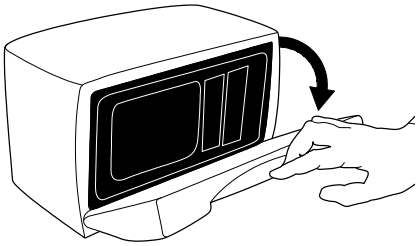
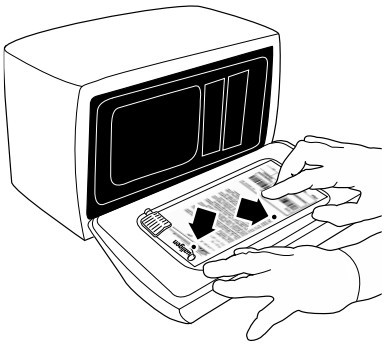
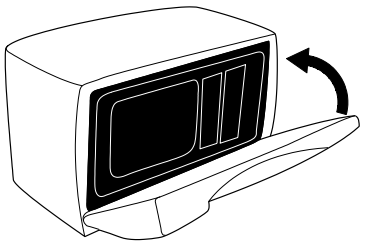
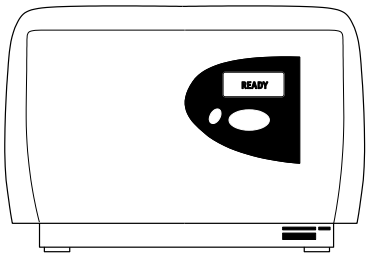
Closely follow FastStep 2 FastSteps Guide		Use only Qualigen recommended pipette tips. The tips are available through your local distributor or Qualigen. Be sure that the pipette operates smoothly and does not stick. It is very important that the tip is properly seated on the pipette. If it is not, there is a high likely hood of short sampling which will directly affect patient results.	

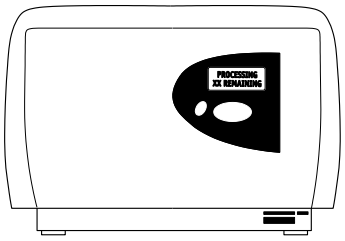
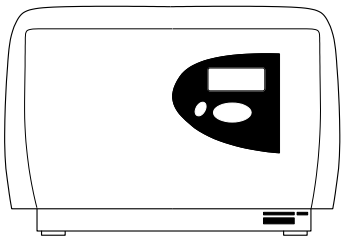
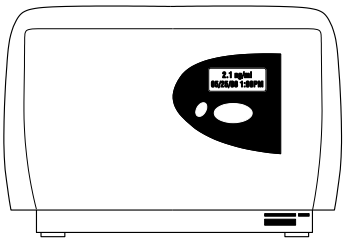
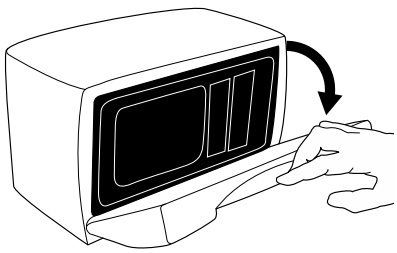
FastPack® IP System Procedure

Action	Instrument	Information	Illustration
Closely follow FastSteps 3 through 5 from your FastSteps Guide.		Use serum, plasma, calibrators or controls only. Always wear gloves when handling samples. It is very important that the pipette tip is firmly placed in the injection port. If any sample leaking is detected, immediately dispose of the FastPack® IP and begin again with a new FastPack® IP and sample.	
STOP! – The Following two steps are for FastPack® IP Vitamin D and SHBG			
Eject the sample into the pre-treatment buffer (Vitamin D) or Sample Diluent (SHBG) tube by pressing down on the pipette plunger to the first stop. Replace the screw cap tightly onto the buffer tube.		**Each patient sample, calibrator or control must be thoroughly mixed with the FastPack® Pre-treatment buffer before running a FastPack® IP Vitamin D assay.**	

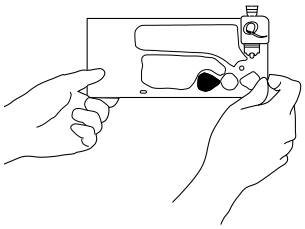
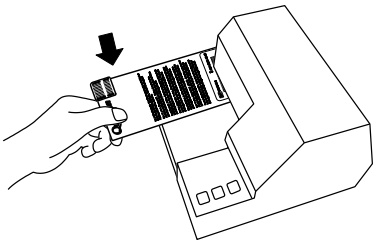
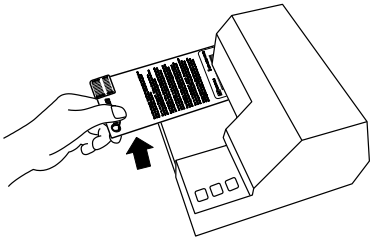
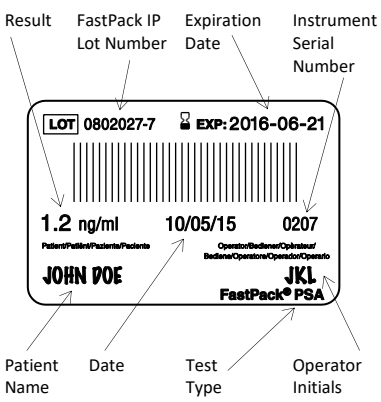
		Invert the buffer tube at least 3 times to thoroughly mix together the sample and buffer. Follow the FastSteps for Vitamin D Guide steps 4 and 5 to complete sample delivery to the FastPack® IP.	

