

FDA-APPROVED HIV TESTS

- [Abbott HIVABTM HIV-1/HIV-2 \(rDNA\) EIA](#)

A person who has antibodies to HIV-1 is **presumed to be infected with the virus**... Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate... AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically... EIA testing cannot be used to diagnose AIDS...”

RECALL 23 Nov 2010 – Reaction Tray lots with ABBOTT PRISM HBsAg and/or ABBOTT PRISM HIV O Plus and to contact ABBOTT for an alternate lot of ABBOTT PRISM Reaction Trays.

RECALL 23 Sep 2010 – Calibration failures when PRISM-HIV-1 Group O Positive Assay Control (2) (Symbol: OPC) is out of specification high.

- [Abbott HIVAB HIV-1 EIA](#)

A person who has antibodies to HIV-1 is **presumed to be infected with the virus**... Clinical correlation is indicated... to decide whether a diagnosis of HIV infection is accurate.

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RECALL 23 Sep 2010 – Calibration failures when PRISM-HIV-1 Group O Positive Assay Control (2) (Symbol: OPC) is out of specification high.

- [Abbott HIVAG-1 Monoclonal \(1989\)](#)

It is intended to be used as an **aid in the diagnosis and prognosis of patients with HIV-1 infection.**

[RECALLED \(1999\)](#)

Device not to be sold or distributed by Abbott after December 6, 1999 in the United States, **but are available Internationally.** No longer shipped to US customers ([2003](#)).

[Plasma Donor Screening](#)

[Recommendations \(1995\)](#)

... specimens that are repeatedly reactive in the screening assay but which are negative or indeterminate (invalid) by the criteria set forth for neutralization by the manufacturer **should be considered**

[INDETERMINATE.](#)

[Adverse Event Report \(1999\)](#)

... “the usefulness of p24 antigen as a marker of viral load is limited since the antigen is detectable in only 20% of asymptomatic patients...”

[DOJ Consent Decree \(1999\)](#)

... permanent injunction involves the company’s diagnostic devices division... **In order to protect the public health, [FDA sought action by the Department of Justice.](#)**

PRE-SUME /pri'zum/ verb, -sumed, -sum·ing.
verb (used with object)
1. **to take for granted, assume, or suppose:** *I presume you're tired after your drive.*
2. Law - **to assume as true in the absence of proof to the contrary.**
3. **to undertake with unwarrantable boldness.**
4. to undertake (to do something) without right or permission: to presume to speak for another.

verb (used without object)
5. **to take something for granted; suppose.**
6. **to act or proceed with unwarrantable or impertinent boldness.**
7. **to go too far in acting unwarrantably or in taking liberties** (usually followed by on or upon): Do not presume upon his tolerance.

Synonyms
presuppose. 6. **overstep.**

- [Abbott HIVAG-1 \(1989\)](#)

It is intended to be used as an **aid in the diagnosis and prognosis of patients with HIV-1 infection.**

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[RECALL 23 Sep 2010](#) – Calibration failures when PRISM-HIV-1 Group O Positive Assay Control (2) (Symbol: OPC) is out of specification high.

- [Abbott HIVAB™ HIV-1/HIV-2 \(rDNA\) EIA](#)

A person who has antibodies to HIV-1 is **presumed to be infected with the virus...** Clinical correlation is indicated... to decide whether a diagnosis of HIV infection is accurate.

[RECALL 23 Nov 2010](#) – Reaction Tray lots with ABBOTT PRISM HBsAg and/or ABBOTT PRISM HIV O Plus and to contact ABBOTT for an alternate lot of ABBOTT PRISM Reaction Trays.

[RECALL 23 Sep 2010](#) – Calibration failures when PRISM-HIV-1 Group O Positive Assay Control (2) (Symbol: OPC) is out of specification high.

