Genscreen™ HIV-1 Ag Assay
2 plates - 192

ENZYME IMMUNOASSAY (EIA) FOR DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE I (HIV-1) P24 ANTIGEN IN HUMAN SERUM, PLASMA AND CELL CULTURE SUPERNATANT

[IVD] CE 0459

883669 - 2014/01
CLINICAL VALUE

The etiologic agent of Acquired Immunodeficiency Syndrome (AIDS) is a retrovirus which has been named Human Immunodeficiency Virus (HIV). HIV has been isolated from patients with AIDS and from healthy persons at high risk for AIDS[1]. Transmission is known to occur by intimate sexual contact, through the use of contaminated needles, by transfusions of contaminated blood products, and perinatally from infected mother to fetus or child[2]. Evidence of previous exposure to HIV is usually demonstrated by the presence of virus-specific antibody in an individual’s serum or plasma after exposure to the virus. Prior to the appearance of detectable antibodies, there is an early period of time when free viral antigens circulate in the blood. One of these viral antigens is the major viral core protein, p24. HIV antigen assays can be used to detect the presence of viral antigens, and thus HIV infection, prior to seroconversion. The antigenemic period preceding the appearance of HIV antibodies is variable and can last for days or weeks in infected individuals. As an individual seroconverts, virus specific antibodies complex with the circulating antigens such that the levels of free antigens in the blood drop or disappear entirely[3-5]. Antigenemia may develop again later as the disease progresses[6].

The Genscreen™ HIV-1 Antigen Assay is intended to be used as a screen for donated blood and plasma and as an aid in the diagnosis and prognosis of HIV-1 infection.

2 - PRINCIPLE OF THE Genscreen™ HIV-1 ANTIGEN ASSAY

The Genscreen™ HIV-1 Antigen Assay is an enzyme immunoassay for the detection of HIV-1 core antigen (p24) in human serum and plasma specimens. The “Genscreen™ HIV-1 Antigen Confirmatory” Test (code 71121) is a supplemental assay used with the HIV-1 Antigen Assay to confirm the presence of HIV p24 antigen in repeatedly reactive samples.

The Genscreen™ HIV-1 Antigen Assay is based upon the use of a solid phase prepared with mouse monoclonal antibody to HIV-1 Antigen, of a first conjugate prepared with biotinylated sheep anti-p24 antibody and a second conjugate prepared with avidin coupled to peroxidase of Raifort.

The performance of the test includes the following reaction steps:

1. Specimen Diluent is added to each well. The samples to be tested and the control sera are added to their respective wells. If HIV-1 Ag is present in the specimen, it will bind to the antibodies coated on the well. Any HIV-1 Ag bound to the well will remain during the subsequent washing.

   The color of the Specimen Diluent changes from green to blue to confirm that a sample (or control) has been added to the well.

2. Conjugate 1 is then added to each well and the wells are incubated. This allows the biotinylated sheep anti-p24 antibody in Conjugate 1 to bind to any HIV-1 Ag that is bound to the well. The antigen-antibody complexes remain bound during the subsequent wash step.

3. Conjugate 2 is then added to the wells and allowed to incubate. The avidin in Conjugate 2 binds specifically to the antibody-HIV-1 Ag complexes that are bound to the well. Any unbound conjugate is removed by washing.

4. Working TMB Solution is added to the plate and allowed to incubate. A blue or blue-green color develops in proportion to the amount of HIV-1 Ag present in the sample. Color development is stopped by the addition of acid, which changes the blue-green color to yellow. The optical absorbance of specimens and controls is determined spectrophotometrically at a wavelength of 450/620-700 nm.
### CONTENTS OF THE Genscreen™ HIV-1 ANTIGEN ASSAY