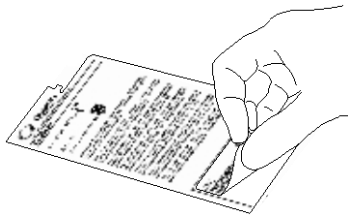
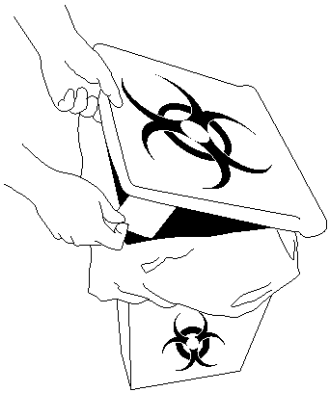
Running Patient Samples - Continued

Action	Instrument	Information	Illustration
Open the FastPack® IP analyzer door.			
Place FastPack® IP on the door. Align the pins on the door with the holes in the FastPack® IP.		It is only possible to align the FastPack® IP in one direction.	
Close the analyzer door.		If the door is not closed, the analyzer will not run.	
Press the BLUE button.	"**Ready**"	The door will lock, and the analyzer will run the test. All the test information is read by the analyzer from the bar code on the FastPack® IP label. Refer to the Troubleshooting section if an error message is displayed	

Action	Instrument	Information	Illustration
	"**Processing XX min. remain**"	The screen will display test status and time remaining. Press the Cancel button if test needs to be stopped in an emergency.	
When test is complete, analyzer will beep.			
The analyzer will provide the test result on the display.	Example: "**2.1 ng/mL 06/21/20 1:00PM**" or "**2.1 ng/mL 21/06/20 13:00**"	The result will remain displayed for one minute after the door is opened or until another test is run. When a new test is run, the previous test result is erased from the analyzer memory and display.	
Open the analyzer door.	"**Insert FastPack in Printer**"	The analyzer will start beeping and display "Insert FastPack® in Printer" until result is printed.	

FastPack® IP System Procedure

Action	Instrument	Information	Illustration
Remove and inspect the FastPack® IP. Check the inside of the analyzer door for fluid. If there is fluid on the FastPack® IP or the analyzer, disregard the result and properly dispose of the pack. Implement the cleaning procedure.		Confirm that all chambers have burst. Fluid should easily flow between all chambers. Observe that most of the fluid in the FastPack® IP is yellow. If there is no yellow fluid, disregard the result and rerun a new FastPack® IP.	
Slip the FastPack® IP into the external printer from the **LEFT SIDE** with the label side up and the label facing towards the rear of the external printer. Be sure that the edge of the FastPack® IP goes to the far edge of the external printer.		The printer will print and release the FastPack® IP automatically. It is important to insert the FastPack® from the left side of the printer to avoid tangling or twisting the printer ribbon.	
Remove the FastPack® IP from the **LEFT SIDE** of the external printer.		It is important to remove the FastPack® IP from the left side of the printer to avoid tangling or twisting the printer ribbon.	
Find the result printed on the FastPack® IP peel-off label. Patient Result Units Date of Test Instrument Serial #		All the necessary information for Quality Control is now included on the peel-off label.	**FastPack® IP label after Printing** 

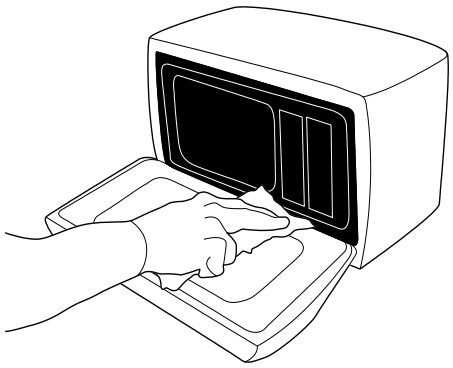
Action	Instrument	Information	Illustration
Peel off the label and place it in the patient record.			
Discard the FastPack® IP into a Biohazard container.			

Cleaning the FastPack® IP System

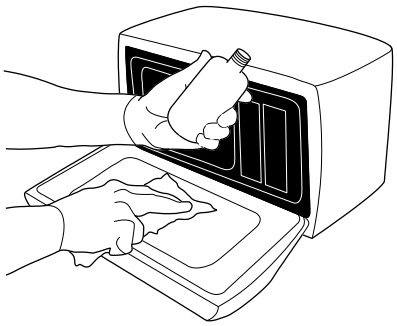
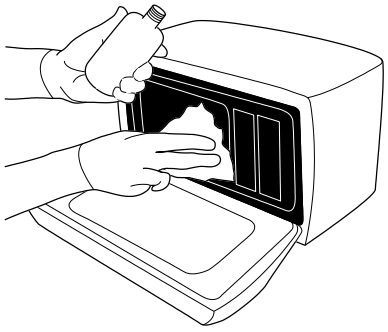
Note: Always wear protective gloves when cleaning or disinfecting the analyzer.

The FastPack® IP System analyzer is completely self-enclosed, and only requires periodic cleaning to remove excess sample. Use a damp cloth to wipe down the entire exterior and interior compartment of the analyzer. Do not use solvents to wipe down the exterior of the analyzer.

