Snibe Diagnostic

CE 0123 REF

130219008M:100 tests/kit
130619008M: 50 tests/kit
130719008M: 30 tests/kit

# MAGLUMI® HIV Ab/Ag Combi (CLIA)

## INTENDED USE

The kit is an *in vitro* chemiluminescence immunoassay for the simultaneously qualitative determination of HIV-1 p24 antigen and antibodies to HIV- 1(Group M and Group O), HIV-2 in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System，and the assay is used for an aid in diagnosis of HIV-1/HIV-2 infection and for screening of blood donations.

## SUMMARY

The human immunodeficiency virus (HIV) is a lentivirus (a subgroup of retrovirus) that causes HIV infection and over time acquired immunodeficiency syndrome (AIDS). Infection with HIV occurs by the transfer of blood, semen, vaginal fluid, pre-ejaculate, or breast milk. Within these bodily fluids, HIV is present as both free virus particles and virus within infected immune cells[1-2]. The World Health Organization and UNAIDS estimate that the number of individuals living with HIV grew from 7 million in 1990 to 36.9million in 2017while the annual deaths due to AIDS increased from 0.3 million in 1990 to a peak of 2.2 million in 2005, followed by a decline to 0.94 million in 2017reported by UNAIDS. In 2013 alone, there were 2.1 million new infections, and 1.5 million deaths[3].

HIV is different in structure from other retroviruses. It is roughly spherical with a diameter of about 120 nm, around 60 times smaller than a red blood cell. It is composed of two copies of positive single-stranded RNA that codes for the virus's nine genes enclosed by a conical capsid composed of 2,000 copies of the viral protein p24. The single-stranded RNA is tightly bound to nucleon capsid proteins, p7, and enzymes needed for the development of the virion such as reverse transcriptase, proteases, ribonuclease and integrase. A matrix composed of the viral protein p17 surrounds the capsid ensuring the integrity of the virion particle[4-6].

Two types of HIV have been characterized: HIV-1 and HIV-2. HIV-1 is the virus that was initially discovered and termed both LAV and HTLV-III. It is more virulent, more infective, and is the cause of the majority of HIV infections globally. HIV-1 is not just one virus, but mainly comprises three groups M (major), N (non-M, non-O), O (outlier). Group M was the first to be discovered and represents the pandemic form of HIV-1. Group O is much less prevalent than group M, and is largely restricted to Cameroon, Gabon, and neighboring countries. Group N is even less prevalent than group O[7]. Group M is currently classified into nine subtypes (A-D, F-H, J, K), as well as more than 40 different circulating recombinant forms (CRFs)[8].

The lower infectivity of HIV-2 compared to HIV-1 implies that fewer of those exposed to HIV-2 will be infected per exposure. Because of its relatively poor capacity for transmission, HIV-2 is largely confined to West Africa[9-10].In comparison to HIV-1, HIV-2 exhibits a reduced infectivity, a lower replicative capacity, and an increased susceptibility to antibody-mediated neutralization. During the course of HIV-2 infection, CD4 declines slowly and the clinically latent phase can last for decades. Still, infection with HIV-2 can lead to acquired immune deficiency syndrome (AIDS) and effective antiretroviral treatments are crucial for preventing disease progression[11-12].

Individuals with recent HIV acquisition may be more infectious than individuals with established infection. The HIV antibodies screening assays have been widely used since 1985[13].But HIV antibody testing alone may fail to identify HIV-infected individuals during the several weeks following HIV acquisition[14]. By detecting the HIV-1 p24 antigen in blood specimens of recently infected patients with a high viral load, HIV infection can be detected about 6 days earlier than with traditional antibody assays[15].The MAGLUMI HIV Ab/Ag Combi (CLIA) detects both antigen and antibodies simultaneously, thereby shortening the seroconversion window and aiding early detection of HIV infection.

## TEST PRINCIPLE

Sandwich chemiluminescence immunoassay.

