



DoubleCheckGold™

HIV 1&2 Whole Blood



Code: 70633020

Format: 20 Tests

For in vitro diagnostic use only.

The **DoubleCheckGold™ HIV 1&2 Whole Blood** test is a single reagent immunoassay for the qualitative detection of antibodies to human immunodeficiency virus types 1 and 2 (HIV-1 and HIV-2) in human serum or plasma and whole blood. 20 individual tests may be performed with one kit.

INTRODUCTION

The Human Immunodeficiency Virus (HIV) is a retrovirus, identified in 1983 as the etiologic agent for the Acquired Immunodeficiency Syndrome (AIDS). The HIV virus consists of a genomic RNA molecule associated with a reverse transcriptase (RT), protected by a capsid and an envelope. Two types, HIV-1 and HIV-2, have been distinguished.

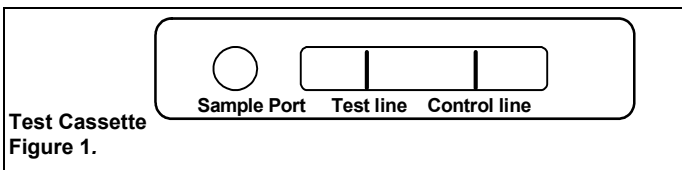
The major routes of HIV transmission are sexual contact, contamination by blood or blood products, and mother-to-newborn transmission. HIV primarily affects CD4 lymphocytes. The progressive decrease of the CD4 level during development of the disease facilitates opportunistic infections with fatal consequences. Testing serum for antibodies to HIV is currently the most common method of screening for infection.

DoubleCheckGold™ HIV 1&2 Whole Blood test is a rapid single-use immunoassay based on immunochromatography. It employs unique reagents for the rapid and reliable detection of antibodies to HIV-1 and HIV-2 in human serum, plasma and whole blood without instrumentation.

PRINCIPLE OF THE TEST

Recombinant proteins representing the immunodominant regions of the **envelope** and **gag** proteins of HIV-1 and HIV-2 are immobilized at the Test region of the nitrocellulose strip. HIV-1 and HIV-2 proteins, linked to colloidal gold are impregnated below the Test region of the cassette. A narrow band of the nitrocellulose membrane is also sensitized as a Control region.

During testing, sample is applied to the Sample Port of the test cassette (see Figure 1), followed by three drops of Wash Reagent and then allowed to react. Antibodies specific to HIV-1 or HIV-2 proteins will react with the colloidal gold conjugate particles.



The antibody HIV protein-colloidal gold complexes move by chromatography along the membrane to the Test and Control regions of the test cassette.

A positive reaction is indicated by the presence of two colored bands: a pink/red band in the Test zone and a second red band in the Control region of the cassette.

A negative reaction indicating the absence of human antibodies directed against HIV results in only one red band visible in the Control region of the cassette.

The appearance of the Control band indicates the proper performance of the test.

KIT CONTENTS

- 20 test cassettes
Each test cassette contains colloidal gold HIV protein conjugate, recombinant HIV proteins as Test line and a Control line.
- 1 Wash Reagent bottle (10 ml).
- 20 Whole blood applicators.
- Package Insert

Materials required but not provided:

- Lancet
- Test tube
- Precision pipette with disposable tips for dispensing 10 µl.
- Timer or stopwatch.

STORAGE AND STABILITY

The **DoubleCheckGold™ HIV 1&2 Whole Blood** test cassettes and wash solution may be stored at 2-30°C.

No kit components should be used after the kit expiry date.

SAFETY AND PRECAUTIONS

This kit is for *in vitro* diagnostic use only.

- Do not smoke, eat or drink in areas in which specimens are handled.
- Wear surgical gloves and laboratory clothing. Follow accepted laboratory procedures for working with human serum or plasma.
- Dispose of all specimens, used Reaction Cassettes and other materials used with the kit as biohazardous waste.
- All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
- Do not mix reagents and cassettes from different lots.
- Do not use the kit after expiry date.

HANDLING OF SPECIMENS

Either serum/plasma or whole blood may be tested. Serum or plasma specimens may be stored for 7 days at 2-8°C before testing. To store for more than 7 days, freeze specimen at -20°C. After thawing, samples should be mixed. Avoid repeated freezing and thawing.

Whole blood: venous blood or finger stick blood can be used. Whole blood samples collected in the presence of anticoagulants can be kept for up to three days at 2-8°C. In the absence of anticoagulants, use the samples as quickly as possible, before the specimens start to clot.