If a FastPack® IP has leaked inside the FastPack® IP analyzer, perform the following cleaning procedure:



FastPack® IP System Cleaning Procedure

Action	Illustration
Wipe the inside of the door panel with a soft cloth soaked with a mild disinfectant or any hospital grade disinfectant to remove any potential contaminant that may impact performance of the analyzer. Note: Do not press too hard as the silicone membrane can be torn with excessive force.	
Wipe the membrane side of the analyzer chamber with a mild disinfectant to eliminate any potential active chemiluminescence chemicals that may impact performance.	

Troubleshooting

Troubleshooting the FastPack® IP System Analyzer

These messages are possible errors that may occur. The FastPack® IP System analyzer will sound with a beep each time an error message is displayed

If a problem persists, please contact your local distributor or call Qualigen, Inc. System Support at 877-770-6127; or e-mail System Support at systemsupport@qualigeninc.com.

Display	Cause	Action
"**Bar Code Failure**"	Bar code reader has failed or analyzer door bar code label is illegible or defaced.	Check for obstruction and try FastPack® IP or card again. Turn off analyzer for 3 seconds, then power on analyzer. Reattempt to process the sample. Contact System Support.
"**Cal Fail**"	Calibrator result is outside of the acceptable range.	Re-run a new calibrator sample and be certain the FastPack® IP has a proper fill. If error persists, perform a Calibration Reset, then re-calibrate the analyzer.
"**New Lot Requires Calibration**"	Different lot of FastPacks is being used.	Use the same FastPack® lot previously used or re-calibrate the analyzer for the new lot of FastPacks.
"**Time to Re-Calibrate**"	Time between calibrations has expired.	Run calibration for desired assay.
"**Calibrator Expired**"	Calibrator has passed expiration date or system date is incorrect.	• Verify system date is correct. • If correct, obtain a new Calibration Kit.
"Calibration Incomplete"	User attempted to run patient or control prior to passing 2 Calibrations	Run another calibration. 2 CAL PASS results are required prior to running patient or control tests.
	User forgot to insert calibration card prior to running calibration	Insert Calibration Card and press blue button prior to running calibration
"**Close Door**"	Door is not completely closed.	Close Door.

"**Date Error**"	A date that is not possible has been entered.	Re-enter correct date.

Troubleshooting the FastPack® IP System

Display	Cause	Action
"**Door Failure**"	Silicone shield incorrectly installed	Verify that edges of silicone shield are flush with back plate
	FastPack® IP or card has slipped off positioning pin	Verify that FastPack® IP or card is correctly positioned
	Door latch has failed	Contact System Support
"**Expired Pack**"	FastPack® IP has passed expiration date or system date is incorrect	• Verify system date is correct. • If correct, obtain new lot of FastPack® IP
"**Unable to Read Barcode**"	FastPack bar code label is illegible	Reposition barcode label approx. ⅛-inch lower and re-try
	Reader non-functional.	Turn off analyzer for 3 seconds, then power on analyzer. Reattempt to process the sample.
"**Invalid Label**" "**Unknown Test**"	Wrong test-type pack.	Verify that FastPack® IP and Calibrator card are of the same test-type.
	Correct software version not installed.	Contact System Support
"**Restricted test type due to temp**"	Operator attempted to run a FastPack® test that is incompatible with the temperature of the analyzer.	Attempt to run the FastPack® on an analyzer that is temperature compatible.
"**Missing Pack**"	There is no pack in the analyzer.	Insert FastPack® IP.
"**Motor Failure**"	Motor has failed.	Run diagnostic. If it fails, contact System Support.
"**PMT Background High _ _ _**"	PMT background reading is high during self-diagnostic or at beginning of a test. This may result from contamination, leakage of ambient light in the analyzer, or attempting to use a previously used FastPack® IP.	Ensure that the used FastPack® IP is not still in the Instrument. Ensure that the instrument is not in direct sunlight. Follow cleaning procedure. Run self-diagnostic. Contact System Support if message persists.

Troubleshooting the FastPack® IP System

Display	Cause	Action
"**PMT Failure**"	PMT Failure; Light Leak.	Ensure that the analyzer is not in direct sunlight. Contact System Support.
"**Shutter Failure**"	Shutter Failure	Contact System Support.
"**Pressure Failure**"	System has a severe pressure leak. Air pump not functioning.	Contact System Support.
"**Remove FastPack**"	A FastPack® IP is in the analyzer when attempting to run diagnostics.	Remove FastPack® IP. Upon closing door, diagnostics will automatically begin.
"**Temperature Out of Range**"	Target temperature is 37 C. If displayed temperature is < 37 C, temp is too low. This may occur if door is left open for long duration.	Close door. Recheck after 5 minutes. If problem persists, contact System Support.
	Target temperature is 37 C. If temperature is > 37 C, temp is too high. This may occur if room temperature is too warm (>32°C or 90°F).	Move analyzer to a cooler location or wait approximately 15 minutes between runs. If problem persists, contact System Support.
"**TempInvalid Test D=XX.XC M=XX.XC**"	Temperature has exceeded correct range during a test, and the current temperatures are displayed. The target temperature is 37 C ±0.5 C. "D" indicates the Door temperature and "M" indicates the Main temperature,	Discard pack. Retry test. If problem persists, contact System Support.
"**Test Cancelled**"	Cancel was pressed during a test.	Cancelling a test will require the use of a new FastPack® IP and new sample.
"**Thermistor Failure**"	Thermistor has failed.	Contact System Support.

