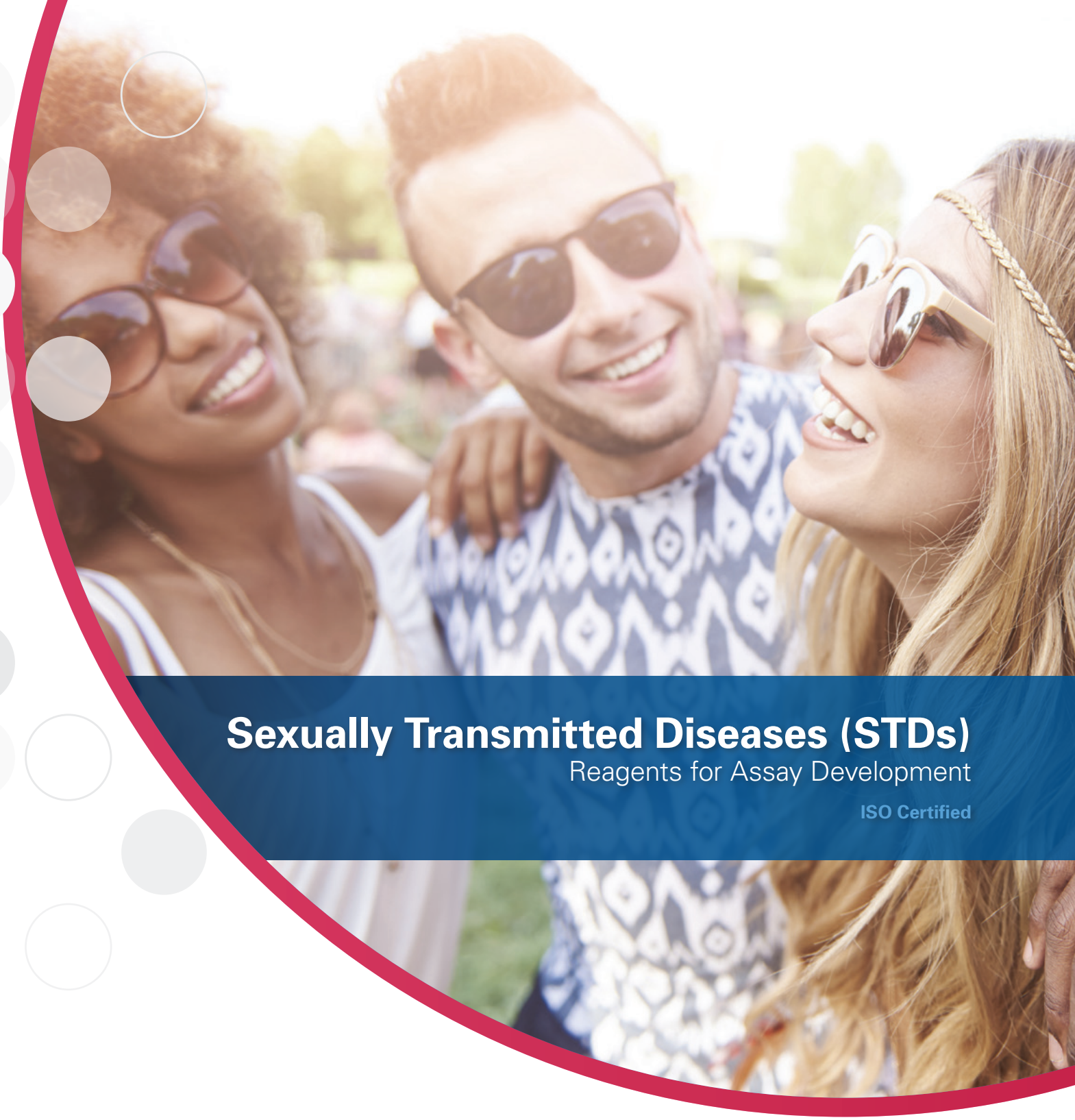

Sexually Transmitted Diseases (STDs)

Reagents for Assay Development

ISO Certified

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www.MeridianLifeScience.com

STD Diagnostic Testing Overview

Sexually transmitted diseases (STDs) are a major global cause of acute illness, infertility, long-term disability and death, with serious medical and psychological consequences to millions of men, women and infants. Today, over 30 bacterial, viral and parasitic pathogens have been identified that can be transmitted sexually.

STDs are generally acquired by sexual contact specifically through blood, semen, or vaginal and other bodily fluids. Many STDs (chlamydia, gonorrhea, hepatitis, HIV, papillomavirus, herpes and syphilis) can also be transmitted non-sexually such as from mother to infant during pregnancy or childbirth, or through blood transfusions, or shared needles. Many STDs cause no symptoms, therefore an infection may go unnoticed until complications occur. Worldwide, more than 1 million people acquire a STD every day which has a profound impact on sexual and reproductive health globally. STDs rank among the top five disease categories for which adults seek health care.

ESTIMATED NEW CASES OF CURABLE SEXUALLY TRANSMITTED INFECTIONS (GONORRHEA, CHLAMYDIA, SYPHILIS AND TRICHOMONIASIS) **BY WHO REGION, 2008**

There are more than 30 known pathogens that cause STDs which include bacteria (gonorrhea, syphilis, chlamydia), parasites (trichomoniasis), and viruses (HPV, herpes, HIV). Each year, an estimated 500 million people become infected with one of the four "classic" STDs (chlamydia, gonorrhea, syphilis and trichomoniasis). In addition, more than 530 million people are infected with genital herpes (HSV-2) and more than 290 million women have a human papillomavirus (HPV) infection.

One of the major concerns regarding the control of STDs is that the majority of infections remain asymptotic and infected individuals can unknowingly pass on the infection for several years. In addition, without proper diagnosis and treatment, STDs can have serious consequences beyond the immediate impact of the infection itself, such as:

- An increased risk (more than 3x) of acquiring HIV
- Stillbirth, neonatal death, low-birth-weight and prematurity, sepsis, pneumonia, neonatal conjunctivitis, and congenital deformities in infected pregnant woman
- Cervical cancer in women
- Infertility

SEXUALLY TRANSMITTED DISEASE (STD) DIAGNOSTIC ASSAYS

Early and rapid diagnosis of STDs increases the chance to limit effects of the disease. Since many people infected by an STD have little or no symptoms of their infection, they put others (including unborn children for pregnant mothers) at risk.

There are five main methods for the diagnosis of STDs which include (1) culture (2) microscopy (3) detection of antigens or enzymes (4) detection of nucleic acid sequences (NAAT) and (5) detection of antibodies. Of the five approaches, the assays that provide the most rapid diagnosis have gained the most acceptance. As a result, this has largely limited the traditional use of culture and increased development efforts on rapid tests using microscopy, detection of antibodies by rapid serologic methods, and specific detection of cellular components, including antigens, enzymes, or nucleic acid sequences (especially with amplification).

Company Overview

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LIFE DISCOVERED. LIFE DIAGNOSED.

Meridian Life Science, Inc. is a leading large scale manufacturer of:

- Antibodies
- Viral antigens
- Recombinant proteins
- PCR enzymes
- Nucleotides
- Critical assay reagents

Meridian has been providing innovative life science solutions and building trusted partnerships for over 40 years. Meridian's focus is to offer products and services that help to advance the development of diagnostic assays and vaccine development.

- Commercial scale manufacturing of antigens and antibodies with protein purification expertise
- Full line of immunoassay reagents, including antigens, antibodies and blockers
- Large scale production of reagents for molecular assays
- Technical support with assay development experience
- Dedicated R&D and manufacturing teams
- Robust and mature Quality System

ISO certified

Extensive Capabilities and Services

Immunodiagnostics

- Antigens & Antibodies
- Recombinant Proteins
- Blocking reagents

Molecular Diagnostics

- Nucleotides
- enzymes
- qPCR/PCR reagents
- NGS reagents

Contract Services

- Antigens & Antibodies
- Cell & Viral Banking
- PCR/qPCR Assay Development

Global Presence

MERIDIAN BIOSCIENCE, INC.
Parent Company | Founded in 1977 | Nasdaq: VIVO
Headquartered in Cincinnati, OH | 750+ Employees | Presence in 70+ Countries.

North America

MEMPHIS, TN
Viral Antigens
Recombinant Proteins
In Vitro Antibodies
PCR Reagents

BILLERICA, MA
Magellan, Leadcare

BOCA RATON, FL
In Vivo Antibodies

QUEBEC, CANADA
GenePOC, Molecular Diagnostics

EMEA

LONDON, UK
PCR Manufacturing & Sales
PCR /qPCR Molecular Reagents

LUCKENWALDE, GERMANY
Large Scale Nucleotides
PCR Enzymes
Manufacturing

PARIS, FRANCE
EU Diagnostics Sales & Admin

WATERLOO, BELGIUM
EU Diagnostics Sales & Admin

MILAN, ITALY
EU Diagnostics Sales & Admin

MODI'IN, ISRAEL
BreathID® Breath Test Systems

Asia Pacific

SYDNEY, AUSTRALIA
Warehouse & Sales

BEIJING, CHINA
Wholly Owned
Subsidiary

Catalog Guide

HIV-1 & HIV-2

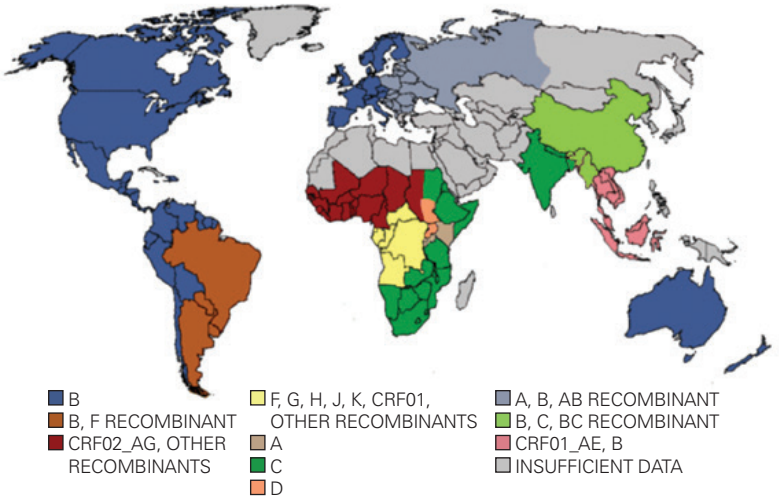
Antigen and Antibody Detection Assays

Human immunodeficiency virus (HIV) is a lentivirus that causes acquired immunodeficiency syndrome (AIDS), a condition that leads to progressive failure of the immune system. HIV is a well-documented progressive disease and if left untreated, it is almost always fatal.

