HIV-1 Western Blot Kit Orasure Epitope Inc
Do not use this kit as the sole basis of diagnosis of HIV-1 infection.
A Negative result does not exclude the possibility of HIV-1 infection.
http://www.orasure.com/docs/pdfs/products/orasure_hiv_1_western_blot/OraSure-HIV-1-Western-Blot-Package-Insert.pdf
http://www.medkb.com/Uwe/Forum.aspx/aids/2401/Western-Blot-to-confirm-ELISA-not-to-be-used-as-diagnosis
OraSure-HIV-1-Western-Blot-Package-Insert.pdf

Roche The COBAS AmpliPrep TaqMan HIV-1 Test is not intended for use as a screening test for the presence of HIV-1 in blood
http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBlodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm092878.pdf
http://molecular.roche.com/assays/Pages/COBASTaqManHIV-1TestHPS.aspx
hivtest_cobas_ampliprep.pdf

Roche The AMPLICOR HIV-1 MONITOR Test, v1.5
is not intended to be used as a screening test for HIV-1
The AMPLICOR HIV-1 MONITOR Test, v1.5 is not intended to be used as a screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.
http://molecular.roche.com/assays/Pages/COBASAMPLICORHIV-1MONITORTestv15.aspx
http://molecular.roche.com/assays/Pages/AMPLICORHIV-1MONITORTestv15.aspx
hivtest_AMPLICOR_MONITOR_ACTG.pdf

Roche UltraSensitive Roche Monitor Test, v1.5- Boom Extraction
This test is not intended to be used as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection.
There are six diagnostic methods currently in use to detect HIV infection: EIA for antibody detection, Western Blot for the detection of antibody directed against specific viral components, viral culture, EIA for HIV-1 antigen detection, indirect immunofluorescence assay, and radio immunoprecipitaion assay. **Most of these methods, however, do not provide a sensitive and specific method for the direct measurement of HIV-1 viral activity.**
hivtest_Roche_UltraSensitive.pdf

The NucliSens HIV-1 QT assay is not intended to be used as a screening test for HIV-1
The NucliSens HIV-1 QT assay is not intended to be used as a screening test for HIV-1 nor is it to be used as a diagnostic test to confirm the presence of HIV-1 infection.
HIVtest_Biomerieux_NucliSens.pdf

The OraSure HIV-l Western Blot Kit is not intended for use with blood
The OraSure HIV-l Western Blot Kit is not intended for use with blood, serum/plasma or urine specimens, or for screening or reinstating potential blood donors.
http://www.fda.gov/downloads/biologics
bloodvaccines/bloodbloodproducts/approved
products/premarketapprovalspmas/ucm091829.pdf
hivtest_westernblots.pdf

ABBOT HIV test HIVAB HIV-1/HIV-2 (rDNA) EIA
HIVAB HIV-1/HIV-2 (rDNA) EIA is an in vitro enzyme immunoassay for the qualitative detection of antibodies to human immunodeficiency viruses type 1 and/or type 2 (HIV-1/HIV-2) in human serum, plasma, or cadaveric serum.
Sensitivity and Specificity **At present, there is no recognized standard for establishing the presence or absence of antibodies to HIV-1 and HIV-2 in human blood.**
Sensitivity for HIV-1 antibodies was computed based on the clinical diagnosis of AIDS. For HIV-2, sensitivity was expressed in terms of detection rate using investigational confirmation assay results as a basis for comparison. Specificity is based on assay of blood donations from random donors. Sensitivity for HIV-1 antibody was shown to be equivalent to a previously licensed test based on

comparative studies in various clinical groups including AIDS, ARC, and High Risk.
WARNING: FDA has licensed this test kit for use with human serum, plasma, or cadaveric serum specimens only. Use of this licensed test kit with specimens other than those specifically approved for use with this test kit may result in inaccurate test results.
http://www.fda.gov/downloads/BiologicsBlood
Vaccines/SafetyAvailability/TissueSafety/ucm095983.pdf
hivtest_Abbot_HIVAB.pdf

BioLytical Laboratories Insti HIV-1/HIV-2 antibody test
Absence of antibodies to HIV does not indicate that an individual is absolutely free of HIV-1 or HIV-2; HIV has been isolated from seronegative individuals prior to seroconversion.
http://www.biolytical.com/insti_doc/CEInsert.pdf
hivtest_biolytical.pdf

BioLytical Laboratories Insti HIV-1/HIV-2 antibody test
The INSTI HIV-1/HIV-2 assay has not been validated for detection of antibodies to HIV-1 Group O or N subtypes.
There is no single standard for detecting the sensitivity or specificity of an antibody test for HIV in human sera, plasma or whole blood. However, the generally accepted method to express the sensitivity and specificity of a given test in terms of the detection rate is to compare results to approved supplemental assay results, such as ELISA and Western Blot.
http://www.biolytical.com/insti_doc/CEInsert.pdf
hivtest_biolytical.pdf

ELISA test
"At present there is no recognized standard for establishing the presence or absence of HIV-1 antibody in human blood." (Abbott Laboratories, ELISA HIV Antibody Test Insert, section "Sensitivity and Specificity")

ELISA Test
"At present there is no recognized standard for establishing the presence or absence of HIV-1 antibody in human blood." (Abbott Laboratories, ELISA HIV Antibody Test Insert, section "Sensitivity and Specificity") "EIA testing cannot be used to diagnose AIDS... The risk of an asymptomatic person with a repeatedly reactive serum developing AIDS or an AIDS-related condition is not known." (Abbott Laboratories, ELISA HIV Antibody Test Insert, section "Limitations of the Procedure") "Clinical studies continue to clarify and refine the interpretation and medical significance of the presence of antibodies to HIV-1." (Abbott Laboratories, ELSA HIV Antibody Test Insert, section "Limitations of the Procedure")

Western Blot Test
"Do not use this kit as the sole basis of diagnosis of HIV-1 infection." (Eptope, Inc., Western Blot HIV Antibody Test Insert, section "Limitations of the Procedure") “The clinical implications of antibodies to HIV-1 in an asymptomatic person are not known.” (Calypte, Cambridge Biotech HIV-1 Western Blot Kit, section “Limitations of the Serum and Plasma Procedure”)

PCR "Viral Load" Test
"The AMPLICOR HIV-1 MONITOR test, is not intended to be used as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection." (Roche, Amplicor HIV-1 Monitor Test Kit, section "Intended Use")