"**Time Error**"	A time that is not possible has been entered.	Re-enter correct time.

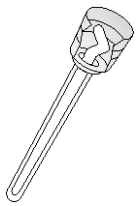
Troubleshooting the FastPack® IP System

Display	Cause	Action
"**>XX units**"	FastPack® IP Test result is higher than the maximum reportable result.	Report result as >XX units. If desired send sample to reference lab for confirmation.
"**<XX units**"	FastPack® IP Test result is lower than the minimum reportable result.	Report result as <XX units.
"**One Control Out of Range**"	Full volume of Control not filled into FastPack® IP. Misread Control range card.	Re-run Control Verify that the correct range is being read for the Control lot # being used.
	Expired Controls.	Verify the expiration date on the vial of the Control being used.
	Contaminated Controls.	Verify that the Controls were stored and used properly.
	Wrong Control used.	Verify that the correct Control vial was used.
"**Both Controls Out of Range**" (High or low)	Reagents have been stored at room temperature.	Re-calibrate and run Controls.
	Problem with Calibration.	Reset Calibration.
"**Both Controls Out of Range**" (One high and the other low)	Problem with Sample filling.	•Check pipette for proper operation. • See section titled Troubleshooting FastPack® IP Injection Port and Pipette.
Unrefrigerated FastPacks® IP	Delayed Delivery	Contact Qualigen System Support
	Refrigerator Malfunction	Contact Qualigen System Support
Red and Blue buttons unresponsive. Display text does not move	Internal Electrical Disturbance	Turn off analyzer for 3 seconds, then turn on. Process a new unused FastPack

Troubleshooting the FastPack® IP Injection Port and Pipette

Important Note

Proper performance of the pipette is critical to obtain accurate test results. If at any time, you note the pipette plunger sticking, or if plunger operation feels rough, replace with a new pipette.

Problem	Cause	Action
Pipette does not draw up or dispense any sample	Pipette tip may not be properly seated. The white piston inside the pipette tip should move up and down when the plunger is depressed. If it does not, the tip is not properly seated or the piston is warped. 	Eject the pipette tip. Seat a new pipette tip properly. Refer to the FastSteps (proper techniques for sampling).
Sample is leaking from the injection port.	The pipette is not properly seated in the injection port.	Discard the leaking FastPack® and start with a new unused FastPack®. When inserting the pipette tip into the injection port, ensure that the tip is fully inserted all the way into injection port so that it is properly seated. After injecting the fluid and ejecting the pipette tip, make sure you do not inadvertently pull out the tip. This will cause the pipette tip and/or the white internal piston to be unseated and potentially allow leakage of sample. Contact System Support 877-770-6127.

Analyzer Software Upgrade

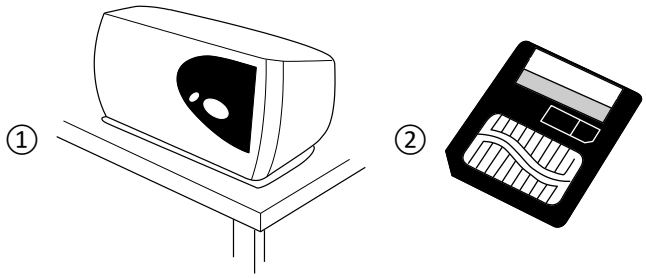
Check the back of your FastPack analyzer to determine if it is equipped with a Smart Media Card slot or a USB port.

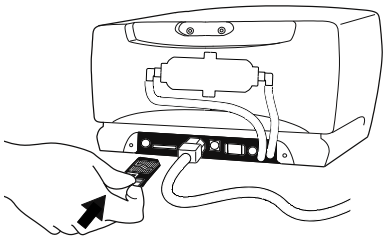
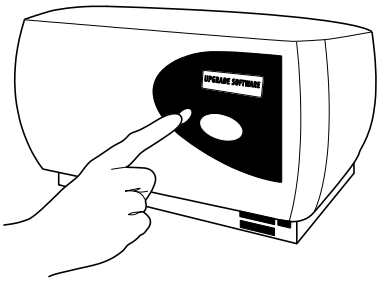
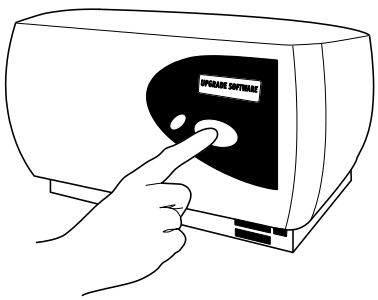
Follow the appropriate Software Upgrade Procedure that corresponds with your specific FastPack Analyzer.

