

INNO-LIA™* HIV I/II Score

研究用

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Symbols used



Manufacturer
Fabricant
Hersteller
Fabbricante
Fabricante



In Vitro Diagnostic Medical Device
Dispositif médical de diagnostic *in vitro*
In-Vitro-Diagnostikum
Dispositivo medico-diagnostico *in vitro*
Producto sanitario para diagnóstico *in vitro*
Dispositivo médico para diagnóstico *in vitro*



Batch code
Code du lot
Chargenbezeichnung
Codice del lotto
Código de lote
Código do lote



Catalogue number
Référence du catalogue
Bestellnummer
Numero di catalogo
Número de catálogo
Referência de catálogo



Use By
Utiliser jusque
Verwendbar bis
Utilizzare entro
Fecha de caducidad
Prazo de validade



Consult Instructions for Use
Consulter les instructions d'utilisation
Gebrauchsanweisung beachten
Consultare le istruzioni per l'uso
Consulte las instrucciones de uso
Consulte as instruções de utilização



Biological risks
Risques biologiques
Biogefährdung
Rischio biologico
Riesgo biológico
Risco biológico



Temperature limitation
Limites de température
Temperaturbegrenzung
Limiti di temperatura
Límite de temperatura
Limites de temperatura



Contains sufficient for <n> tests
Contenu suffisant pour "n" tests
Inhalt ausreichend für <n> Prüfungen
Contenuto sufficiente per "n" saggi
Contenido suficiente para <n> ensayos
Conteúdo suficiente para "n" ensaios



Negative Control
Contrôle négatif
Negativkontrolle
Controllo negativo
Control negativo
Controlo negativo



Positive Control
Contrôle positif
Positivkontrolle
Controllo positivo
Control positivo
Controlo positivo

STRIPS	Strips Bandelettes Teststreifen Strisce Tiras
SAMP DIL	Sample Diluent Diluant échantillon Probenverdünner Diluyente del campione Diluyente de la muestra Diluyente da amostra
WASH SOLN 5x	Wash Solution 5x Solution de lavage 5x 5x konzentrierte Waschlösung Soluzione di lavaggio 5x Solución de lavado 5x Solução de lavagem 5x
CONJ	Ready-to-use Conjugate Conjugué prêt à l'emploi Gebrauchsfertiges Konjugat Coniugato pronto all'uso Conjugado listo para usar Conjugado pronto a utilizar
SUBS BCIP/NBT	Ready-to-use Substrate BCIP/NBT Substrat BCIP/NBT prêt à l'emploi Gebrauchsfertiges BCIP/NBT-Substrat Substrato BCIP/NBT pronto all'uso Sustrato BCIP/NBT listo para usar Substrato BCIP/NBT pronto a utilizar
STOP SOLN	Stop Solution Solution d'arrêt Stopplösung Soluzione di stop Solución de parada Solução de paragem

English

Intended use

The INNO-LIA™ HIV I/II Score is a Line Immuno Assay (LIA®), to confirm the presence of antibodies against the human immunodeficiency virus type 1 (HIV-1), including group O, and type 2 (HIV-2) in human serum or plasma. The INNO-LIA™ HIV I/II Score also differentiates between HIV-1 and HIV-2 infections. It is intended as a supplementary assay on specimens found to be reactive using an anti-HIV screening procedure.

Test principle

Recombinant proteins and synthetic peptides from HIV-1 and HIV-2, and a synthetic peptide from HIV-1 group O are coated as discrete lines on a nylon strip with plastic backing.

Five HIV-1 antigens are applied: sgp120 and gp41, which detect specific antibodies to HIV-1, and p31, p24, and p17, which may also cross-react with antibodies to HIV-2. HIV-1 group O peptides are present in the HIV-1 sgp120 band. The antigens gp36 and sgp105 are applied to detect antibodies to HIV-2.

In addition to these HIV antigens, four control lines are coated on each strip: anti-streptavidine line, ± cut-off line (human IgG), 1+ positive control line (human IgG) and one strong 3+ positive control line which is also the sample addition control line (anti-human Ig). The INNO-LIA™ HIV I/II Score is based on the enzyme immunoassay principle (EIA).

The test sample is incubated in a test trough together with the multiple antigen-coated test strip. HIV antibodies, if present in the sample, will bind to the individual HIV antigen lines on the strip. Afterwards, a goat anti-human IgG labelled with alkaline phosphatase is added and will bind to any HIV antigen/antibody complex previously formed. Incubation with enzyme substrate (BCIP/NBT) produces a dark brown color in proportion to the amount of HIV antibody present in the sample. Color development is stopped with sulfuric acid.

If the sample contains no HIV-specific antibodies, the labelled antihuman antibody will not be bound to antigen/antibody complex so that only a low standard background color develops.

Reagents***Description, preparation for use and recommended storage conditions***

- If kept at 2 - 8°C, opened or unopened, all reagents are stable until the expiration date. Do not freeze reagents. Do not use the kit beyond the expiration date.