- [Abbott Prism HIV O-Plus](#)

The presence of HIV-1 and/or HIV-2 antibodies is not a diagnosis of AIDS... A person who has antibodies to HIV-1 is [presumed to be infected with the virus...](#) **Clinical correlation is indicated** with appropriate counseling, medical evaluation, and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

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- [ARCHITECT HIV Ag/Ab Combo](#)

The ARCHITECT HIV Ag/Ab Combo assay result and supplemental **assay results should be interpreted in conjunction with the patient's clinical presentation, history, and other laboratory results...** An individual who has antibodies to HIV is **presumed to be infected with the virus...** **Clinical correlation is indicated** with appropriate counseling, medical evaluation... [to determine whether a diagnosis of HIV infection is accurate.](#)

- [Bio-Rad Multispot HIV-1/HIV-2 Rapid Test](#)

A person who has antibodies to HIV-1 is **presumed to be infected with the virus...** Clinical correlation is indicated... to decide whether a diagnosis of HIV infection is accurate.

[RECALL 6 June 2008](#) – The typographical error will be corrected for future shipments of Multispot.

[RECALL 13 May 2004](#) – Software error was contained on the ETI-LAB Applications disk for programming the BioRad HIV-1/HIV-2 Plus O assay. The error induced specimen and conjugate incubation temperatures for the assay to remain at ambient temperature rather than the required 37°C temperature.

- [Calypte HIV-1 Urine EIA](#)

False positive results occur more frequently [when testing urine specimens](#) compared to blood specimens... Supplemental testing of repeatedly reactive urine specimens should be performed using only the Cambridge HIV-1 Western Blot Kit before the HIV-1 status of an individual can be determined.

- [Cambridge Biotech HIV-1 Western Blot Kit](#)

Slight ambiguities exist in the designation of the molecular weights of the HIV-1 antigens.... a diagnosis of Acquired Immunodeficiency Syndrome or AIDS can only be made **clinically** if a person meets the case definition of AIDS established by the Centers for Disease Control... [The clinical implications of antibodies to HIV-1 in an asymptomatic person are not known.](#)

- [Chembio HIV 1/2 STAT-PAK™ Assay](#)

The Chembio HIV 1/2 STAT-PAK™ test suggests the presence of antibodies to HIV-1 and/or HIV-2 in the specimen... AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically... [A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus... and may or may not be infected with HIV.](#)

- [COBAS® AmpliScreen HIV-1 Test, version 1.5](#)

This (test) is intended to be **used in conjunction with licensed tests for detecting antibodies to HIV-1.** (It) [may not be used to replace HIV-1 antibody detection tests such as EIA or Western Blot.](#)

[RECALL 8 June 2010](#) – HIV-1 MONITOR Quantitation Standard (HIM QS) vials in the COBAS AMPLICOR HIV-1 MONITOR Test, v1.5 generate low or no absorbance signals. This results in invalid HIM QS results.

[RECALL 27 Oct 2009](#) – HIV-1 MONITOR Quantitation Standard (QS) copy number encoded on the HIV-1 MONITOR Multi-Reagent (CS3) Cassette, packaged within the COBAS ® AmpliPrep/ COBAS ® AMPLICOR HIV-1 MONITOR Test, US IVD.

[RECALL 24 Jun 2004](#) – Roche has confirmed increased frequency of occurrence of "blue foci" with the Avidin-Horseradish Peroxidase (AV-HRP) Conjugate Lot E09659.

- [Coulter HIV-1 P24 AG Assay](#)

AIDS and AIDS-related conditions are syndromes that **can only be established by clinical diagnosis**... A person who has HIV-1 P-24 antigen **is presumed to be infected with the virus**... Medical diagnosis and evaluation should include confirmation of all test results using a freshly drawn specimen. .. the HIV-1 p24 Antigen ELISE Test System and the HIV-1 p24 Antigen Neutralization Kit [may aid in the clinical evaluation of disease progression](#).

- [Fluorognost HIV-1 IFA](#)

The presence or absence of antibodies to HIV-1 in a test specimen is determined by [the subjective comparison and differentiation](#) of the intensity and the pattern of fluorescence between the uninfected control cells and the HIV-1 infected cells... An individual with a POSITIVE IFA for antibodies to HIV-1 should be referred for medical evaluation, which may include additional testing. The intensity of the fluorescence observed in HIV-1 positive specimens does not bear a strict correlation to the antibody titer, [or to the presence of antibody](#) directed against particular HIV-1 antigens.

