NEW LAV BLOT I

18 determinations

CONFIRMATION KIT FOR ANTI-HIV-1 ANTIBODIES DETECTION IN SERUM/PLASMA BY IMMUNOBLOTTING

IVD For In Vitro Diagnostic Use

Manufacturer Quality Control
All the products manufactured and commercialised by Bio-Rad are under complete quality system starting from reception of raw material to the final commercialisation of the product. Each lot is submitted to a quality control and only is released on the market when conforming to the acceptance criteria. The records relating to production and control of each single lot are kept within our company.
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1 - INTENDED USE
The NEW LAV-BLOT I kit is intended to detect human anti-HIV-1 antibodies in serum or plasma by immunoblotting in order to confirm a positive anti-HIV-1 response and specify its antigenic specificity within the scope of AIDS diagnosis.

2 - CLINICAL VALUE
Acquired immunodeficiency syndrome (AIDS) was described and identified as a well-characterized disease in 1981. Three retroviruses (LAV, HTLV III, ARV), related to the Lentivirus group and not differentiated by conventional serological tests, were isolated from lymphocytes of patients with AIDS or AIDS prodromes. The decision of grouping these three viruses under the same denomination (HIV) was taken in 1986.
Viral transmission mainly occurs by sexual or blood route. Various measures were taken by Health Authorities to limit the virus spreading; controls of blood donations became required in order to eliminate potentially infectious samples.
Screening is based on the detection of antibodies in serum or plasma using the enzyme immunoassay technique.
The quality of the antigens used in these tests does not allow eliminating some non-specific responses. Considering the severity of the stated diagnosis, it is required to confirm or invalidate the screening test results by another technique. WHO experts recommend immunoblotting (Western Blot).
This technique allows characterizing the antibodies directed against each virus protein, and thus confirming seropositivity or identifying possible non-specific reactions.
The NEW LAV-BLOT I kit includes all the reagents required to perform confirmatory tests by immunoblotting.

3 - PRINCIPLE OF THE TEST
The test is based on indirect ELISA technique on a nitrocellulose strip containing all the HIV-1 constituent proteins and an internal anti-IgG control. The band corresponding to the internal control is localized on the strip end without any number, before the P 18 reaction and allows to validate the addition of the sample and reagents as well as the correct progress of the procedure.
Inactivated HIV-1 proteins are separated according to their molecular weights by polyacrylamide gel electrophoresis in dissociating and reducing medium and subsequently electrically transferred onto a nitrocellulose membrane sheet.
The procedure comprises the following steps:
1. Strip rehydration.
2. Incubation of the samples to be confirmed or the control sera.
   If anti-HIV-1 antibodies are present, they bind to the identified viral proteins, present on the strip.
3. After washing, the alkaline phosphatase-labeled anti-human IgG antibodies are incubated. The conjugate binds to anti-HIV-1 antibodies captured on the solid phase.
4. After washing and removing the excess conjugate, the color development solution allows demonstrating the enzymatic activity of the complexes bound to nitrocellulose.
5. The appearance of specific colored bands allows demonstrating the presence of anti-HIV-1 antibodies in the sample.
4 - CONTENTS OF THE KIT
All the reagents are intended to “in vitro” diagnostic use only.
Each kit contains reagents sufficient for 18 determinations. The determinations may be performed in multiple independent runs.