Analyzer Software Upgrade Using Smart Media Card

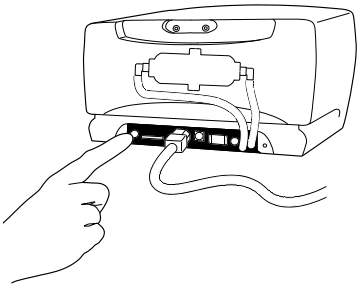
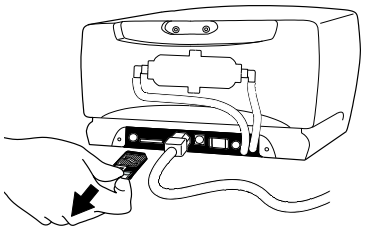
What You Need

1. FastPack® IP System analyzer
2. Smart Media Card

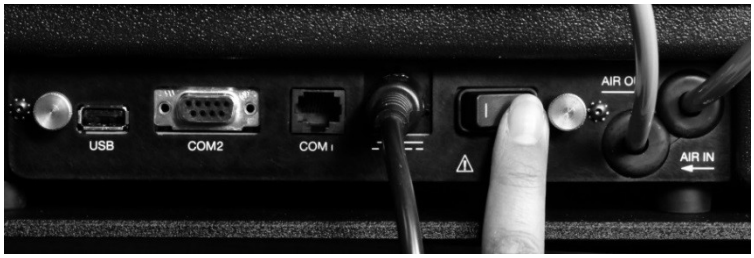
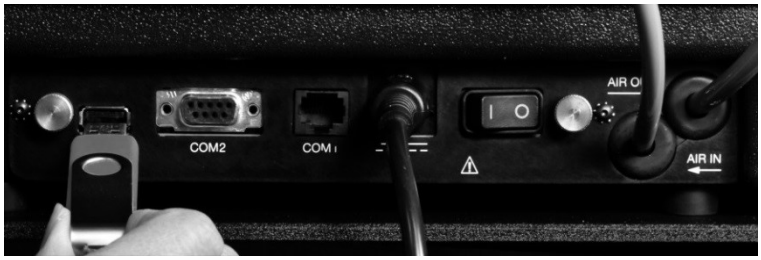
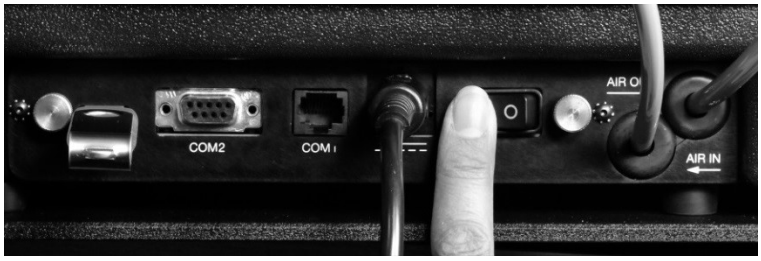
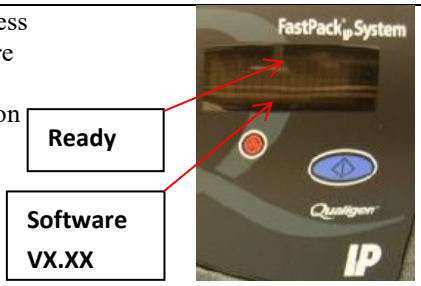


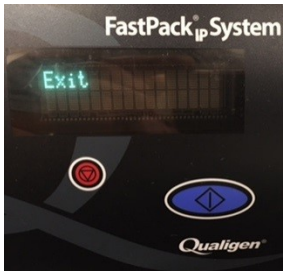
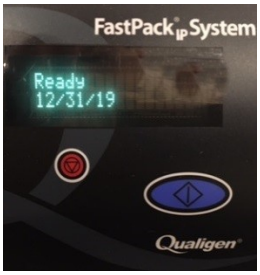
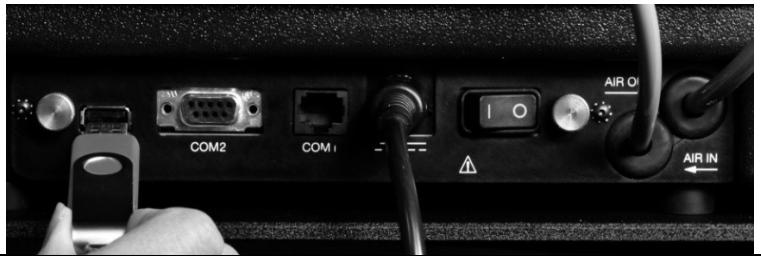
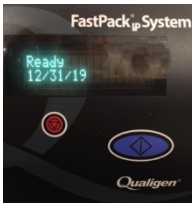
Action	Instrument	Information	Illustration
With the analyzer on and in "Ready" mode, insert the Smart Media Card into the port on the back of the analyzer labeled "SMART MEDIA CARD".	"**Ready**"	The gold side of the Smart Media Card should face up. The notch on the Smart Media Card will be inserted first.	
Scroll to "Upgrade Software" by pressing the RED button on the analyzer.	"**Upgrade Software**"		
Press the BLUE button to select the "Upgrade Software" menu option.	"**Checking…**"	The unit will start by checking the software and finish by going through Self-Diagnostics. The entire sequence should take about 2 minutes. If the analyzer should get stuck at any step, call Qualigen System Support. If an error message is displayed, DO NOT turn off the machine. Follow the instructions on the display. If the error persists, call Qualigen System Support.	

Upgrade Procedure

Action	Instrument	Information	Illustration
When the analyzer returns to “Ready” mode, press the EJECT button next to the port and remove the Smart Media Card. Return the Smart Media Card after the upgrade is complete.	“**Ready**”	After the software is completely installed, “Software VX.XX” appears in the display and the self-diagnostics will run automatically. Once the diagnostics are complete, “Ready” will appear on the screen. It is acceptable to remove the card at this time.	 