The sample, ABEI-1 labeled with HIV-1 p24 monoclonal antibody and magnetic microbeads coated with HIV-1 p24 monoclonal antibody and HIV-1/HIV-2 antigens are mixed thoroughly and incubated. HIV-1 p24 antigen in the sample bind to HIV-1 p24 monoclonal antibody coated magnetic microbeads and ABEI-1 labeled with HIV-1 p24 monoclonal antibody, reacting to form sandwich complexes. HIV-1/HIV-2 antibodies present in the sample bind to HIV-1/HIV-2 antigens coated magnetic microbeads, reacting to form sandwich complexes. Perform a wash cycle after a precipitation in a magnetic field. ABEI-2 labeled with HIV-1/HIV-2 antigens are added, and bind to the complex through interaction with HIV-1/HIV-2 antibodies. After precipitation in a magnetic field, the supernatant is decanted and then a wash cycle is performed. Subsequently, the Starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLUs), which is proportional to the concentration of HIV-1 p24 antigen and HIV-1/HIV-2 antibodies present in the sample.

## REAGENTS

**Kit Contents**

| Component | Description | 100 tests/kit | 50 tests/kit | 30 tests/kit |
|---|---|---|---|---|
| **Magnetic Microbeads** | Magnetic microbeads coated with HIV-1 p24 antibody (~15.0 μg/mL), HIV-1 antigen (~2.00 μg/mL) and HIV-2 antigen (~4.00 μg/mL) in PBS buffer, $NaN_3$ (<0.1%). | 2.5 mL | 2.0 mL | 1.0 mL |
| **Calibrator Low** | A low concentration of HIV-1 p24 antigen (2.171 AU/mL), BSA, $NaN_3$ (<0.1%). | 3.0 mL | 2.0 mL | 2.0 mL |
| **Calibrator High** | A high concentration of HIV-1 p24 antigen (229.885 AU/mL), BSA, $NaN_3$ (<0.1%). | 3.0 mL | 2.0 mL | 2.0 mL |
| **ABEI-1 Label** | ABEI labeled with HIV-1 p24 antibody (~0.167 μg/mL) in Tris-HCl buffer, $NaN_3$ (<0.1%). | 17.5 mL | 10.0 mL | 6.3 mL |
| **ABEI-2 Label** | ABEI labeled with HIV-1 antigen (~16.7 ng/mL) and HIV-2 antigen (~31.3 ng/mL) in Tris-HCl buffer, $NaN_3$ (<0.1%). | 22.5 mL | 12.5 mL | 7.8 mL |
| **Negative Control** | PBS buffer, $NaN_3$ (<0.1%). | 2.0 mL | 2.0 mL | 2.0 mL |
| **Positive Control 1** | A concentration of HIV-1 antibody (10.0 AU/mL), BSA, $NaN_3$ (<0.1%). | 2.0 mL | 2.0 mL | 2.0 mL |
| **Positive Control 2** | A concentration of HIV-2 antibody (20.0 AU/mL), BSA, $NaN_3$ (<0.1%). | 2.0 mL | 2.0 mL | 2.0 mL |
| **Positive Control 3** | A concentration of HIV-1 p24 antigen (5.00 AU/mL), BSA, $NaN_3$ (<0.1%). | 2.0 mL | 2.0 mL | 2.0 mL |
| All reagents are provided ready-to-use. | | | | |

**Warnings and Precautions**

- For *in vitro* diagnostic use.
- For professional use only.
- Exercise the normal precautions required for handling all laboratory reagents.
- Personal protective measures should be taken to prevent any part of the human body from contacting samples, reagents, and controls, and should comply with local operating requirements for the assay.
- A skillful technique and strict adherence to the package insert are necessary to obtain reliable results.
- Do not use kit beyond the expiration date indicated on the label.
- Do not interchange reagent components from different reagents or lots.
- Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).
- All waste associated with biological samples, biological reagents and disposable materials used for the assay should be considered potentially infectious and should be disposed of in accordance with local guidelines.
- This product contains sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Immediately after disposal, flush with a large volume of water to prevent azide build-up. For additional information, see Safety Data Sheets available for professional user on request.

Note: If any serious incident has occurred in relation to the device, please report to Shenzhen New Industries Biomedical Engineering Co., Ltd. (Snibe) or our authorized representative and the competent authority of the Member State in which you are established.

