

Inverness Medical Professional Diagnostics
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1. What is the name of your company's point-of-care testing product or product line?
 (For multiple products/lines, please complete NO MORE THAN THREE separate questionnaires.)

Clearview® COMPLETE HIV 1/2 and Clearview® HIV 1/2 STAT-PAK®

2. What does this test detect?

Human Immunodeficiency Virus Type 1 & 2 (HIV 1/2)

3. Is this product:

a self-contained point-of-care test (requiring no equipment)?

a single-patient test for use in point-of-care equipment?

a point-of-care analyzer?

an accessory or supply used by point-of-care equipment?

other point-of-care equipment?

4. What kind of specimen/sample is tested?

Whole blood (fingerstick or venipuncture), serum, and plasma.

5. Where is this product used? Check as many as apply:

at a community screening event

in a physician's office or outpatient clinic

at an inpatient's bedside

in an inpatient staff-access area

in a critical-care unit

elsewhere: Hospital Laboratory, Emergency Department, Labor & Delivery

6. How long does it take to obtain test results, under ideal conditions?

15 - 20 minutes

7. How are test results made available?

For the Clearview STAT-PAK, read the test result between 15 and 20 minutes after the addition of the sample and running buffer. Reactive Test Results may be observed and read earlier than 15 minutes. To verify a Nonreactive Test Result, wait the entire 15 minutes after starting the test. Do not read results after 20 minutes.

For the Clearview COMPLETE, read the test result between 15 and 20 minutes after collection of the sample and seating the barrel into the buffer vial. Reactive Test Results may be observed and read earlier than 15 minutes. To verify a Nonreactive Test Result, wait the entire 15 minutes after starting the test. Do not read results after 20 minutes.

8. What credentials/licensures are required to run this test?

A CLIA Waiver is required to run this product in a CLIA Waived setting.

9. How long does it take to train the person who administers/interprets the test?

1 hour

10. What is the typical cost:

• per test? STAT-PAK \$17.50 (List); COMPLETE \$18.50 (List)

• for initial setup (including purchase, installation, and training, as applicable)?

Purchase of 1 test kit and control set is required; training is included. Pricing is dependent upon institution type (Public Health/Hospital/POL) and volume.

11. In brief, how does this product (not your company) differ most from competing products?

Clearview COMPLETE HIV 1/2 is a unique 3-in-1 self-contained barrel format which handles collection, processing, and analysis of only 2.5 μ L of blood, serum, or plasma. A lancet and adhesive bandage are supplied with each test device for ease of use in the POC test environment or outreach setting. The ease of use and self-contained format, combined with a long shelf life of 24 months, make the Clearview COMPLETE ideal in any test environment.

Clearview HIV 1/2 STAT-PAK is a simple cassette based format which utilizes a 5 μ L sample for analysis. Sample buffer and 5 μ L collection loops are provided with each kit. The simple cassette based format, small sample size, and long shelf life make the Clearview STAT-PAK ideal in any test environment.

Both tests are 99.7% Sensitive and 99.9% Specific. Controls are sold separately and also have a 24 month shelf life.