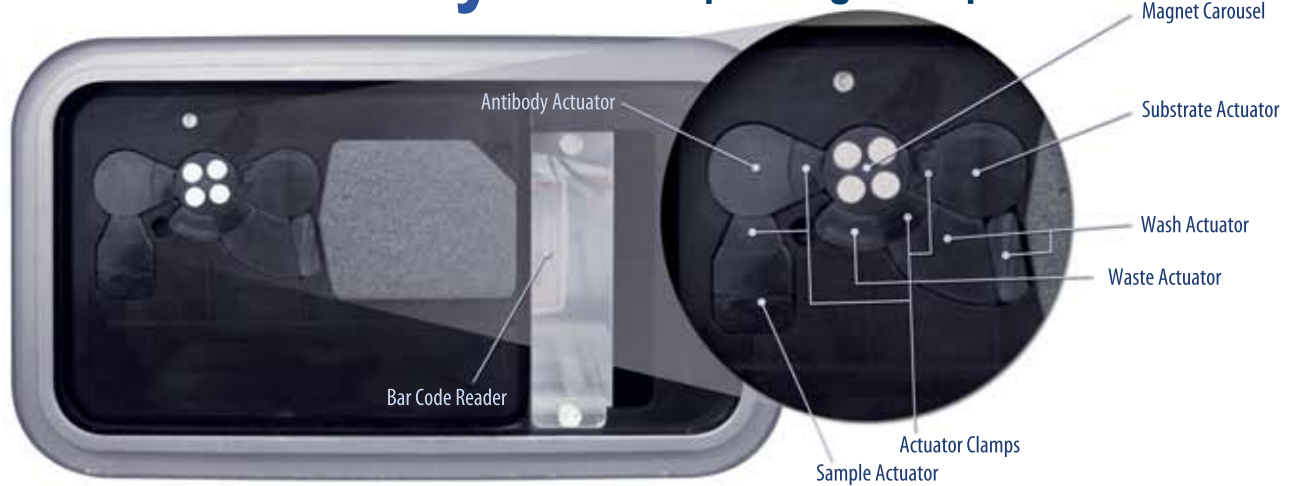


# FastPack® IP System Operating Principle



The FastPack IP® analyzer performs a test by automatically mixing and moving the sample and reagents within the pack. Controlled by software, 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 at 50 PSI supplied by a small air compressor in the analyser.

During the entire run of the FastPack, temperature control of  $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  for the FastPack is achieved by heating metal plates that adjoin the FastPack. The light produced is read by a photomultiplier tube. The analyzer provides a light-tight seal around the pack through precise tolerances in the analyzer door and frame during the test process.

The FastPack IP® analyzer performs a comprehensive self diagnostic test each night. Throughout testing, the analyzer monitors temperature, air pressure, background light, system power, and force profiles of seal ruptures and clamps.

To simplify the process of introducing the patient sample into the FastPack, an ingenious but simple method has been developed. The FastPack IP® System allows the technician to insert the sample directly into the pouch through an injection port (IP). The sample is secured by ejecting the tip while it is inserted in the port. This acts as a seal so the patient sample is effectively captured within the FastPack.

## FastPack® IP System Product Specifications

FastPack® IP Analyzer  
 Operating Temperature:  $15^{\circ}\text{C}$  ( $59^{\circ}\text{F}$ ) to  $32^{\circ}\text{C}$  ( $90^{\circ}\text{F}$ )  
 Operating Humidity: 10% to 80% relative humidity  
 Operating Altitude:  $\leq 2000\text{ m}$  (6562 ft.)  
 Pollution Degree: 2  
 Installation Category: II  
 Display Output: 2 line alphanumerical display  
 Data Output: RS232. 9600 baud, ASCII text  
 Field Service Options: ROM card firmware upgrade  
 Electrical Requirements:  $100\text{-}240 \pm 10\%\text{VAC}$ , 1.9A  
 Power Consumption: 100 Watts (maximum)  
 Size: 13 x 9 x 12 inches (33 x 23 x 30 cm)  
 Weight: 27 lbs (12.25 kg)

This product is intended for indoor use only.

## Storage Conditions

FastPack® IP Analyzer  
 Storage Temperature:  $15^{\circ}\text{C}$  ( $59^{\circ}\text{F}$ ) to  $32^{\circ}\text{C}$  ( $90^{\circ}\text{F}$ )  
 Humidity: 10% to 80% relative humidity  
 Stacking Limits: Not to exceed four high

## Downloading Data

The FastPack® IP system (when Com 1 is configured for a computer) allows the output of test results to a computer. Data is automatically output through the RS232 connection on the back of the FastPack IP analyzer at the completion of each test.

To obtain data, connect a serial cable (PN15000112) from the FastPack IP analyzer RS232 port to the computer and configure Com 1 for a computer.

