



**Determine<sup>TM</sup>**  
PRODUCT  
CATALOG

INFECTIOUS DISEASE

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# DETERMINE™ HIV-1/2

**Determine™ HIV-1/2** is an *in vitro*, visually read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as an aid to detect antibodies to HIV-1/HIV-2 from infected individuals.

- Clear, dependable results in 15 minutes
- Maximize testing efficiency with a few simple steps
- Can be used with whole blood, serum or plasma
- Enables fast linkage to care
- Detects a wide variety of subtypes (refer to IFU)
- Shelf life: 18 months
- Storage conditions: 2-30° C
- Sample volume: 50 µL



## PROCEDURE

### 1 Prepare Test

Tear one strip from the right and remove cover.

### 2 Add Sample

#### Fingerstick Whole Blood

Add 50 µL of whole blood to the Sample Pad. When all the blood is absorbed into the Sample Pad, immediately apply one drop of Chase Buffer to the Sample Pad.

#### Venipuncture Whole Blood

Add 50 µL of whole blood to the Sample Pad. Wait 1 minute and add one drop of Chase Buffer.

#### Plasma or Serum

Add 50 µL of serum or plasma to the Sample Pad.

### 3 Read Result

Wait a minimum of 15 minutes (up to 60 minutes) and read result.

	POSITIVE	NEGATIVE	INVALID
<b>CONTROL</b>			
<b>PATIENT</b>			

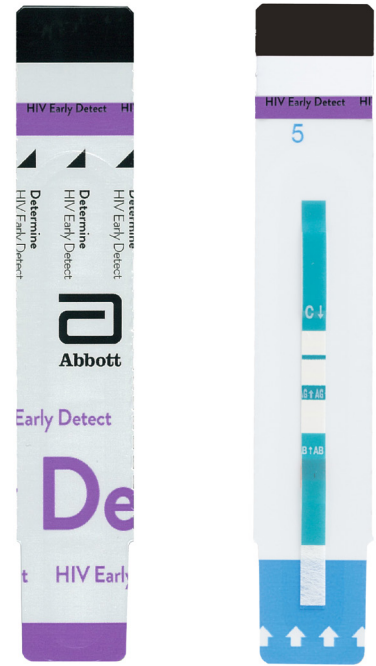
## ORDERING INFORMATION

DESCRIPTION	SPECIMEN	QUANTITY	CATALOG NO.
Determine™ HIV-1/2	Whole Blood/Serum/Plasma	20 Tests/Kit	7D2346 (CE)/7D2342 (Non-CE)
Determine™ HIV-1/2	Whole Blood/Serum/Plasma	100 Tests/Kit	7D2347 (CE)/7D2343 (Non-CE)
Determine™ HIV-1/2 SET (tests, capillary tubes, lancets, buffer)	Fingerstick Whole Blood	100 Tests/Kit	7D2343SET (Non-CE)
Chase Buffer	For Whole Blood	2.5 mL, 100 tests	7D2243 (CE and Non-CE)
EDTA Capillary Tubes	Fingerstick Whole Blood	100 Tubes	7D2227 (CE)/7D2222 (Non-CE)

# DETERMINE™ HIV EARLY DETECT

**Determine™ HIV Early Detect** is an *in vitro*, visually read qualitative immunoassay for the detection of antibodies (Ab) to HIV-1 and HIV-2 and the detection of non-immunocomplexed (free) HIV-1 p24 antigen (Ag) in human capillary and venous whole blood, plasma or serum.

- Detects more acute infections
- Helps increase case finding
- Facilitates fast linkage into appropriate care
- Robust to major known circulating subtypes (refer to IFU)
- Rapid, accurate result in just 20 minutes
- Easy to use – minimal training and no expensive lab equipment
- Sensitivity: 100%  
(Please refer to the Product Insert for the analytical sensitivity of HIV-1 p24 Antigen)
- Specificity: 99.72%
- Shelf life: 18 months
- Storage conditions: 2-30° C
- Sample volume: 50 µL

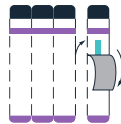


## PROCEDURE

1

### Prepare Test

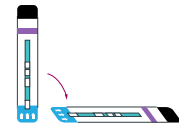
Tear one strip from the right and remove cover.



2

### Place Test

Place one strip on a flat surface where the test is to be performed.

