

CORTEZ DIAGNOSTICS, INC.

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InstaTest HIV 1 & 2

Catalog No. 177575-25

INTRODUCTION

Acquired immune deficiency syndrome (AIDS), characterized by the progressive loss of T-helper cell immune functions, is associated with human immunodeficiency viruses (HIVs). HIV-1 is prevalent in the Americas, Europe, Central African nations and other countries to which it spreads. HIV-2, prevalent in West African nations, is now reported in India. Because HIV is not an endogenous retrovirus in humans, the presence of antibodies to HIV is acceptable evidence of infection or prior exposure to this virus. The Cortez HIV 1/2 multi-epitope protein contains all relevant antigenic epitopes of *env* and *gag* common to both HIV-1 and HIV-2.

PRINCIPLE OF THE ASSAY

Multiple epitope fusion HIV-1 and HIV-2 proteins are bound to the membrane of the filtration device. When antibodies to HIV-1 and HIV-2 are present in the test serum, they react with the recombinant proteins and attach to the solid-phase. Non-reactive antibodies are filtered through with the wash buffer. Human IgGs bound on the membrane are visualized by reacting with colloidal gold Protein A. The appearance of TWO RED DOTS (one corresponding to the procedural control and one to the recombinant HIV 1 and 2 proteins) indicates a positive reaction. The appearance of a single red dot corresponding to procedural control indicates a negative reaction.

COMPONENTS

1. Filtration device with recombinant HIV-1 and HIV-2 fusion protein and procedural control.
2. Wash buffer in dropper vial.
3. Colloidal gold conjugate in dropper vial.
4. Fixative solution (optional use).
5. Sample dispenser - to add patient serum.

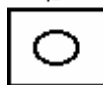
ADVANTAGES

1. Simple to perform - No instruments required.
2. Results in 2-3 minutes.
3. Recombinant HIV-1 and HIV-2 proteins with sensitivity of 99.5% and specificity of 99.5%.
4. Suitable for field use.
5. Stable for 1 year or more.

OBSERVE UNIVERSAL PRECAUTION FOR HANDLING BODY FLUIDS. DECONTAMINATION / DISPOSE OF WASTE APPROPRIATELY.

TEST PROCEDURE

Bring all reagents and the filtration devices to room temperature before performing the assay. (Allow time, approximately 30 seconds, for solutions to be absorbed before proceeding to the next step)

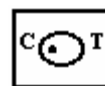


1. Dispense 2 drops of wash buffer.
2. Dispense 2 drops of patient serum.
3. Dispense 2 drops of wash buffer.
4. Dispense 2 drops of colloidal gold conjugate.
5. Dispense 2 drops of wash buffer.
6. In positives, two red dots develop within 1-2 minutes. In negatives, one red dot will appear within 1-2 minutes.

TOTAL TIME = 2-3 minutes



Positive Result



Negative Result

RESULTS

Appearance of TWO RED DOTS in the center of the filtration device indicates positive reactivity. Appearance of ONE RED DOT indicates negative reactivity. Fresh or stored specimen may be used. The color of the dot fades with time. OPTIONAL: Add 1 drop of fixative to the device to stabilize the developed dot.

The Cortez Devices have been sensitized with higher amounts of recombinant antigens for assessing very low positive reactive samples. Positive samples when tested with these devices should generate a stronger color reaction. There is no need to test non-reactive samples with these devices.

Note: Please note that HIV 1&2 Flow-Through Test is a Screening test and any positive result should be confirmed by Western Blot Method or other confirmatory methods.

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