<table>
<thead>
<tr>
<th>Identification on label</th>
<th>Description</th>
<th>Presentation/Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 Microplate</td>
<td>Microplate 12 strips of 8 wells coated with murine monoclonal antibodies to HIV-1 p24</td>
<td>71120 2 plates</td>
</tr>
<tr>
<td>R2 Concentrated washing solution (20X)</td>
<td>Concentrated washing solution (20X) Tris NaCl buffer, pH 7.4 Preservative: ProClin™ 300 (0.04%)</td>
<td>1 vial 235 ml</td>
</tr>
<tr>
<td>R3 Specimen diluent</td>
<td>Specimen diluent Triton™ X-100 (2%) Lithium Chlorid (2%) Sample addition dye (green) Preservative: ProClin™ 300 (0.5%)</td>
<td>1 vial 20 ml</td>
</tr>
<tr>
<td>C0 Negative control</td>
<td>Negative control Human serum non reactive for HIV antigen and Ag HBs, and antibodies to HIV-1, HIV-2, HCV, HTLV-I 0.005% Gentamicin sulfate Preservative: ProClin™ 300 (0.5%)</td>
<td>1 vial 10 ml</td>
</tr>
<tr>
<td>C1 Positive control</td>
<td>Positive control Purified, disrupted HIV-1 antigen Preservative: ProClin™ 300 (0.5%)</td>
<td>1 vial 7 ml</td>
</tr>
<tr>
<td>R4 Concentrated conjugate 1</td>
<td>Concentrated conjugate 1 (100X) Sheep anti-p24 conjugate, 0.005% Gentamicin sulfate Yellow dye - Preservative: ProClin™ 300 (0.5%)</td>
<td>1 vial 1 ml</td>
</tr>
<tr>
<td>R5 Concentrated conjugate 2</td>
<td>Concentrated conjugate 2 (100X) Avidin-HRP conjugate, 0.005% Gentamicin sulfate Green dye - Preservative: ProClin™ 300 (0.5%)</td>
<td>1 vial 1 ml</td>
</tr>
<tr>
<td>R6 Conjugate Diluent</td>
<td>Conjugate diluent Buffer with protein stabilisers Preservative: ProClin™ 300 (0.5%)</td>
<td>1 vial 100 ml</td>
</tr>
<tr>
<td>R8 Substrate buffer</td>
<td>Substrate buffer Citric acid and Sodium acetate solution pH 4.0 containing H₂O₂ (0.015%) and dimethyl sulfoxide (DMSO) 4%</td>
<td>1 vial 60 ml</td>
</tr>
<tr>
<td>R9 Chromogen: TMB solution (11X)</td>
<td>Chromogen: TMB solution Solution containing 3.3’, 5.5’ tetramethylbenzidine (TMB)</td>
<td>1 vial 5 ml</td>
</tr>
<tr>
<td>R10 Stopping solution</td>
<td>Stopping solution Sulphuric acid solution (H₂SO₄ 1N)</td>
<td>2 vials 2 x 28 ml</td>
</tr>
</tbody>
</table>

### 4 - MATERIAL REQUIRED BUT NOT PROVIDED
- Distilled water
- Household bleach (5% to 8% sodium hypochlorite) which may be diluted to a minimum concentration of 10% bleach (or 0.5% sodium hypochlorite). Alternative disinfectants include: 70% ethanol or 0.5% Wescodyne™ (West Chemical Products, Inc.).
- Precision pipettes to deliver volumes from 10 μl to 200 μl, 1 ml, 5 ml, and 10 ml (accurate within ± 10%). A multichannel pipettor capable of delivering 100 μl or 200 μl is optional.
- Graduated cylinders of 25 ml, 100 ml, 1000 ml.
- Container for contaminated residues.
- Water bath or dry incubator*, thermostatically set at 37±1°C or 40 ± 1°C.
- Manual, semiautomatic or automatic microplate washer (*).
- Microplate reader equipped with 450 nm and 620-700 nm filters (*).
- Null strips for testing partial on automate.
- EIA reagent reservoirs (optional).
Disposal gloves
• Absorbent paper
• Clean plastic containers (either polystyrene or polypropylene) for preparation of Working Conjugate Solutions and TMB Solution.
• Cell Culture Medium, e.g. RPMI-1640 containing 10% fetal calf serum, equivalent to that used for infected cell culture (when testing cell culture samples).

(*) Consult us for detailed information about the equipment recommended by our technical department.

