



DoubleCheckGold™

HIV 1&2



Code: 70632020

Format: 20 tests

For in vitro diagnostic use only.

The **DoubleCheckGold™ HIV 1&2** test is a single reagent immunoassay for the qualitative detection of antibodies to human immunodeficiency viruses types 1 and 2 (HIV-1 and HIV-2), as well as HIV-1 type O, in human serum or plasma. 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 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 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 and a biochemical that recognizes human antibodies is dispensed at the Control region of the strip. HIV-1 and HIV-2 proteins, linked to colloidal gold are impregnated on the gold pad, placed between the sample pad and the nitrocellulose strip.

The assay is initiated by applying the sample to the Sample Port of the test cassette (see *Figure 1*). The subsequent addition of two drops of Wash Reagent facilitates the flow of the specimen into the cassette and onto the test strip. Antibodies specific to HIV-1 or HIV-2 proteins will react with the colloidal gold conjugate particles.

Test Cassette

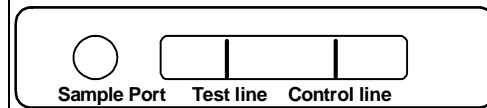


Figure 1.

The antibody HIV protein-colloidal gold complexes move by chromatography along the nitrocellulose 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 (marked by T) and a second red band in the Control region of the cassette (marked by C).

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 **DoubleCheckGold™ HIV 1&2** test Cassettes.
Each test cassette contains a test strip comprising a sample pad, a gold pad impregnated with colloidal gold HIV protein conjugate, a nitrocellulose strip with immobilized recombinant HIV proteins as Test line and an antibody-binding reagent as Control line, an absorbent material to facilitate flow through the cassette.
- 1 Wash Reagent bottle (10 ml).
- Package Insert

Materials required but not provided:

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

Storage and Stability

The **DoubleCheckGold™ HIV 1&2** test cassettes and wash solution may be stored at 2-30°C. After first use, the Wash Reagent should 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 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.

Test Procedure

Preparing the Test

- Read all Test Instructions carefully before starting the test.
- 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 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 2 drops (approx. 70 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.

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.

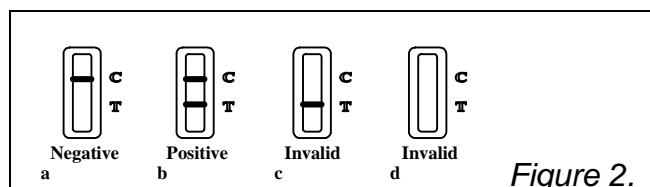


Figure 2.

Important:

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

Limitations

The **DoubleCheckGold™ HIV 1&2 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 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 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 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.

Performance Characteristics

A. Multicenter Study

A multicenter study was carried out in 6 sites: France, Israel, Mozambique, Nigeria, Brazil and Venezuela on 1285 infected patients including HIV-1, HIV-2 and co-infection, as well as 2518 HIV negative blood donors. Results are detailed in table 1.

Table 1. Multicenter study

Country	Year	Total No of Samples	Positive	Negative
France	2002	627	426	201
Israel	2002	688	388	300
Mozambique	2002	682	132	550
Nigeria	2002	30	15	15
Brazil	2003	1430	174	1256
Israel	2003	246	100	146
Venezuela	2003	100	50	50
Total	/	3803	1285	2518

The following performance characteristics were calculated:

- Sensitivity – 99.9%
- Specificity – 99.6%

B. Seroconversion

The capability of the **DoubleCheckGold™ HIV 1&2 test** to detect early HIV-1 seroconversion was assessed on serum samples collected from 11 patients with documented HIV-1 seroconversion phase and on 3 seroconversion commercial panels (BioClinical Partners, USA; NABI, USA) with Western blotting as the reference assay. Detection of seroconversion by the **DoubleCheckGold™ HIV 1&2 test** preceded detection by Western blot assay by an average of 7 days.

C. HIV – 1 type O

The capability of the **DoubleCheckGold™ HIV 1&2 test** to detect HIV-1 type O was evaluated on samples from Cameroon.

HIV -1 type O-positive specimens were detected.













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
	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>ORGANICS</p> <p>Organics 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>Organics 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: 7632020/E19/OR (12/2006)</p>
---	--