**Reagent Handling**

- To avoid contamination, wear clean gloves when operating with a reagent kit and sample. When handling reagent kit, replace the gloves that have been in contact with samples, since introduction of samples will result in unreliable results.
- Do not use kit in malfunction conditions; e.g., the kit leaking at the sealing film or elsewhere, obviously turbid or precipitation is found in reagents (except for Magnetic Microbeads) or control value is out of the specified range repeatedly. When kit in malfunction conditions, please contact Snibe or our authorized distributor.
- To avoid evaporation of the liquid in the opened reagent kits in refrigerator, it is recommended that the opened reagent kits to be sealed with reagent seals contained within the packaging. The reagent seals are single use, and if more seals are needed, please contact Snibe or our authorized distributor.



- Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.
- Use always the same analyzer for an opened reagent integral.
- For magnetic microbeads mixing instructions, refer to the Preparation of the Reagent section of this package insert.
- For further information about the reagent handing during system operation, please refer to Analyzer Operating Instructions.

**Storage and Stability**

- Do not freeze the integral reagents.
- Store the reagent kit upright to ensure complete availability of the magnetic microbeads.
- Protect from direct sunlight.

| Stability of the Reagents | |
|---|---|
| Unopened at 2-8°C | until the stated expiration date |
| Opened at 2-8°C | 6 weeks |
| On-board | 4 weeks |

| Stability of Controls | |
|---|---|
| Unopened at 2-8°C | until the stated expiration date |
| Opened at 10-30°C | 6 hours |
| Opened at 2-8°C | 6 weeks |
| Frozen at -20°C | 3 months |
| Frozen and thawed cycles | no more than 3 times |

## SPECIMEN COLLECTION AND PREPARATION

**Specimen Types**

Only the specimens listed below were tested and found acceptable.

| Specimen Types | Collection Tubes |
|---|---|
| **Serum** | Tubes without additive/accessory, or tubes containing clot activator or clot activator with gel |
| **Plasma** | Sodium-citrate (1:9), K2-EDTA, K3-EDTA, Li-Heparin, Na-heparin, ACD-B, CPD, CPDA and K-Oxalate/NaF |

- The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. Follow tube manufacturers' instructions carefully when using collection tubes.

**Specimen Conditions**

- Do not use heat-inactivated samples or grossly hemolyzed/hyperlipidaemia specimens and specimens with obvious microbial contamination.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some serum specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the serum specimen is centrifuged before a complete clotting, the presence of fibrin may cause erroneous results.
- Samples must be free of fibrin and other particulate matter.
- To prevent cross contamination, use of disposable pipettes or pipette tips are recommended.

**Preparation for Analysis**

- Inspect all specimens for foam. Remove foam with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
- Frozen specimens must be completely thawed before mixing. Mix thawed specimens thoroughly by low speed vortexing or by gently inverting. Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous. If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Specimens should be free of fibrin, red blood cells, or other particulate matter. Such specimens may give reliable results and must be centrifuged prior to testing. Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.
- The sample volume required for a single determination of this assay is 200 μL.

**Specimen Storage**

Specimens removed from the separator, red blood cells or clot may be stored up to 2 days at 10-30°C or 5 days at 2-8°C, or 12 months frozen at -20°C. Frozen specimens subjected to up to 5 freeze/thaw cycles have been evaluated.

**Specimen Shipping**

- Package and label specimens in compliance with applicable local regulations covering the transport of clinical specimens and infectious substances.
- Do not exceed the storage limitations listed above.

## PROCEDURE

**Materials Provided**

HIV Ab/Ag Combi (CLIA) assay, control barcode labels.

**Materials Required (But Not Provided)**

- General laboratory equipment.
- Fully-auto chemiluminescence immunoassay analyzer Maglumi 600, Maglumi 800, Maglumi 1000, Maglumi 2000, Maglumi 2000 Plus, Maglumi 4000, Maglumi 4000 Plus, MAGLUMI X 3, MAGLUMI X6,MAGLUMI X8, or Integrated System Biolumi 8000 and Biolumi CX8.
- Additional accessories of test required for the above analyzers include Reaction Module, Starter 1+2, Wash Concentrate, Light Check, Tip, and Reaction Cup. Specific accessories and accessories' specification for each model refer to corresponding Analyzer Operating Instructions.
- Please use accessories specified by Snibe to ensure the reliability of the test results.

