A total of 488 potentially cross-reacting specimens were tested, the results are presented in Table 2.

Table 2

Potentially cross-reacting specimens	No. of specimens tested	KHB® Diagnostic Kit HIV (1+2) Antibody (Colloidal Gold)v2	
		Negative	Positive
Rheumatoid factor	10	10	0
Cytomegalovirus	5	5	0
Epstein Barr Virus	13	11	2
Malaria	85	85	0
Syphilis	52	51	1
Herpes	5	5	0
HBsAg	124	124	0
Anti-HCV	115	114	1
Anti-HBc	15	15	0
Anti-HTLV⅓	15	15	0
Anti-HEV	5	5	0
Specimens from STI clinics	10	10	0
Trypanosomiasis	24	24	0
E Coli infected	10	10	0
Total	488	484	4

Sensitivity

A total of 750 HIV-1 and HIV-2 antibody positive specimens were tested by KHB® Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) V2 (Table 3).

Table 3

Population	No. of specimens tested	KHB® Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) V2		Sensitivity
		Positive	Negative	
HIV-1 Ab positive specimens	360	360	0	100%
non-B subtypes HIV-1 Ab positive specimens	40	40	0	100%
HIV-2 Ab positive specimens	100	100	0	100%
HIV Ab positive specimens	250	250	0	100%
Total	750	750	0	100%

Performance characteristics in comparison with an agreed reference standard

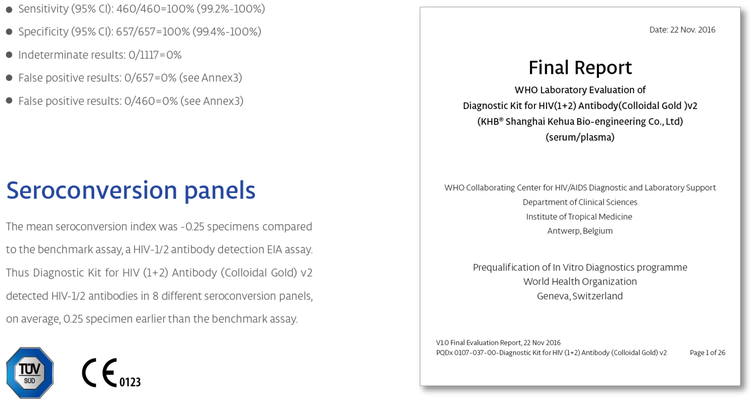
	Initial (95% CI)	Final(95% CI)
Sensitivity%	100% (99.2%-100%)	100% (99.2%-100%)
Specificity%	100% (99.4%-100%)	100% (99.4%-100%)
Invalid rate%	0%	
Inter-reader variability%	0.09%	

	Reference testing results			
Diagnostic Kit for HIV (1+2) Antibody (Colloida Gold) v2 Final results		HIV+	HIV-	Total
	HIV (1&2)+	460	0	460
	HIV-1+	0	0	0
	HIV-2+	0	0	0
	HIV-	0	657	657
	Total	460	657	1117

- Sensitivity (95% CI): 460/460=100% (99.2%-100%)
- Specificity (95% CI): 657/657=100% (99.4%-100%)
- Indeterminate results: 0/1117=0%
- False positive results: 0/657=0% (see Annex3)
- False positive results: 0/460=0% (see Annex3)

Seroconversion panels

The mean seroconversion index was -0.25 specimens compared to the benchmark assay, a HIV-1/2 antibody detection EIA assay. Thus Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) v2 detected HIV-1/2 antibodies in 8 different seroconversion panels, on average, 0.25 specimen earlier than the benchmark assay.



Date: 22 Nov. 2016

Final Report

WHO Laboratory Evaluation of
Diagnostic Kit for HIV(1+2) Antibody(Colloidal Gold)v2
(KHB® Shanghai Kehua Bio-engineering Co., Ltd)
(serum/plasma)

WHO Collaborating Center for HIV/AIDS Diagnostic and Laboratory Support
Department of Clinical Sciences
Institute of Tropical Medicine
Antwerp, Belgium

Prequalification of In Vitro Diagnostics programme
World Health Organization
Geneva, Switzerland

V1.0 Final Evaluation Report, 22 Nov 2016
PQDx 0107-037-00-Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) v2 Page 1 of 26

Shanghai Kehua Bio-engineering Co., Ltd | ADD:1189 North Qinzhou Road, 200233, Shanghai, P.R.China
Tel:86-21-64950625 86-8008203370 | FAX:+86-21-64950975 | EN0078 | Website: http://www.skhb.com

POCT

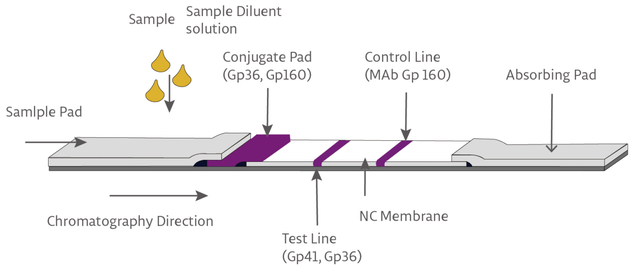
KHB

KHB® Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) V2

Features and Benefits

- **Superior Raw Material**
  Our HIV 1+2 rapid test who utilized superior gp 160 antigens as the major raw material, which is expressed in mammalian cells in our labs. Unlike the antigen expressed in E. Coli, this antigen has great solubility in water, high sensitivity, and very low cross-reactivity. With this superior antigen, the sensitivity and specificity of the kit is ensured.
- **"Sandwich" Testing Principle**
  Based on the double antigen"Sandwich" principle, this kit can easily detect the HIV antibody (both IgG and IgM) within 2-3 weeks after infection.
- **Easy to Use**
  Small Sample Size: 40μL
  Reads the result within 15-25 minutes
  No equipment required
- **Suitable for whole blood, serum, and plasma samples**

