

# **STI PrEP Comprehensive**

Provider:		Sex:	Collected:	
Patient:	Date o	of Birth:	Received:	
	Accession #:		Completed:	
Tests - DBS	Results	Flag	Reference Range	
Creatinine	0.90 mg/dL		0.30 - 1.02 mg/dL	
Hepatitis B Surface antigen	Negative		Negative	
HIV 1/2 Antigen/Antibody (4th Generation)	Presumptive Positive		Negative	
Herpes 2 IgG (HSV 2)	Positive		Negative	
Syphilis IgG	Equivocal		Negative	
Tests - Urine (yellow top tube)	Results	Flag	Reference Range	
Chlamydia trachomatis DNA	Positive		Negative	
Neisseria gonorrhoeae DNA	Negative		Negative	
Trichomonas vaginalis DNA	Positive		Negative	
Tests - Rectal Swab	Results	Flag	Reference Range	
Chlamydia trachomatis DNA	Positive		Negative	
Neisseria gonorrhoeae DNA	Negative	$\Delta$	Negative	
Tests - Throat Swab	Results	Flag	Reference Range	
Chlamydia trachomatis DNA	Positive		Negative	
Neisseria gonorrhoeae DNA	Negative		Negative	

# About These Tests:

## Presumptive Positive Result:

Presumptive positive result is not a final reported test result, it means the specimen initially tested positive. The standard procedure calls to retest an initial positive result in duplicate for confirmation. However, there is insufficient sample volume for confirmation. Please resubmit using serum to complete testing.

Test results should be evaluated in relation to patient symptoms, clinical history, and other laboratory findings. Individuals should review their results with a healthcare provider.

## Creatinine (Enzymatic Assay)

Creatinine reference range is gender specific and for age >= 18 years. The limit of detection (LoD) for DBS is the same as standard venous serum, which is 0.3 mg/dL. Hematocrit level (the volume percentage of red cells in a blood sample) <30% or >65% may result in >15% or >0.3 mg/dL bias in DBS creatinine result compared to venous serum.

# Hepatitis B Surface Antigen (EIA)

Positive Hepatitis B Surface Antigen (HBs Ag) test results should be followed up by a confirmatory neutralization procedure utilizing human anti-HBs. For follow-up confirmatory testing, please submit a serum specimen.

The limit of detection (LoD) for DBS HBs Ag is 5.0 IU/mL. In comparison, the LoD for standard venous serum method is 0.156 IU/mL. DBS sample is less sensitive than the standard venous serum by 32-fold. DBS samples should NOT be used to rule out HBV infection or to determine whether a treatment has achieved an undetectable HBs Ag level.

## HIV 1/2 Antigen-Antibody (EIA)

HIV 1/2 Antigen-Antibody is a primary screening test. A negative result is negative for all three components, HIV-1 antigen and HIV-1/HIV-2 antibodies. If there is a possibility of very early infection leading to a negative initial antigen/antibody test, such as when recent exposure is suspected,

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consider testing for HIV-1/2 PCR.

A Positive HIV 1/2 Antigen-Antibody test should be followed up with a supplemental antibody test that differentiates HIV-1 antibodies from HIV-2 antibodies.

DBS HIV 1/2 Ag-Ab antibody is less sensitive than venous serum by 32-fold. The limit of detection (LoD) for DBS HIV 1/2 Ag-Ab is 1/32 titer dilution. In comparison, the LoD for standard venous serum method is 1/1024.

A negative HIV 1/2 Ag-Ab test result does not exclude the possibility of exposure.

## Herpes Simplex Virus Antibody (EIA)

Equivocal Herpes Simplex 2 (HSV-2) antibody test result should be followed by a second specimen 10 to 14 days later. If the second specimen is also equivocal, primary or recent infection is not likely. If the second specimen is positive, previous exposure to HSV-2 can be considered.

DBS HSV-2 antibody is less sensitive than venous serum by 2-fold. The limit of detection (LoD) for DBS HSV-2 antibody is 1/4 titer dilution. In comparison, the LoD for standard venous serum method is 1/8. A negative HSV-2 antibody test result does not exclude the possibility of exposure to HSV-2. Levels of HSV-2 antibody may be undetectable in early infection.

# Treponema pallidum (Syphilis) Antibody (EIA)

Anti-treponemal (Syphilis) antibody testing has been shown to be an effective way to screen for infection with Treponema pallidum. Negative results indicate that Syphilis is unlikely. Because anti-treponemal antibodies persist after treated infection, guidelines recommend performing a non-treponemal (RPR) test to determine if the infection is current or past when the Syphilis antibody test result is positive. For follow-up testing on RPR, please submit a serum specimen

DBS Syphilis antibody is less sensitive than venous serum by 4-fold. The limit of detection (LoD) for DBS Syphilis antibody is 1 titer dilution. In comparison, the LoD for standard venous serum method is 1/4. A negative Syphilis antibody test result does not exclude the possibility of exposure to T. pallidum (Syphilis). Levels of Syphilis antibody may be undetectable in early infection.

## **DBS Testing**

The result from a dried blood spot (DBS) specimen is an estimation of the result that an individual would have received from a venous blood specimen.

A DBS result can be affected by how the sample is collected, stored, and transported. Thus, it is important to adhere to strict collection procedures and specimen stability windows.

The DBS tests are developed with analytical performance characteristics determined and validated by US BioTek Laboratories in pursuant of the CLIA regulations. These tests have not been cleared or approved by the U.S. Food and Drug Administration (FDA).

## Health Information and Privacy

US BioTek Laboratories is required to report positive results for Chlamydia, Gonorrhea, HIV, Syphilis, HBV, and HCV to public health authorities.

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