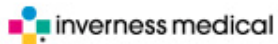


Clearview® Rapid HIV Test Training

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Agenda

- CDC Recommendations
- Inverness Medical Support
- Product Training
 - Clearview[®] COMPLETE HIV 1/2

Changes in CDC HIV Screening Guidelines

OLD

Targeted Testing based on risk assessment (MSM or IDU)
Recommended for those seeking STD treatment.
Voluntary for Prenatal Care
Required written consent & counseling
High prevalence areas $\geq 1\%$

NEW*

Routine, voluntary HIV screening for all persons
age 13-64 in healthcare settings, *not risk based*.
Opt-out screening/part of general consent.
All unknown status at the time of L&D.
No required consent or counseling.



*CDC. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. MMWR 2006; 55 (No. RR-14): 1-17.



Support Materials

Technical Product Information

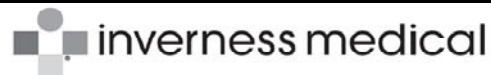
- Quick Reference Cards
- CLIA Packet/CLSI – COMPLETE
- Live Technical Support:
(877) 441-7440

Training Support, English/Spanish

- Interpretation Guides
- Interpretation Quizzes
- Subject Information Notices
- DVD Training Video
- Interactive Flash Demos (*Eng. only*)

Product Information

	STAT-PAK®	COMPLETE	CONTROLS	Accessory Kit
KIT SIZE	20 Tests	25 Tests	1 Set containing : HIV 1 Reactive HIV 2 Reactive Non reactive	36 Pipettes 36 Weight Boats
ORDER NO	92110	92111	92112	92115
CLIA STATUS	Waived for *Whole Blood	Waived* *Whole Blood		
STORAGE CONDITIONS	Room Temperature (46 to 86°F)		Refrigerate (36-46°F)	N/A
SHELF LIFE	24 MONTHS from date of manufacture			No Expiration
SAMPLE	Fingerstick & Venipuncture Whole Blood, Serum or Plasma		For use with Clearview HIV Rapid Tests	For use only with Clearview COMPLETE HIV 1/2
PERFORMANCE	Sensitivity = 99.7% Specificity = 99.9%	<i>For all sample types</i>	Waived* *Whole Blood	
CPT CODE	86703 - \$20.02* Natl. Medicare Avg.			



*2009 Clinical Diagnostic Laboratory Fee Schedule, www.cms.hhs.gov/ClinicalLabFeeSched/



Clearview[®] COMPLETE HIV 1/2



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Materials Required But Not Provided

- Timer or Watch
- Disposable gloves
- Sterile gauze pads
- Antiseptic wipes
- Biohazard disposable container
- Collection devices for specimens (other than fingerstick whole blood specimens)

Prior to Testing

- Read the package Insert completely before using the assay
- Remember to **always observe** “CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens”*

Begin Testing

- Gather testing materials
- Let the test materials come to the operating temperature of 18 - 30°C (64 to 86°F)
- If the test kit is used outside the operating temperature of 18 - 30°C (64 to 86°F), use the kit controls to ensure proper performance of the test
- Set up the workspace with cover and timer
- Put on gloves
- Provide the “subject information” pamphlet to the person being tested.

Handling Precautions for COMPLETE

- Confirm the presence of the sample filter and absorbent pad prior to performing the test. If either is missing, Do Not Use.
- Do not use any test device if the pouch has been perforated.
- If desiccant packet is missing, DO NOT USE, discard test device, and use a new test device.
- Each test device is for single use only.
- Do not use the reagent beyond their expiration date.
- Do not mix reagents from different lot numbers of kits.
- The sampler must be inserted into buffer vial immediately after the sample application.
- Adequate lighting is required to read the test results.