A Brief of Overview



KIT COMPONENTS

Component (product code)	50 tests R-401-50-C-2	50 tests KH-R-02	50 tests KH-R-02-CE	1 test R-401-1-C-CE	25 tests R-401-25-C-1-CE	Accessories kit A-GOLD-01
HIV (1+2) antibody test cassette	50	50	50	1	25	N/A
Sample diluent	4ml × 1 bottle	4ml × 1 bottle	4ml × 1 bottle	0.5ml ×1 bottle	4ml ×1 bottle	N/A
Safety lancet	50	N/A	N/A	1	25	50
Alcohol pad	50	N/A	N/A	1	25	50
Disposable transfer pipette	50	N/A	N/A	1	25	50
Instruction for use	1 pcs	1 pcs	1 pcs	1 pcs	1 pcs	1 pcs

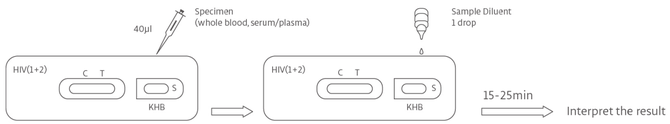
Principle of the Procedure

The Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) V2 from KHB adopts the solid phase colloidal gold immunochromatographic technology for the qualitative detection of antibodies against HIV-1/HIV-2. The gold HIV-1 gp 160 conjugate and the gold HIV-2 gp36 conjugate are coated to the conjugate pad in advance. The test line (recombinant gp36 and gp41 antigens) and the control line (monoclonal antibody against gp160) are pre-coated on the surface of Nitrocellulose (NC) membrane. When the specimen is added to the sample pad, it migrates through the conjugate pad, reconstitutes and mixes with the colloidal gold-antigen complex and moves on till the end of the strip. A reddish-purple test line will be visible in the strip if there are enough antibodies against HIV-1/HIV-2 in the specimen. If the specific antibodies are absent, or present at a very low level, no test line appears.

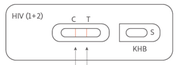
Test Procedure

Equilibrate all specimens and the devices to room temperature (18-28℃) before testing.
Sample diluent from different batches cannot be mixed.

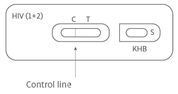
- Take out a test cassette from the foil pouch, and place it on a horizontal surface.
- Use the specimen of either serum/plasma or whole blood: Add 40μl of specimen to the specimen area firstly (Figure 1), then slowly add 1 drop of sample diluent vertically to the same area (Figure 2). Please avoid direct contact of the diluent bottle with the specimen area.
- Incubate the cassette at room temperature (18-28℃) and read the result after 15 minutes but not more than 25 minutes. Reading the test before 15 minutes or after 25 minutes may cause false result.



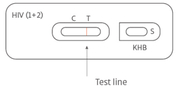
Results



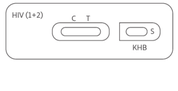
Positive result. Clear visible reddish-purple bands appear both at the C-line and the T-line of the cassette.



Negative result. A reddish-purple band appears only at the C-line of the cassette.



Invalid result. A reddish-purple band appears only at the T-line of the cassette. Repeat the test and contact KHB® supplier if the C-line remains invisible.



Invalid result. A reddish reddish-purple band appears at neither the C-line nor the T-line of the cassette. Repeat the test of the sample. If the result remains the same, then the result is invalid and contact KHB® supplier.

Precaution

The test is for in vitro diagnostic use only. The test cassette is for single use only. The precautions are included, but not limited to the following:

[Safety Precautions]

Wear gloves during the entire testing process.

- Do not pipette by mouth.
- Do not eat or smoke while handling specimens.
- Clean and disinfect all the areas that may be contaminated by spills of specimens or reagents with appropriate disinfectant.
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials as if they were infectious wastes, in a biohazard container.

[Handing Precautions]

- Do not mix and interchange different specimens.
- The sample diluent is specific for each lot of reagent. Do not use diluents from different lots.
- Do not perform the test under environment which leads to rapid evaporation (e.g. high temperature (>45℃) and low humidity, fast flow).
- Use of hemolytic specimens, rheumatoid factors-contained specimens and lipidemic, icteric specimens may cause invalid results or false results.
- Pooled specimens or specimens other than specified (e.g. saliva, urine) are strictly forbidden to be tested.
- Ensure that the specified volume of specimen is added by either precision pipette or specimen transfer pipette.

SHELF LIFE: 18 Months
STORAGE: 4-30℃

PERFORMANCE CHARACTERISITCS

Specificity

A total of 3400 specimens including serum/plasma and whole blood were tested by KHB® Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) V2 (Table 1).

Table 1

Population	No. of specimens tested	KHB® Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) V2		Specificity
		Negative	Positive	
Blood donor specimens	2500	2500	0	100%
Whole blood donation specimens	500	500	0	100%
Hospitalized patient specimens	200	200	0	100%
Pregnant women specimens	200	200	0	100%
Total	3400	3400	0	100%