<table>
<thead>
<tr>
<th>LABEL</th>
<th>REAGENT COMPOSITION</th>
<th>PRESENTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>HIV-1 Nitrocellulose Strip</td>
<td>18 strips in 3 trays (6 cells each)</td>
</tr>
<tr>
<td></td>
<td>Activated by transfer of HIV-1 viral proteins and internal anti-IgG control</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strips are placed in disposable trays</td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td>Buffer Solution/Diluent (5X)</td>
<td>1 vial 100 ml</td>
</tr>
<tr>
<td></td>
<td>Buffer Solution/Diluent (Concentrated 5X)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contains 0.5% chloroform</td>
<td></td>
</tr>
<tr>
<td>R3</td>
<td>Negative Control</td>
<td>1 vial 0.2 ml</td>
</tr>
<tr>
<td></td>
<td>Human serum negative for HBsAg, anti-HIV-1 and anti-HIV-2 and anti-HCV antibodies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Preservative: &lt; 0.1% sodium azide</td>
<td></td>
</tr>
<tr>
<td>R4</td>
<td>Anti-HIV-1 Positive Control</td>
<td>1 vial 0.2 ml</td>
</tr>
<tr>
<td></td>
<td>Human serum positive for anti-HIV-1 antibodies, negative for anti-HCV antibodies and HBsAg, heat-inactivated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Preservative: &lt; 0.1% sodium azide</td>
<td></td>
</tr>
<tr>
<td>R5</td>
<td>Conjugate</td>
<td>1 vial 40 ml</td>
</tr>
<tr>
<td></td>
<td>Goat alkaline phosphatase-labeled anti-human IgG antibodies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Preservative: &lt; 0.1% sodium azide</td>
<td></td>
</tr>
<tr>
<td>R6</td>
<td>Color Development Solution (BCIP/NBT)</td>
<td>1 vial 40 ml</td>
</tr>
<tr>
<td></td>
<td>5 Bromo-4 Chloro-3 Indolyl Phosphate (BCIP) and NitroBlue Tetrazolium (NBT) as developing buffer</td>
<td></td>
</tr>
</tbody>
</table>

5 - PRECAUTIONS
The reliability of results depends on correct observance of the following Good Laboratory Practices:
- Do not use expired reagents.
- Do not mix reagents from different lots within a given test run.

Note: It is possible to use other buffer solution (Label identification: R2 in blue) and color development solution (R6) lots with the restriction that the very same lot is used within a given test run.
- Before use, it is required to wait 30 minutes to allow the reagents stabilizing at room temperature (18-30°C).
- Carefully reconstitute reagents avoiding any contamination.
- Use glassware thoroughly washed and rinsed with distilled water or preferably, disposable material.
- Use a new dispensing tip for each sample.
- Never use the same container to dispense conjugate and color development solution.
- Check pipettes for accuracy and precision and if the instruments being used are correctly working.
- Do not change the assay procedure.
- Control sera should be tested in parallel with patient samples for each test run.
- Do not allow strips to dry more than 10 minutes during the test.
- If suspended particles are present in the development solution, allow to settle in the vial before pipetting. (These particles do not interfere with the test).
6 - HEALTH AND SAFETY INSTRUCTIONS

All the kit reagents are intended to “in vitro” diagnostic use.

- Never handle the strips with bare hands: Use plastic tweezers.
- Wear disposable gloves when handling reagents.
- Do not pipette by mouth.
- Human source material used in the preparation of the negative control (R3) was tested and found non-reactive for hepatitis B surface antigen (HBsAg), and anti-HIV-1, anti-HIV-2, and anti-HCV antibodies.
- Human source material used in the preparation of the positive control (R4), was tested and found non-reactive for hepatitis B surface antigen (HBsAg), and anti-HCV. It was heat-inactivated.
- 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.
- 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.
- Some reagents contain sodium azide as a preservative. Sodium azide may form copper or lead azides in laboratory plumbing. Such azides are explosive. To prevent azide build-up, flush the pipes with a large amount of water if solutions containing azide are discarded into the sink after inactivation.

7 - EQUIPMENT REQUIRED BUT NOT SUPPLIED

- Distilled or demineralized water.
- 100 ml, 250 ml and 500 ml graduated cylinders.
- 2 ml graduated pipettes.
- Automatic or semi-automatic pipettes, adjustable or fixed, allowing measuring or dispensing 20 µl.
- Disposable gloves.
- Liquid jet vacuum pump with safety bottle.
- Sodium hypochlorite (Bleach).
- Absorbent paper.
- Tweezers.
- 1, 2 or 3 dimensional shaker (shaking to ensure a homogeneous environment and total immersion of the strips during the shaking steps).
- Container for biohazardous waste.
- Protective glasses.
8 - REAGENT RECONSTITUTION AND STORAGE

Each kit contains reagents sufficient for 18 determinations. The determinations may be performed in multiple independent runs.