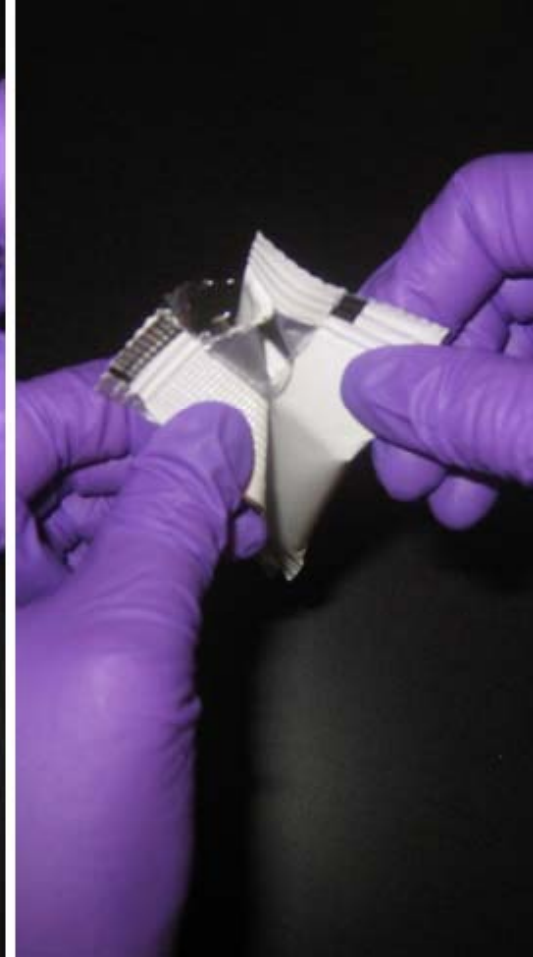
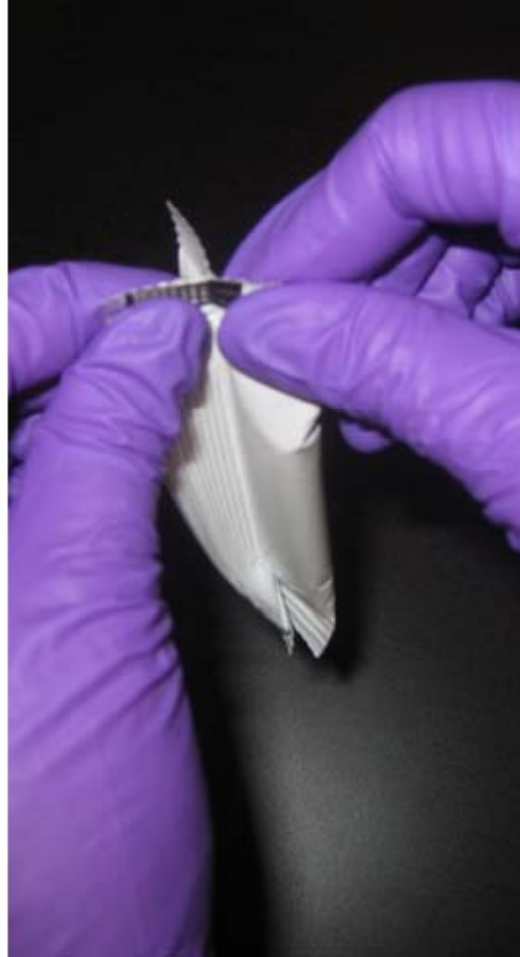
Kit Contents



Each Kit contains 25 tests:

- 1 Product Insert
- 1 Quick Reference Card
- 25 Subject Information Notices
- 25 Disposable Test Stands
- 25 Pouches, each containing:
 - Test Device
 - Buffer Vial attached to Test Device
 - Sterile Safety Lancet
 - Bandage
 - Desiccant Package

Open pouch from black mark



Test Materials



Remove Buffer Cap from Barrel and Place in Stand



Fingerstick Collection



Steps

- Clean finger with antiseptic wipe
- Allow to dry, or wipe with sterile gauze
- Puncture finger with sterile lancet