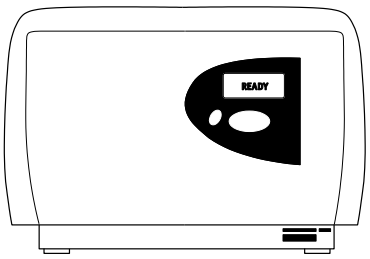
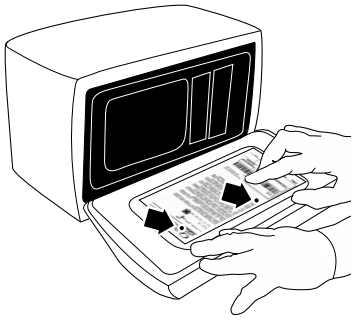
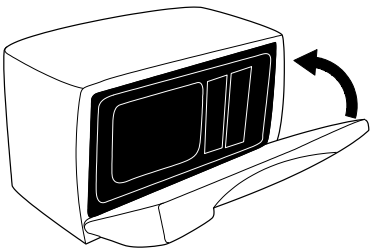
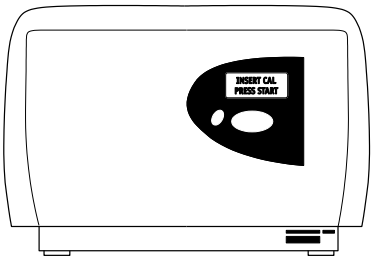
Analyzer Software Upgrade Using USB

1. Power off the **analyzer**	
2. Insert **USB drive** into the USB port in back of the analyzer	
3. Power on the analyzer. The screen will be blank for about 15 seconds. The newly installed software version number will then appear for 2 seconds. The Analyzer will automatically perform self-diagnostics for about 3 minutes, and then the screen will display “Ready”.	
4. Confirm the software was loaded successfully. **Note: If the software was not loaded successfully, repeat all previous steps**	With “Ready” on the screen, press the red button until the Software Version Number appears. Confirm that the software version number is the version you intended to install. 

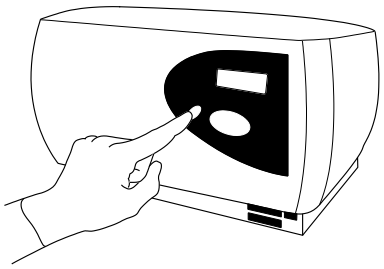
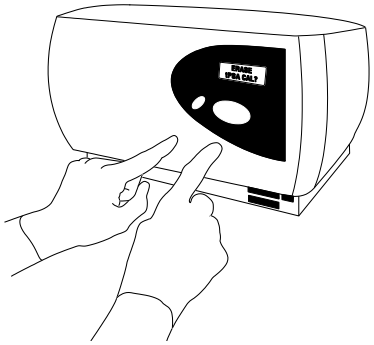
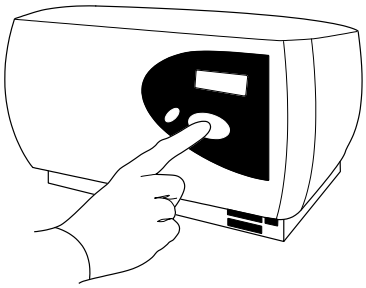
5. If software was loaded successfully…	Continue pressing the red button until you reach “Exit” then press the blue button. The screen will display “Ready”.  
6. Power off analyzer. Remove USB stick.	 
7. Power on the analyzer. Analyzer will proceed through self-diagnostics, then screen will display”Ready” The analyzer is now ready for use.	 

Calibration Reset

Calibration Reset Procedure

Action	Instrument	Information	Illustration
	"**Ready**"		
Place the Calibrator Card, for the test type calibration you want to erase, on the door. Align the pins on the door with the holes in the Calibration Card.	"**Ready**"		
Close the analyzer door.			
Press the BLUE button.	"**Remove Cal Card, Press Start**"		

Calibration Reset Procedure

Action	Instrument	Information	Illustration
Press and hold the RED button		Analyzer will beep four times.	
Release the RED button when the beeping stops.	Example: "**Erase tPSA Cal?**"	If you do not want to erase the calibration press the RED button, again. After "Erase tPSA Cal" is displayed, the screen will toggle between different displays.	
Press the BLUE button.	Example: "**tPSA has been erased**"	This will erase the calibration. Follow the Calibration Procedure to re-calibrate the analyzer.	

Downloading Data

Smart Media Card Reader Equipped Model

The FastPack® IP System (when COM1 is configured for a computer) allows for the output of test results to a personal computer (PC). The computer can be connected using a serial cable Qualigen Part Number 15000112. The cable connects to the RJ-45 jack on the rear panel of the FastPack Analyzer and terminates with a female DB-9 connector compatible with input to a PC serial port. The cable is approximately 6 feet in length. Data is automatically output at the completion of each test.

The output data is ASCII text with the following comma delimited fields:

Result Value (numerical or pass/fail for calibrator or controls)
Units
Date
Time
Instrument Serial Number
SW Revisions
Test Type

Patient ID

The communications protocol will be:

Serial Comm RS232
Baud Rate 9600
Parity None
Data bits 8
Stop bits 1

The "Recall last result" command can send the information for the last test run out to the PC.