5 - HEALTH AND SAFETY INSTRUCTIONS
All the reagents included in the kit are intended for “in vitro” diagnostic use.
• Wear disposable gloves when handling reagents and samples and thoroughly wash your hands after having handled them.
• Do not pipette by mouth.
• Human source material used in the preparation of the negative control was tested and found non reactive for HIV-1 antigen, anti-HIV1 and anti-HIV2 antibodies, hepatitis B antigen (HB Ag), anti-HCV antibodies, anti HTLV1/HTLV 2 antibodies and anti HIV1/HIV2.
• The positive control is heat inactivated by dissociating agent.
• Because no known test method can offer complete assurance that the HIV, Hepatitis B or C virus or other infectious agents are absent, consider these reagents, as well as patient samples, as potentially infectious and handle them carefully.
• Any equipment directly in contact with samples and human source reagents as well as buffer solutions should be considered as contaminated products and treated accordingly.
• Avoid spilling samples or solutions containing samples.
• Contaminated surfaces should be cleaned 10% diluted bleach. If the contaminating fluid is an acid, the contaminated surfaces should be first neutralized with sodium bicarbonate, then cleaned with bleach, and dried with absorbent paper. The material used for cleaning should be discarded into a biohazardous waste container.
• Samples, human source reagents, as well as contaminated material and products should be discarded after decontamination:
  - either by soaking into bleach at a final concentration of 5% sodium hypochlorite (1 volume of bleach per 10 volumes of contaminated fluid or water) for 30 minutes.
  - or by autoclaving at 121°C for 2 hours minimum.
Autoclaving is the best method to inactivate HIV and HBV.
CAUTION: DO NOT PLACE SOLUTIONS CONTAINING SODIUM HYPOCHLORITE IN THE AUTOCLAVE.
• The Safety Data Sheet is available upon request.
• Avoid any contact of the substrate buffer, the chromogen and the stopping solution with the skin and mucosa (toxicity, irritation or burn hazard).
• Do not forget to neutralize and/or autoclave the wash waste solutions or any fluid containing biological samples before discarding them into the sink.
• Chemicals should be handled and discarded in accordance with Good Laboratory Practices.
• For hazard and precaution recommendations related to some chemical components in this test kit, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instruction for use. The Safety Data Sheet is available on www.bio-rad.com.

6 - PRECAUTIONS
The reliability of results depends on correct observance of the following Good Laboratory Practices:
• The name of the test, as well as a specific identification number for the test, are written on the frame of each microtiterplate. This specific identification number is stated on each strip too.
Genscreen™ HIV-1 Ag Assay: Specific ID number = 49
Verify the specific identification number before use. If the identification number is missing, or different from the stated number above, the strip should not be used.
• Do not use expired reagents.
• Do not change the assay procedure.
• Carefully reconstitute reagents avoiding any contamination.
• Do not mix reagents from different lots within a given test run.
Remark: For washing solution (R2, label identification: 20X coloured green), peroxidase substrate buffer (R8, label identification: TMB buf, coloured blue), chromogen (R9, label identification: TMB 11X, coloured purple) and stopping solution (R10, label identification: 1N coloured red), it is possible to use other lots than those contained in the kit, provided the same lot is used within a given test run. These reagents can be used with some other products of our company. In addition, the wash solution (R2, label identification: 20X coloured green) can be mixed with the 2 other wash solutions included in various Bio-Rad Reagent kits (R2, label identifications: 10X coloured blue or 10X coloured orange) when properly reconstituted, provided only one mixture is used within a given test run. Contact our technical service for detailed information.
Before use, it is required to wait 30 minutes to allow the reagents stabilizing at room temperature (18-30°C).

Do not carry out the test in the presence of reactive vapours (acid, alkaline, aldehyde vapours) or dust that could alter the enzymatic activity of the conjugate.

Use glassware thoroughly washed and rinsed with distilled water or preferably, disposable material.

Do not allow the micoplate to dry between the end of the washing operation and the reagent distribution.

Use a new dispensing tip for each sample.

Check pipettes for accuracy and precision and if the instruments being used are correctly working.

Washing: Carefully follow the washing procedures described to obtain maximum test performance.

Never use the same container to dispense conjugate and color development solution.

The enzyme reaction is very sensitive to metal ions. Consequently, do not allow any metal element to come into contact with the various conjugate or substrate solutions.

The development solution (substrate buffer + chromogen) must be coloured pink. The modification of this pink colour within a few minutes after reconstitution indicates that the reagent cannot be used and must be replaced. Preparation of the development solution can be made in a clean disposable single use plastic tray or glass container that has first been pre-washed with 1N HCl and rinsed thoroughly with distilled water and dried. This reagent must be stored in the dark.

7 - COLLECTION AND HANDLING OF SPECIMENS
Collect a blood sample according to the current practices. Serum, plasma, or cell culture samples may be used. The following anticoagulants have been evaluated and found to be acceptable: EDTA, heparin, sodium citrate, CPDA-1, and ACD. Samples which are collected into anticoagulant tubes should completely fill the tube as labeling indicates to avoid improper dilution. Remove the serum or plasma from the clot or red cells as soon as possible to avoid hemolysis. Extensive hemolysis may affects test performance. Specimens with observable particulate matter should be clarified by centrifugation prior to testing. Suspended fibrine aggregates or particles may produce falsely positive results. Cell culture samples that require dilution prior to testing may be diluted with cell culture medium that is equivalent to that used to culture the cells.