Wipe away first drop of blood



Collect Sample filling narrow tip of Barrel



Push the Device Tip through the Foil Cover



You will feel three snaps:

Snap 1: through foil

Snap 2: into cap

Snap 3: fully seated

Push Barrel into Cap



You will feel three snaps:

Snap 1: through foil

Snap 2: into cap

Snap 3: fully seated

Fully Seated



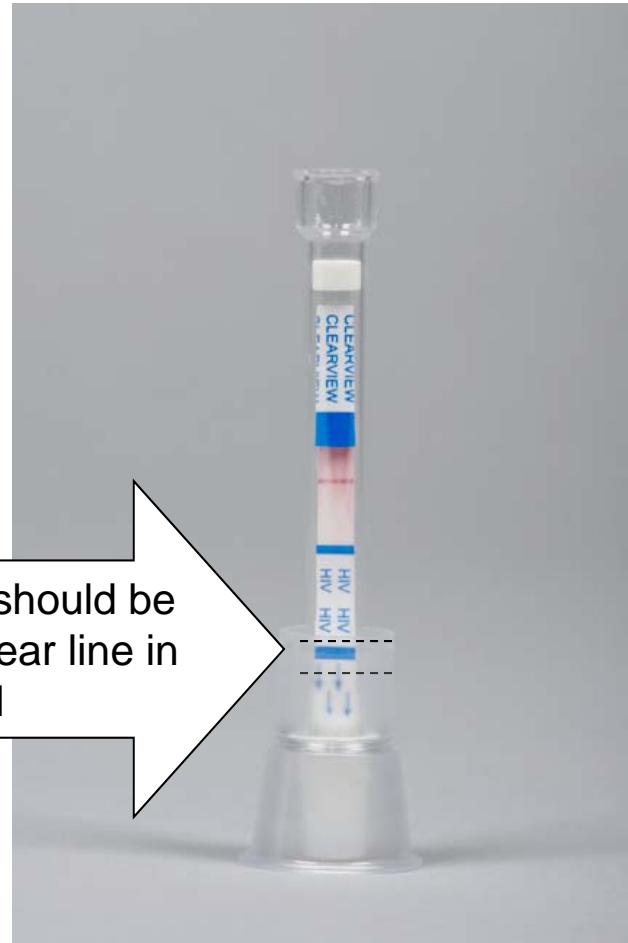
You will feel three snaps:

Snap 1: through foil

Snap 2: into cap

Snap 3: fully seated

Confirm Device is Fully Seated



Bottom blue line should be visible within the clear line in the stand

If you do not see **pink/purple** flow within 3 minutes,
Push Again!
(then **start timer**)

Start timer after the addition of running buffer

Read the Test Result between 15 and 20 minutes



Read the test result between 15 and 20 minutes
(after the device has been fully seated into the buffer vial)

