



DoubleCheckGoldTM

HIV 1&2



Code: 70632100 Version: 632/100/E5 Format: 100 tests

The **DoubleCheckGold HIV 1&2** 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. 100 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 and 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. HIV-1 and HIV-2 proteins, linked to colloidal gold are impregnated below the Test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a Control region.

During testing, 10 µl of serum or plasma are applied to the Sample Port of the test device (see *Figure 1*), followed by two 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.

Test Device

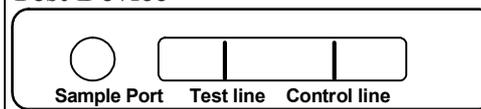


Figure 1.

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

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 device.

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 device.

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

Kit Contents

100 DoubleCheckGold HIV 1&2 Test Devices

Each test device contains colloidal gold HIV protein conjugate, recombinant HIV proteins as Test line and a Control line.

Wash Reagent

1 Wash Reagent dropper 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 devices 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 Devices 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 devices from different lots.
- Do not use the kit after expiry date.

Handling of Specimens

Either serum or plasma may be tested. Specimens may be stored for 7 days at 2°-8°C before testing. To store for more than 7 days, freeze specimens at -20°C. 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 devices, if refrigerated) to room temperature.
- Remove the required number of **DoubleCheckGold HIV 1&2** test devices from their aluminum pouches.
- Perform the test at room temperature.

Test Instructions

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.
4. The results should be read at the end of the 15 minute incubation time.

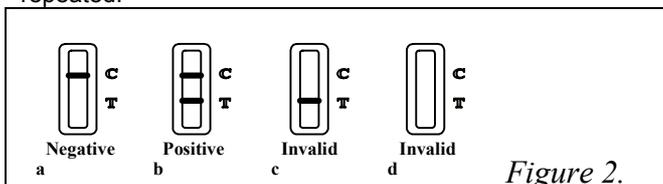
The results are stable for an additional 10 minutes (25 minutes after the application of the sample).

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 devices (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.



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 **HIV 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.

References

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