DO NOT USE HEAT-INACTIVATED SPECIMENS.
The samples should be stored at +2-8°C if the screening is carried out within 7 days or deep-frozen at −20°C. The plasma must be quickly thawed by warming for a few minutes in a water bath at 40°C (to avoid fibrin precipitation). Given HIV Ag instability, temperatures over 40°C cannot be used. Samples that have been frozen and defrozen more than 3 times cannot be used. If the specimens are to be shipped, they must be packaged in accordance with the regulations in force regarding the transport of aetiological agents.

DO NOT USE CONTAMINATED, HYPERLIPAEIC OR HYPEHAEMOLYSED SERA OR PLASMA.
Remark: Samples containing up to 80 mg/l bilirubin, 36 mg/l Immunoglobulin M or G, lipemic samples containing up to the equivalent of 5 g/l lipides, and hemolyzed samples containing up to 2.5 g/l hemoglobin do not affect the results.

8 - RECONSTITUTION OF THE REAGENTS
NOTE: Before use, allow reagents to reach room temperature (18-30°C) except concentrated conjugate 1 and 2 (R4 and R5).

Ready-to-use reagents:
• Reagent R1: Microplate
Each frame support containing 12 strips is wrapped in a sealed foil bag. Cut the bag using scissors or a scalpel 0.5 to 1 cm above the sealing. Open the bag and take out the frame. Put the unused strips back into the bag. Close the bag carefully and put it back into storage at +2-8°C.

• Reagent R3: Specimen Diluent
• Reagent C0: Negative Control
• Reagent C1: Positive Control
• Reagent R10: Stopping Solution

Reagents to be reconstituted:
• Concentrated Washing Solution (20X): R2
Dilute 1:20 in distilled water to obtain the ready-for-use washing solution. Prepare 800 ml for one plate of 12 strips.

• Working Conjugate Solution 1 (R4 + R6) and Working Conjugate Solution 2 (R5 + R6):
Conjugates 1 (R4) and 2 (R5) are supplied as 100X concentrates. Prepare separate Working Conjugate Solution 1 and Working Conjugate Solution 2 by diluting each conjugate 1:101 in Conjugate Diluent (R6). Prepare in clean, plastic containers. Note Conjugate Concentrate lot number, date and time of preparation, and date and time of expiration (24 hours from preparation) on container. Mix Working Reagents gently prior to use. After mixing, Working Conjugate Solution 1 is yellow and Working Conjugate Solution 2 is green.
**Enzyme Development Solution (R8 + R9)**
Dilute 1:11 the chromogen (R9) in the substrate buffer (R8). (ex: 1 ml reagent R9 +10 ml reagent R8). 10 ml are necessary and sufficient for 1 to 12 strips. Homogenize.

**9 - STORAGE CONDITIONS - SHELF LIFE**
The kit should be stored at +2-8°C. Each reagent contained in the Genscreen™ HIV-1 Ag Assay kit can be used after a first opening until the expiry date mentioned on the package except specific instruction:

R1: After the vacuum-sealed bag has been opened, the microwell strips stored at +2-8°C in the carefully resealed bag can be used for 1 month.
R2: The diluted washing solution can be stored at +2-30°C during 2 weeks. The concentrated washing solution (R2) can be stored at +2-30°C.
R8 - R9: After the reconstitution, the reagent stored in the dark can be used for 6 hours at room temperature (18-30°C).
R4 - R5: After the reconstitution, the working conjugate solutions can be used for 24 hours at room temperature (18-30°C).