There are two major types of HIV, type 1 (HIV-1) and type 2 (HIV-2). HIV-1 viruses are further divided into groups M, N, O, P. Group M viruses are the most common group and are predominately responsible for the AIDS pandemic. Group M is further subdivided into clades based on
their genetic sequences, which tend to concentrate within specific geographic regions. The clade that an individual becomes infected with can be a major factor in the rate of progression to AIDS; specifically clades C, D and G are 8 times more likely to develop AIDS.

HIV-2 has been found to be less pathogenic than HIV-1 and it is not widely seen outside of West Africa. This strain is also divided into groups A to H. Groups A and B are epidemic. HIV-2 is less easily transmitted than HIV-1 and the time between infection and symptoms tends to be longer. Despite its relative geographic confinement, HIV-2 should be considered in all patients exhibiting symptoms of HIV.

GLOBAL DISTRIBUTION AND GENETIC DIVERSITY OF THE NINE MAJOR HIV-1 CLADES AND RECOMBINANTS



Source: pbs.org

HIV is divided into three main stages:

Acute Retroviral Syndrome: Early symptoms of HIV are defined as acute retroviral syndrome and they appear 3-6 weeks after infection and can easily be confused with the symptoms of the flu or other milder diseases. As a result, most infections remain undiagnosed until they progress to more advanced stages.

Clinical Latency (inactivity or dormancy): This period is sometimes called asymptomatic HIV infection or chronic HIV infection. During this phase HIV is active but reproduces at very low levels. People who are on antiretroviral therapy may live with clinical latency for several decades. Toward the middle and end of this period, the viral load begins to rise and the CD4+ cell count begins to drop. The World Health Organization (WHO) sub-classifies this period into three stages based on the CD4+ cell count of the individual:

STAGE 1: the CD4+ cell count is at least 500 cells per microliter
STAGE 2: the CD4+ cell count is 350 to 499
STAGE 3 (advanced HIV disease, or AHD): The CD4+ cell count is 200 to 349

AIDS (Acquired Immunodeficiency Syndrome): This is the stage of infection that occurs when the immune system is badly damaged and an infected individual become vulnerable to opportunistic illnesses. The CD4+ cell count is less than 200 or the percent of CD4+ cells is less than 15% of all lymphocytes. Without treatment, people who are diagnosed with AIDS typically survive about 3 years. Once a dangerous opportunistic illness is acquired, life expectancy without treatment falls to about 1 year.

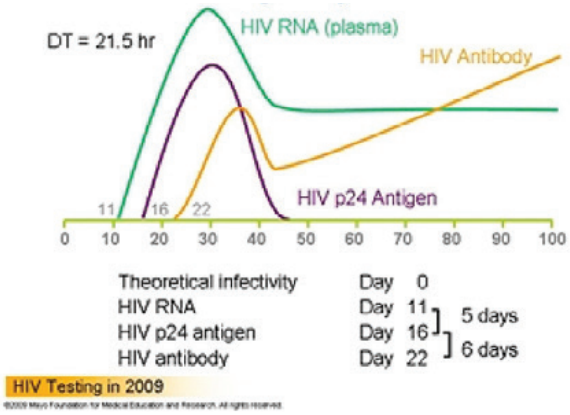
DIAGNOSIS

Laboratory diagnosis is the only way to confirm an HIV infection and there are specific serologic markers that can be detected in the early course of an infection.

HIV RNA: detectable by current molecular methods at about 11 days from the time of HIV infection
HIV P24 ANTIGEN: detectable 16 days from the time of infection
HIV ANTIBODIES: detectable 22 days from the time of infection

During the early infection stage (acute retroviral syndrome) the flu-like symptoms are accompanied by a burst of viral replication that can be detected in the blood. The detection of p24 antigen (viral capsid protein) is directly correlated to the amount of virus (viral load) circulating in the infected individual. Antibodies against specific HIV proteins and glycoproteins (e.g. p24, gp41, gp120) are produced between 2-8 weeks after infection and remain detectable in the blood thereafter.

HIV MARKERS DURING EARLY INFECTION



Source: mayomedicallaboratories.com

The screening test most widely used to detect exposure to HIV is the "HIV Antibody Test". The first test was approved in 1985 by the FDA and it still remains one of the WHO recommended HIV diagnostics. Advances in technologies and critical reagents have enabled the development of new generation HIV Antibody Tests, which are able to detect an infected individual earlier and with greater accuracy. The 4th generation HIV Antibody Test is capable of diagnosing an HIV infection 3-4 weeks after transmission by simultaneously detecting both HIV antibody and p24 antigen. In addition, many of these tests can also distinguish between acute and established HIV infections, as well as detect antibodies to HIV groups M and O, and HIV-2.

The commercial HIV diagnostic testing market has expanded to include several testing formats such as Western blot, immunofluorescence (IFA), and lateral flow as well as various sample types such as saliva, urine, and nucleic acids. Regardless of the type of screening test used, a positive result requires follow up with a second test to confirm a diagnosis of HIV.

REAGENTS FOR SEROLOGY TESTING

HIV-1 p24 Antibodies

An early marker of infectivity. The detection of p24 antigen directly correlates to the amount of virus in an infected individual.

PAIR	C01653M	**MAb to HIV-1 p24** • Capture or Detection antibody	Paired MAbs for Sandwich ELISA, Lateral Flow and CLIA Antigen Detection Assays
	C65690M	**MAb to HIV-1 p24** • Capture or Detection antibody	
PAIR	C01653M	**MAb to HIV-1 p24** • Isotype: IgG1 • Capture antibody or Detection Antibody	Paired MAbs for Sandwich ELISA and Lateral Flow Antigen Detection Assays
	C01655M	**MAb to HIV-1 p24** • Isotype: IgG1 • Capture antibody or Detection Antibody	
PAIR	C01657M	**MAb to HIV-1 p24** • Isotype: IgG1 • Capture antibody	Paired MAbs for Sandwich ELISA Antigen Detection Assays
	C01655M	**MAb to HIV-1 p24** • Detection antibody	
PAIR	C01655M	**MAb to HIV-1 p24** • Capture or Detection antibody	
	C01656M	**MAb to HIV-1 p24** • Isotype: IgG1 • Capture or Detection antibody	
PAIR	C01656M	**MAb to HIV-1 p24** • Capture antibody or Detection Antibody	
	C65690M	**MAb to HIV-1 p24** • Capture antibody or Detection Antibody	
PAIR	C01657M	**MAb to HIV-1 p24** • Capture antibody or Detection Antibody	
	C65690M	**MAb to HIV-1 p24** • Capture antibody or Detection Antibody	

HIV-1 & HIV-2

Antigen and Antibody Detection Assays

REAGENTS FOR SEROLOGY TESTING

HIV Recombinant Antigens

HIV p24, gp41, and gp36 are markers of an HIV infection. They are produced 2-8 weeks after initial exposure and remain detectable in the blood thereafter.

VTI340 | **HIV-1 p24 Recombinant Antigen**
- Represents the entire protein of 231 a.a. (Strain HxB2)
- Produced in *Pichia pastoris*
- Buffer: 0.2 M Sodium Phosphate, pH 7.0 ± 0.2

R18550
- Represents the C-terminus of gp120 and most of gp41
- Produced in *E. coli*, no fusion partner
- Molecular weight of 27.3 kDa
- Buffer: 50 mM Tris, pH 8.0, containing 0.1% SDS, 5 mM DTT, 2.5 mM EDTA

R65908
- Represents HIV-1 gp41 protein
- Produced in *E. coli*, contains a β-gal fusion partner
- Molecular weight of 146 kDa
- Buffer: 10 mM Na_2CO_3, 10 mM EDTA, 14 mM β-ME, 0.05% Tween 20

Suitable for ELISA Antibody Detection Assays

R01454 | **HIV-1 gp41 Recombinant Antigen, Type "O"**
- Represents HIV-1 gp41, Type "O" protein
- Produced in *E. coli*, contains a β-gal fusion partner
- Reacts with human HIV type O positive serum
- Buffer: 1.5 M Urea, 25 mM Tris-HCl, pH 8.0 containing 50% glycerol

Suitable for ELISA and Lateral Flow Antibody Detection Assays

PAIR

R01625 | **HIV gp120 and gp41 Recombinant Chimeric Antigen**
- Represents a.a. 480-620
- Produced in *E. coli*
- Buffer 20 mM Phosphate Buffer, 0.1% Sodium Dodecyl Sulfate, pH 7.4
- Capture antigen

R01626
- Represents a.a. 485-631
- Produced in *E. coli*
- Buffer 20 mM Phosphate Buffer, 0.1% Sodium Dodecyl Sulfate, pH 7.4
- Detection antigen

PAIR

R01630 | **HIV gp120 and gp41 Recombinant Chimeric Antigen**
- Represents a.a. 480-620
- Produced in *E. coli*
- Buffer Tris-HCl Buffer, pH 8.5, Ethylenediaminetetraacetic (EDTA)
- Capture antigen

R01626
- Detection antigen

PAIR

R01631 | **HIV gp120 and gp41 Recombinant Chimeric Antigen**
- Represents a.a. 480-620
- Produced in *E. coli*
- Buffer Tris-HCl Buffer, pH 8.5, Ethylenediaminetetraacetic (EDTA)
- Capture antigen

R01626
- Detection antigen

Suitable for Lateral Flow and ELISA Antibody Detection Assays

VTI360 | **HIV-2 gp36 Recombinant Antigen**
- Represents the ecto-domain of gp36
- Produced in *Pichia pastoris,* contains a 6-His tag
- Buffer: 6 M Urea, 0.02 M Tris-HCl, 0.5 M NaCl, pH 7.0 to 8.0 at room temperature

R65911
- Represents the HIV-2 gp36 protein
- Produced in *E. coli*, contains a β-gal fusion partner
- Molecular weight of 148 kDa
- Buffer: 10 mM Na_2CO_3, 10 mM EDTA, 14 mM β-ME, 0.05% Tween 20

R8A114
- Represents HIV-2 gp36 protein, a.a. 390-702
- Produced in *E. coli*, contains a β-gal fusion partner at the N-terminus
- Molecular weight of 34 kDa with a 114 kDa β-gal tag
- Buffer: 0.01 M Na_2CO_3; 0.01 M Na_3 EDTA, 0.014 M β-ME, 0.05% Tween 20

Suitable for ELISA Antibody Detection Assays

HSV-1 & HSV-2

Antibody and Antigen Detection Assays

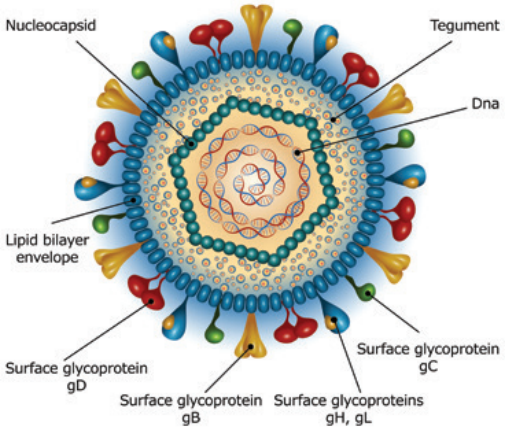
Herpes simplex virus (HSV) types 1 and 2 are common infections worldwide. However, the majority of infected individuals remain undiagnosed because they are asymptomatic.