- [Genetic Systems rLAV – Bio-Rad Laboratories](#)

A person who has antibodies to HIV-1 is [presumed to be infected with the virus](#)... Clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

[RECALL 6 June 2008](#) – The typographical error will be corrected for future shipments of Multispot.

[RECALL 13 May 2004](#) – Software error was contained on the ETI-LAB Applications disk for programming the BioRad HIV-1/HIV-2 Plus O assay. The error induced specimen and conjugate incubation temperatures for the assay to remain at ambient temperature rather than the required 37°C temperature.

- [Genetic Systems HIV-1 HIV-2 Peptide \(Plus O\) EIA](#)

It is indicated... **as an aid in the diagnosis of infection** with HIV-1 and/or HIV-2... A person who has antibodies to HIV-1 **is presumed to be infected with the virus**... Clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing **to decide whether a diagnosis of HIV infection is accurate**.

RECALL 6 June 2008 – The typographical error will be corrected for future shipments of Multispot.

RECALL 13 May 2004 – Software error was contained on the ETI-LAB Applications disk for programming the BioRad HIV-1/HIV-2 Plus O assay. The error induced specimen and conjugate incubation temperatures for the assay to remain at ambient temperature rather than the required 37°C temperature.

- [Genetic Systems HIV-2 EIA](#)

(The) use of this test is “as an aid in the diagnosis of potential infection with Human Immunodeficiency virus Type 2 (HIV-2).” ... the FDA currently does not recommend routine use of the Genetic Systems HIV-2 EIA in blood establishments. (21 June 1990)

RECALL 6 June 2008 – The typographical error will be corrected for future shipments of Multispot.

RECALL 13 May 2004 – Software error was contained on the ETI-LAB Applications disk for programming the BioRad HIV-1/HIV-2 Plus O assay. The error induced specimen and conjugate incubation temperatures for the assay to remain at ambient temperature rather than the required 37°C temperature.

- [Genetic Systems HIV-1 Western Blot Bio-Rad](#)

A person who has antibodies to HIV-1 is **presumed to be infected with the virus... Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.**

RECALL 6 June 2008 – The typographical error will be corrected for future shipments of Multispot.

RECALL 13 May 2004 – Software error was contained on the ETI-LAB Applications disk for programming the BioRad HIV-1/HIV-2 Plus O assay. The error induced specimen and conjugate incubation temperatures for the assay to remain at ambient temperature rather than the required 37°C temperature.

- [Home Access HIV-1 Test System](#)

The Home Access- HIV Test System... **is intended to provide education** about HIV infection and risk reduction and to offer counseling medical/psychosocial referrals, and assistance in partner notification.

RECALL 6 Oct 2006 – Lancets may not be sterile.

- [INSTI™ HIV-1 Antibody Test](#)

The presence of HIV antibodies indicates past exposure to HIV but is not a diagnosis of AIDS, which can only be made by a physician. **A person who has antibodies to HIV-1 is presumed to be infected with the virus...** Clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

- [Maxim HIV-1 Urine EIA](#)

False positive results... occur more frequently when testing urine specimens compared with testing blood specimens. **Supplemental testing... should be performed using only the [Cambridge Biotech HIV-1 Urine Western Blot Kit](#) before the HIV-1 status of an individual can be determined.**

- [Murex SUDS HIV-1 Test](#)

... a person who has antibodies to HIV-1 is [presumed to be infected with the virus](#)... The SUDS HIV-1 Test alone cannot be used to diagnose AIDS, even if the recommended investigation of reactive specimens suggests a high probability that the antibody to HIV is present.

- [NucliSens HIV-1 QT](#)

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](#). As with any diagnostic test, results from the NucliSens HIV-1 QT assay should be interpreted [with consideration of all clinical and laboratory findings](#).

RECALL 17 May 2004 – Some components of the NucliSens Automated Isolation reagents contain the raw material guanidine isothiocyanate (GuSCN). Some irregularities have been observed with one lot of this raw material, which may affect the sensitivity and accuracy of assays, such as the NucliSens HIV QT.