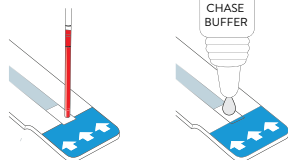


3

### Add Sample

#### Fingerstick Whole Blood

Add 50 µL of whole blood to the Sample Pad. When all the blood is transferred from the capillary tube to the Sample Pad, immediately apply one drop of chase buffer to the Sample Pad.



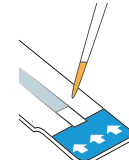
#### Venipuncture Whole Blood

Add 50 µL of whole blood (precision pipette) to the Sample Pad. Wait 1 minute and add one drop of Chase Buffer.



#### Serum or Plasma

Add 50 µL of serum or plasma (precision pipette) to the Sample Pad.



4

### Read Results

Read the test result between 20 and 40 minutes after the addition of the sample. **Do not read the test result after 40 minutes and before 20 minutes.** The control line should appear for all results. If it does not appear, the results are invalid and should be repeated using a new test strip.



RESULT KEY



	POSITIVE			NEGATIVE		INVALID		
	Ab	Ag	Ab/Ag	Ab	Ag	Ab	Ag	Ab
CONTROL	C↓	C↓	C↓	C↓	C↓	C↓	C↓	C↓
ANTIGEN	AG↑	AG↑	AG↑	AG↑	AG↑	AG↑	AG↑	AG↑
ANTIBODY	AB↑	AB↑	AB↑	AB↑	AB↑	AB↑	AB↑	AB↑

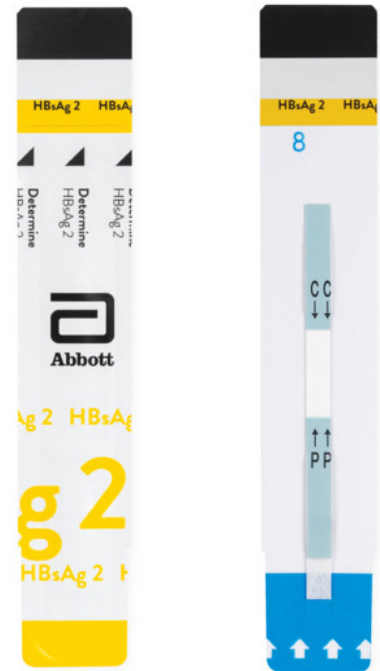
## ORDERING INFORMATION

DESCRIPTION	SPECIMEN	QUANTITY	CATALOG NO.
Determine™ HIV Early Detect	Whole Blood/Serum/Plasma	20 Tests/Kit	7D2846 (CE)/7D2842 (Non-CE)
Determine™ HIV Early Detect	Whole Blood/Serum/Plasma	100 Tests/Kit	7D2847 (CE)/7D2843 (Non-CE)
Determine™ HIV Early Detect SET (tests, capillary tubes, lancets, buffer)	Fingerstick Whole Blood	100 Tests/Kit	7D2843SET (Non-CE)
Chase Buffer	For Whole Blood	For 100 Tests	7D2243 (CE and Non-CE)
EDTA Capillary Tubes	Fingerstick Whole Blood	100 Tests/kit	7D2227 (CE)/7D2222 (Non-CE)
Determine™ HIV Controls	–	3 positive & 1 negative bottle	7D2253 (CE and Non-CE)

# DETERMINE™ HBsAg 2

**Determine™ HBsAg 2** is an *in vitro*, visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum. The test is intended as an aid to detect HBsAg from infected individuals.

- Detecting infection earlier can lead to better patient outcomes
- Rapid turnaround time helps reduce patients lost to follow up, facilitating fast linkage to care
- Simple procedure with no special expertise or lab equipment required
- Flexibility of multiple sample types: Serum/Plasma, Fingerstick Whole Blood, Venipuncture Whole Blood
- Detects major HBsAg mutants (refer to Product Insert)
- Analytical sensitivity: 0.1 IU/mL
- Specificity: 99.6%
- Time to result: 15 minutes
- Shelf life: 18 months
- Storage conditions: 2-30° C
- Sample volume: 50 µL

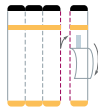


## PROCEDURE

1

### Prepare Test

Tear one strip from the right and remove cover.



2

### Place Test

Place one strip on a flat surface where the test is to be performed.