HSV-1 is usually transmitted during childhood through contact with oral secretions (cold sores). Seroprevalence studies indicate about 60% of adults in the United States are infected with this virus. HSV-2 is usually spread by sexual contact (genital herpes). Consequently this infection usually occurs later in life and the seroprevalence rates vary dramatically by geographic region.

Both HSV-1 and HSV-2 establish a lifelong, latent infection in the nervous system and there is no cure. Antiviral medications can reduce the frequency, duration and severity of outbreaks and over a period of several years, many infected individuals experience less severe symptoms and fewer outbreaks, although they are still contagious to others.

The greatest risk of an HSV infection is in neonates and infants, when an infected mother passes it to her fetus in utero or during delivery. A neonatal HSV infection can be devastating to an infant and 70 - 85% of these infections are caused by HSV-2. Many infants infected with HSV are born prematurely and approximately 4% can develop congenital HSV which has serious consequences including death.

HERPES SIMPLEX VIRUS



DIAGNOSIS

Diagnostic methods include serological tests such as ELISA and IFA, as well as PCR blood tests and cell culture. Generally tests detect antibodies (IgG or IgM) to HSV-1 or HSV-2, however, due to a high degree of genetic similarity between the HSV viruses, many tests cannot distinguish between a type 1 or type 2 infection. The recent discovery of serologically distinct HSV viral envelope glycoproteins gG-1 (HSV-1) and gG-2 (HSV-2) have enabled the development of new type-specific assays. These assays generally use both purified recombinant type-specific gG-1 and gG-2 antigens, and native HSV common antigens to both HSV and HSV-2 and can discriminate between HSV-1 or HSV infection.

REAGENTS FOR SEROLOGY TESTING

7305 | **HSV-1 Native Antigen**

7309 | **HSV-1 Native Antigen (Concentrate)**
- Strain F produced in Vero cells
- >10% viral protein
- Buffer: 0.1M Glycine, pH 9.5 ± 0.2

7705 | **HSV-2 Native Antigen**

7749 | **HSV-2 Native Antigen (Concentrate)**
- Strain G produced in Vero cells
- >10% viral protein
- Buffer: 0.1M Glycine, pH 9.5 ± 0.2

IgG Detection for ELISA and CLIA

VTI520 | **HSV-1 Recombinant Antigen, Glycoprotein G 1**
- Represents amino terminal Met1-Asp190 and fused with superoxide dismutase 1 (SOD)
- Produced in *Saccharomyces cerevisiae*
- Buffer: 0.05M Malonate with 6.0M Urea, pH 5.2 ± 0.2

VTI530 | **HSV-2 Recombinant Antigen, Glycoprotein G 2**
- Represents unique sequences not present in HSV-1
- Fused with superoxide dismutase 1 (SOD)
- Produced in *Saccharomyces cerevisiae*
- Buffer: 50mM NaH_2PO_4, 160mM KCl, 5mM DTT, pH 7.0 ± 0.1

IgM Detection & Type specific for ELISA and CLIA

C05014MA | **MAb to HSV-1 Nucleocapsid protein (155kDa)**
- Reacts with HSV-1 Glycoprotein G 1
- Cross-reacts with HSV-2 nuclear protein

C66150M | **MAb to HSV-1 Glycoprotein G 1**
- Reacts with HSV-1 Glycoprotein G 1

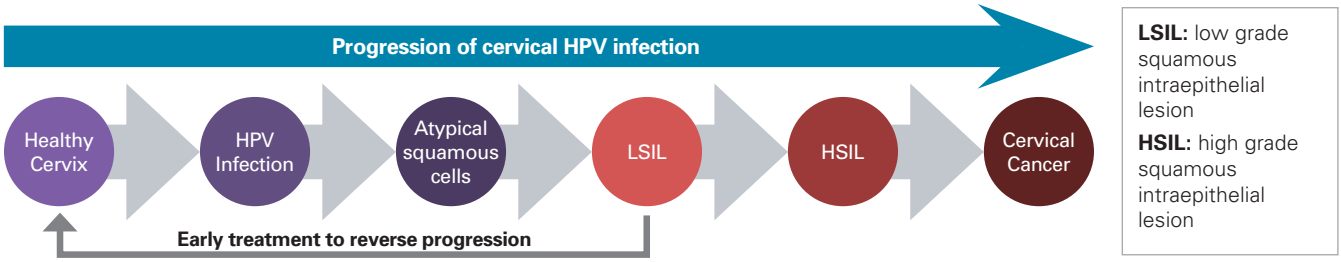
IFA Detection

Human Papilloma Virus (HPV)

Antigen Detection Assays

Human papilloma virus (HPV) refers to a group of more than 150 related viruses that cause warts (papillomas) on different parts of the body including the hands, feet, genitals, or anus. It is one of the most common STDs and although most HPV infections self-resolve, some types can cause cervical cancer in women and anal cancers in both men and women.

Up to 75% of sexually active males and females will have an HPV infection at some point in their lifetime and symptoms are generally mild or non-existent. Most HPV infections (about 70%) go away without any treatment within 1–2 years. However, there are over 40 types of HPV and becoming immune to one type does not protect an individual from becoming infected with another type. Persistent infection with high-risk HPV types over many years can cause precancerous changes leading to cervical cancer, which is the second most common cancer in women worldwide, second only to breast cancer.



Source: https://uwaterloo.ca/foldvari-group/research-program/gene-therapy

HPVs are grouped into types based on their degree of causing cancer. Low-risk HPV types such as HPV-6 and HPV-11, are rarely associated with cancer and are the major cause (99%) of genital warts (World Health Organization). However there are 14 high-risk HPV types that are known to cause cancer, including HPV-16, HPV-18, HPV-31, HPV-33, HPV-35, HPV-39, HPV-45, HPV-51, HPV-52, HPV-56, HPV-58, HPV-59 and HPV-68. The most common high-risk types are HPV-16 and HPV-18 which cause about 70% of cervical cancers. HPV infection with HPV 16 or 18 can also cause anal, vaginal, vulvar, penile and some oral cavity and oropharyngeal cancers. HPV-33 has also been found in cancer of the anus and vulva.

DIAGNOSIS

Traditionally, genital HPV infection is detected by a Pap smear and does not distinguish between high- and low-risk types. There are several DNA HPV tests, some of which are approved for marketing by the FDA, that can detect high-risk types of HPV. However in developing countries where more than 85% of cervical cancer deaths occur, the resources, infrastructure, and technological expertise and the need for repeated screening at frequent intervals, have made conventional molecular and cytology-based (Pap smear) screening prohibitively difficult. Ideally, screening tests suitable for low resource settings should be simple, rapid, cost effective and provide information regarding the HPV oncogenic activity.

Research has demonstrated that both HPV E6 and E7 oncoproteins mediate the development of cervical cancer. Their overexpression, which can be measured by mRNA transcripts or detection of the expressed proteins, directly correlates with the severity of cervical histopathology and the risk for precanerous progression. Accordingly, many commercial assays have been developed for the detection of precancerous high-risk HPV 16 and HP18 E6 and E7 proteins, in which positive results are suggestive of an increased risk of cervical cancer.

REAGENTS FOR SEROLOGY TESTING

PAIR

C86013M | **MAb to HPV 16 (E7)**
- Reactive with HPV Type 16, E7 protein
- Cross-reacts with E7 protein of HPV type 18
- Isotype: IgG2b
- Capture antibody

PAIR

C86718M | **MAb to HPV 18 (E7)**
- Reactive with HPV Type 18, E7 protein
- Does not cross-react with E7 protein of HPV type 16
- Isotype: IgG1
- Capture antibody

C86238M | **MAb to HPV 18 (E7)**
- Reactive with HPV Type 18, E7 protein
- Does not cross-react with E7 protein of HPV type 16
- Isotype: IgG2b
- Detection antibody

Paired MAbs for Sandwich ELISA Antigen Detection Assays

MAV56-013 | **MAb to HPV 16 (E7)**
- Reactive with HPV Type 16, E7 Protein
- Isotype: IgG2a

Suitable for use in ELISA, RIA and IFA Antigen Detection Assays

MAV56-981 | **MAb to HPV 16 (L1)**
- Reactive with HPV Type 16, L1 (Major Capsid Protein)
- Isotype: IgG2a

Suitable for use in IHC Antigen Detection Assays

MAV56-965 | **MAb to HPV 18 (E6)**
- Reactive with the E6 of HPV Type 18 and Type 16
- Isotype: IgG1

Suitable for use in IHC and Western Blot Antigen Detection Assays

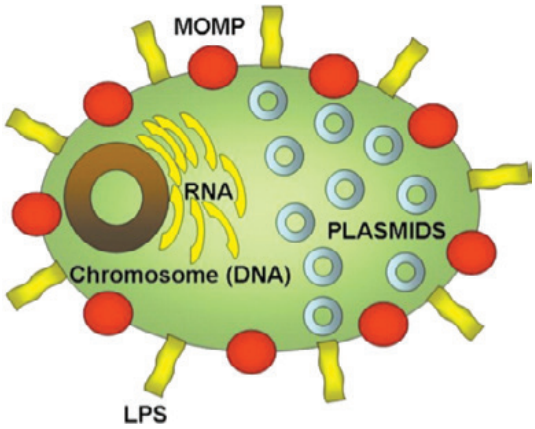
Chlamydia trachomatis

Antigen and Antibody Detection Assays

Chlamydia is the most common sexually transmitted infection in humans and it is caused by the bacterium *Chlamydia trachomatis*. It affects 5% to 10% of the world's population and it is particularly common in young adults under 25 years. It is a major public health concern due to its prevalence and potential long-term consequences.

An estimated 100 million *Chlamydia trachomatis* infections occur annually among sexually active adolescents and young adults in the world. Its prevalence is due to the majority of cases (75% of women and 50% of men) having minimal to no symptoms, therefore it often goes undiagnosed and can be spread unknowingly. Infection is associated with non-gonococcal urethritis in men and several inflammatory reproductive tract syndromes in women such as inflammation of the uterine cervix and pelvic inflammatory disease (PID). If left untreated in women, 20% will become infertile, 18% will experience debilitating, chronic pelvic pain, and 9% will have a life-threatening tubal pregnancy. Furthermore, *C. trachomatis* infection during pregnancy leads to infant conjunctivitis and pneumonia and maternal postpartum endometriosis.