Ready to use reagents
- R1: HIV-1 nitrocellulose strips.
- R3: Negative control.
- R4: Anti-HIV-1 positive control.
- R5: Conjugate.
- R6: Color development solution (BCIP/NBT).

Reagent to be reconstituted
- R2: Buffer solution/diluent (5X)

Preparation: shake the vial before collection. Dilute the buffer solution/diluent to 1:5 in distilled water (e.g. for a complete tray: 30 ml buffer solution + 120 ml distilled water). Homogenize.

Storage
Store the kit at +2-8°C. Once opened, all the kit reagents may be stored at +2-8°C until the expiration date stated on the box (except for specific instructions). The diluted buffer solution/diluent (R2) is stable for 1 month at +2-8°C.
Avoid any microbial contamination of the reagents.

9 - SAMPLE COLLECTION AND HANDLING

Collect a blood sample according to the current practices.
The tests should be performed with undiluted serum or plasma samples (EDTA, heparin, citrate).
Extract the serum or plasma from the clot or red cells as soon as possible in order to avoid hemolysis.
Extensive hemolysis may affect test performance. Samples with aggregates should be clarified by centrifugation prior testing. Suspended fibrin particles or aggregates may yield falsely positive results.
The samples can be stored at +2-8°C if the test is performed within 7 days or they may be deep-frozen at -20°C. Plasma samples should be quickly thawed by heating for a few minutes at 40°C (to limit fibrin precipitation).
Samples that have been frozen and thawed more than 3 times should not be used.
If the samples have to be shipped, they should be packaged in accordance with the regulations effective for the transport of etiological agents.
DO NOT USE CONTAMINATED, HYPERLIPEMIC OR HYPERHEMOLYSED SERUM OR PLASMA SAMPLES.

Note: Samples containing up to 90 g/l albumin, 100 mg/l bilirubin, lipemic samples containing up to the equivalent of 36 g/l trioleine, and hemolyzed samples containing up to 10 g/l hemoglobin do not affect the test results.

10 - TEST PROCEDURE

1. Before use, it is required to wait 30 minutes to allow reagents stabilizing at room temperature (18-30°C).

Remove the transparent cover of the tray being used.

Make sure that the strip side with the reference mark and the number is visible, so that the viral proteins on this side are covered by the various reaction media throughout the test.

Strips should be carefully handled with plastic tweezers.

Do not allow the strips to dry more than 10 minutes during the test.

The controls supplied should be tested in parallel with patient samples for each test run.
The positive control is required to validate the test and correctly interpret the bands.

2. Add 2 ml of the reconstituted buffer solution/diluent into each cell.

Incubate for 5 ± 1 minutes at room temperature (18-30°C) under shaking.

3. Add 20 µl of each sample or control serum into the corresponding cell.

Incubate for 2 hours ± 5 minutes at room temperature (18-30°C) under shaking.
4. Completely drain the contents of each cell using a vacuum pump with a trap containing a disinfectant (25% bleach). Make sure that the strip does not move during aspiration; use the aspiration well designed for this use. Rinse under the tap the aspiration tip, which is in contact with the samples between each aspiration to avoid sample cross-contamination. Wash each strip with 2 ml of the reconstituted buffer solution/diluent and immediately remove it by aspiration, following the same precautions. Wash each strip twice, allow the contact for 5 minutes, under shaking, with 2 ml of the reconstituted buffer solution/diluent (i.e. a total of 3 wash steps). Remove the solution used for the last washing.

5. Dispense 2 ml of conjugate into each cell, the conjugate solution should be previously stabilized at room temperature. Incubate for 1 hour ± 5 minutes at room temperature (18-30°C) under shaking.