- [OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test](#)

A reactive result using the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test **suggests the presence of HIV-1 and/or HIV-2 antibodies in the specimen.** The (test) is **intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2.** AIDS and AIDS-related conditions are [clinical syndromes and their diagnosis can only be established clinically](#).

- [OraQuick® Rapid HIV-1 Antibody Test](#)

A Reactive result... **suggests the presence of anti-HIV-1 antibodies** in the specimen. The OraQuick® Rapid HIV-1 Antibody Test is **intended as an aid in the diagnosis of infection with HIV-1**. A Reactive result using the OraQuick® Rapid HIV-1 Antibody Test [suggests the presence of anti-HIV-1 antibodies in the specimen...](#) (It) is **intended as an aid in the diagnosis of infection** with HIV-1.

- [OraSure HIV-1 Western Blot Kit](#)

A person who has antibodies to HIV-1 is [presumed to be infected with the virus...](#) Clinical correlation is indicated... to decide whether a diagnosis of HIV infection is accurate... **Do not use this kit as the sole basis of diagnosis of HIV-1 infection.**

- [Procleix ® HIV-1/HCV Assay](#)

The (test) may be used as an aid in the diagnosis of HIV-1 infection (and) can be considered a supplemental test that confirms HIV-1 infection for specimens that are repeatedly reactive on a licensed donor screening test... The (test) [may not be used to replace antibody-detection tests such as an EIA test for HIV-1 or HCV.](#)

[RECALL 18 Jan 2005](#) – Procleix HIV-1 / HCV Assay, Master Lot 401254, was found to contain an elevated level of copper. The source of the elevated copper was the raw material, Trehalose, which is also a component of the Enzyme Reagent. The increase in copper may affect kit performance.

- [Reveal™ Rapid HIV -1 Antibody Test](#)

A Reactive test result using the Reveal™ Rapid HIV -1 Antibody Test [suggests the presence of anti-HIV-1 antibodies in the specimen.](#) The (test) is intended to be used **as an aid in the diagnosis of infection with HIV -1**. AIDS and AIDS-related conditions are **clinical syndromes and their diagnosis can only be**

established clinically. Results of the (test) should not be used in isolation, but **in conjunction with the clinical status, history, and risk factors of the individual being tested...**

- [Roche Amplicor HIV-1 Monitor Test](#)

The test is intended for use **in conjunction with clinical presentation** and other laboratory markers as an indicator of disease prognosis by measuring baseline HIV-I RNA levels or to monitor the effects of antiretroviral drug therapy on HIV-I RNA levels. 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.](#)

[RECALL 8 June 2010](#) – HIV-1 MONITOR Quantitation Standard (HIM QS) vials in the COBAS AMPLICOR HIV-1 MONITOR Test, v1.5 generate low or no absorbance signals. This results in invalid HIM QS results.

[RECALL 27 Oct 2009](#) – HIV-1 MONITOR Quantitation Standard (QS) copy number encoded on the HIV-1 MONITOR Multi-Reagent (CS3) Cassette, packaged within the COBAS ® AmpliPrep/ COBAS ® AMPLICOR HIV-1 MONITOR Test, US IVD.

[RECALL 24 Jun 2004](#) – Roche has confirmed increased frequency of occurrence of "blue foci" with the Avidin-Horseradish Peroxidase (AV-HRP) Conjugate Lot E09659.

- [Sure Check® HIV 1/2 Assay](#)

A Reactive Test Result using the... test [suggests the presence of antibodies to HIV-1 and/or HIV-2 in the specimen.](#) The (test) is **intended as an aid in the diagnosis of infection with HIV-1/2.** AIDS and AIDS-related conditions are clinical syndromes and their diagnosis **can only be established clinically.** A person who has antibodies to HIV-1 or HIV-2 is **presumed to be infected with the virus...**

- [Trugene HIV-1 Genotyping Kit](#)

The TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System [is not indicated for use as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection](#). FDA identified risks to health associated with the use of the device included inaccurate detection of resistance mutations present in a patient's viral swarm. **This could result in continuance of therapies that are no longer appropriate or it could result in changes to new inadequate therapies.** In both cases **the patient's viral load may increase, worsening the clinical prognosis and accelerating the development of drug resistant viruses.** [Patients may be needlessly subjected to serious, deleterious side effects of inappropriate antiviral drugs. Furthermore, failure of the assay to give any results at all \(sequence failure\) can deny or delay beneficial, appropriate therapies, which may also result in high viral loads.](#)

- [UltraQual HIV-1 RT-PCR assay](#)

The (test)... is indicated for the qualitative detection of HIV-1 ribonucleic acid (RNA) **in pools of human Source Plasma...** This method may be used as an alternative to licensed HIV-1 p24 antigen tests [for screening Source Plasma](#).

- [Uni-Gold™ Recombigen® HIV](#)

A Reactive result... suggests the presence of anti-HIV-1 antibodies in the specimen. (The test) is intended as an aid in the diagnosis of infection with HIV-1. [AIDS and AIDS-related conditions are clinical symptoms and their diagnosis can only be established clinically.](#)

[RECALL 12 Feb 2008](#) - There is a potential of false positive results on negative patients samples, while negative results remain true negatives. Customers are instructed to discontinue use of this lot and a re-evaluation of positive patient results is recommended if they have not been confirmed with a highly specific second tier test such as Western Blot.

- [Versant® HIV-1 RNA 3.0 Assay](#)

This test is-intended for use **in conjunction with clinical presentation** and other laboratory markers of disease status as an aid in management of individuals infected with HIV-1. (It) is **not intended for use as a screening assay for HIV infection or as a diagnostic test to confirm the diagnosis of HIV infection.**

- [Vironostika® \(Avioq\) HIV-1 Microelisa System](#) ¹

In most settings, a person who has antibodies to HIV-1 is **presumed to be infected with the virus...** AIDS and AIDS-related conditions are clinical syndromes and their **diagnosis can only be established clinically.**

RECALL 10 Apr 2007 - bioMérieux, Inc is initiating a voluntary recall of the Vironostika HIV-1 Microelisa System for Lot# 160354.

RECALL 20 July 2006 – Reagent appears cloudy and/or flocculent. Use of cloudy EnzAbody could possibly increase risk of inaccurate HIV test results in patients and therefore should be avoided.

- [Vironostika \(Avioq\) HIV-1 Oral Fluid HIV Microelisa System](#)

False negative results occur more frequently when testing OraSure® HIV-1 specimens **compared with testing blood specimens...** If the specimen is repeatedly reactive, the probability that antibodies to HIV are present is high... Specimens found repeatedly reactive by ELISA and positive by **additional, more specific tests are considered positive for antibodies to HIV-1. Clinical correlation is indicated... to decide whether a diagnosis of HIV infection is accurate.**

¹ Test manufacturer [bioMérieux warns](#): “Because of the consequences associated with an HIV positive diagnosis and the possibility of false positives, it is absolutely necessary for a confirmation test to be performed before a positive diagnosis is made... The information contained in this booklet is given as a guideline only and is not intended to be exhaustive. It in no way binds BioMérieux to the diagnosis or the treatment prescribed by the physician.”

[RECALL 10 Apr 2007](#) - bioMerieux, Inc is initiating a voluntary recall of the Vironostika HIV-1 Microelisa System for Lot# 160354.

[RECALL 20 July 2006](#) – Reagent appears cloudy and/or flocculent. Use of cloudy EnzAbody could possibly increase risk of inaccurate HIV test results in patients and therefore should be avoided.

- [Vironostika® HIV-1 Plus O Microelisa System](#)

...should be confirmed with a confirmatory test, e.g., Western Blot testing... [Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.](#)

[RECALL 10 Apr 2007](#) - bioMerieux, Inc is initiating a voluntary recall of the Vironostika HIV-1 Microelisa System for Lot# 160354.

[RECALL 20 July 2006](#) – Reagent appears cloudy and/or flocculent. Use of cloudy EnzAbody could possibly increase risk of inaccurate HIV test results in patients and therefore should be avoided.