**10 - ASSAY PROCEDURE**
Two procedures for the detection of HIV-1 p24 Antigen in human serum or plasma, or cell culture samples, are described below:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Specimen Incubation</th>
<th>Conjugate 1 Incubation</th>
<th>Conjugate 2 Incubation</th>
<th>Color Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>37°C incubation</td>
<td>Static incubation 37 ± 1°C, dry heat, 60 ± 5 min.</td>
<td>Static incubation 37 ± 1°C, dry heat, 30 ± 5 min.</td>
<td>Static incubation 37 ± 1°C, dry heat, 30 ± 5 min.</td>
<td>Static incubation 18 to 30°C, in the dark, 30 ± 5 min.</td>
</tr>
<tr>
<td>40°C incubation</td>
<td>Static incubation 40 ± 1°C, dry heat, 60 ± 5 min.</td>
<td>Static incubation 40 ± 1°C, dry heat, 30 ± 5 min.</td>
<td>Static incubation 40 ± 1°C, dry heat, 30 ± 5 min.</td>
<td>Static incubation 18 to 30°C, in the dark, 30 ± 5 min.</td>
</tr>
</tbody>
</table>

For samples that are originally tested at either 37°C or 40°C, any repeat testing or confirmation must be tested using the same procedure.

The expected run time for this procedure is approximately 2h30 from initiation of the first incubation step. Each run of this assay must proceed to completion without interruption after it has been started.

Two Positive Controls and three Negative Controls must be run on each plate. Three cell culture medium controls are necessary instead of the kit Negative Control (C0) when testing cell culture samples. The cutoff for patient samples is determined by the controls on each individual plate.

Avoid exposure of the plates to light during the final incubation step (following the addition of the Working TMB Solution).

Strictly follow the proposed procedure and apply the following Good Laboratory Practice:
1. Carefully establish the sample distribution and identification plan,
2. Prepare the dilute washing solution,
3. Take the carrier tray and the strips (R1) out of the protective pouch,
4. Apply directly, without prior washing of the plate and in succession:
   - 50 μl of diluent in each well
   - 150 μl of negative control serum (C0) in well A1- B1 – C1
   - 150 μl of positive control serum (C1) in wells D1- E1
   - 150 μl of specimens in wells G1, etc...

Depending on the used system, it is possible to modify the position of controls or the order of distribution.
Three cell culture medium controls are necessary instead of the kit Negative Control when testing cell culture samples. Ensure that the Sample Diluent is well mixed with the specimen (or control).

N.B.: The sample distribution can be visually controlled at this step of the manipulation: after adding the sample, the diluent turns from green to blue to assure that the sample or control has been added to the well. When properly mixed, the contents of each well are a uniform color. Cell culture samples may not exhibit a color change depending on which cell culture medium is used. (Refer to section 12 for automatic verification - SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE PIPETTING).

5. If possible cover the microplate with adhesive film. Press firmly all over the plate to ensure adequate tightness.
6. Incubate the plate for 60 ± 5 minutes at 37 ± 1°C or 40 ± 1°C using a dry-heat static incubator.
7. Remove the adhesive film. Aspirate the contents of all wells into a container for biohazardous waste (containing sodium hypochlorite). Add into each well a minimum of 0.370 ml of washing solution. Respect a soak time for 20 to 60 seconds. Aspirate again. Repeat this procedure 4 times (i.e. a total of a minimum of 5 washes). The residual volume must be lower than 10 μl (if necessary, dry the plate by turning it upside down on absorbent paper).
8. If an automatic washer is used, follow the same procedure (refer to section 10: recommendations)
9. Quickly distribute 100 μl of the Working Conjugate Solution 1 into all wells.
10. Quickly distribute 100 μl of the Working Conjugate Solution 2 into all wells.

11. Calculation and interpretation of the results

11.1 - Calculation and interpretation of the results

1 - Validation of results

A run is valid if the following criteria are met:
• The absorbance value of each Negative Control (NC) (or cell culture control, if applicable) is greater than 0.000 AU and less than or equal to 0.100 AU. One Negative Control value may be discarded and the mean of the Negative Controls may be calculated from the two remaining values. The NC mean may be calculated from the two remaining absorbance values. If two or more Negative Controls are out of limit, the plate is invalid and must be repeated.
• The mean absorbance value of the Positive Controls (PCX) must be greater than or equal to 0.500 AU and the individual absorbance values must be within a reproducibility range of 0.65 to 1.35 times the PCX. No Positive Control values may be discarded.