7. Dispense 2 ml of color development solution into each cell. If suspended particles are present in the development solution, allow to settle in the vial before pipetting. (These particles do not interfere with the test.) Incubate under shaking and monitor the appearance of the coloration. All the bands corresponding to the viral proteins should be observed with the positive control serum. (Development time: 5 minutes at least).

8. Stop the reaction by removing the development solution and rinsing the strips 3 times with distilled water.

9. Dry the strips between 2 sheets of absorbent paper at room temperature (18-30°C). Sort the strips, position them perfectly using the reference mark. Validate then interpret. CAUTION: do not stick adhesive plastic band on the strip side corresponding to the viral proteins.

11 - VALIDATION, READING AND INTERPRETATION OF RESULTS

Validation
The internal anti-IgG control band should be present with a strong color. It allows to validate the addition of the sample, reagents as well as the correct progress of the test procedure. The absence or weak intensity of the coloration of the internal anti-IgG control band indicates either that the sample or reagents were not dispensed or that the test procedure was not followed. Positive control: presence of all band corresponding to the viral proteins and the control band Negative control: none of the viral protein should be present, the control band is present.

Reading
The presence of anti-HIV-1 constituent protein antibodies in controlled samples is shown by the appearance of specific colored bands (blue-purple). Their position corresponds to the molecular masses of the viral proteins listed in the following table.

IMPORTANT
Use the positive control (cf figure page 14) to locate and identify the shown antibodies and check that the internal control band is present on each test strip. Each specific and readable band must be interpreted.
Interpretation

<table>
<thead>
<tr>
<th>INTERPRETATION</th>
<th>WHO CRITERIA*</th>
<th>CRSS CRITERIA**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>2 ENV ± GAG ± POL</td>
<td>1 ENV + (1 GAG or 1 POL)</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>1 ENV ± GAG ± POL</td>
<td>GAG + POL</td>
</tr>
<tr>
<td></td>
<td>GAG + POL</td>
<td>GAG</td>
</tr>
<tr>
<td></td>
<td>GAG</td>
<td>POL</td>
</tr>
<tr>
<td></td>
<td>POL</td>
<td>ENV</td>
</tr>
<tr>
<td>Negative</td>
<td>No band</td>
<td>Non-classified bands</td>
</tr>
<tr>
<td></td>
<td>Non-classified bands</td>
<td>Non-classified bands</td>
</tr>
</tbody>
</table>

*WHO: World Health Organization, **CRSS: Consortium for Retrovirus Serology Standardization.

Note
- The “indeterminate” category may reflect one of the following alternatives: seroconversion, HIV-2 infection or a cross-reaction with other retroviruses.
- Contamination with a positive serum may cause a positive or indeterminate profile.

12 - PERFORMANCE

Specifics on blood donors and hospitalized patients

A population of 419 Elisa HIV negative samples (214 samples from blood donors and 205 samples from hospitalized patients) was tested with NEW LAV BLOT I.

The same results, given below, were obtained no matter which interpretation criteria were used (WHO or CRSS).

<table>
<thead>
<tr>
<th>Samples</th>
<th>Number of samples</th>
<th>Negatives</th>
<th>Indeterminate</th>
<th>Positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donors</td>
<td>214</td>
<td>180</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>Hospitalized patients</td>
<td>205</td>
<td>186</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>419</td>
<td>366</td>
<td>53</td>
<td>0</td>
</tr>
</tbody>
</table>

87% 13% 0%
Specifics on samples which may present cross-reactions

57 Elisa HIV negative samples which were positive for viruses including HBV, HCV, HTLV, HSV, EBV, VZV and CMV or presented the following pathologies: HAMA, RF, ANA, Toxoplasmosis, and 5 samples from pregnant women were tested with NEW LAV BLOT I.

48 samples were found to be negative, 14 were found to be indeterminate: 3 p25, 3 p18, 5 p55, 1 p52, 1 p34 and 1 p52. None were found to be positive. The same results were obtained no matter which interpretation criteria were used (WHO or CRSS).

