

HIV/AIDS
prevention
begins with
knowledge of
HIV status.

The Alere Determine™ HIV-1/2
Outstanding performance versus industry standards

Meter Kit Contents	Sample Type	Kit Size	Product Code
Alere Determine™ HIV 1/2	Serum Plasma *Whole Blood	20 Tests	7D2222
Alere Determine™ HIV 1/2	Serum Plasma *Whole Blood	100 Tests	7D2227
Alere Determine™ HIV 1/2 (CE)	Serum Plasma *Whole Blood	20 Tests	7D2346
Alere Determine™ HIV 1/2 (CE)	Serum Plasma *Whole Blood	100 Tests	7D2347

Accessories	Kit Size	Product Code
EDTA Capillary Tubes	100 Tests	7D2222
EDTA Capillary Tubes (CE)	100 Tests	7D2227
Chase Buffer	100 Tests	7D2243
Chase Buffer (CE)	100 Tests	7D2247

Alere: The leader in point-of-care testing

The Alere Determine™ TB LAM Ag
Rapid 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 Ag/Ab Combo
Detecting the HIV infection an average 5–7 days earlier than the 3rd generation rapid antibody tests.

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Product availability varies by region

Distributed by:



References

- HIV Assays: Operational Characteristics (Phase 1). Report 14: Simple/Rapid Tests. Geneva, World Health Organisation, 2004. <http://www.who.int/eh/2>
- 2004 Report on the Global AIDS Epidemic: 4th global report. Geneva, Joint United Nations Programme on HIV/AIDS (UNAIDS), 2004. <http://www.unaids.org>
- Centres for Disease Control and Prevention. Syphilis Fact Sheet. May, 2004. <http://www.cdc.gov/std/Syphilis/STD Fact-Syphilis.htm>
- A total of 869 HIV-1 and HIV-2 antibody positive serum and plasma specimens from Asia, Africa, North America and South America were tested by Determine HIV-1/2 and a commercially available test.
- A total of 1,594 serum and plasma specimens from Asia, West Africa, and North America were tested by Determine HIV-1/2 and a commercially available test.

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Knowing Through Screening



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

Actual size



Most HIV infection is diagnosed based on antibody detection¹

Significant disease burden

- Some 37.8 million people are living with HIV²
- 4.8 million people were newly infected in 2003²
- The incidence continues to rise, especially in women²

Linked to other sexually transmitted diseases

- 2 to 5 fold increased risk of acquiring HIV infection when syphilis is present³
- HIV virus is transmitted more readily in people with untreated STDs²

Simple, rapid diagnostic tests can help

- Diagnose individual infection
- Prevent mother-to-child transmission
- Monitor HIV prevalence
- Screen blood donations

The Alere Determine™ HIV-1/2

A rapid *in vitro* qualitative immunoassay for detection of antibodies to the Human Immunodeficiency Virus Type (HIV-1) and Type 2 (HIV-2)

<http://www.kimhung.vn>

Detects all known subtypes of HIV

Rapid

- Clear, dependable results in 15 minutes

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

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

The Alere Determine™ HIV-1/2 Point-of-care diagnostics that provides accurate and reliable results in just 15 minutes.

Excellent sensitivity⁴

Population	Determine™ HIV-1/2	Test A
HIV-1 positive	100%	100%
HIV-2 positive	100%	100%
HIV-1 Subtypes A-G	100%	Not tested
HIV-1 Group O	100%	Not tested
Total	100%	100%

Excellent sensitivity⁵

Population	Determine™ HIV-1/2	Test A
Seronegatives Serum	99.89%	100%
Plasma	100%	100%
Pregnant females	100%	100%
West Africans	97.96%	97.96%
Disease states other than HIV and potentially interfering substances	98.86%	99.45%
Total	99.75%	99.87%