2 - Calculation of the mean absorbances

From the validated controls, determine the mean absorbances for the Negative Controls and Positive Controls by dividing the sum of their absorbance values by the number of acceptable controls.
3 - Cut-off Value
Determine the cutoff value by adding 0.070 to the NC mean (NCX) as shown in the example below:
Cut-off = 0.070 + NCX
Example : NCX = 0.033 - Cut-off = 0.070 + 0.033 = 0.103

4 - Interpretation of results
The presence or absence of HIV-1 antigen is determined by relating the absorbance value of the specimen to the cutoff value.
Specimens with absorbance values that are <0.000 must be repeated. Those with values greater than the upper linearity limits of the reader should be reported as reactive.
Specimens with absorbance values less than the cutoff value are considered non-reactive by the Genscreen™ HIV-1 Antigen Assay and may be considered negative for HIV-1 Antigen. Further testing is not required.
Specimens with absorbance values greater than or equal to the cutoff value are considered initially reactive by the Genscreen™ HIV-1 Antigen Assay. Initially reactive specimens should be retested in duplicate to validate the initial test results. If, after repeat testing, the absorbance values of both duplicate specimens are less than the cutoff value, the original specimen may be considered non-repeatedly reactive and negative for HIV-1 antigen. Reasons for non-repeatedly reactive specimens include:
• inadequate microplate washing
• cross-contamination of non-reactive specimens with HIV-1 Ag from a high titered specimen
• contamination of the substrate buffer by oxidising agents (bleach, metal ions, etc…)
• contamination of the stopping solution
If, after repeat testing, the absorbance value of either of the duplicates is greater than or equal to the cutoff value, the initial result is reproducible and the specimen must be considered reactive with the Genscreen™ HIV-1 Antigen Assay, in conformance with limits described hereafter. Specimens that have been found repeatedly reactive by the Genscreen™ HIV-1 Antigen Assay should be verified with the Genscreen™ HIV-1 Antigen Confirmatory Assay (Product No. 71121). The specimen can be considered positive for HIV-1 antigen only if the HIV-1 antigen can be neutralized by the confirmatory procedure.

12 - SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE AND REAGENT PIPETTING

Spectrophotometric verification of sample pipetting
After the dispensing of the sample diluent (R3) and of the samples, it is possible to verify the presence of samples to be tested into the wells by a spectrophotometric reading at 620 nm: the optical density of a well containing sample is greater than 0.250 (a lower OD indicates a poor dispensing of the sample).
REMARK: Cell culture samples may not change colour according to the cell culture medium. In this case, do not apply the automatic verification.

Spectrophotometric verification of development solution pipetting
It is possible to verify the presence of pink development solution into the well by automatic reading at 490 nm: a well with development solution must have an optical density greater than 0.100 (a lower OD indicates a poor dispensing of the development solution).

13 - PERFORMANCES

Sensitivity
• 138 patients infected by HIV at different stages (AIDS, ARC, others) have been tested and found positives with the test Genscreen™ HIV-1 Antigen Assay.
• 20 well documented seroconversions panels were studied. The results obtained are comparable to those observed with other HIV Ag assay. At least 64 early seroconversion samples were tested with Genscreen™ HIV-1 Antigen Assay.
• 55 cell culture supernatants of HIV 1 (53 group M and 2 group O) and the dilution panel “Ag VIH SFTS 96” have been found positives with the Genscreen™ HIV-1 Antigen Assay test except 2 dilutions of group O cell culture supernatants.
  - The 53 cell culture supernatants of the HIV-1 group M are composed of the following genotypes: 10 genotypes of A, 10 of B, 9 of C, 5 of D, 11 of E, 2 of F, 2 of G, 1 of H, 2 of J, and 1 of N.
  - The dilution panel “Ag VIH SFTS 96” includes the following genotypes: A, B, C, D, E, F, G, H genotypes from the Group M and 1 from the group O.

Analytical Sensitivity
The limit of detection has been estimated less than 2 IU/ml by testing the WHO 1st International Reference NIBSC code 90/636 and found at 0.36 IU/ml CI95% [0.08 – 0.65 IU/ml] with 3 different batches during internal evaluation. The sensitivity limit of the test has been evaluated on a range of dilutions prepared from the French national standard (purified viral lysate of genotype B diluted in negative citrated plasma) and the BBI panel (PRA 801). The sensitivity limit has been estimated at 8 pg/ml Ag HIV whatever protocol is.
The calibration curve obtained with HIV-1 Ag Standard (code 72217) calibrated sample is linear between 0 to 5 IU/ml (or 0 to 100 pg/ml).
Diagnostic Specificity
The diagnostic specificity evaluated on:
• 4038 blood donors has been estimated at 99.95%.
• 209 clinical patients has been estimated at 100%.
A panel of 105 patient samples has been tested. It is composed of samples:
• containing antibodies to HAV, HCV, HTLV, HSV, EBV, Rubella, Toxoplasma Gondii, Treponema Pallidum, CMV.
• containing auto-Ab, IgG, IgM rhumatoid factor
• from pregnant women, cirrhosis population, multiply transfused and patients reached of Systemic lupus erythematosus. Only one sample came from and patient reached of Systemic lupus erythematosus has been found reactive with the Genscreen™ HIV-1 Ag Assay test but not confirmed with the confirmatory test.