Sensitivity on HIV-1 positive samples

203 Elisa HIV-1 positive samples were tested with NEW LAV BLOT I: 5 HIV group O, 8 at the start of infection (positive antigen or viral load) and 84 samples from different countries such as China, Niger and India. Below are the results by criterion.

<table>
<thead>
<tr>
<th>Samples</th>
<th>WHO CRITERIA*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 ENV ± GAG ± POL</td>
<td>CRSS CRITERIA**</td>
</tr>
<tr>
<td>1 ENV + (1 GAG or 1 POL)</td>
<td></td>
</tr>
<tr>
<td>Samples</td>
<td>Number of samples</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------</td>
</tr>
<tr>
<td>HIV Positive</td>
<td>203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Samples</th>
<th>Number of samples</th>
<th>Indeterminate</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Positive</td>
<td>101</td>
<td>56</td>
<td>45</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Samples</th>
<th>WHO CRITERIA*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 ENV ± GAG ± POL</td>
<td>CRSS CRITERIA**</td>
</tr>
<tr>
<td>1 ENV + (1 GAG or 1 POL)</td>
<td></td>
</tr>
<tr>
<td>Samples</td>
<td>Number of samples</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------</td>
</tr>
<tr>
<td>HIV Positive</td>
<td>101</td>
</tr>
</tbody>
</table>

4% | 96% | 0.5% | 99.5%

* WHO: World Health Organization, ** CRSS: Consortium for Retrovirus Serology Standardization.

Sensitivity on HIV-2 positive samples

A total of 101 HIV-2 positive samples among which 6 were HIV-1 and HIV-2 positive with PEPTI-LAV were tested with NEW LAV BLOT I.

<table>
<thead>
<tr>
<th>Samples</th>
<th>WHO CRITERIA*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 ENV ± GAG ± POL</td>
<td>CRSS CRITERIA**</td>
</tr>
<tr>
<td>1 ENV + (1 GAG or 1 POL)</td>
<td></td>
</tr>
<tr>
<td>Samples</td>
<td>Number of samples</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------</td>
</tr>
<tr>
<td>HIV Positive</td>
<td>101</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Samples</th>
<th>Number of samples</th>
<th>Indeterminate</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Positive</td>
<td>101</td>
<td>56</td>
<td>45 %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Samples</th>
<th>WHO CRITERIA*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 ENV ± GAG ± POL</td>
<td>CRSS CRITERIA**</td>
</tr>
<tr>
<td>1 ENV + (1 GAG or 1 POL)</td>
<td></td>
</tr>
<tr>
<td>Samples</td>
<td>Number of samples</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------</td>
</tr>
<tr>
<td>HIV Positive</td>
<td>101</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Samples</th>
<th>Number of samples</th>
<th>Indeterminate</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Positive</td>
<td>101</td>
<td>56</td>
<td>45 %</td>
</tr>
</tbody>
</table>

* WHO: World Health Organization, ** CRSS: Consortium for Retrovirus Serology Standardization.
Sensitivity on seroconversion panels

55 samples from 17 seroconversion panels (BBI, NABI and BCP) and 10 samples from 4 hospitalized patients, for a total of 21 seroconversion panels, were tested with NEW LAV BLOT I.

<table>
<thead>
<tr>
<th>Samples</th>
<th>Positive</th>
<th>Indeterminate</th>
<th>Negative</th>
<th>Positive</th>
<th>Indeterminate</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>65</td>
<td>2</td>
<td>46</td>
<td>17</td>
<td>37</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>3%</td>
<td>71%</td>
<td>26%</td>
<td></td>
<td>57%</td>
<td>17%</td>
<td>26%</td>
</tr>
</tbody>
</table>

* WHO: World Health Organization, ** CRSS: Consortium for Retrovirus Serology Standardization.

In conclusion, the use of CRSS criteria increases the test’s sensitivity by producing a significant drop in the number of indeterminate results in favor of positive results.