- All reagents and the plastic tube containing the test strips must be brought to room temperature (18 - 25°C) approximately 30 minutes before use and returned to the refrigerator (2 - 8°C) immediately after use.
- Alterations in the physical appearance of kit reagents may indicate instability or deterioration.

Reagents supplied:

<u>Component</u>	<u>Quantity</u>	<u>Ref.</u>	<u>Description</u>
Strips	20	57330	Containing 20 INNO-LIA™ HIV antigen-coated test strips.
Sample Diluent	30 ml	57304	Containing color-coded (green) phosphate buffer containing sodium chloride, detergent, bovine protein stabilizers and 0.3% chloroacetamide (CAA) as preservative.
Negative Control	0.12 ml	57307	Containing base matrix of human origin with 0.01% methylisothiazolone (MIT)/ 0.1% CAA as preservative.
Positive Control	0.12 ml	57306	Containing inactivated human serum positive for antibodies to HIV with 0.01% MIT/0.1% CAA as preservative.
Ready-to-use Conjugate	45 ml	57301	Containing color-coded (red) goat anti-human IgG labeled with alkaline phosphatase in Tris buffer containing bovine stabilizers, detergent and 0.01% MIT/0.1% CAA as preservative.
Ready-to-use Substrate BCIP/NBT	45 ml	57302	Containing 5-bromo-4-chloro-3-indolyl phosphate/nitroblue tetrazolium in dimethyl formamide, with 0.01% MIT/ 0.1% CAA as preservative.
Stop Solution	45 ml	57303	Containing 0.1 mol/l sulfuric acid.
Wash Solution	45 ml	57299	Containing color-coded (blue) Tris buffer containing sodium chloride, detergent and 0.02% bromo-nitro-dioxane as preservative, to be diluted 5x in distilled water. Diluted wash solution is stable for 2 weeks if kept at 2 - 8°C.
Incubation tray	2	-	With 11 troughs each.
Adhesive sealers	5	-	
Data reporting sheet	1		For storage of developed strips.
Reading card	1		For identification of reactive antigen lines.

Materials required but not provided

- Distilled or deionized water.
- Precision pipettes with disposable tips capable of delivering 10 µl, 20 - 200 µl, and 200 - 1000 µl, respectively.
- Orbital mixer or rocker (see Directions for incubation).
- Vortex mixer or equivalent.
- Graduated cylinders: 10, 25, 50, and 100 ml.
- Tweezers for strip handling.
- Timer.
- Optional:
 - hot air fan (hair dryer) or dry incubator at 37°C.
 - a repetitive pipette together with disposable vials for the addition of stop solution, conjugate, substrate and wash solution.
 - vacuum aspirator which contains 5% sodium hypochlorite solution in a waste bottle.

Safety and environment

- **Please refer to the Material Safety Data Sheet (MSDS) and product labelling for information on potentially hazardous components. The most recent MSDS version is available on the website www.innogenetics.com.**



R43, S24-37

Irritant! (Xi) Avoid contact with skin. May cause sensitization by skin contact. Wear suitable gloves. **Contains 2-Chloroacetamide:** Sample Diluent, Ready-to-use Conjugate, Ready-to-use BCIP/NBT Substrate, Negative Control and Positive Control.

- Specimens, Positive Control and Negative Control should always be handled as potentially infectious.
- The Positive Control has been found to be negative for anti-HCV and HBsAg. The Negative Control has been found to be negative for anti-HIV-1/HIV-2, anti-HCV and HBsAg. No test method can offer complete insurance that blood products will not transmit infectious agents. Therefore, all blood components and biological materials should be considered as being potentially infectious and should be handled as such. Only adequately trained personnel should be permitted to perform the test procedure. All blood components and biological materials should be disposed of in accordance with established safety procedures.
 - Autoclave for at least 15 minutes at 121°C.
 - Incinerate disposable material.

- Mix liquid waste with sodium hypochlorite so that the final concentration is $\pm 1\%$ sodium hypochlorite. Allow to stand overnight before disposal. CAUTION: Neutralize liquid waste that contains acid before adding sodium hypochlorite.
- Use of personal protective equipment is necessary: gloves and safety spectacles when manipulating dangerous or infectious agents.
- Waste should be handled according to the institution's waste disposal guidelines. All federal, state, and local environmental regulations should also be observed.
- Do not aspirate the stop solution in a waste bottle, which contains sodium hypochlorite.

Specimen (collection and handling)

- The **INNO-LIA™ HIV I/II Score** may be performed on human serum or plasma collected in tubes containing citrate, heparin or EDTA as anticoagulants.
- Before storage, serum or plasma should be separated from blood clot or blood cells by centrifugation.
- Store the specimens at 2 - 8°C. For storage longer than one week, freeze at -20°C or lower.
- Do not use heat-treated specimens.
- Repeatedly (more than 3 times) frozen and thawed samples may produce erroneous results.