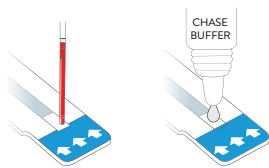


3

### Add Sample

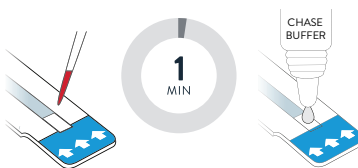
#### Fingerstick Whole Blood

Add 50 µL of whole blood to the Sample Pad. When all the blood has been transferred from the capillary tube to the middle of the Sample Pad, immediately apply one drop of Chase Buffer to the Sample Pad.



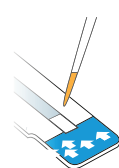
#### Venipuncture Whole Blood

Add 50 µL of whole blood (precision pipette) to the middle of the Sample Pad. Wait 1 minute and add one drop of Chase Buffer.



#### Serum or Plasma

Add 50 µL of serum or plasma (precision pipette) to the Sample Pad.



4

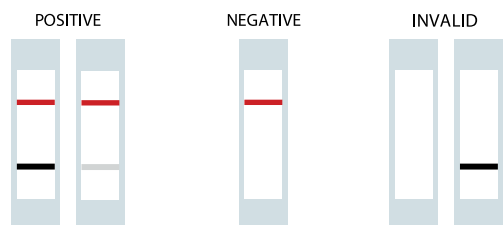
### Read Results

Read the test result between 15 and 30 minutes after the addition of the sample. **Do not read the test result after 30 minutes.** The control line should appear for all results. If it does not appear, the results are invalid and should be repeated.



CONTROL  
—  
PATIENT  
—

Interpret any visible bar (even very faint) in the window as a valid result.



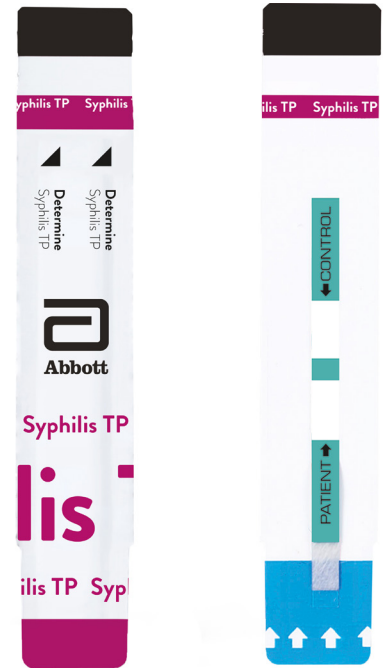
## ORDERING INFORMATION

DESCRIPTION	SPECIMEN	QUANTITY	CATALOG NO.
Determine™ HBsAg 2	Whole Blood/Serum/Plasma	20 Tests/Kit	7D2946 (CE)/7D2942 (Non-CE)
Determine™ HBsAg 2	Whole Blood/Serum/Plasma	100 Tests/Kit	7D2947 (CE)/7D2943 (Non-CE)
Determine™ HBsAg 2 SET (tests, capillary tubes, lancets, buffer)	Fingerstick Whole Blood	100 Tests/Kit	7D2943SET (Non-CE)
Chase Buffer	Whole Blood	2.5 mL, 100 tests	7D2243 (CE and Non-CE)
EDTA Capillary Tubes	Fingerstick Whole Blood	100 Tubes	7D2227 (CE)/7D2222 (Non-CE)

# DETERMINE™ SYPHILIS TP

**Determine™ Syphilis TP** is an *in vitro*, visually read qualitative immunoassay for the detection of antibodies to *Treponema pallidum*, which is the bacteria that causes syphilis infection, in human serum, plasma or whole blood.

- Accurate and reliable results in just 15 minutes, ensuring testing and treatment of patients in the same visit
- Easy to transport and store, with no refrigeration required and storage conditions of 2-30°C
- No power or water source is needed to run the test
- The test can use whole blood, serum or plasma
- Collection can be by fingerstick or venipuncture
- Shelf life: 15 months
- Sample volume: 50 µL



## PROCEDURE

### 1 Prepare Test

Tear one strip from the right and remove cover.

### 2 Add Sample

#### Fingerstick Whole Blood

Add 50 µL of whole blood to the Sample Pad. When all the blood is absorbed into the Sample Pad, immediately apply one drop of Chase Buffer to the Sample Pad.

