CLINICAL LABS OF HAWAII

Rapid HIV-1/2 Antigen/Antibody Combo

Test Update

As part of our commitment to provide the highest quality medical laboratory service, Clinical Labs of Hawaii is pleased to offer the Rapid Alere Determine™ HIV–1/2 Ag/Ab Combo qualitative immunoassay for the simultaneous detection of Human Immunodeficiency Virus Type 1 (HIV-1) p24 antigen (Ag) and antibodies (Ab) to HIV Type1 and Type 2 (HIV-1 and HIV-2) in human serum or EDTA plasma.

Test Code: **HIVSCP (3966)**

Specimen Requirement: **0.5 ml Serum or EDTA plasma**

Specimen Stability: **Room Temperature: 2 days**
Refrigerated: 7 days

1. The Reactive result is interpreted as Preliminary Reactive for HIV-1 p24 antigen and/or antibodies to HIV-1 and/or HIV-2.
2. Reactive test results are confirmed by HIV 1 Ag w/ HIV 1/2 Abs Combo; 4th Generation HIV Combo with Reflex to HIV 1/2 Ab Differentiation Assay. A Nonreactive result does not preclude the possibility of exposure to HIV or infection with HIV.
3. A person who has HIV-1 p24 antigen or antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus. However, a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.
4. Specimens from individuals infected with HIV-1 and/or HIV-2 who are receiving antiretroviral (ART) therapy may produce false negative test results.
5. Specimens from individuals with Toxoplasma IgG, human anti-mouse antibodies, rheumatoid factor, elevated triglycerides (above 600 mg/dL), herpes simplex virus infection, hospitalized and cancer patients may give false positive test results.

Sample	Dilution	Percent Reactive	95% Confidence Interval
HIV-1 Weakly Reactive	1:1500	97% (58/60)	88.6% - 99.1%
HIV-2 Weakly Reactive	1:2000	95% (57/60)	86.3% - 98.3%
True Negative	N/A	3% (2/62)	0.9% - 11.0%

Alere Determine HIV-1/2 Ag/Ab Combo is not intended for newborn screening or for use with cord blood specimens or specimens from individuals less than 12 years of age. Alere Determine HIV-1/2 Ag/Ab Combo is not intended for use in screening blood, plasma, cell, or tissue donors.

Reference:

1. Package Insert, Alere Determine™ HIV-1/2 Ag/Ab Combo CLSI + More Packet.