**Assay Procedure**

Preparation of the Reagent

- Take the reagent kit out of the box and visually inspect the integral vials for leaking at the sealing film or elsewhere. If there is no leakage, please tear off the sealing film carefully.
- Open the reagent area door; hold the reagent handle to get the RFID label close to the RFID reader (for about 2s); the buzzer will beep; one beep sound indicates successful sensing.
- Keeping the reagent straight insert to the bottom along the blank reagent track.
- Observe whether the reagent information is displayed successfully in the software interface, otherwise repeat the above two steps.
- Resuspension of the magnetic microbeads takes place automatically when the kit is loaded successfully, ensuring the magnetic microbeads are totally resuspended homogenous prior to use.

Assay Calibration

- Select the assay to be calibrated and execute calibration operation in reagent area interface. For specific information on ordering calibrations, refer to the calibration section of Analyzer Operating Instructions.
- Execute recalibration according to the calibration interval required in this package insert.

Quality Control

- When new lot used, check or edit the quality control information.
- Scan the control barcode, choose corresponding quality control information and execute testing. For specific information on ordering quality controls, refer to the quality control section of the Analyzer Operating Instructions.

Sample Testing

- After successfully loading the sample, select the sample in interface and edit the assay for the sample to be tested and execute testing. For specific information on ordering patient specimens, refer to the sample ordering section of the Analyzer Operating Instructions.

To ensure proper test performance, strictly adhere to Analyzer Operating Instructions.

**Calibration**

Traceability: The method of HIV-1 p24 antigen has been standardized against the WHO International Standard 90/636, the method of HIV 1 and anti HIV 2 antibodies have been standardized against the Snibe internal reference standard.

Test of assay specific calibrators allows the detected relative light unit (RLU) values to adjust the master curve.
Recalibration is recommended as follows:

- Whenever a new lot of Reagent or Starter 1+2 is used.
- Every 28 days.
- The analyzer has been serviced.
- Control values lie outside the specified range.

**Quality Control**

Controls are recommended for the determination of quality control requirements for this assay and should be run in singlicate to monitor the assay performance. Refer to published guidelines for general quality control recommendations, for example Clinical and Laboratory Standards Institute (CLSI) Guideline C24 or other published guidelines[16].

Quality control is recommended once per day of use, or in accordance with local regulations or accreditation requirements and your laboratory's quality control procedures, quality control could be performed by running the HIV Ab/Ag Combi assay:

- Whenever the kit is calibrated.
- Whenever a new lot of Starter 1+2 or Wash Concentrate is used.

Controls are only applicable with MAGLUMI and Biolumi systems and only used matching with the same top seven LOT numbers of corresponding reagents. For each target value and range refer to the label.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate value ranges should be established for all quality control materials used.

Control values must lie within the specified range, whenever one of the controls lies outside the specified range, calibration should be repeated and controls retested. If control values lie repeatedly outside the predefined ranges after successful calibration, patient results must not be reported and take the following actions:

- Verify that the materials are not expired.
- Verify that required maintenance was performed.
- Verify that the assay was performed according to the package insert.
- If necessary, contact Snibe or our authorized distributors for assistance.

If the controls in kit are not enough for use, please order HIV Ab/Ag Combi (CLIA) Controls (REF: 160201175MT) from Snibe or our authorized distributors for more.

## RESULTS

**Calculation**

The analyzer automatically calculates the HIV Ab/Ag Combi concentration in each sample by means of a calibration curve which is generated by a 2-point calibration master curve procedure. The results are expressed in AU/mL. For further information please refer to the Analyzer Operating Instructions.

**Interpretation of Results**

The expected range for the HIV Ab/Ag Combi assay was obtained by testing 704 reference individuals (425 HIV Ab/Ag Combi negative people and 279 HIV Ab/Ag Combi positive patients) in China, gave the following expected value:

- Non-reactive: A result less than 1.0 AU/mL (<1.0 AU/mL) is considered to be negative.
- Reactive: A result greater than or equal to 1.0 AU/mL (≥1.0 AU/mL) is considered to be positive.

