

Hepatitis B
remains endemic
in large portions
of the world.

The Alere™ Determine™ HBsAg
Outstanding performance versus industry standards

Order Details	Sample Type	Kit Size	Product Code
Alere™ Determine HBsAg	Serum Plasma *Whole Blood	100 Tests	7D2543

*For Whole Blood application please order Chase Buffer.

Accessories	Kit Size	Product Code
EDTA Capillary Tubes	100 Tests	7D2222
Chase Buffer	100 Tests	7D2243

Alere: The leader in point-of-care testing

The Alere Determine™ TB LAM Ag

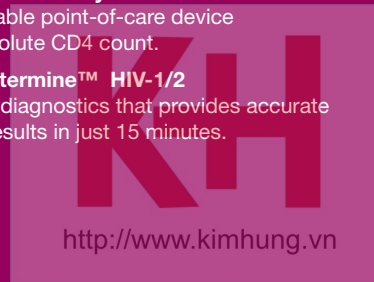
Innovative point-of-care diagnostic tool designed for HIV & TB co-infected individuals.

The Alere Pima™ Analyser

The only portable point-of-care device providing absolute CD4 count.

The Alere Determine™ HIV-1/2

Point-of-care diagnostics that provides accurate and reliable results in just 15 minutes.



Distributed by:

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Product availability varies by region



References

1. Lavanchy D. Hepatitis B virus epidemiology, disease burden, treatment, and current and emerging prevention and control measures. J Viral Hepatitis 2004;11:97.
2. World Health Organisation. Department of Communicable Diseases Surveillance and Response. WHO/CDS/LYO/2002.2:Hepatitis B. <http://www.who.int/emc>.
3. A total of 434 HBsAg seropositive serum and whole blood specimens from Asia and North America were tested by Determine HBsAg and a commercially available test.
4. A total of 1,908 serum, plasma, and whole blood specimens from Asia, West Africa, and North America were tested by Determine HBsAg and a commercially available test.

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The Alere Determine™ HBsAg

Containing a global health problem

detect... diagnose... determine...



Actual size



Rapid diagnostic tests play a pivotal role in infection control

Significant disease burden

- 2 billion people are infected worldwide¹
- 350 million people currently have chronic hepatitis B virus (HBV) infection¹
- Three quarters of the world's population live in endemic areas²
- 4 million people each year are newly infected²
- 1 million people a year die from hepatitis B or associated liver diseases^{1,2}
- HBV is the 10th leading cause of death worldwide¹

Chronic carriers present a continued threat

- Infected infants can carry and transmit HBV for many years beyond childhood²
- Carrier individuals look healthy and have no symptoms but are highly infectious²
- HIV-positive and other immunocompromised individuals are common carriers²

HBV is easily transmissible

- Mother to newborn baby
- Child to child in endemic areas
- By sexual contact
- Through blood transfusions
- Contact with infected blood or other bodily fluids

Value of simple, reliable diagnostic tests

- Detect active infection, acute and chronic
- Screen blood before transfusion
- Help contain spread of infection

The Alera Determine™ HBsAg Test

A rapid *in vitro* qualitative immunoassay for detection of Hepatitis B Surface Antigen
An important early marker of infection... helps in diagnosing acute infection, confirming chronic infection, and screening blood supplies

Rapid

<http://www.kimhung.vn>

- Clear, dependable results in 15 minutes
- Facilitates prompt, appropriate follow-up of infected patients

Simple procedure

- **Step 1**, add 50µl of sample to pad. If using whole blood, add chase buffer.
- **Step 2**, wait 15 minutes, then read the result
Two red bars = positive. One red bar in the control window = negative.
(No red bar in the control window means test is invalid.)
- Requires minimal training and no equipment
- So easy it can be used at the lowest levels of health care service

Flexible

- Can use whole blood or serum/plasma
- Collection can be by fingerstick or venipuncture

Easy to transport and store

- No refrigeration required
- Storage conditions 2-30°C
- No power or water source needed to run the test

The Alera Determine™ HBsAg Test

Point-of-care diagnostics that provides accurate and reliable results in just 15 minutes.

Excellent sensitivity³

Population	Determine™ HBsAg	Test A
HBsAg Positive Serum	94.64%	90.08%
Whole blood	98.36%	N/A
Total	95.16%	90.08%

Excellent specificity⁴

Population	Determine™ HBsAg	Test A
Seronegatives Serum	99.85%	99.85%
Plasma	100%	100%
Whole Blood	100%	100%
Pregnant females	100%	100%
West Africans	100%	100%
Disease states other than HBV and potentially interfering substances	100%	100%
Total	99.95%	99.95%