

# At Home PrEP Test (Expanded Follow-Up)

Provider:	Sex:	Collected:
Patient:	Date of Birth:	Received:
	Accession #:	Completed:

Tests - DBS	Results	Flag	Reference Range
Creatinine	0.90 mg/dL		0.30 - 1.02 mg/dL
HIV 1/2 Antigen/Antibody (4th Generation)	Negative		Negative

Tests - Urine (yellow top tube)	Results	Flag	Reference Range
Chlamydia trachomatis DNA	Negative		Negative
Neisseria gonorrhoeae DNA	Negative		Negative
Trichomonas vaginalis 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.

## 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, 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.

#### **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**

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