Configuring Data Output – Smart Media Card Reader Equipped Model:
The FastPack Analyzer has a setup menu that is accessed using the two buttons on the front panel. When the instrument is in the standby mode "Ready" is displayed on the LED display. Pressing the red button enters the setup menu. The red button scrolls through the choices, the blue button selects the choice currently displayed.

Press the red button until the display shows one of the following:
"Result=printer" or "Result=computer"

If the display shows "Result=computer" it is currently configured for output to a computer and pressing the blue button will change the configuration to make it work with the external printer. To leave the setup menu with the FastPack Analyzer configured to output to a computer **DO NOT PRESS THE BLUE BUTTON**, press the red button until the "Exit" option is displayed and then press the blue button to exit the setup menu.

If the display shows "Result=printer" it is currently configured for output to a printer and pressing the blue button will change the configuration to make it work with a computer. To configure the FastPack Analyzer for a Computer **PRESS THE BLUE BUTTON**. The system will beep, move the displayed text from the first line of the display to the second line to confirm that the configuration was changed. There will be a delay of a few seconds while the system stores the configuration in nonvolatile memory, then the system will return to the standby mode and display "Ready".

If the FastPack Analyzer is configured for output to an external printer, it will prompt the operator to "Insert FastPack In Printer" each time a result is going to be sent out the communication port. The output can be canceled by pressing the red button.

USB Port Equipped Model

The USB port in the back of the analyzer is an input dedicated specifically for analyzer software upgrades.

COM 1 is an output port dedicated for printer output using an RS 232 connection. Output to printer may be turned on or off in the analyzer menu by toggling the option between "Set Printer ON" or "Set Printer OFF". If output to printer is enabled, the analyzer will prompt the operator to “Insert FastPack In Printer” each time a test completes.

COM 2 is dedicated for computer output using a standard “straight through” DB9 to DB9 cable connected to a computer. This would not be a “null modem” type of cable, and this cable may vary depending on the specific computer connection. Computer output at COM 2 is always on whether or not the port is connected.

The output data is ASCII text with the following comma delimited fields:

Result Value (numerical or pass/fail for calibrator or controls)
Units
Date
Time
Instrument Serial Number
SW Revisions
Test Type

Patient ID

The communications protocol will be:

Baud Rate 9600
Parity None
Data bits 8
Stop bits 1

Computer Output Format:

The result is output as ASCII text with the fields delimited by a comma. The output fields are as follows:

Field	Example Output
Result	3.5ng/mL
Date/Time	12/25/19 14:35
Instrument Serial Number	1234
Instrument Software Version	1.31
Assay Identification	TSTO
Raw Instrument Reading (RLU/Second)	543210
Flag denoting sample dilution 1/100 (D), 1/10,000 (X), or WHO tPSA/fPSA result (W)	D

Calibration does not yield a numeric result, so result field will be “Cal A Pass”, “Cal B Pass”, “Cal A Fail”, “Cal B Fail”, or “Cal Fail”. Assay Identification for current and future tests are as follows:

Assay	Identifier
PSA	tPSA
PSA (Europe)	PSA2
Free PSA	fPSA
Testosterone	TSTO
TSH	TSH2
Free T4	fT4
Vitamin D	VitD
hCG	hCG
SHBG	SHBG

Care should be taken not to send ASCII text or control characters to the FastPack Analyzer as it may disrupt operation and/or data transfer.

FastPack® IP System Product Specifications

FastPack® IP System Analyzer

Ambient Operating Temperature:	15 °C (59 °F) to 32 °C (90 °F)
Operating Humidity:	10% to 80% relative humidity
Operating Altitude:	≤ 2000 m (6562 ft.)
Pollution Degree:	2
Installation Category:	II
Display Output:	2 line alphanumerical display
Data Output	RS232, 9600 baud, ASCII text
Field Service Options:	Firmware upgrade by ROM card or USB
Electrical Requirements:	100-240 ± 10% VAC, 1.9A
Power Consumption	100 Watts (maximum)
Size:	13 x 9 x 12 inches (33 x 23 x 30 cm)
Weight:	28.64 lbs (12.99 kg)
Operating Air Pressure:	40psi min. 60psi max

This product is intended for indoor use only.

UDI Information:

Found on the 2-D barcode on the inside of the door.

The UDI is a unique number that indicates it is an IP instrument and has a unique serial number.

Software Information:

The FastPack IP Analyzer runs on proprietary embedded software and allows, in its default state, only unidirectional communication from the system to a connected computer. The system does not have to be connected to a computer but if it is it is recommended that the computer and the IT network implement normal computer and network security measures.