CHLAMYDIA TRACHOMATIS MORPHOLOGY



Source: Nature.com

In most cases, chlamydia can be easily treated with antibiotics with a cure rate of 95%. However, many people don't know they have the disease until it has caused serious complications. Young adults under age 25 and others at high risk (e.g. pregnant women) should be tested for chlamydia once a year even if they are symptom-free.

DIAGNOSIS

Culture testing for *C. trachomatis* has been the reference standard, however antigen detection using ELISA-based assays, direct fluorescent antibody (DFA) tests and nucleic acid hybridization tests have increased in popularity due to their relative ease-of-use. EIA methods initially developed for the detection of *C. trachomatis* measured lipopolysaccharide (LPS) antigen expressed by the chlamydial elementary bodies which is common to all four chlamydia species (*C. trachomatis, C. pneumoniae, C. psittaci*, and *C. pecorum*). Newer tests for *C. trachomatis* use antibodies against chlamydial heat shock protein 60 (cHSP60) or the major outer membrane protein (MOMP) which do not cross-react with the other chlamydia species or with other organisms that contain LPS.

REAGENTS FOR SEROLOGY TESTING

PAIR

C01566M | **MAb to *Chlamydia trachomatis* LPS**
- Isotype: IgG
- Capture antibody

C01565M | **MAb to *Chlamydia trachomatis* LPS**
- Isotype: IgG
- Detection antibody

Paired MAbs for Sandwich Lateral Flow Antigen Detection Assays

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MAV07-347 | **MAb to Chlamydia Species LPS**
- Reactive with serovars: A, B, Ba, C, D, E, F, G, H, I, J, K, L1, L2, L3 and *C. psittaci*
- Isotype: IgG2

MAV06-086 | **MAb to *Chlamydia trachomatis* MOMP**
- Reactive with major outer membrane protein (MOMP)
- Isotype: IgG2

Suitable for use in ELISA Antigen Detection Assays

C66436M | **MAb to *Chlamydia trachomatis* and *Chlamydophila psittaci***
- Reacts with a glycolipid antigen on *C. trachomatis* and *C. psittaci*
- Isotype: IgG3

Suitable for use in IFA and IHC Antigen Detection Assays

C65168M | **MAb to Chlamydia Species LPS**
- Reactive with elementary bodies from *C. trachomatis* serovars D, E, F, G, H, I, J, K and L2
- Genus specific, cross reactive with *C. pneumoniae* and *C. psittaci*
- Isotype: IgG1

C01363M | **MAb to Chlamydia Species MOMP**
- Specific for major outer membrane protein (MOMP)
- Recognizes 15 serovars of *C. trachomatis*
- Isotype: IgG2a

C65166M | **MAb to Chlamydia Species MOMP**
- Specific for major outer membrane protein (MOMP)
- No reactivity with *C. pneumoniae*
- Isotype: IgG2a

Suitable for use in ELISA, IFA, and IHC Antigen Detection Assays

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R02121 | **Native *Chlamydia trachomatis* Antigen**
- *C. trachomatis* LGV Type-2, Elementary Bodies (EB)
- Produced in Mouse L Cells infected with *C. trachomatis* elementary bodies
- Buffer: PBS, pH 7.2

IgM & IgG Detection EIA Assays, including Rapid-IgM Capture Formats

Neisseria gonorrhoeae

Antigen Detection Assays

Neisseria gonorrhoeae is gram-negative bacteria that causes infections in the urethra, cervix, vagina or anus. It is one of the two most common STDs in the United States along with chlamydia. If left untreated, gonorrhea infections can spread in the reproductive tract, causing prostatitis and epididymitis in men, or pelvic inflammatory disease (PID) in women.

The World Health Organization (WHO) estimates that there are 88 million new cases of gonorrhea each year. It is common for infected individuals to not have any symptoms and unknowingly spread the disease. Asymptotic infections along with the emergence of multidrug-resistant *N. gonorrhoeae*, present a significant challenge in controlling gonorrhea.

MORPHOLOGY OF *N. GONORRHOEAE*

If left untreated, gonorrhea may last for weeks or months with a high risks of complications. Significant problems include: infertility in both men and women, infection in the joints and other areas of the body, and an increased risk for HIV/AIDS. Women with gonorrhea infections before or during pregnancy are also at increased risk for pregnancy complications such as stillbirth and premature birth. In addition, babies can become infected with gonorrhea during the birth process, leading to eye and joint infections and possible life-threatening blood infections. Men who have had a gonorrhea infection have a significantly increased risk of having prostate cancer.

DIAGNOSIS

Traditionally, gonorrhea is diagnosed with gram stain and culture as they have 100% specificity; however, newer rapid antigen detection assays are needed as alternatives. Significant disadvantages of culture include variable sensitivity, complex logistics, and slow turnaround times and new tests need to have improved sensitivity, ease of handling, and rapid processing. All gonorrhea tests use a sample of body fluid from the affected area.

REAGENTS FOR SEROLOGY TESTING

C01818M
C01819M
C01820M

MAb to *Neisseria gonorrhoeae*

- Reactive with 9 strains of *N. gonorrhoeae*, *N. lactamica* and *N. Meningitidis*
- Non-reactive with *N. mucosa*, *N. perflava*, *N. sicca*, *G. vaginalis*, group B Streptococcus, *Candida albicans*, Hemophilus influenza type B, *C. trachomatis*, *T. vaginalis*, *M. genitalium*, *U. urealyticum* and HSV-2

Suitable for use in ELISA and IFA Antigen Detection Assays

B65111R

PAb to *Neisseria gonorrhoeae*

- Produced in rabbits using immunogen of whole *N. gonorrhoeae* (ATCC 31426)
- Specific for all antigens
- Antiserum is not absorbed and may react with related microorganisms
- >95% pure, purified by Protein A chromatography

Suitable for use in ELISA and IFA Antigen Detection Assays

Syphilis *(Treponema pallidum)*

Antibody Detection Assays

Syphilis is a sexually transmitted bacterial infection caused by the spirochete bacterium *Treponema pallidum*. It is passed from person to person through direct contact with a syphilis sore and causes a systemic infection with symptoms that vary depending on the stage of the disease.

About 12 million people worldwide are infected with syphilis and > 90% of cases are in developing countries. Syphilis can spread through sexual contact or in pregnancy (mother to fetus), however it can be easily and effectively be treated with antibiotics. Without treatment, an infection can lead to serious consequences including small tumors (called gummas), neurological problems (stroke, meningitis, deafness, demetia), cardiovascular disease and an increased risk of HIV infection (2-5x). An infected baby can also develop serious problems such as cataracts, deafness, seizures, or death. It has been reported that untreated early syphilis in pregnant women results in perinatal death in up to 40% of cases. If acquired during the 4 years before pregnancy, it can lead to infection of the fetus in 80% of cases (CDC, 2013 Sexually Transmitted Diseases Surveillance).

ESTIMATED NUMBER OF CASES OF SYPHILIS AMONG ADULTS WORLDWIDE

Source: WHO (http://www.who.int/tdr/dw/syphilis_map.htm)

The signs and symptoms of syphilis vary depending on which of the four stages it presents (primary, secondary, latent, and tertiary). During the first (primary) stage of syphilis, a sore appears at the point of contact where syphilis was transmitted. The sore is usually painless, lasts 3-6 weeks, and heals without treatment. Secondary syphilis occurs approximately 4-10 weeks after the primary infection and usually starts with a rash on one or more areas of the body (and these rashes harbor bacteria and are infectious). Other symptoms may include fever, sore throat, malaise, weight loss, hair loss, and headache. The latent stage of syphilis begins when all of the symptoms disappear. An latent infected person can continue to have syphilis for years without any symptoms. Without treatment, a third of infected people develop tertiary syphilis, which usually occurs 3-30 years after the initial infection.

DIAGNOSIS

Syphilis has several clinical manifestations, making it difficult to diagnose based on clinical symptoms alone. Also, *T. pallidum* cannot be isolated in culture so confirmation must be performed either by ELISA-based serological assays or by direct visual inspection using microscopy. Serological tests are more commonly used, however all syphilis diagnostic assays are unable to distinguish between the stages of the disease.

Syphilis *(Treponema pallidum)*

Antibody Detection Assays

CATEGORIES OF SEROLOGICAL TESTING FOR SYPHILIS

1. Treponemal tests which are aimed at detecting an antigen or an antibody to *T. pallidum*. Examples include EIA assays that detect IgG and/or IgM and IgA antibodies to *T. pallidum*.
2. Non-treponemal tests which look for indirect indications of the infection such as the presence of cardiolipins (a mitochondrial membrane lipid), which are released when a treponeme bacteria damages cells. Since these tests do not detect the bacteria directly they usually require confirmation testing.

The *T. pallidum* genome is 1.14 Mb and encodes a putative 1,041 proteins (Genome Sequencing Project). Different strains of *T. pallidum (Tp)* may express different repertoires of Tp proteins as demonstrated by various immunologic studies (Leader, B. et al. (2003) *Infect. Immun. 71:6054-6057*). In the past few years, several highly immunogenic lipoproteins have been identified as diagnostic targets throughout all stages of a syphilis infection, including Tp17, Tp15, Tp44.5 (TmpA), Tp47, Tp41, Tp35 (TmpC) and Tp0453. Specifically, early immune responses have been shown to be against Tp47 and some of the flagellar proteins, followed by Tp15 and Tp17. Tp0453 has also been shown to be a promising diagnostic marker with very high sensitivity in early detection. For this reason, several commercial tests have been developed using a combination of these immunogenic antigens and have proven to be highly sensitive and specific for the diagnosis of an active or latent syphilis infection. Also recent developments include rapid formats that can be performed at the point of care, including agglutination tests using latex particles coated with treponemal antigen or lateral flow assays.