Assay results should be interpreted in conjunction with the patient's clinical presentation, history, and other laboratory results. All initially reactive should be redetermined in duplicate with the HIV Ab/Ag Combi assay. If the concentration values <1.0 AU/mL are found in both cases, the samples are considered negative for antibodies and p24 antigen against HIV. And repeatedly reactive samples must be confirmed according to recommended confirmatory algorithms.

Results may differ between laboratories due to variations in population and test method. It is recommended that each laboratory establish its own reference interval.

## LIMITATIONS

- Results should be used in conjunction with patient's medical history, clinical examination and other findings.
- If the HIV Ab/Ag Combi results are inconsistent with clinical evidence, additional testing is needed to confirm the result.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies[17,18]. Additional information may be required for diagnosis.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or animal serum products can be prone to this interference and anomalous values may be observed[19].
- Bacterial contamination or heat inactivation of the specimens may affect the test results.
- The intended testing population are individuals with suspected HIV-1/HIV-2 infection and blood donors.

## SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

**Precision**

The precision of the HIV Ab/Ag Combi assay was evaluated in accordance with CLSI document EP5-A2. 4controls and 6human serum pools containing different concentration of analyte were assayed in duplicate at two independent runs per day for 20 testing days. The result is summarized in the following table:

| Sample | Mean(AU/mL) (N=80) | Within-Run | | Between-Run | | Total | |
|---|---|---|---|---|---|---|---|
| | | SD(AU/mL) | %CV | SD(AU/mL) | %CV | SD(AU/mL) | %CV |
| HIV-1 antibody (Low Positive) | 4.966 | 0.308 | 6.20 | 0.169 | 3.40 | 0.388 | 7.81 |
| HIV-2 antibody (Low Positive) | 4.096 | 0.250 | 6.10 | 0.108 | 2.64 | 0.288 | 7.03 |
| HIV-1 p24 Ag (Low Positive) | 4.129 | 0.277 | 6.71 | 0.091 | 2.20 | 0.310 | 7.51 |
| HIV-1 antibody (High Positive) | 51.238 | 1.809 | 3.53 | 0.508 | 0.99 | 2.023 | 3.95 |
| HIV-2 antibody (High Positive) | 27.984 | 1.076 | 3.85 | 0.860 | 3.07 | 1.377 | 4.92 |
| HIV-1 p24 Ag (High Positive) | 201.269 | 2.244 | 1.12 | 1.188 | 0.59 | 2.566 | 1.27 |
| Negative Control | 0.218 | NA | NA | NA | NA | NA | NA |
| Positive Control 1 | 9.667 | 0.471 | 4.87 | 0.418 | 4.32 | 0.630 | 6.52 |
| Positive Control 2 | 20.501 | 0.828 | 4.04 | 0.474 | 2.31 | 0.954 | 4.65 |
| Positive Control 3 | 4.977 | 0.292 | 5.87 | 0.137 | 2.75 | 0.322 | 6.47 |

NA = not applicable

**Endogenous and drug interference**

There is no interference when the interference concentrations are: Bilirubin ≤31.7 mg/dL; Hemoglobin ≤2000 mg/dL; Intralipid ≤2000 mg/dL, RF ≤1500 IU/mL, HAMA ≤612 ng/mL, Phenylbutazone ≤200 μg/mL, Aspirin ≤1000 μg/mL, Acetaminophen ≤400 μg/mL, Ibuprofen ≤500 μg/mL, Sodium salicylate ≤500 μg/mL, N-acetylcysteine ≤150 μg/mL, Methyldopa ≤25 μg/mL, Theophylline ≤60 μg/mL, Metformin ≤12 μg/mL, Isosorbidedinitrate ≤6 μg/mL, Rifampicin ≤48 μg/mL, Doxycycline ≤18 μg/mL, Cefoxitin ≤6600 μg/mL, Cyclosporine ≤2 μg/mL, Metronidazole ≤125 μg/mL, Ascorbic acid ≤60 μg/mL, Biotin ≤50 μg/mL.

**Analytical Sensitivity**

Limit of Blank (LoB) =0.300 AU/mL.

Limit of Detection (LoD) =1.200 AU/mL.