TEST PROCEDURE

Preparing the Test

- Read all test Instructions before starting the test and follow them carefully.
- Bring samples (as well as the Wash Reagent and the cassettes, if refrigerated) to room temperature (15-30°C).
- Remove the required number of **DoubleCheckGold™ HIV 1&2 Whole Blood** test cassettes from their aluminum pouches.
- Perform the test at room temperature (15-30°C).

TEST INSTRUCTIONS

Serum or Plasma

1. Using a precision pipette with disposable tips carefully apply 10 µl of specimen to the Sample Port. Discard the pipette tip as biohazard waste.
2. Immediately add 3 drops (approx. 100 µl) of Wash Reagent to Sample Port.
3. Run test at room temperature (15-30°C).
4. The results should be read at the end of the 15 minute incubation time.

Whole Blood

The whole blood sample applicator device for the **DoubleCheckGold™ HIV 1&2 Whole Blood** kit consists of a pretreated cotton wool swab. The cotton wool end serves for the collection of the sample and its application onto the Sample Port of the reaction cassette. A minimal sample volume of 50 µl of whole blood is required (approximately two drops).

If finger stick whole blood is used, drop at least two drops into a test tube (at least 50 µl), by squeezing the finger, then dip the applicator into the blood. If venous blood is used, be sure to mix the tube gently (do not vortex) before dipping the applicator.

1. Dip the swab of the applicator completely into the whole blood sample and swirl. Do not leave the applicator soak in the blood sample for more than 1 min.
2. Remove the applicator from the sample test tube.
3. **After 10 seconds**, apply the swab end of the applicator onto the Sample Port of the reaction cassette, pressing gently, in order to allow the transfer of sufficient amount of sample to the reaction cassette. A successful transfer is indicated by the red spot visible after removing the applicator from the Sample Port of the cassette.
4. Dispose of the used applicator as of infected material.
5. Add 3 drops (approx. 100 µl) of Wash Reagent to Sample Port.
6. Run test at room temperature (15°-30°C).
7. The results should be read at the end of the 15 minute incubation time.

Remarks:

- Do not use the same applicator more than once. If two or more tests are run in parallel, use a different applicator for each sample, each time.
- Do not use the applicator for serum or plasma. The results are stable for an additional 10 minutes (25 minutes after the application of the sample).

INTERPRETATION OF THE RESULTS

Validation

In order to confirm the proper functioning of the test and to demonstrate that the results are valid, the Control line should appear on all cassettes (see Figure 2, a, b).

The absence of the **Internal Control** line (see Figure 2, c, d) should be considered an **invalid** result and the test repeated.

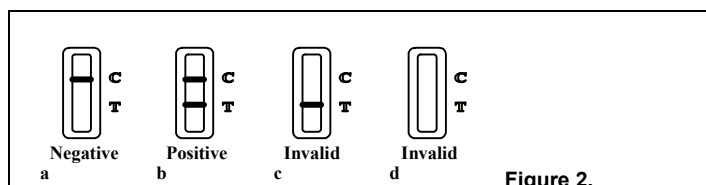


Figure 2.

Important:

Any faintly colored Test line must be suspected to represent a positive reaction and must be investigated further.

CLINICAL EVALUATION

The **DoubleCheckGold™ HIV 1&2 Whole Blood** test was evaluated in four independent clinical sites that were selected to assess the performance of the kit in diverse clinical settings. The clinical sites were in France (Dr. Poujade, Gonesse), Israel (Dr. KraOz, Rambam Medical Center), Mexico (Dr. Guerrero, CNTS), and South Africa (Dr. Schoub, NHLS). The results are shown in the following tables.

Sensitivity of the DoubleCheckGold™ HIV 1&2 Whole Blood test on serum/plasma

Country	Positive Samples	
	Reference Kit	DoubleCheckGold™ HIV 1&2 Whole Blood
France	166	166
South Africa	250	249
Mexico	100	100
Total	516	515

Sensitivity: 99.8%

Sensitivity of the DoubleCheckGold™ HIV 1&2 Whole Blood test on whole blood

Country	Positive Samples	
	Reference Kit	DoubleCheckGold™ HIV 1&2 Whole Blood
Israel	72	72
France	80	80
Total	152	152

Sensitivity: 100%

Specificity of the DoubleCheckGold™ HIV 1&2 Whole Blood test on serum/plasma

Country	Negative Samples	
	Reference Kit	DoubleCheckGold™ HIV 1&2 Whole Blood
France	249	247
South Africa	250	250
Mexico	400	397
Total	899	894