Storage Conditions

FastPack® IP System Analyzer

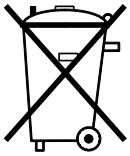
Storage Temperature:	15 °C (59 °F) to 32 °C (90 °F)
Humidity:	10% to 80% relative humidity
Stacking Limits:	Not to exceed four high

Statement of Compliance

FCC, Sec 15	Class A Radiated Conducted Emissions
EN 61326-1	Class A Radiated Conducted Emissions
IEC 1000-3-2	Powerline Harmonics Test
IEC 1000-3-3	Powerline Flicker Test
IEC 1000-4-2	ESD Immunity
IEC 1000-4-3	Radiated Susceptibility
IEC 1000-4-4*	EFT Immunity
IEC 1000-4-5	Lightning Surge Immunity
IEC 1000-4-6*	RF Common Mode Immunity
IEC 1000-4-11	Voltage Dips & Short Interruptions
Low Voltage Directive	72/23/EEC
EN 61010-1	Safety Requirements
EN 61010-2	
UL 61010-1	
CSA 22.2 NO. 61010-1	
CSA 22.2 NO. 61010-2	

**IEC 100-4-4 and IEC 1000-4-6 were passed under criterion C.*

Disposal



This product contains recyclable materials. Do not dispose of this product as unsorted waste. Please contact your local dealer or Qualigen, Inc. for disposal instructions.

Principle of Operation

Sample is added to the FastPack® via the injection port. The FastPack® contains all the premeasured reagents, in sealed chambers, necessary to perform the desired test. The pack label contains a bar code with all necessary information required by the analyzer to run the test.

The FastPack® IP System analyzer performs the test by automatically mixing and moving the sample and reagents within the pack. The sample and reagents are moved from one chamber to another by applying uniform pressure to the compartment by means of internal pressure pads extended from the analyzer. The pressure pads are driven by compressed air supplied by a small air compressor in the analyzer.

The FastPack® IP System analyzer is capable of running both sandwich, and competitive formatted immunoassays. For the sandwich type assays, the chemical principle is as follows: A sample of unknown analyte concentration is mixed with an excess amount of known concentration of capture and labeled antibody solution. This mixture is incubated for a preset time to allow the capture antibody and the labeled antibody to bind to the analyte in a sandwich format. This mixture is then brought into contact with the coated paramagnetic particles, which bind to the capture antibody (and thus the analyte). The amount of

labeled antibody bound to the paramagnetic particles is directly proportional to the analyte concentration in the sample.

For the competitive type assays, an immuno-reactive form of the analyte is bound to the paramagnetic particles. Initially, the sample is mixed with a labeled antibody, and this mixture is added to the analyte-bound paramagnetic particles. The analyte in the sample competes with the particle-bound analyte for the labeled antibody. The amount of labeled antibody which binds to the paramagnetic particles is inversely proportional to the analyte concentration in the sample.

For both assay formats, the antibody-bound paramagnetic particles are processed the same in the analyzer. The analyzer uses a magnet to hold the paramagnetic particles with their attached labeled antibody complex while they are washed repeatedly. The wash removes any unbound antibody. Finally, a substrate solution is added which reacts with the labeled antibody to emit light.

During the entire run of the FastPack® IP, temperature control of 37 ± 0.5°C for the FastPack® IP is achieved by heating metal plates that adjoin the FastPack® IP. The light produced is read by a photomultiplier tube. The analyzer provides a light-tight seal around the pack during the test process.

The FastPack® IP System analyzer performs a comprehensive self-diagnostic test each night at 12:00 am. The same test is performed when "Run Diagnostic" is selected in the set-up menu. Throughout testing, the analyzer monitors temperature, air pressure, background light, system power, and force profiles of seal ruptures and clamps.

Limitation of Procedure

Please read the information packaged in the FastPack® IP Reagent Kit regarding up-to-date product specifications and limitations.

Warranty (For U.S. Only)

Qualigen FastPack® IP System Limited (1 year) Warranty

Qualigen warrants, to the original purchaser, that the FastPack® IP System will be free from defects in materials and workmanship for a period of one year from the date of purchase.

Qualigen's liability for all matters arising under this warranty shall be limited solely to the repair or (in Qualigen's sole discretion) replacement of the product. If Qualigen reasonably determines that a repair or replacement is covered by this warranty, Qualigen shall bear the cost of shipping the repaired or replacement product to the customer. Risk of loss or damage during shipments under this warranty shall be the responsibility of the party shipping the product. If product shipped to Qualigen under this warranty is not suitably packaged for shipment, any physical damage present to the product on receipt by Qualigen (and not previously reported) shall be presumed to have occurred in transit and will be the responsibility of the customer. The customer must obtain a Return Authorization from Qualigen prior to shipping the product back to Qualigen.

Qualigen shall not be obligated under this warranty if the need for repairs or replacements directly or indirectly results from customer's: (i) failure to use or store the product as specified by Qualigen; (ii) failure to properly perform the services or maintenance required in the Operator's Manual for a product; (iii) repairs to a product by persons other than Qualigen service personnel; (iv) replacement of parts with other than Qualigen genuine parts; (v) negligence or negligent operation of any product; or (vi) alterations or modifications of any product without authorization from Qualigen.

THIS WARRANTY, TOGETHER WITH ANY OTHER WRITTEN WARRANTY THAT MAY BE ISSUED BY QUALIGEN, IS THE SOLE AND EXCLUSIVE WARRANTY AS TO QUALIGEN PRODUCTS, EXTENDS ONLY TO THE CUSTOMER AND IS EXPRESSLY IN LIEU OF ANY ORAL OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY AGAINST INFRINGEMENT.

Support / Services / Supplies

For questions concerning the FastPack® IP System or if supplies or services are needed, contact your local FastPack® IP System dealer or Qualigen, Inc.

Authorized Representative

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Schiffgraben 41
30175 Hanover, Germany

CH REP

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Notes:

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DIAGNOSTICS

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