Protein	*T. Pallidum* Genome
Tp0453	Outer-membrane protein 30 kDa
Tp15 (Tp0171)	Membrane-associated 15 kDa lipoprotein
Tp17 (Tp0435)	Membrane-associated 17 kDa lipoprotein
Tp41	41 kDa homolog of galactose-glucose-binding protein
Tp47 (Tp0574)	Membrane-associated 47 kDa lipoprotein with carboxypeptidase properties
TmpA/ Tp44.5 (Tp0768)	Membrane lipoprotein 42 kDa

REAGENTS FOR SEROLOGY TESTING

***T. pallidum* p15 Recombinant Antigens**

R8A101

- Represents the full length p15 protein
- Produced in *E. coli* and fused with a β-gal tag at the N-terminus (>95% pure)
- Molecular weight of 60kDa
- Buffer: 8 M Urea, 20 mM Tris-HCl, pH 8.0 containing 10 mM β-Mercaptoethanol

Suitable for ELISA, Lateral Flow and Western Blot Antibody Detection Assays

R01531

- Mosaic protein representing immunodominant regions of p15
- Produced in *E. coli* and fused with a 6-His tag
- Molecular weight of 19kDa
- Buffer: 150 mM Imidazole, 25 mM Sodium Phosphate, pH 8.0 containing 150 mM NaCl, 50% Glycerol

Suitable for ELISA Antibody Detection Assays

REAGENTS FOR SEROLOGY TESTING

T. pallidum p17 Recombinant Antigens

R8A201
- Represents the full length p17 protein
- Produced in *E. coli* and fused with a β-gal tag at the N-terminus (>95% pure)
- Molecular weight of 63kDa
- Buffer: 8 M Urea, 20 mM Tris-HCl, pH 8.0 containing 10 mM β-Mercaptoethanol

Suitable for ELISA, Lateral Flow and Western Blot Antibody Detection Assays

R01528
- Mosaic protein representing immunodominant regions of p17
- Produced in *E. coli* and fused with a β-gal tag
- Molecular weight of 137kDa
- Buffer: 4 M Urea, 5 mM Tris-HCl, pH 8.0 containing 10 mM DTT, 0.5 mM EDTA, 50% glycerol

Suitable for ELISA Antibody Detection Assays

T. pallidum p41 Recombinant Antigen

R01529
- Represents the full length p41 protein
- Produced in *E. coli* and fused with a β-gal tag
- Molecular weight of 153kDa
- Buffer: 4 M Urea, 5 mM Tris-HCl, pH 8.0 containing 10 mM DTT, 0.5 mM EDTA, 50% glycerol

Suitable for ELISA Antibody Detection Assays

T. pallidum p47 Recombinant Antigens

R8A403
- Represents the full length protein p47
- Produced in *E. coli* and fused with a β-gal tag at the N-terminus (≥95% pure)
- Molecular weight of 92kDa
- Buffer: 8 M Urea, 20 mM Tris-HCl, pH 8.0 containing 10 mM β-Mercaptoethanol

Suitable for ELISA and Western Blot Antibody Detection Assays

R01568
- Mosaic protein representing immunodominant regions of p47
- Produced in *E. coli* and fused with a 6-His tag
- Molecular weight of 45kDa
- Buffer: 150 mM Imidazole, pH 8.0, 150 mM NaCl, 25 mM Sodium Phosphate, 50% glycerol

Suitable for ELISA Antibody Detection Assays

T. pallidum TmpA (Tp44.5) Recombinant Antigens

R8A404
- Represents the full length protein TmpA
- Produced in *E. coli* and fused with a β-gal tag at the N-terminus (>95% pure)
- Molecular weight of 42kDa
- Buffer: 8 M Urea, 20 mM Tris-HCl, pH 8.0 containing 10 mM β-Mercaptoethanol

Suitable for ELISA, Lateral Flow and Western Blot Antibody Detection Assays

R01530
- Represents TmpA protein, a.a. 23-41 and 288-325
- Produced in *E. coli* and fused with a GST tag
- Molecular weight of 32kDa
- Buffer: 4 M Urea, 5 mM Tris-HCl, pH 8.0 containing 10 mM DTT, 0.5 mM EDTA, 50% glycerol

Suitable for ELISA Antibody Detection Assays

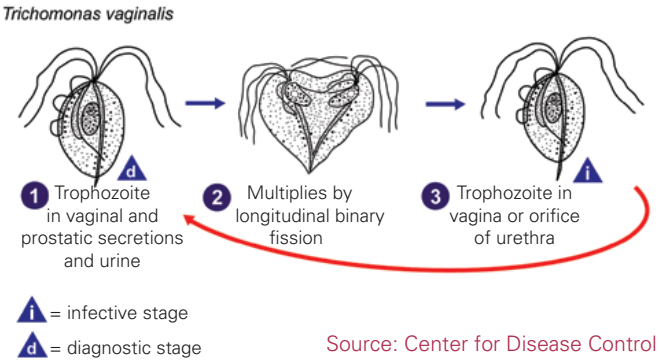
Trichomonas vaginalis

Antigen Detection Assays

Trichomonas vaginalis is an anaerobic, flagellated protozoan parasite and the most common curable STD. The World Health Organization (WHO) estimates that 170-190 million cases of infection are acquired annually worldwide and are increasing each year. As a result, *T. vaginalis* is receiving more attention, prompting an increased demand for both diagnosis of trichomoniasis and screening for asymptomatic infections.

Trichomonas vaginalis is a single cell flagellum parasite that lives in the female vagina and the male urethra. Infections are transmitted directly when the organism moves from one host to another, usually during sexual contact. It has long been recognized as a common cause of vaginitis, known as trichomoniasis. Infection of the female genital tract can also result in cervicitis, urethritis, and adverse pregnancy outcomes including premature rupture of membranes and low birth weight babies. Though it was once virtually ignored, *T. vaginalis* infection in men is now recognized as an important cause of nongonococcal urethritis and is associated with prostatitis and male infertility. In addition, trichomoniasis is a risk factor for sexual transmission of HIV. It has been demonstrate to play a critical role in amplifying HIV transmission by lowering the barrier of access to lymphocytes and macrophages.

T. VAGINALIS LIFE CYCLE



Source: Center for Disease Control

DIAGNOSIS

Approximately 70% of women with *T. vaginalis* do not exhibit symptoms and consequently diagnosis based on clinical symptoms alone is unreliable. The most commonly used method of diagnosis is direct microscopic observation (wet mount) of vaginal secretions and although both rapid and inexpensive, the sensitivity of this technique is generally very low (50 to 70%). Newer methods, such as rapid antigen testing and transcription-mediated amplification, have demonstrated greater sensitivity, often detecting 3-5 times more *T. vaginalis* infections than wet-mount microscopy. There is also a move towards self-testing as existing commercial antigen-detection assays are easy to use and provide reliable results in approximately 10 minutes.

Screening of asymptomatic women with HIV infection for *T. vaginalis* is recommended because of the adverse events associated with asymptomatic trichomoniasis and HIV infection. Screening should also be considered for persons receiving care in high-prevalence settings (e.g., STD clinics and correctional facilities) and for asymptomatic persons at high risk for infection.

REAGENTS FOR SEROLOGY TESTING

C65675M | **MAb to *Trichomonas vaginalis***

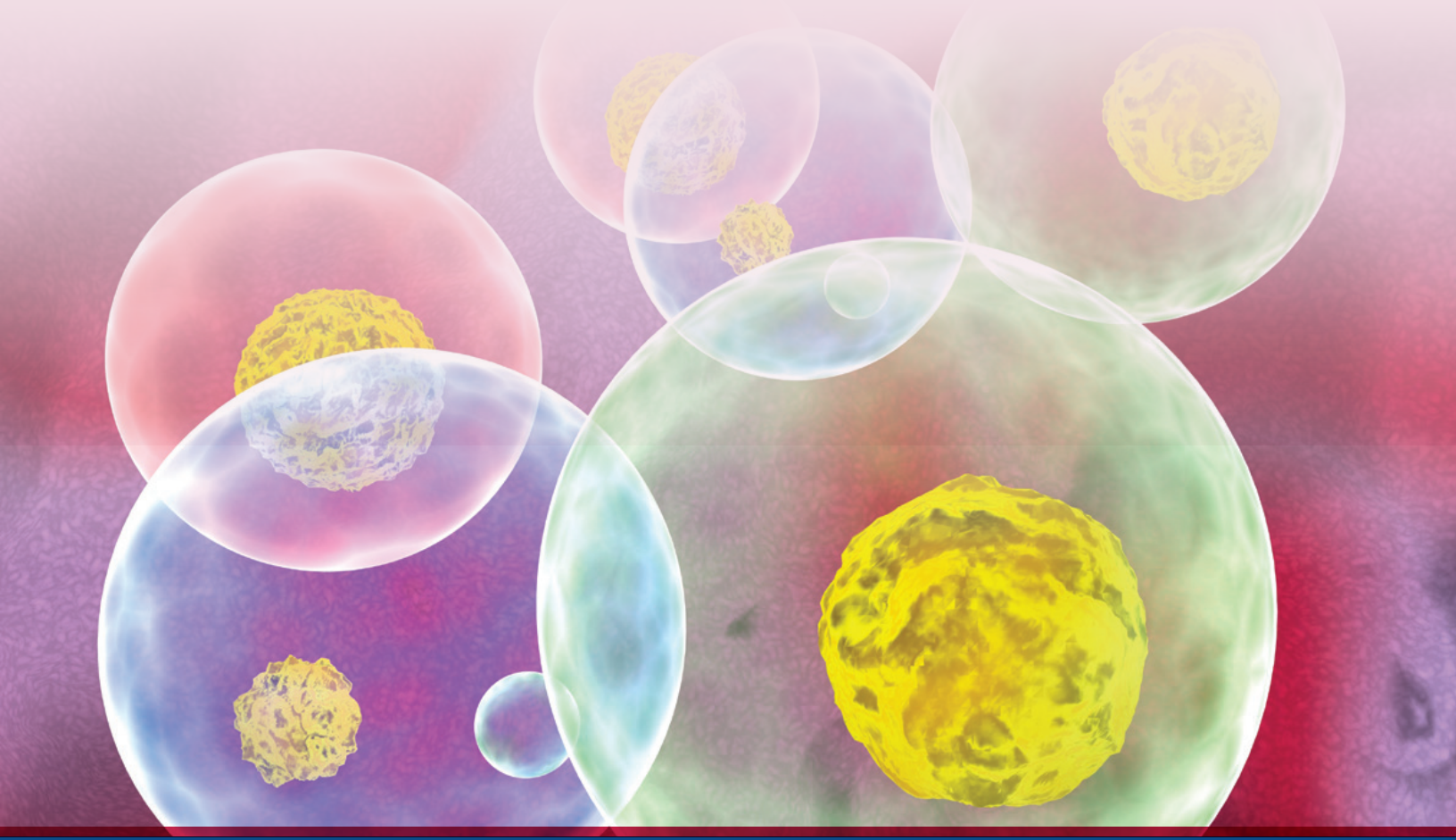
- Specific to the p65 adhesive protein of *T. vaginalis*
- p65 is one of 5 adhesion proteins in *T. vaginalis* and is specficially responsible for binding the parasite to the target cell in a ligand-receptor fashion
- Isotype: IgG1