Reproducibility

- **Intra-trial**
  One HIV negative sample and 3 diluted positive samples (2 weak and 1 medium) were tested 6 times in the same trial. The interpretations were made using both criteria. The same results were obtained no matter which interpretation criteria were used (WHO or CRSS).

- **Inter-trial**
  One HIV negative sample and 6 diluted positive samples (3 weak, 3 medium) and 3 strong positive samples were tested over 5 days. The interpretations were made using both criteria. The same results were obtained no matter which interpretation criteria were used (WHO or CRSS).

13 - LIMITATIONS OF THE TEST

- The variability of HIV-1 (group M and group O) and HIV-2 viruses makes it impossible to exclude the possibility of false negative reactions. No known test method can offer complete assurance that the HIV virus is absent.
- A positive screening test associated with a negative confirmatory test may occur during the first stage of infection; hence, a negative result indicates that the tested sample does not contain anti-HIV antibodies detectable with NEW LAV BLOT I. Such a result does not, however, exclude the possibility of a recent HIV-1/HIV-2 infection. A new sample should be tested later.
- The presence of a single ENV strip for a sample that has been confirmed positive with NEW LAV BLOT I according to CRSS criteria does not exclude the possibility of an HIV-2 infection.
- An “indeterminate” profile does not exclude one of the following situations: seroconversion, HIV-2 infection, or a cross-reaction with other retroviruses.
- An atypical profile with weak envelope protein reactions (GP 120/GP 160) contrasting with the clear positivity on proteins from GAG and POL suggests the possibility of an infection by a HIV-2 or a HIV-1 group O and requires additional investigations.

14 - REFERENCES

Positive Control R4 example profile

**Caution:** precise bands may differ in reality. Don’t use this picture for final interpretation. Use the positive control strip to identify the patient antibodies and check that the internal control band is present on each strip.
(GB) - CE marking (European directive 98/79/CE on in vitro diagnostic medical devices)
(FR) - Marquage CE (Directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro)
(ES) - Marcado CE (Directiva europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro)
(IT) - Marchiatura CE (Direttiva europea 98/79/CE relativa ai dispositivi medico-diagnostici in vitro)
(DE) - CE Konformitätssennzeichnung (Europäische Richtlinie 98/79/EG über in vitro-Diagnostika)
(PT) - Marcação CE (Directiva europeia 98/79/CE relativa aos dispositivos médicos de diagnóstico in vitro)
(SE) - CE-märkning (Europeiskt direktiv 98/79/EG om medicintekniska produkter för in vitro-diagnostik)
(DK) - CE-mærkningen (Europa direktiv 98/79/EF om medicinsk udstyr til in vitro-diagnostik)
(GR) - Χαρακτηρισμός CE (Ευρωπαϊκή οδηγία 98/79/ΕΕ για τα προϊόντα σωματικού χαράκτηρα που χρησιμοποιούνται σε ιντερνατική επιπλοκή)
(PL) - CE oznaczenie (Dyrektywa unijna 98/79/CE dotycząca produktów medycznych do badań in vitro)
(LT) - CE ženklas (Euroopa direktiiv 98/79/CE dėl in vitro diagnostikos medicinos prietaisų)
(HU) - CE jelzés (98/79/CE Európai Irányelv az in vitro orvosi diagnosztikai eszközökért)
(EE) - CE märgistus (Euroopa direktiv 98/79/CE in vitro diagnostika-laineisideadmete kohta)
(SK) - CE označenie o zhode (Európska direktíva 98/79/CE pre in vitro diagnostické zdravotnícky postupy)
(CZ) - CE značka (Evropská direktiva 98/79/CE o diagnostických zdravotníckych prostředcích in vitro)
(NO) - CE-marking (EU-direktiv 98/79/CE om medisinsk utstyr til in vitro-diagnostikk)
(RO) - Marca CE (Directiva europeana 98/79/CE pentru dispozitive medicale de diagnostic in vitro)
(BG) - CE маркировка (Европейска директива 98/79/CE за ин витро диагностичните медицински изделия)