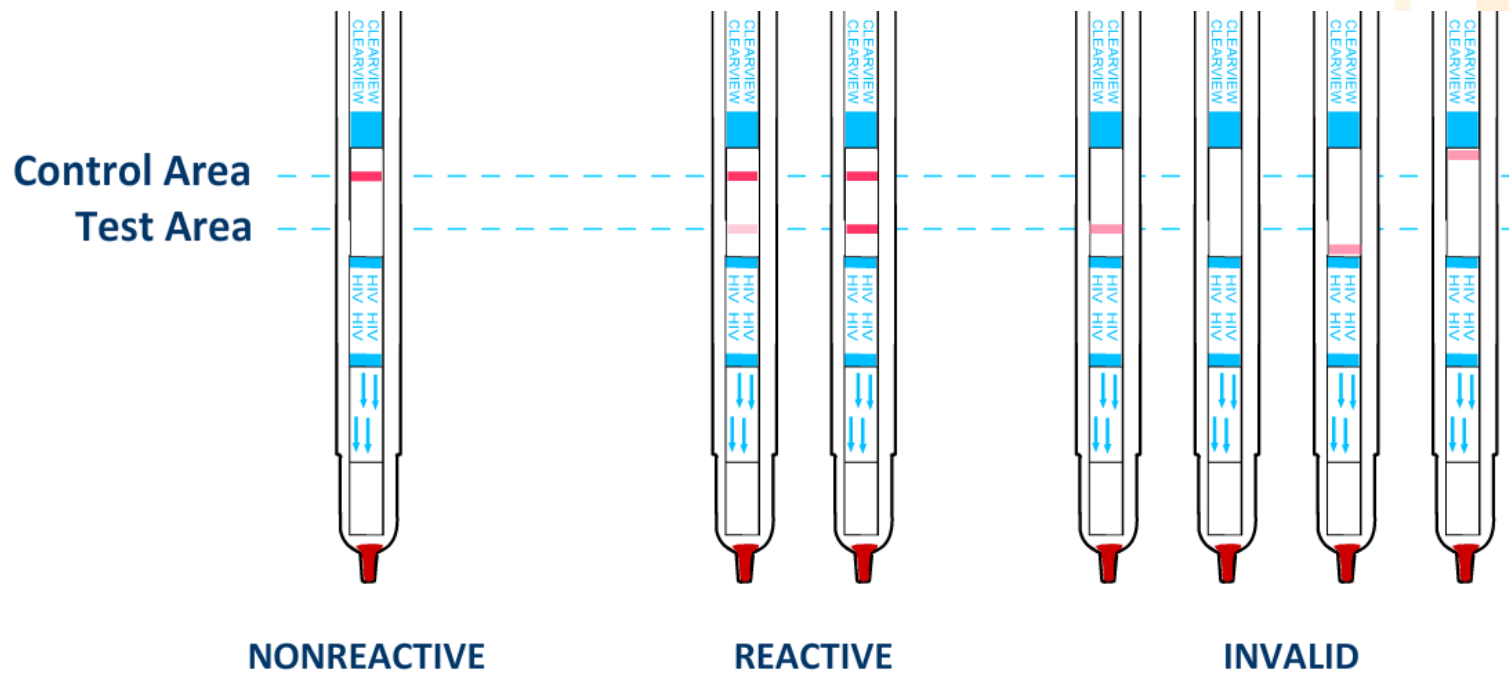


Reactive Test Results may be observed and read earlier than 15 minutes. To verify a Nonreactive Test Result, wait the entire 15 minutes after starting the test. **Do not read results after 20 minutes.**