- [ViroSeq™ HIV-1 Genotyping System](#)

The ViroSeq™ HIV-1 Genotyping System is used for **identifying mutations in the pol gene** of the human immunodeficiency virus, type one (HIV-1).

CD4 TEST KITS

- [FlowCollect™ Human CD4/CD8 T Cell Kit](#)

“FOR RESEARCH USE ONLY – Not for use in diagnostic procedures.”

- [CD154/IL5/CD4 Detection Kit](#)

Unless otherwise specifically indicated, all Miltenyi Biotec products and services are **for research use only and not for diagnostic or therapeutic use.**

- [Dynal® T4 Quant Kit](#)

Dynal T4 Quant Kit is ideal for quick and easy quantification of human CD4+ T cells after monocyte depletion... Immunomagnetic cell separation using Dynal T4 Quant Kit enables a rapid and direct quantification of CD4+ T cells... Isolate CD4+ T cells from monocyte-depleted blood within 10 minutes using **Dynabeads CD4...** (see next) (NO EVIDENCE OF FDA APPROVAL)

- [Dynabeads® CD4](#)

This product is **for research use only**. Not intended for any animal or human therapeutic or diagnostic use unless otherwise stated.

- [MultiTEST CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC](#)

Laboratories must establish their own normal reference ranges for the MultiTEST CD3/CD8/CD45/CD4 reagent parameters that can be affected by sex of patient, age of patient, and preparative technique. Race of patient and individual variations of epitope expression can also have an effect, although sufficient data is not available to establish this. Age, sex, clinical characteristics, and race of patients should be known when a reference range is determined. [Reference ranges provided are for information only.](#)

- [Guava® Express CD3/CD4 Reagent Kit](#)

This product is for Research Use Only and is not intended for diagnostic use... Guava Technologies, Inc. is [not liable for property damage, personal injury, or economic loss caused by the use of this product.](#)

- [PointCare Now](#)

Has not received FDA clearance. Current PointCare AuRICA system using CD4 gold nanoparticles is FDA cleared.

TEST FACILITIES

Quest Diagnostics

- [\\$302 Million - Misbranded Test Kit Scandal \(Apr 2009\)](#)

Quest Diagnostics Incorporated (“Quest”) and its subsidiary, Nichols Institute Diagnostics (“NID”), have entered into a global settlement with the United States to resolve **criminal and civil claims** concerning various types of diagnostic test kits that NID manufactured, marketed and sold to laboratories throughout the country until 2006. The payment of \$302 million will resolve these allegations and represents one of the largest recoveries ever in a case involving a medical device.

- [HIV Viral Loads \(May 2006\)](#)

In a routine blood draw at quest diagnostics, a comparison of the three tests showed an **unacceptable difference between the three tests**.

LabCorp

- [Warning Letter \(Oct 2007\)](#)

FDA has determined that the PreGen-Plus assay is a test that was designed, developed, validated, and marketed by EXACT Sciences rather than a test that was developed and validated by LabCorp. As such, **this device is not within the scope of laboratory developed tests** over which the agency has traditionally applied enforcement discretion... **no clearance or approval for the PreGen-**

Plus assay, therefore **it is adulterated...** and it is not the subject of an approved premarket approval... This device is also misbranded...

- [Warning Letter \(29 Sep 2008\)](#)

FDA has determined that the OvaSure™ is a test that was designed, developed, and validated by investigators at Yale University and not LabCorp... This device is not within the scope of laboratory developed tests over which the agency has traditionally exercised enforcement discretion. ... this product is a device because it is intended for use in the diagnosis of disease or other conditions, or in the cure, treatment, prevention, or mitigation of disease. .. you do not have marketing clearance or approval from the FDA, marketing OvaSure™ is in violation of the law. The device is adulterated... misbranded... because you did not notify the agency of your intent to introduce the device into commercial distribution...

- [Adverse Event Report \(21 Aug 2007\)](#)

This is in reference to labcorp growth hormone, serum test number 004275.



NOTE: This document was inspired and produced by Christine Johnson, who compiled [her initial list](#) for *Continuum* in 1996. Without her assistance and help from OMSJ’s associates, this report would not have been possible.