Paired MAbs for Sandwich ELISA Antigen Detection Assays

Product list

ABBREVIATIONS

6-His – Polyhisitide-tag
Ab – Antibody
Ag – Antigen
β-ME – Beta Mercaptoethanol
β-Gal – Beta Galactosidase
CLIA – Chemiluminescence Immunoassay
CHAPS – 3-[(3-cholamidopropyl)dimethylammonio] -1-propanesulfonate
DB – Dot Blot
DFA – Direct Immunofluorescence Assay
DTT – Dithiothreitol
EDTA – Ethylenediaminetetraacetic acid
EIA, ELISA – Enzyme Immunoassay, Enzyme-linked immunosorbent assay
FCS – Fetal Calf Serum
GST – Glutathione S-transferase
GSH – Glutathione
IgG – Immunoglobin G
IgM – Immunoglobin M
IFA – Immunofluorescence Assay
LF – Lateral Flow
Lysate – Cells which have been lysed
Met – Methionine
MAb – Monoclonal antibody
NaCl – Sodium Chloride
NAAT – Nucleic acid amplification test
PAb – Polyclonal antibody
OD – Optical density
PBS – Phosphate Buffer Saline
PCR – Polymerase Chain Reaction
Purified – Refer to the Product Specification Sheet regarding the extent of purification and the purification process used.
SDS-PAGE – Sodium dodecyl sulfate polyacrylamide gel electrophoresis
WB – Western Blot
UV-Vis – Ultraviolet–visible spectroscopy

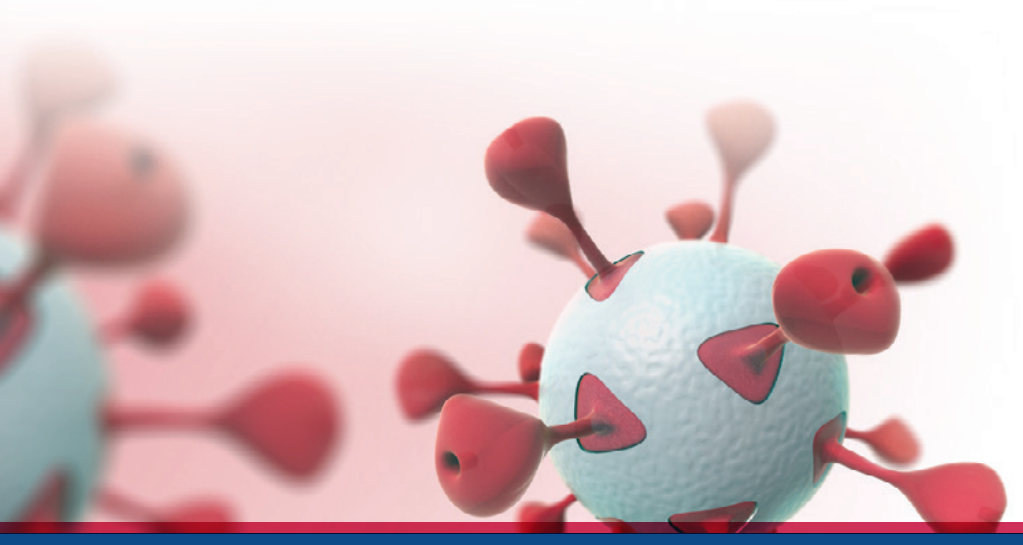


Product list

Chlamydia trachomatis

Chlamydia affects 5% to 10% of the world's population and it is particularly common in young adults under 25 years old. It is a major public health concern due to its prevalence and potential severe long-term consequences. Diagnostic tests for Chlamydia include EIA assays that detect specific chlamydial antigens such as the lipopolysaccharide (LPS) antigen expressed by the chlamydial elementary body and which is common to all four chlamydia species *(C. trachomatis, C. pneumoniae, C. psittaci, and C. pecorum)*. Newer tests for *C. trachomatis* use antibodies against chlamydial heat shock protein 60 (cHSP60) or the major outer membrane protein (MOMP) which do not cross-react with the other chlamydia species or with other organisms that contain LPS.

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Chlamydia trachomatis LGV Type-2 (Strain 434) EB	Ag	R02121	Mouse L Cells	EIA	Purified	N/A
Chlamydia species LPS	MAb	C65168M	Mouse	EIA,IFA,IHC(p)	Purified	IgG1
Chlamydia species LPS	MAb	C65815M	Mouse	EIA,IFA,IHC(p)	Purified	IgG1
Chlamydia species LPS	MAb	MAV07-347	Mouse	N/A	Purified	IgG2b
Chlamydia trachomatis LPS	MAb	C01565M	Mouse	LF,Pr	Purified	IgG
Chlamydia trachomatis LPS	MAb	C01566M	Mouse	LF,Pr	Purified	IgG
Chlamydia trachomatis (MOMP)	MAb	C01363M	Mouse	EIA,IFA,IHC	Purified	IgG2a
Chlamydia trachomatis (MOMP)	MAb	C65166M	Mouse	EIA,IFA,IHC	Purified	IgG2a
Chlamydia trachomatis (MOMP)	MAb	MAV06-086	Mouse	N/A	Purified	IgG2a
Chlamydia trachomatis	MAb	C66435M	Mouse	IFA,IHC(p)	Purified	IgG3,k
Chlamydia trachomatis and Chlamydia psittaci	MAb	C66436M	Mouse	IFA,IHC(p)	Purified	IgG3
Chlamydia trachomatis (EB's all antigens)	PAb	B65252G	Goat	IFA	FITC	N/A
Chlamydia trachomatis (EB's all antigens)	PAb	B65252R	Rabbit	IFA	FITC	N/A
Chlamydia trachomatis (EB's all antigens)	PAb	B65256G	Goat	EIA,IFA	Purified	N/A
Chlamydia trachomatis (EB's all antigens)	PAb	B65256R	Rabbit	EIA,IFA	Purified	N/A
Chlamydia trachomatis (EB's all antigens)	PAb	B65253R	Rabbit	EIA,ICC	HRP	N/A
Chlamydia trachomatis (MOMP)	PAb	B65261G	Goat	IFA	Biotin	N/A
Chlamydia trachomatis (MOMP)	PAb	B65266G	Goat	IFA	Purified	N/A



Human Immunodeficiency Virus Type 1 (HIV-1) & 2 (HIV-2)

Human Immunodeficiency Virus Type 1 (HIV-1) & Human Immunodeficiency Virus Type 2 (HIV-2): A lentivirus that causes acquired immunodeficiency syndrome (AIDS), a condition that leads to progressive failure of the immune system. HIV disease has a well-documented progression and if left untreated, it is almost always fatal. To this day, the screening test most widely used to detect the HIV antibodies in the blood is the "HIV Antibody Test" which is based on the detection of antibodies to HIV (e.g. p24, gp41, gp120). The 4th generation HIV Antibody Test is capable of diagnosing an HIV infection 3-4 weeks after transmission by simultaneously detecting both HIV antibody and p24 antigen.

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
HIV-1						
HIV-1, p24, Recombinant	Ag	VTI340	*P. pastoris*	EIA,WB	Purified	N/A
HIV-1, gag p24 (a.a. 77-436) Strain IIIB, Recombinant	Ag	R8A111	*E. coli*	EIA,WB	Purified	N/A
HIV-1, gp41 Type O, Recombinant	Ag	R01454	*E. coli*	EIA,LF,WB	Purified	N/A
HIV-1, Envelope gp41 (a.a. 466-753) Recombinant	Ag	R8A113	*E. coli*	EIA,WB	Purified	N/A
HIV-1, Envelope gp41, Recombinant	Ag	R65908	*E. coli*	EIA	Purified	N/A
HIV-1, nef (a.a. 3-190) Recombinant	Ag	R8A112	*E. coli*	EIA	Purified	N/A
HIV-1 Integrase p31 (a.a. 9-289) Recombinant	Ag	R01488	*E. coli*	EIA,LF,WB	Purified	N/A
HIV-1, C-terminal gp120 + most of gp41, Recombinant	Ag	R01593	*E. coli*	EIA,WB	Purified	N/A
HIV-1, C-terminal, gp120 + most of gp41, Recombinant	Ag	R18550	*E. coli*	EIA,WB	Purified	N/A
HIV-1 gp41, Recombinant	Ag	R01633	*E. coli*	EIA, LF	Purified	N/A
HIV-1, gp120 (v3 loop region) Recombinant	Ag	R01276	*E. coli*	EIA	Purified	N/A
HIV-1, gp160 (a.a. 283-674) Recombinant	Ag	R01532	*E. coli*	EIA	Purified	N/A
HIV, gp120 + gp41 chimeric	Ag	R01625	*E. coli*	EIA,LF,Pr	Purified	N/A
HIV, gp120 + gp41 chimeric	Ag	R01626	*E. coli*	LF,Pr	Purified	N/A
HIV, gp120 + gp41 chimeric	Ag	R01630	*E. coli*	LF,Pr	Purified	N/A
HIV, gp120 + gp41 chimeric	Ag	R01631	*E. coli*	LF,Pr	Purified	N/A
HIV-1, gp120	PAb	B65961B	Goat	EIA,WB	Biotin	N/A
HIV-1, gp120	PAb	B65961G	Goat	EIA,WB	Purified	N/A
HIV-1, gp120	PAb	B65961P	Goat	EIA,WB	HRP	N/A
HIV-1, p24 Recombinant	Ag	R01627	*E. coli*	EIA,WB	Purified	N/A
HIV-1, p17	MAb	C8A014M	Mouse	EIA,IHC(f),IP, WB	Purified	IgG1
HIV-1, p24	MAb	C01653M	Mouse	EIA,LF,Pr,WB	Purified	IgG1
HIV-1, p24	MAb	C01655M	Mouse	EIA,LF,Pr	Purified	IgG1
HIV-1, p24	MAb	C01656M	Mouse	EIA,Pr	Purified	IgG1
HIV-1, p24	MAb	C01657M	Mouse	EIA,Pr	Purified	IgG1
HIV-1, p24	MAb	C11998M	Mouse	EIA,Pr	Purified	IgG1
HIV-1, p24	MAb	C11999M	Mouse	EIA,Pr	Purified	IgG1
HIV-1, p24	MAb	C65489M	Mouse	EIA,IFA	Purified	IgG1
HIV-1, p24	MAb	C65499M	Mouse	EIA,Pr	Purified	IgG1
HIV-1, p24	MAb	C65690M	Mouse	EIA,LF,Pr	Purified	IgG1
HIV-1, p24	MAb	C65941F	Mouse	EIA,IFA,IHC(f), WB	FITC	IgG1
HIV-1, p24	MAb	C65941M	Mouse	EIA,IFA,IHC(f), Pr,WB	Purified	IgG1
HIV-1, gp41	MAb	C18812M	Mouse	EIA	Purified	IgG1
HIV-1, gp41	MAb	C65911M	Mouse	WB	Purified	IgG2
HIV-1, gp41	MAb	C8A015M	Mouse	EIA,WB	Purified	IgG1
HIV-1 (purified Virions)	PAb	B65875G	Goat	IFA	Purified	N/A
HIV-1 (purified Virions)	PAb	B65873G	Goat	EIA	HRP	N/A
HIV-1, p24	PAb	B65951B	Goat	EIA,WB	Biotin	N/A
HIV-1, p24	PAb	B65951P	Goat	EIA,WB	HRP	N/A
HIV-1, p24	PAb	B65951F	Goat	EIA,IFA,WB	FITC	N/A
HIV-1, p24	PAb	B65951G	Goat	EIA,IFA,WB	Purified	N/A
HIV-1, gp41	PAb	B65971G	Goat	WB	Purified	N/A

