OVERVIEW

Orgenics, a member of the Inverness Medical Group, is an international biotechnological company that specializes in the development, manufacturing and marketing of manual, automated and rapid test kits for the diagnosis of infectious diseases.

Orgenics products are designed for the decentralized laboratories where throughput does not warrant investments in capital equipment as well as major diagnostic centers (including blood banks), that often use Orogenics products as second opinion diagnostics.

Orgenics products are marketed world wide through out vast net of distributorships.

With an experienced and qualified team of scientists in R&D, Orogenics responds quickly to new market developments and to specific needs in cases of new emerging medical threats.

Orgenics' expertise in developing diagnostic tests for infectious diseases has been recognized by the most stringent health authorities worldwide including the EU, USA and the WHO. All of Orogenics products are manufactured to the highest standards and are sold in over 110 countries around the globe.

*Simplicity of operation, rapidity, competitive pricing and high standards are the features that mark Orogenics products.*
The ImmunoComb® Test

- The ImmunoComb® is a solid-phase EIA (enzyme immunoassay).

- The solid phase is a plastic Comb with 12 teeth, sensitized at different spots with reactive materials and an internal control.

- All reagents for the test are sealed with foil in a Developing Plate, containing 6 rows of 12 premixed, prefilled wells.

- The specimens are deposited in the wells of the first row of the Developing Plate.

- The test is performed in a quick and easy procedure, by moving the Comb from row to row at specified intervals.

- Results are visible within minutes, appearing as gray-blue spots on the surface of the Comb’s teeth.
**The ImmunoComb® System**

**Easy Procedure:**
1. Draw and add specimens and controls to Row A.

2. Insert the Comb in Row A, incubate.

3. Insert the Comb in Row B and agitate (repeat the same procedure for rows c,d and e).

4. Color reaction in Row F.

5. Insert the comb in row e again to stop the reaction.

6. Read results. Keep Comb for long-term documentation and patient follow-up.

*If needed, you may bend and break the Comb for individual testing.*
EVERY LAB AND POINT OF CARE UNIT CAN BENEFIT FROM THE MULTIPLE ADVANTAGES OF EIA, WITHOUT THE NEED FOR COSTLY STAFF TRAINING, PROCEDURES AND EQUIPMENT

ImmunoComb® HIV kits are truly simple and exceptionally accurate tests for the detection of HIV antibodies in serum or plasma. ImmunoComb® HIV kits meet the most demanding cost performance requirements.

**ImmunoComb® II - HIV products**

- ImmunoComb® II HIV 1&2 TriSpot Ag-Ab
- ImmunoComb® II HIV 1&2 BiSpot
- ImmunoComb® II HIV 1&2 CombFirm
A 4th generation HIV assay for the qualitative and differential detection of antibodies to Human Immunodeficiency Viruses types 1 and 2 (HIV-1 and HIV-2) and for the simultaneous detection of HIV-1 p24 antigen in human serum or plasma

- Early detection of seroconversion
- Detection of the p24 Antigen
- Separate detection of p24 antigen and HIV antibodies
- Differential detection between antibodies to HIV-1 and HIV-2
- Detection of all HIV-1 groups and subtypes
- Sensitivity: for HIV-1 Antibodies: 100%
- Sensitivity: for HIV-2 Antibodies: 100%
- Sensitivity: for HIV p24 Antigen: 10 pg/ml
- Specificity: 99.3%
- Test duration: 85 minutes at room temperature
The simultaneous detection of the antibodies and the viral GAG p24 antigen reduces the seroconversion “window” period by 4-7 days and thus, enables early detection of HIV infection.

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<tr>
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<td>60433002</td>
<td>ImmunoComb® II HIV 1&amp;2 TriSpot Ag-Ab</td>
<td>36 tests</td>
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A rapid test intended for the qualitative and differential detection of IgG antibodies to HIV 1&2 in human serum or plasma.

- Fast and easy procedure, results are visible within minutes with the sensitivity and specificity of the most accurate ELISA.

- Detection of HIV-1, HIV-2 and Subtype O

- Use of synthetic peptides as antigens leads to early detection of HIV infection with shortened "window period", and to increased clinical sensitivity.

- Sensitivity: 100%

- Specificity: 99.4%

- Test duration – 36 minutes at room temperature

- CE-Marked

- Evaluated by the World Health Organization

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The confirmatory test for the presence of HIV antibodies in samples found positive by a screening test.

- Differential detection – reactivity for antibodies to HIV types 1 or 2 may be rapidly confirmed in a single simple test.

- Use of synthetic antigens (recombinants and peptides) – the test employs five distinct recombinant and synthetic HIV antigens for the rapid serological determination of the HIV antibody profile.

- Uncompromising quality – sensitivity and specificity comparable to the most accurate Western Blots.

- Sensitivity: 99.7%

- Specificity: 100%

- Test duration – 66 minutes at room temperature

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<tr>
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DoubleCheckGold™ Ultra HIV 1&2 test is a single use rapid immunoassay based on immunochromatography. It employs unique reagents for the quick and reliable detection of antibodies for HIV-1 and HIV-2 in human serum, plasma and whole blood without instrumentation and without the need for an applicator.

The DoubleCheckGold™ Ultra HIV 1&2 offers a new level of excellence and advantages:
- Excellent performance.
- Serum, Plasma and Whole Blood specimens.
- Easy, rapid lateral flow assay.
- Detection of all HIV-1 types, subtypes and circulating recombinant forms (CRF).
- Storage and test procedures at room temperature.
- Results available in 15 minutes.
- Simple to use and easy to handle.

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DoubleCheckGold™ Ultra

Principle of the test

Sample application

Sample pad

NC membrane

Absorbent pad

Antibody Gold-Conjugate Binding

Gold complex capture by immobilized antigens

HIV Antibodies

HIV antigen—colloidal gold conjugate

Mouse IgG—colloidal gold conjugate
DoubleCheckGold™
HIV 1&2 Test

A rapid immunochromatography assay for HIV-1 and HIV-2 antibodies screening in human serum, plasma and whole blood.

The DoubleCheckGold™ HIV 1&2 test has all the necessary assets for selection as first choice in the HIV detection algorithms whether in point of-care units, voluntary detection centers, prevention of mother-child transmission (PMTCT) programs centers or as part of epidemiological monitoring programs.

The DoubleCheckGold™ HIV 1&2 opens a new level of excellence and advantages:
- Easy and rapid lateral flow assay
- Excellence performance
- Was selected by the Clinton Foundation and evaluated by the WHO
- Detecting of all HIV-1 types and subtypes
- Storage and test procedure at room temperature
- Results available in 15 minutes
- Simple to use and easy to handle

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<tr>
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<td>DoubleCheckGold™ HIV 1&amp;2</td>
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<tr>
<td>70633020</td>
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<td>DoubleCheckGold™ HIV 1&amp;2 Whole Blood</td>
<td>Bulk</td>
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DoubleCheckGold™
Principle of the test

Sample application

Sample pad
NC membrane
Absorbant pad

Antibody Gold-Conjugate Binding

Gold complex capture by immobilized antigens

Specific Antibodies
HIV antigen – colloidal gold conjugate

Non-specific antibodies
Control conjugate