Accuracy
The intra-assay reproductibility has been evaluated by testing 3 positive samples and one negative sample 30 times in the same run.
The inter-assay reproductibility has been evaluated by testing 3 positive samples and one negative sample during 5 days with 2 different technicians.
The coefficient of variation for positive samples was less than 10%.

14 - LIMITS OF THE TEST
• The Genscreen™ HIV-1 Antigen Assay Procedure and the Interpretation of Results must be followed when testing serum, plasma, or cell culture specimens for the presence of HIV-1 antigen. The user of this kit is advised to read the package insert carefully prior to conducting the test. In particular, the test procedure must be carefully followed for sample and reagent pipetting, plate washing, and timing of the incubation steps.
• A designation of reactive for HIV-1 antigen must not be based on a single reactive test result. Additional testing, such as confirmatory testing, is required to establish the specificity of any specimen reactive by the screening procedure.
• All highly sensitive immunoassays have a potential for non-specific reactions which can lead to false positive results. The proportion of reactives that are false will depend on the sensitivity and specificity of the test kit.
• Negative results can occur if the quantity of marker present in the sample is too low for the detection limits of the assay, or if the marker which is detected is not present during the stage of disease in which a sample is collected.
• The variability of HIV virus doesn’t allow to exclude the possibility of false negative results. No known test method can offer complete assurance that the HIV virus is absent.
• Failure to add specimen or reagent as instructed in the procedure could result in a falsely negative test. Repeat testing should be considered where there is clinical suspicion of infection or procedural error.
• An absorbance value of less than 0.000 AU indicates a procedural or instrument error and must be repeated.
• Factors that can affect the validity of results include failure to add the specimen to the well, inadequate washing of microplate wells, failure to follow stated incubation times and temperatures, addition of wrong reagents to wells, the presence of metals, or splashing of bleach into wells.
• Performances of the test have not been evaluated on post mortem samples or on biological fluid other than serum, plasma or cell culture specimens.
• The sample diluent coloration may not change in presence of cell culture samples according to the cell culture medium.
• Even the analytical sensitivity estimated at 8 pg/ml during the evaluations of this test, it may vary according to the operating conditions and due to the variability inter-batch. Consequently, Bio-Rad guarantees only the analytical sensibility below 15 pg/ml.
• The colorimetric method for the samples, conjugate and development solution deposition verification does not allow to verify the accuracy of the dispensed volumes. This method only shows the presence of sample, conjugate and development solution into wells. The rate of wrong answers with this method is closely linked to the accuracy of the utilized system (cumulated coefficient of variation of dispensing and reading over 10% significantly decrease the quality of the verification).
• In case of very poor washing efficiency after the conjugate incubation, the automatic verification of the development solution pipetting (by reading OD of wells at 490 nm) may provide wrong results with OD above 0.100 in the absence of development solution. However this phenomena has not been observed during evaluation on 939 tested samples.


This product contains human or animal components. Handle with care.
**BG**

опасно

Причина тежки изгаряния на кожата и сериозно увреждане на очите. Може да причини алергична кожна реакция. Предизвиква сериозно дразнене на очите.

Използването на ръкавици/предпазно облекло/предпазна очна маска за лице.

ПРИ КОНТАКТ С ООО СИТТЕ: Промивайте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако има такива и доколкото това е възможно. Продължавайте да промивате.


**CZ**

Nebezpečí


**EN**

Danger

Causes severe skin burns and eye damage. May cause an allergic skin reaction. Causes serious eye irritation.

Use protective gloves/protection clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN: Wash with plenty of soap and water. IF SWALLOWED: Rinse mouth. DO NOT INDUCE VOMITING. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention.

**ES**

Peligro

Provoca quemaduras graves en la piel y lesiones oculares graves. Puede provocar una reacción alérgica en la piel. Provoca irritación ocular grave.

Llevar guantes que aíslen del frío/gafas/máscara. EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si llena y resulta fácil. Seguir aclarando. EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes. EN CASO DE INGESTION: Enjuagar la boca. NO provocar el vómito. EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitar inmediatamente las prendas contaminadas. Aclararse la piel con agua u ducharse. En caso de irritación o erupción cutánea: Consultar a un médico. Si persiste la irritación ocular: Consultar a un médico.