#### Venipuncture Whole Blood

Add 50 µL of whole blood to the Sample Pad. Wait 1 minute and add one drop of Chase Buffer.

#### Plasma or Serum

Add 50 µL of serum or plasma to the Sample Pad.

### 3 Read Result

Wait a minimum of 15 minutes (up to 24 hours) and read result.

RESULT KEY

LINE	POSITIVE	NEGATIVE	INVALID
CONTROL			
PATIENT			

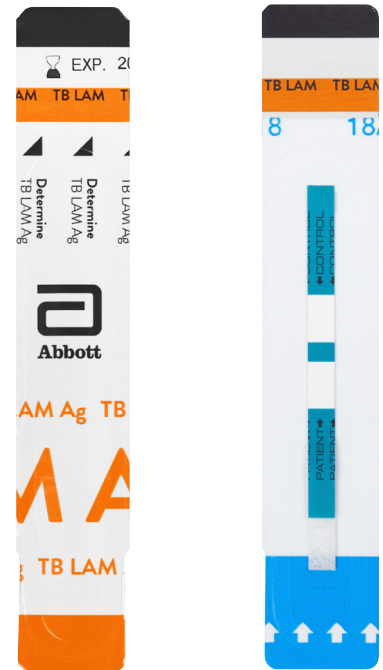
## ORDERING INFORMATION

DESCRIPTION	SPECIMEN	QUANTITY	CATALOG NO.
Determine™ Syphilis TP	Serum, Plasma, Whole Blood	100 Tests/Kit	7D2443 (CE and Non-CE)
Determine™ Syphilis TP	Serum, Plasma, Whole Blood	30 Tests/Kit	7D2442 (CE and Non-CE)
Determine™ Syphilis TP SET (tests, capillary tubes, lancets, buffer)	Fingerstick Whole Blood	100 Tests/Kit	7D2443SET (Non-CE)
Chase Buffer	For Whole Blood	100 Tests/Kit	7D2243 (CE and Non-CE)
EDTA Capillary Tubes	For Whole Blood	100 Tubes	7D2227 (CE)/7D2222 (Non-CE)

# DETERMINE™ TB LAM Ag

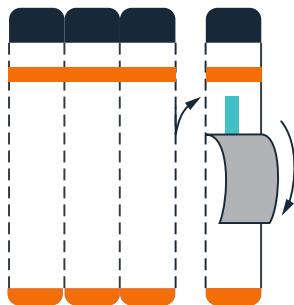
**Determine™ TB LAM Ag** is an *in vitro*, visually read, qualitative immunoassay for the detection of lipoarabinomannan (LAM) antigen of mycobacteria in human urine as an aid in the diagnosis of active mycobacterial infection in HIV-positive individuals with clinical symptoms of tuberculosis. Make rule-in decisions in minutes at the point of care, enabling earlier treatment for your patients.

- Pulmonary and extrapulmonary TB detection
- Best performance in immunosuppressed patients
- Convenient urine (unprocessed) sample
- Antigen detection test
- Results in 25 minutes
- Storage conditions: 2–30°C

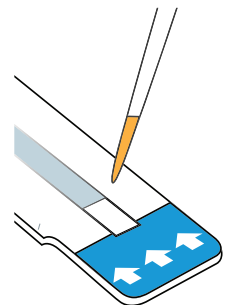


## PROCEDURE

- 1 Prepare Test**  
Tear one strip from the right and remove cover.



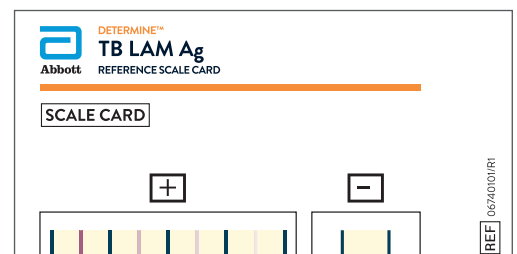
- 2 Add Sample**  
Apply 60 µL of urine to the sample pad.



- 3 Read Results**  
Wait 25 minutes and read the results.



- 4 Check Results**  
Check results against the Reference Scale Card.



## ORDERING INFORMATION

DESCRIPTION	SPECIMEN	QUANTITY	CATALOG NO.
Determine™ TB LAM Ag	Urine	25 Tests/Kit	7D2741

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