Clearview Complete HIV 1/2
Package Insert Questionnaire

Please answer the questions below.
In the right-hand column, also note the page of the package insert where you found the answer.

We suggest that you underline or highlight the answers in your package insert for future reference.

Question	Package Insert Page #
COMPLEXITY	
1. This **waived** complexity rapid HIV test can be used for the following specimen types (circle all that apply): • Fingerstick whole blood • Venipuncture whole blood • Oral fluid • Plasma • Serum	Page _____
INTENDED USE	
2. This test detects antibodies to (circle all that apply): • HIV-1 • HIV-2 • HBV • HCV	Page _____
RESTRICTIONS	
3. Test providers must use the manufacturer's instructional materials. True False	Page _____
4. Clients must receive the "Subject Information" pamphlet before specimen collection and appropriate information when test results are provided. True False	Page _____
SUMMARY AND EXPLANATION OF THE TEST	
5. The absence of antibody to HIV is absolute proof that an individual is free of HIV infection and incapable of transmitting the virus. True False	Page _____
MATERIALS PROVIDED	
6. Are kit controls and retractable lancets included in the Test Kit? True False	Page _____

WARNINGS	
7. This test should be performed at temperatures in the range of (circle all that apply): • 45 – 100 degrees Fahrenheit • 59 – 80.6 degrees Fahrenheit • 18 – 30 degrees Celsius • 64 – 86 degrees Fahrenheit	Page _____
8. Clients infected with HIV-1 and/or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results. True False	Page _____
SAFETY PRECAUTIONS	
9. Which of the following statements about handling and testing **blood** specimens are correct (circle all that apply): • Handle as if capable of transmitting infectious agents • Wearing disposable gloves is optional • Dispose of used gloves in regular trash • Do not eat, drink, or smoke in the area	Page _____
HANDLING PRECAUTIONS	
10. Which of the following statements about handling instructions are correct (circle all that apply): • Testing Devices can be re-used. • Do not use the test beyond the expiration date. • The expiration date is printed on the pouch. • Do not mix reagents from different kit lot numbers. • Use adequate lighting when reading results	Page _____
STORAGE INSTRUCTIONS	
11. Unused Test Kits can be stored at (circle all that apply): • 59 – 99 degrees Fahrenheit • 46 – 86 degrees Fahrenheit • 8 – 30 degrees Celsius • 15 – 32 degrees Celsius	Page _____
GENERAL TEST PREPARATION	
12. When Kit contents are stored in the refrigerator, they must be brought to room temperature (64 degrees – 86 degrees Fahrenheit / 18 – 30 degrees Celsius. True False	Page _____
SPECIMEN COLLECTION AND TESTING PROCEDURE	
13. If there is no absorbent packet included with the Test Device: • Report it to the manufacturer • Discard the Device and test with a new Pouch • Perform the test using the Test Device with the missing packet.	Page _____
QUALITY CONTROL	

14. A pink-purple line within the control area of the Test Device must be present in all valid tests: True False	Page _____
15. If the built-in Control Line is present, it indicates that (circle all that apply): • A specimen was added to the Vial. • The fluid migrated through the Test Device. • Test is valid whether or not the sample is reactive or non-reactive.	Page _____
TEST RESULT AND INTERPRETATION OF TEST RESULT	
16. A reactive test result means that (circle all that apply): • HIV-1 or HIV-2 antibodies have been detected. • The Control Line was absent; the Test Line was absent. • The Test Line is interpreted as preliminary positive.	Page _____
17. If a test is invalid (circle all that apply): • It can not be interpreted. • Repeat the test with a new pouch and sample. • Report the test as negative.	Page _____
LIMITATIONS OF THE TEST	
18. A non-reactive result can occur if the client has recently been exposed to HIV. True False	Page _____
19. A person who has participated in an HIV vaccine study may develop antibodies to HIV. True False	Page _____