(GB) - For in vitro diagnostic use
(FR) - Pour diagnostic in vitro
(ES) - Para diagnóstico in vitro
(IT) - Per uso diagnostico in vitro
(DE) - In-vitro-Diagnostikum
(PT) - Para uso em diagnóstico in vitro
(SE) - In vitro-diagnostik
(DK) - In vitro diagnose
(GR) - Για in vitro διαγνωστικά χρήση
dl (PL) - Do stosowania in vitro
(LT) - in vitro diagnostikai
(HU) - Csak in vitro diagnosztikai alkalmazásra
(EE) - In vitro diagnositiiskeas kasutamiseks
(SK) - Na diagnostiku in vitro
(CZ) - Pro diagnostiku in vitro
(NO) - Til in vitro-diagnostikk
(RO) - Pentru diagnostic in vitro
(BG) - За ин витро диагностика

(GB) - Catalogue number
(FR) - Référence catalogue
(ES) - Número de catálogo
(IT) - Numero di catalogo
(DE) - Bestellnummer
(PT) - Número de catálogo
(SE) - Katalognummer
(DK) - Katalognummer
(GR) - Αριθμός κατάλογου
(PL) - Numer katalogu
(LT) - Katalogo numeris
(HU) - Cikkszám
(EE) - Katalooginumber
(SK) - Katalogové číslo
(CZ) - Katalogové číslo
(NO) - Katalognummer
(RO) - Număr de catalog
(BG) - Каталожен номер

(GB) - Manufacturer
(FR) - Fabricant
(ES) - Fabricante
(IT) - Produttorre
(DE) - Hersteller
(PT) - Fabricante
(SE) - Tillverkare av
(DK) - Fremstillett af
(GR) - Κατασκευαστής
(PL) - Producent
(LT) - Gamintojas
(HU) - Gyártó
(EE) - Tootja
(SK) - Výrobcu
(CZ) - Výrobce
(NO) - Produsent
(RO) - Producător
(BG) - Производител

(GB) - Authorised Representative
(FR) - Représentant agréé
(ES) - Representante autorizado
(IT) - Distributore autorizzato
(DE) - Bevollmächtigter
(PT) - Representante Autorizado
(SE) - Auktoriserad representant
(DK) - Autoriseret repræsentant
(GR) - Εξουσιοδοτημένος αντιπροσωπός
(PL) - Upoważniony Przedstawiciel
(LT) - Įgaliotasis atstovas
(HU) - Meghatalmazott Képviselő
(EE) - Voltatud esindaja
(SK) - Autorizovaný zástupca
(CZ) - Zpínomocněný zástupce
(NO) - Autorisert representant
(RO) - Reprzentant autorizat
(BG) - Упълномощен представител

(GB) - Batch code
(FR) - Code du lot
(ES) - Código de lote
(IT) - Codice del loto
(DE) - Chargen-Bezeichnung
(PT) - Código do lote
(SE) - Batchnr
(DK) - Batchkoden
(GR) - Κώδικας παρτίδας
(PL) - Numer serii
(LT) - Serijos numeris
(HU) - Gyártási szám
(EE) - Partii kood
(SK) - Číslo šarže
(CZ) - Číslo šarže
(NO) - Partikode
(RO) - Număr de lot
(BG) - Партиден номер

(GB) - Expiry date YYYY/MM/DD
(FR) - Date de peremption AAAA/MM/JJ
(ES) - Estable hasta AAAA/MM/DD
(IT) - Da utilizzare prima del AAAA/MM/GG
(DE) - Verwendbar bis JJJJ/MM/TT
(PT) - Data de expiração AAAA/MM/DD
(SE) - Utgångsdatum ÄÄÄÄ/MM/DD
(DK) - (DK) - Anvendes før AAAA/MM/DD
(RO) - Date expirarii AAAA/LL/ZZ
(BG) - Срок на годност година/месец/ден
Storage temperature limitation

Consult Instruction for use