**FI**

Vaara

Voi aiheuttaa allergisen ihoreaktion. Ärsyytää voimakkaasti silmiä. Käytä suojakäsineitä/suojavaihtetusta/silmien suojaamista/

**DANGER**

Provoque des brûlures de la peau et des lésions oculaires graves. Peut provoquer une allergie cutanée. Provoque une sévère irritation des yeux.


**PERICOLO**


**PRAZOS**


**POŠNOST**


**Veselé**

Consult a doctor if:
- You have eye irritation:
  - Seek medical advice.
  - If irritation persists, contact a doctor.
  - Use cold water/ take a shower. In the case of eye irritation, you can:
    - Wash with soap and water.
    - In case of ingestion:
      - Wash with plenty of water.
      - Do not induce vomiting. IN CASE OF CONTACT WITH THE SKIN:
        - Wash with soap and water.
        - In case of irritation of the skin:
          - Wash with soap and water.
          - In case of irritation:
            - Wash with soap and water.
            - If irritation persists:
              - Consult a doctor.

Prevent skin irritation:
- Wear plastic gloves/protective clothing/eyewear.
- Avoiding contact with the skin.
- Avoid contact with the skin/conservative:
  - Consult a doctor.
  - In case of irritation:
    - Wash with soap and water.
    - In case of contact:
      - Wash with plenty of water.
      - Do not induce vomiting.

Prevent eye irritation:
- Use cold water for more than a few minutes.
- Take out contact lenses, if possible.
- Wash with soap and water.
- In case of ingestion:
  - Wash with plenty of water.
  - Do not induce vomiting.

Prevent allergic reactions:
- Wash with soap and water.
- In case of irritation:
  - Wash with soap and water.
  - In case of irritation:
    - Consult a doctor.

Prevent contact with eyes:
- Use cold water for more than a few minutes.
- Take out contact lenses, if possible.
- Consult a doctor.
- In case of irritation:
  - Wash with soap and water.
  - In case of contact:
    - Wash with plenty of water.
    - Do not induce vomiting.

Prevent contact with the skin:
- Wash with soap and water.
- In case of irritation:
  - Wash with soap and water.
  - In case of irritation:
    - Consult a doctor.

Prevent contact with the skin/conservative:
- Consult a doctor.
- In case of irritation:
  - Wash with soap and water.
  - In case of contact:
    - Wash with plenty of water.
    - Do not induce vomiting.

Prevent eye irritation:
- Use cold water for more than a few minutes.
- Take out contact lenses, if possible.
- Consult a doctor.
- In case of irritation:
  - Wash with soap and water.
  - In case of contact:
    - Wash with plenty of water.
    - Do not induce vomiting.

Prevent contact with eyes:
- Use cold water for more than a few minutes.
- Take out contact lenses, if possible.
- Consult a doctor.
- In case of irritation:
  - Wash with soap and water.
  - In case of contact:
    - Wash with plenty of water.
    - Do not induce vomiting.

Prevent contact with the skin:
- Wash with soap and water.
- In case of irritation:
  - Wash with soap and water.
  - In case of irritation:
    - Consult a doctor.

Prevent contact with the skin/conservative:
- Consult a doctor.
- In case of irritation:
  - Wash with soap and water.
  - In case of contact:
    - Wash with plenty of water.
    - Do not induce vomiting.

Prevent eye irritation:
- Use cold water for more than a few minutes.
- Take out contact lenses, if possible.
- Consult a doctor.
- In case of irritation:
  - Wash with soap and water.
  - In case of contact:
    - Wash with plenty of water.
    - Do not induce vomiting.

Prevent contact with eyes:
- Use cold water for more than a few minutes.
- Take out contact lenses, if possible.
- Consult a doctor.
- In case of irritation:
  - Wash with soap and water.
  - In case of contact:
    - Wash with plenty of water.
    - Do not induce vomiting.

Prevent contact with the skin:
- Wash with soap and water.
- In case of irritation:
  - Wash with soap and water.
  - In case of irritation:
    - Consult a doctor.

Prevent contact with the skin/conservative:
- Consult a doctor.
- In case of irritation:
  - Wash with soap and water.
  - In case of contact:
    - Wash with plenty of water.
    - Do not induce vomiting.