Product list

Human Immunodeficiency Virus Type 1 (HIV-1) & 2 (HIV-2) continued

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
HIV-2						
HIV-2, gp36, Recombinant	Ag	VTI360	*P. pastoris*	EIA,WB	Purified	N/A
HIV-2, gp36, Recombinant	Ag	R01634	*E. coli*	EIA, LF	Purified	N/A
HIV-2, gp36 seq	Ag	R18220	Synthetic	EIA,WB	Purified	N/A
HIV-2, Envelope (a.a. 390-702) Recombinant	Ag	R8A114	*E. coli*	EIA	Purified	N/A
HIV-2, Envelope gp36, Recombinant	Ag	R18410	*E. coli*	EIA,WB	Purified	N/A
HIV-2, Envelope gp36, Recombinant	Ag	R65911	*E. coli*	EIA	Purified	N/A
HIV-2, gp36	MAb	C18386M	Mouse	EIA	Purified	IgG1
HIV-2, gp36	MAb	C8A401H	Mouse	EIA,WB	Purified	IgG2a
HIV-1/2						
HIV-1/2, p24	MAb	C01576M	Mouse	EIA,WB	Purified	IgG1
HIV-1/2, p24	MAb	C01577M	Mouse	EIA,WB	Purified	IgG1
HIV-1&2 gp41/O group gp41/gp36, Recombinant	Ag	R01547	*E. coli*	EIA	Purified	N/A

Human Papilloma Virus (HPV)

HPV refers to a group of more than 150 related viruses that can cause warts (papillomas) on different parts of the body including the hands, feet, genitals, or anus. It is one of the most common STDs and although most HPV infections self-resolve, some types can cause cervical cancer in women. Research has demonstrated that both HPV E6 and E7 oncoproteins mediate the development of cervical cancer and their overexpression, which can be measured by mRNA transcripts or detection of the expressed proteins, directly correlates with the severity of cervical histopathology and the risk for precancerous progression. Accordingly, many commercial assays have been developed that detect the high-risk HPV 16 and HP18 E6 and E7 proteins, in which positive results suggest an increased risk of cervical cancer.

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Human Papilloma Virus Type 16 (HPV) L1, Recombinant	Ag	R01428	*Hansenula polymorpha*	WB	Purified	N/A
Human Papilloma Virus Type 18 (HPV) L1, Recombinant	Ag	R01429	*Hansenula polymorpha*	WB	Purified	N/A
Human Papilloma Virus Type 11 (HPV) E7 Protein	MAb	C86166M	Mouse	EIA,Pr,WB	Purified	IgG1
Human Papilloma Virus Type 11 (HPV) E7 Protein	MAb	C86913M	Mouse	EIA,Pr,WB	Purified	IgG1
Human Papilloma Virus Type 16 (HPV) E2 (a.a. 18-41)	MAb	MAV56-271	Mouse	EIA	Purified	IgG1
Human Papilloma Virus Type 16 (HPV) E2 (a.a. 2-17)	MAb	MAV56-261	Mouse	EIA,WB	Purified	IgG1
Human Papilloma Virus Type 16 (HPV) E7 Protein	MAb	C86013M	Mouse	EIA,Pr,WB	Purified	IgG2b
Human Papilloma Virus Type 16 (HPV) E7 Protein	MAb	C86789M	Mouse	EIA,Pr,WB	Purified	IgG1
Human Papilloma Virus Type 16 (HPV) E7 Protein	MAb	C86791M	Mouse	EIA,Pr,WB	Purified	IgG2a
Human Papilloma Virus Type 16 (HPV) E7 Protein	MAb	MAV56-013	Mouse	EIA,FC,IHC(f),IP,WB	Purified	IgG2a
Human Papilloma Virus Type 16 (HPV) L1 Protein	MAb	MAV56-981	Mouse	IHC(p),IP,WB	Purified	IgG2a
Human Papilloma Virus Type 16 (HPV) L1 Protein	MAb	MAV56-981T	Mouse	IHC(p),IP,WB	Purified	IgG2a
Human Papilloma Virus Type 18 (HPV) E6 Protein	MAb	MAV56-965	Mouse	IHC(p),IP,WB	Purified	IgG1
Human Papilloma Virus Type 18 (HPV) E6 Protein	MAb	MAV56-267	Mouse	EIA,IHC,RIA,WB	Purified	IgG1
Human Papilloma Virus Type 18 (HPV) E7 Protein	MAb	C86238M	Mouse	EIA,Pr,WB	Purified	IgG2b
Human Papilloma Virus Type 18 (HPV) E7 Protein	MAb	C86718M	Mouse	EIA,Pr,WB	Purified	IgG1
Human Papilloma Virus Type 18 (HPV) E7 Protein	MAb	C86867M	Mouse	EIA,Pr,WB	Purified	IgG2a
Human Papilloma Virus Type 18 (HPV) Capsid L1 Protein	MAb	C01702M	Mouse	EIA	Purified, Liquid	IgG1

Herpes Simplex Virus Type 1 (HSV-1) & 2 (HSV-2)

HSV infections are common worldwide however, the majority of infected individuals remain undiagnosed. HSV-1 is usually transmitted during childhood through contact with oral secretions (cold sores). HSV-2 is the main cause of neonatal HSV infection (70-85%) which can be devastating to an infant and can develop into congenital HSV which has serious consequences including death. Due to a high degree of genetic similarity between HSV-1 and HSV-2, most viral proteins induce a cross-reactive antibody response that hampers the discrimination between HSV-1 and HSV-2 infections using serological approaches. However, since the discovery of the serologically distinct HSV viral envelope glycoproteins gG-1 (HSV-1) and gG-2 (HSV-2), new type-specific immunoassays have been developed that are capable of discriminating between HSV-1 and HSV-2 infections.

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
HSV-1						
Herpes Simplex Virus Type 1 (HSV-1) Antigen (Strain F) >10% Viral Protein	Ag	7305	Vero Cells	EIA	Partially Purified	N/A
Herpes Simplex Virus Type 1 (HSV-1) Antigen (Strain F) Concentrate	Ag	7309	Vero Cells	EIA	Partially Purified	N/A
Herpes Simplex Virus Type 1 (HSV-1) Glycoprotein D Glycosylated, Recombinant	Ag	VTI510	*Pichia pastoris*	CLIA,WB	Purified	IgG2b
Herpes Simplex Virus Type 1 (HSV-1) Glycoprotein G, Recombinant	Ag	VTI520	*S. cerevisiae*	CLIA,WB	Purified	IgG2b
Herpes Simplex Virus Type 1 (HSV-1) Glycoprotein D, Recombinant	Ag	R18430	*E. coli*	EIA,WB	Purified	IgG2b
Herpes Simplex Virus Type 1 (HSV-1)	MAb	C01290M	Mouse	EIA	Purified	IgG2a
Herpes Simplex Virus Type 1 (HSV-1)	MAb	C01291M	Mouse	EIA	Purified	IgG3
Herpes Simplex Virus Type 1 (HSV-1) Glycoprotein C	MAb	C65141M	Mouse	IFA	Purified	IgG1
Herpes Simplex Virus Type 1 (HSV-1) Glycoprotein D	MAb	C8A020M	Mouse	EIA,IP,WB	Purified	IgG1
Herpes Simplex Virus Type 1 (HSV-1) Glycoprotein G-1	MAb	C66150M	Mouse	WB	Purified	IgG
Herpes Simplex Virus Type 1 (HSV-1) Glycoprotein E	MAb	C65120M	Mouse	EIA,IFA	Purified	IgG1
Herpes Simplex Virus Type 1 (HSV-1) Nucleocapsid Protein (155kDa)	MAb	C05014MA	Mouse	IFA,IP,WB	Purified	IgG1
Herpes Simplex Virus Type 1 (HSV-1)	PAb	B65131G	Goat	EIA,IFA	Purified	N/A
Herpes Simplex Virus Type 1 (HSV-1)	PAb	B65133G	Goat	EIA,IFA	FITC	N/A
Herpes Simplex Virus Type 1 (HSV-1)	PAb	B65134G	Goat	EIA	HRP	N/A
HSV-2						
Herpes Simplex Virus Type 2 (HSV-2) Antigen (Strain G) >10% Viral Protein	Ag	7705	Vero Cells	EIA	Partially Purified	N/A
Herpes Simplex Virus Type 2 (HSV-2) Antigen (Strain G) Concentrate	Ag	7749	Vero Cells	EIA	Partially Purified	N/A
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein D, Glycosylated, Recombinant	Ag	VTI540	*P. pastoris*	EIA,WB	Purified	IgG2b
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein D, Recombinant	Ag	R18530	*E. coli*	EIA,WB	Purified	IgG2b
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein D (gD)	MAb	C01859M	Mouse	EIA, IFA	Purified	IgG1
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein D	MAb	C86302M	Mouse	EIA,WB	Purified	IgG
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein E	MAb	C65901M	Mouse	EIA	Purified	IgG1
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G (gG-2) Recombinant	Ag	R01673	*E. coli*	EIA, LF, CLIA, WB	Purified	N/A
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G	Ag	EV9287	Vero Cells	EIA	Purified	IgG2a
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G (gG)	Ag	R01594	Synthetic	EIA,WB	Purified	N/A
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G (gG)	Ag	R01591	Synthetic	EIA,WB	Purified	N/A
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G, Recombinant	Ag	R18350	*E. coli*	EIA,WB	Purified	IgG2b
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G, Recombinant	Ag	VTI530	*S. cerevisiae*	EIA,WB	Purified	IgG2b
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G	MAb	C65116M	Mouse	IFA	Purified	IgG1

Product list

Herpes Simplex Virus Type 1 (HSV-1) & 2 (HSV-2) continued

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G-2	MAb	C66501M	Mouse	WB	Ascites	IgG
Herpes Simplex Virus Type 2 (HSV-2) Glycoprotein G-2	MAb	C66516M	Mouse	WB	Purified	IgG
Herpes Simplex Virus Type 2 (HSV-2)	MAb	C01292M	Mouse	EIA	Purified	IgG1
Herpes Simplex Virus Type 2 (HSV-2)	PAb	B65121S	Sheep	EIA,IFA,WB	Purified	N/A
Herpes Simplex Virus Type 2 (HSV-2)	PAb	B65123S	Sheep	EIA,IFA,WB	FITC	N/A
Herpes Simplex Virus Type 2 (HSV-2)	PAb	B65124S	Sheep	EIA,ICC,WB	HRP	N/A
HSV-1 & HSV-2						
Herpes Simplex Virus Types 1 & 2 (HSV-1&2) Glycoprotein D	MAb	C01294M	Mouse	EIA,Pr	Purified	IgG1
Herpes Simplex Virus Types 1 & 2 (HSV-1&2) Glycoprotein D	MAb	C65912M	Mouse	EIA,IFA	Purified	IgG2
Herpes Simplex Virus Types 1 & 2 (HSV-1&2)	PAb	B65107R	Rabbit	IFA,WB	Purified	N/A
Herpes Simplex Virus Types 1 & 2 (HSV-1&2)	PAb	B65205R	Rabbit	EIA,ICC	HRP	N/A

Human T-Cell Lymphotropic Virus Type 1 (HTLV-I)

HTLV-1 belongs to a family of retroviruses that infects T-lymphocytes to cause a range of disorders. Infection is usually asymptomatic in the beginning and typically manifests later in life to cause fatal leukemia, debilitative myelopathy, uveitis, infectious dermatitis, or other inflammatory disorders. HTLV-1 can be transmitted via breast milk, sexual contact, and intravenous drug use. Serological assays such as ELISA and PCR for HTLV are widely used in routine screening of blood donors.