The HIV Ab/Ag Combi assay has an analytical sensitivity of ≤ 2.0 IU/mL to HIV-1 p24 Ag. The sensitivity was assessed using three lots of reagent by testing the HIV-1 p24 Antigen, the WHO International Reference Standard, NIBSC code: 90/636 series dilutions on Maglumi 2000 Plus. The results demonstrated a sensitivity of 0.7695 IU/mL*.

* These are representative performance data. Results obtained at individual laboratories may vary.

**Analytical Specificity**

Specimens from randomly selected hospitalized patients and specimens containing potentially cross-reactive / interfering substances, which includes those from individuals with medical conditions unrelated to HIV infection, were tested with the HIV Ab/Ag Combi assay. The results are shown in the table below:

| Specimen Type | N | Non-reactive | Reactive | Specificity (%) |
|---|---|---|---|---|
| Hospitalized patients | 213 | 213 | 0 | 100.00 |
| Potentially cross-reactive samples | 110 | 110 | 0 | 100.00 |
| Potentially interfering samples | 27 | 27 | 0 | 100.00 |
| Total | 350 | 350 | 0 | 100.00 |



[a]The potentially cross-reactive samples belonged to the following categories: Auto-immune diseases (c-ANCA, HAMA, Rheumatoid Factor, Hashimoto Thyroiditis patient), Pregnant women, Hyper IgG/IgM, Flu patients, dialysis patients, Infectious diseases (Anti-TP, Anti-HEV, Anti-HCV, Anti-EBV, Anti-CMV, Anti-VZV, Anti-HSV-1/2, Anti-HAV, HBsAg, Anti-HBc).

[b] The potentially interfering samples belonged to the following categories: Hemolytic, Lipemic, Icteric.

**Clinical Sensitivity**

The resulting sensitivity of confirmed positive samples is 100%. The data from this study are summarized in the following table.

| Specimen Type | N | Reactive | Confirmed reactive | Sensitivity (%) |
|---|---|---|---|---|
| HIV-1 group M (subtypes A-K, CFRs) Ab positive | 452 | 452 | 452 | 100.00 |
| HIV-1 group O Ab positive | 7 | 7 | 7 | 100.00 |
| HIV-1 Ag positive | 50 | 50 | 50 | 100.00 |
| HIV-2 Ab positive | 105 | 105 | 105 | 100.00 |
| Total | 614 | 614 | 614 | 100.00 |

50 cell culture supernatants of different HIV-1 subtypes were all detected reactive by MAGLUMI HIV Ab/Ag Combi assay.

**Clinical Specificity**

In a group of randomly selected blood donors, the specificity of the MAGLUMI HIV Ab/Ag Combi assay was 99.84% in the initial test and 99.98% in the repeat test.

| Group | Initial | | Repeat | |
|---|---|---|---|---|
| | Non-reactive | Reactive | Non-reactive | Reactive |
| Blood donor samples | 5049 | 8 | 5056 | 1 |
| Specificity (Wilson 95% CI) | 99.84% (99.69%~99.92%) | | 99.98% (99.89%~100.0%) | |

**Seroconversion sensitivity**

Seroconversion sensitivity of the HIV Ab/Ag Combi assay has been evaluated by testing 30 commercial seroconversion panels, which have been tested by commercially available CE-marked HIV Ab/Ag Combi assays. The HIV Ab/Ag Combi assay showed equivalent performance compared to the results from other commercially available assays.

**High-Dose Hook**

No false negative result due to high-dose hook effect was found with the HIV Ab/Ag Combi assay. No high-dose hook effect was seen for HIV-1 antibody, HIV-2 antibody and HIV-1 p24 antigen concentrations up to 100000 AU/mL separately.

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## SYMBOLS EXPLANATIONS

| | | | |
|---|---|---|---|
| | Consult instructions for use | | Manufacturer |
| 2°C 8°C | Temperature limit (Store at 2-8°C) | | Use-by date |
| Σ | Contains sufficient for<n> tests | | Keep away from sunlight |
| | This way up | EC REP | Authorized representative in the European Community |
| IVD | *In vitro* diagnostic medical device | CONTENTS | Kit component |
| REF | Catalogue number | LOT | Batch code |
| CE 0123 | CE marking with notified body ID number | | |



Summary of safety and performance is available at Eudamed.

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