Specificity: 99.4%

Specificity of the DoubleCheckGold™ HIV 1&2 Whole Blood test on whole blood

Country	Negative Samples	
	Reference Kit	DoubleCheckGold™ HIV 1&2 Whole Blood
Israel	290	290
France	125	125
Total	415	415

Specificity: 100%

Multicentric study (France, Senegal, Guinea) carried out on 2494 samples including 1720 sera, 492 plasmas and 282 whole blood

Nature of samples

	Serological status	Nature of samples	Origin of samples
1644 negative samples		1096 sera 373 plasmas 175 whole blood	<ul style="list-style-type: none"> - Pregnant women - EBV+ samples - Malaria+ samples - HTLV+ samples - TB+ samples
850 positive samples	HIV-1 (795) HIV-2 (28) HIV-1+2 (27)	624 sera 119 plasmas 107 whole blood	<ul style="list-style-type: none"> - Known seropositive - African origin - Seroconversion

Summary of results

	France	Senegal	Guinea	Global Sensitivity	Global Specificity
Positive (850)	353/353	129/129	368/368	100%	99%
Negative (1644)	418/419	644/650	565/575		

LIMITATIONS

The **DoubleCheckGold™ HIV 1&2 Whole Blood** test procedure and interpretation of results must be followed closely when assaying for the presence of HIV antibodies in serum and plasma.

The **DoubleCheckGold™ HIV 1&2 Whole Blood** test is a screening assay. Since the production of antibodies to HIV may be delayed following initial exposure, non-reactivity with this test must not be considered conclusive evidence that the patient has not been exposed to or infected by HIV.

The **DoubleCheckGold™ HIV 1&2 Whole Blood** test is intended for the testing of undiluted samples only. Samples should not be diluted before testing.

Immunosuppressed or immunocompromised individuals infected with HIV-1 or HIV-2 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results and would not be a reliable test method for such patients.

Infants may receive antibodies from an infected mother or they may not produce antibodies in response to an infection. Therefore, it is necessary to exercise great care in interpreting their results.

AIDS and ARC are clinical syndromes and their diagnosis can only be established clinically. **DoubleCheckGold™ HIV 1&2 Whole Blood** test results cannot be used alone to diagnose AIDS. A negative result does not preclude the possibility of exposure to HIV or infection with HIV.

REFERENCES

Barré-Sinoussi F., Chermann JC., Rey F., et al. 1983. Isolation of T. lymphotropic retrovirus from patient at risk for Acquired Immune Deficiency Syndrome (AIDS). *Science* 224:497-500.

Constantine NT. 1999. HIV antibody testing, p. 105-112. In P.T. Cohen, M.A. Sande, and P.A. Volberding (ed.), *The AIDS knowledge base*, 3rd ed. Lippincott-Williams & Wilkins, Philadelphia, Pa.

Gilmore, N. 1996. Blood and blood product safety, p. 287-301. In J. Mann and D. Tarantola (ed.), *AIDS in the World*, vol II. Oxford University Press, Oxford, England.














Grant AD, De Cock KM. 2001. HIV infection and AIDS in the developing world. British Med. Journal, 322: 1475- 1478.


Janssen RS et al. 1998. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. JAMA 280:42-48.

Schacer TW, Hugu JP, Shea T, et al. 1998. Biological and virological characteristics of primary HIV infection. Ann. Intern. Med. 128: 613-620.

UNAIDS/WHO. 1997. Working Group on Global HIV/AIDS and STD Surveillance. Report on the Global HIV/AIDS Epidemic, p. 1-13. Geneva

Symbols Legend

	Test cassette
	Wash reagent
	Applicator
	Consult Instructions for Use
	Caution, consult accompanying documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Contains sufficient for n tests
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

<p>Manufacturer:</p>  <p>ORGENICS</p> <p>Orgenics Ltd., part of the Inverness Medical Innovations Group. P.O.B 360 Yavne 70650, Israel Tel: ++ 972 8 942 92 01 Fax: ++ 972 8 943 87 58</p>	<p>Authorised Representative in EU:</p> <p>Orgenics France S.A. 19, rue Lambrechts 92400 Courbevoie, France Tel: +33-1 41 99 92 90 Fax: +33-1 41 99 92 95</p> <p>Version: 70633020/E8/OR (12/2006)</p>
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