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

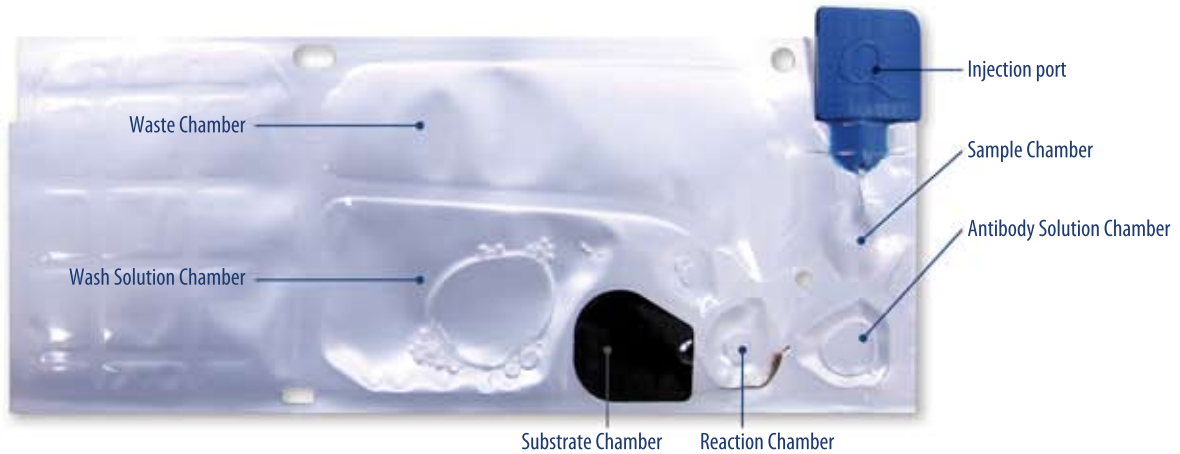
- Results Value  
(Numerical or Pass/Fail for Cals and Controls)
- Units
- Date
- Time
- Analyzer Serial Number
- Software Version
- Test Type

The communications protocol will be:

- Serial Comm RS232
- Baud Rate 9600
- Parity None
- Data Bits 8
- Stop Bits 1
- Recall last result sends this information out to PC for the last test run

Integration of the FastPack IP analyzer to a lab information software package (LIS) is the responsibility of the software developer. Assistance will be given by Qualigen, Inc for the integration.

# FastPack® IP System Assay Principle



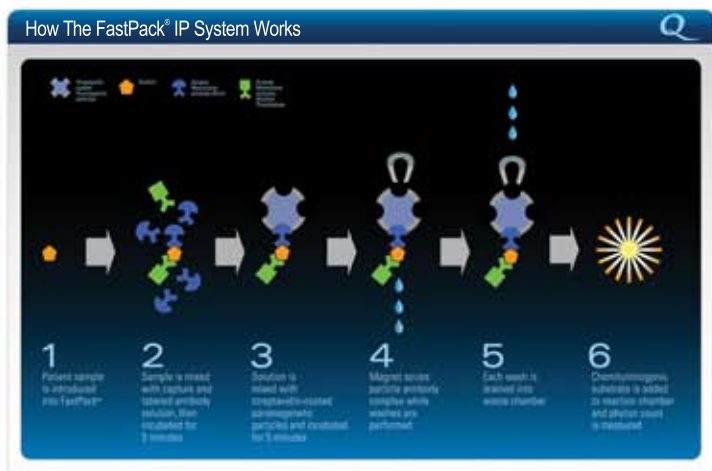
Chamber #	Description	Contents	Explanation
1	Sample Chamber	Serum or Plasma	Patient sample is inserted through a very simple, positive displacement pipette process.
2	Conjugate Chamber	Capture and Labeled Antibodies	Attach and capture the target molecule from the patient sample that is being identified.
3	Reaction Chamber	Paramagnetic Particles	Housed in this space are the coated paramagnetic particles which represent the solid phase of an immunoassay reaction.
4	Substrate Chamber	Light Sensitive Substrate	When everything is properly in place, photons are emitted by the substrate which equates to a target molecule concentration.
5	Wash Solution Chamber	Wash Solution	It is used to wash away excess, unbound materials in the reaction chamber.
6	Waste Chamber	Empty	All spent wash solution is deposited in this waste chamber.

Both “competitive” and “sandwich” type chemiluminescence assays may be run on the FastPack® IP System. Sandwich assays are used with large target molecules such as PSA, TSH and hCG while “Competitive” assays used with very small target molecules. The next paragraph explains, in detail, how a “Sandwich” assay runs in the FastPack.

In a sandwich assay, a sample with an unknown concentration of the analyte is mixed with excess amounts of capture antibody and labeled antibody. The mixture is incubated for a specified time to allow both antibodies to bind to the analyte in a sandwich format (in Chamber 2).

The mixture is then brought into contact with coated paramagnetic particles, which bind to the capture antibody (and thus the analyte).

The analyzer uses a small magnet to hold the paramagnetic particles with their attached sandwiched analyte while they are washed repeatedly (from chamber 4). The wash removes any unbound antibody (all done in Chamber 3). Finally, a substrate solution (from Chamber 6) is added, which reacts with the labeled antibody and emits light, which is directly proportional to the concentration of the analyte in the sample (all in Chamber 3).



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