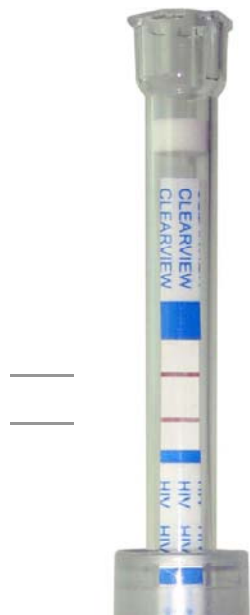


Results Interpretation

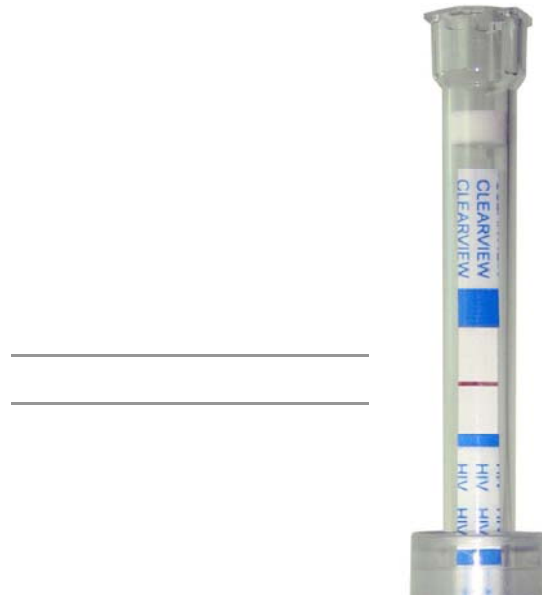
Read the test between 15 and 20 minutes



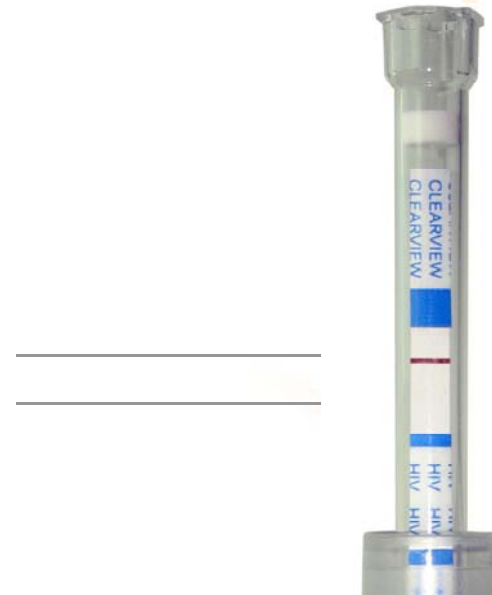
RESULTS?



REACTIVE



INVALID



NONREACTIVE

When to Perform Controls

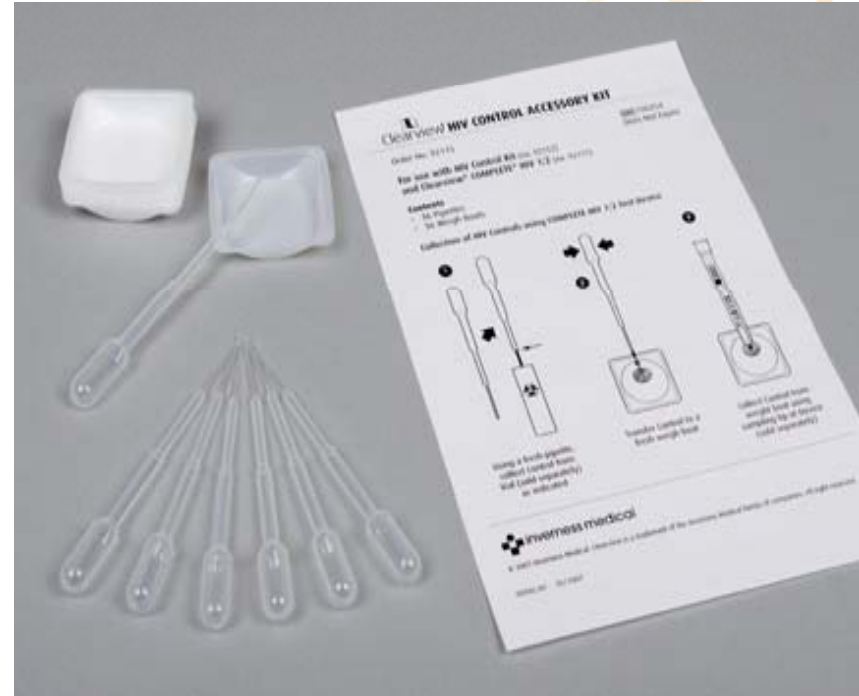
- Each New Operator
- New Lot
- New Shipment
- Local Requirements
- Temperature of test storage falls outside of 8 to 30°C (46 - 86°F)
- Temperature of testing area falls outside of 18 to 30° (64 - 86°F)



Performing Controls with Clearview[®] COMPLETE HIV 1/2

Utilize Accessory Kit (#92115)

1. Use a fresh pipette, collect control from vial
2. Transfer control to a fresh weigh boat
3. Collect control from weight boat using sampling tip of device



Questions?



Thank you!



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