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Human T-Cell Lymphotropic Virus Type 1 Env. C-Terminal of gp46 and most of p21	Ag	R18142	*E. coli*	EIA, WB	Purified	N/A
Human T-Cell Lymphotropic Virus Type 1 gp21 (a.a. 351-404)	Ag	R01433	*E. coli*	EIA, WB, LF	Purified	N/A
Human T-Cell Lymphotropic Virus Type 1 gp46-gp21 (a.a. 165-440)	Ag	R01434	*E. coli*	EIA, WB , LF	Purified	N/A
Human T-Cell Lymphotropic Virus Type 1 p24	Ag	R18152	*E. coli*	EIA, WB	Purified	N/A

Mycoplasma genitalium

Mycoplasma genitalium is a common sexually transmitted disease with many of the same symptoms as gonorrhea and chlamydia. It is a bacterium that infects the urethra, cervix and anus and most infections are asymptomatic. In men, it is the second most common cause of nongonococcal urethritis and in women, M. genitalium is commonly found in association with bacterial vaginosis, cervicitis and pelvic inflammatory disease. An FDA approved assay for M. genitalium is not yet available so diagnosis is usually is made in patient with persist symptoms who test negative for chlamydia and gonorrhea.

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Mycoplasma genitalium	MAb	C01665M	Mouse	EIA, IFA	Purified	IgG2b
Mycoplasma genitalium	MAb	C01666M	Mouse	EIA, IFA	Purified	IgG2b
Mycoplasma genitalium	MAb	C01667M	Mouse	EIA, IFA	Purified	IgG2b
Mycoplasma genitalium	MAb	C01668M	Mouse	EIA, IFA	Purified	IgG2b

Neisseria gonorrhoeae

N. gonorrhoeae is a gram-negative bacteria that causes infections in the urethra, cervix, vagina or anus. It is one of the two most common STDs in the United States along with chlamydia. If left untreated, gonorrhea infections can spread to higher portions of the reproductive tract, causing prostatitis and epididymitis in men, or pelvic inflammatory disease (PID) in women. It can be diagnosed by serologic methods using antigen detection assays, such as direct fluorescent antibody (DFA) testing and enzyme immunoassay (EIA).

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Neisseria gonorrhoeae	MAb	C01818M	Mouse	EIA, IFA	Purified	IgG2b
Neisseria gonorrhoeae	MAb	C01819M	Mouse	EIA, IFA	Purified	IgG2b
Neisseria gonorrhoeae	MAb	C01820M	Mouse	EIA,IFA	Purified	IgG1
Neisseria gonorrhoeae (all antigens)	PAb	B65111B	Rabbit	IFA	Biotin	N/A
Neisseria gonorrhoeae (all antigens)	PAb	B65111R	Rabbit	IFA	Purified	N/A
Neisseria gonorrhoeae (all antigens)	PAb	B65111P	Rabbit	EIA,ICC	HRP	N/A
Neisseria meningitidis (all antigens)	PAb	B65612F	Rabbit	IFA	FITC	N/A
Neisseria meningitidis (all antigens)	PAb	B65612R	Rabbit	EIA,IFA	Purified	N/A

Treponema pallidum (Syphilis)

T. pallidum is a spirochete bacterium that is passed from person to person through direct contact with a syphilis sore. It causes a systemic infection with symptoms that vary depending on the stage of the disease and it can have very serious complications when left untreated. Syphilis has several clinical manifestations, making it difficult to diagnose based on clinical symptoms alone. Also, *T. pallidum* cannot be isolated in culture so confirmation must be performed either via ELISA-based serological assays or by direct visual inspection using microscopy. In the past few years, several highly immunogenic lipoproteins have been identified as diagnostic targets throughout all stages of a syphilis infection, including Tp17, Tp15, Tp44.5 (TmpA), Tp47, Tp41 and Tp35 (TmpC). For this reason, several commercial tests have been developed using a combination of these immunogenic antigens and have proven to be highly sensitive and specific for the diagnosis of an active or latent syphilis infection.

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Treponema pallidum (Syphilis) p15, Recombinant	Ag	R01582	*E. coli*	EIA,WB	Purified	N/A
Treponema pallidum (Syphilis) p15, Recombinant	Ag	R8A101	*E. coli*	EIA,WB	Purified	N/A
Treponema pallidum (Syphilis) p15, Recombinant	Ag	R01531	*E. coli*	EIA	Purified	N/A
Treponema pallidum (Syphilis) p17, Recombinant	Ag	R01583	*E. coli*	EIA,WB	Purified	N/A
Treponema pallidum (Syphilis) p17, Recombinant	Ag	R8A201	*E. coli*	EIA,WB	Purified	N/A
Treponema pallidum (Syphilis) p17, Recombinant	Ag	R01497	*E. coli*	EIA	Purified	N/A
Treponema pallidum (Syphilis) p17, Recombinant	Ag	R01528	*E. coli*	EIA	Purified	N/A
Treponema pallidum (Syphilis) p41, Recombinant	Ag	R18044	*E. coli*	EIA,WB	Purified	N/A
Treponema pallidum (Syphilis) p41, Recombinant	Ag	R18830	*E. coli*	EIA,WB	Purified	N/A
Treponema pallidum (Syphilis) p41, Recombinant	Ag	R01529	*E. coli*	EIA	Purified	N/A
Treponema pallidum (Syphilis) p47, mosaic of immunodominant regions, Recombinant	Ag	R01568	*E. coli*	EIA	Purified	N/A
Treponema pallidum (Syphilis) p47, Recombinant	Ag	R8A403	*E. coli*	EIA,WB	Purified	N/A
Treponema pallidum (Syphilis) p47 Recombinant	Ag	R01606	*E. coli*	EIA, LF, WB	Purified	N/A
Treponema pallidum (Syphilis) Treponemal Membrane Protein A (TmpA) Recombinant	Ag	R8A404	*E. coli*	EIA,WB	Purified	N/A
Treponema pallidum (Syphilis) Treponemal Membrane Protein A (TmpA) Recombinant	Ag	R01530	*E. coli*	EIA	Purified	N/A
Treponema pallidum (Syphilis) Treponemal Membrane Protein A (TmpA) (Syphilis) Recombinant	Ag	R01665	*E. coli*	EIA, WB	Purified	N/A
Treponema pallidum(Syphilis) Treponemal Membrane Protein A (TmpA) Full Length, Recombinant	Ag	R01632	*E. coli*	EIA, LF, WB	Purified	N/A

Product list

Treponema pallidum (Syphilis) continued

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Treponema pallidum (Syphilis) p17/p15/p44.5/p47 Recombinant	Ag	R01705	*E. coli*	EIA	Purified	N/A
Treponema pallidum (Syphilis) p15/p17/p47, Recombinant	Ag	R01681	*E. coli*	LF, Pr	Purified	N/A
Treponema pallidum (Syphilis) p15/p17/p47, Recombinant	Ag	R01682	*E. coli*	LF, Pr	Purified	N/A
Trepenoma pallidum (Syphilis)	MAb	C65811M	Mouse	EIA, IFA, WB	Purified	IgG2b
Trepenoma pallidum (Syphilis) and Trepenoma reiter	MAb	C01706M	Mouse	EIA, WB	Purified	IgG1
Treponema pallidum (Syphilis) p17	MAb	C01705M	Mouse	EIA	Purified, Liquid	IgG2
Treponema pallidum (Syphilis) p17	MAb	C01707M	Mouse	EIA	Purified, Liquid	IgG2
Treponema pallidum (Syphilis) p47	MAb	C01263M	Mouse	EIA,IFA,WB	Purified	IgG2
Treponema pallidum (Syphilis) p47	MAb	C01261M	Mouse	EIA,IFA	Purified	IgG2
Treponema pallidum (Syphilis) (all antigens)	PAb	B65210B	Rabbit	IFA,IHC(p)	Biotin	N/A
Treponema pallidum (Syphilis) (all antigens)	PAb	B65210F	Rabbit	IFA,IHC(p)	FITC	N/A
Treponema pallidum (Syphilis) (all antigens)	PAb	B65210R	Rabbit	IFA,IHC(p)	Purified	N/A
Treponema pallidum (Syphilis) (all antigens)	PAb	B65210P	Rabbit	IHC(p)	HRP	N/A

Trichomonas vaginalis

T. vaginalis is an anaerobic, flagellated protozoan parasite and the most common curable STD. Approximately 70% of women and 30% of men with *T. vaginalis* do not exhibit symptoms so diagnosis based on clinical symptoms alone is unreliable. Although traditional methods such as direct microscopic observation (wet mount) of vaginal secretions are still used, newer methods, such as rapid antigen testing and transcription-mediated amplification, have demonstrated much greater sensitivity.

Specificity	Type	Catalog #	Host / Source	Tested Apps	Format	Isotype
Trichomonas vaginalis	MAb	C01567M	Mouse /Ascites	IFA	Purified	IgG1
Trichomonas vaginalis	MAb	C01568M	Mouse /Ascites	EIA,IFA,Pr	Purified	IgG3
Trichomonas vaginalis	MAb	C01569M	Mouse /Ascites	EIA,IFA,Pr	Purified	IgG3
Trichomonas vaginalis	MAb	C01571M	Mouse /Ascites	EIA,IFA,Pr	Purified	IgG3
Trichomonas vaginalis, p65 adhesive antigen	MAb	C65675M	Mouse /Ascites	EIA,IFA	Purified	IgG1

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