Remarks and precautions

- Do not mix reagents with different lot numbers.
- Frozen reagents, eg. stored too close to cooling element, can cause erroneous results!
- **Make sure the correct sample volume and washing times are used for the test procedure needed.**
- Avoid microbial contamination of reagents.
- Ensure that the samples and controls are homogeneous before use.
- Do not touch the membrane of the strip. Manipulate the strips always with the plastic backing.
- Use a new pipette tip for each specimen.
- Make sure that the test strips are placed in the troughs with their **membrane side facing upwards.**
- All incubation steps should be performed using an orbital shaker or rocker (use rocker only for overnight incubation). The shaking of the solutions over the strips is important in achieving even line staining and maximum sensitivity. During shaking, the strip surface should be completely submerged.
- Cover the troughs with an adhesive sealer to avoid drying of the strips during the sample incubation.

- Unused and developed strips should be kept away from strong light and heat.
- This kit should only be used by personnel trained in clinical laboratory practices.
- Re-use of strips or troughs will result in erroneous results.
- Cutting strips will result in erroneous interpretation of the results.

Manual test procedure

Please read Remarks and precautions before performing the test.

- **16 hours sample incubation**
1. Use the required amount of test troughs, taking into account that for each test run, a Positive and Negative Control should be assayed. Identify test troughs as controls and specimens, and place them in the tray.
 2. Add **1 ml** of **Sample Diluent** to each test trough.
 3. Add **10 µl** of the appropriate **specimen** or **control** to their appropriately labelled troughs.
 4. Remove the required amount of test **strips** from their container, and add one strip to each of the test troughs. The test strip is placed membrane side upwards into the trough using tweezers. **THE STRIPS MUST BE COMPLETELY SUBMERGED.**
 5. **Cover** the troughs with an adhesive sealer (see Remarks and precautions). **Incubate** the samples by placing the tray on a shaker or rocker (see Directions for incubation) and agitate **OVERNIGHT** (16 ± 2 h) at room temperature ($18 - 25^{\circ}\text{C}$).
NOTE:
 - Carefully remove the adhesive sealers to avoid cross-contamination.
 6. **Wash** each test strip **3 times** (5 minutes) with 1 ml **Wash Solution** (see Directions for washing).
 7. Add **1 ml** of **Conjugate Solution** to each test trough.
 8. **Incubate** with the conjugate by placing the test tray on the shaker or rocker and agitate for 30 minutes at room temperature ($18 - 25^{\circ}\text{C}$).
 9. **Wash** each test strip **3 times** (5 minutes) with **1 ml Wash Solution** (see Directions for washing).
 10. Add **1 ml** of **Substrate Solution** to each test trough.
 11. **Incubate** with the substrate by placing the test tray on the shaker or rocker, and agitate for 30 minutes at room temperature ($18 - 25^{\circ}\text{C}$).
 12. Aspirate liquid. Add **1 ml** of **Stop Solution** to each test trough.
 13. **Incubate** with the stop solution by placing the test trough on the shaker or rocker, and agitate for 10 - 30 minutes at room temperature ($18 - 25^{\circ}\text{C}$).
 14. Aspirate the Stop Solution.
 15. **Remove** the strips from the test troughs and place them, membrane side upwards, on absorbent paper using tweezers. As soon as the strips have dried completely, results can be interpreted. To accelerate the drying

process, place strips in a dry incubator at 37°C for 30 minutes or use a hair dryer for 1 minute. Developed strips will retain their color if stored in the dark.

- **3 hours sample incubation**

For the "3 hours sample incubation" protocol the same 15 steps as for the test procedure "16 hours sample incubation" will be followed, but changes to steps 3 - 5 - 6 and 9 have to be taken into account. Sample volume for specimens and controls will increase from 10 - 20 µl (step 3) and sample incubation time changes to 3 hours (step 5). Washing after sample incubation changes for the 3 hours procedure to 3 times 6 minutes (step 6); finally the second washing is 3 times 3 minutes for the 3 hours sample incubation (step 9).

Summary test procedures with highlighted differences (bold), given in following table:

	16 hours sample incubation	3 hours sample incubation
Sample Diluent	1 ml	1 ml
Specimen	10 µl	20 µl
Controls	10 µl	20 µl
LIA® test strips	16 hours ± 2 hours	3 hours
Washing	1 ml/3 x 5 min	1 ml/3 x 6 min
RTU* Conjugate	1 ml/30 min	1 ml/30 min
Washing	1 ml/3 x 5 min	1 ml/3 x 3 min
RTU* Substrate	1 ml/30 min	1 ml/30 min
Stop solution	1 ml/10 - 30 min	1 ml/10 - 30 min

*RTU = Ready-to-use

Directions for washing

- After overnight and 3 hours incubation, carefully remove the adhesive plate sealer.
- The liquid is aspirated from the trough with a pipette, preferentially attached to a vacuum aspirator, which contains 5% sodium hypochlorite solution in the waste bottle.
The tray is held at an angle to allow all liquid to flow to one side of the trough (to the uncoated plastic backing part of each strip).
- Add 1 ml of diluted wash solution to each trough and agitate on a shaker or rocker. Shaking time is indicated in the assay procedure.
- Repeat these steps as many times as indicated in the assay procedure.

NOTE:

- Do not allow the strips to dry between the washing steps.
- Make sure not to damage the surface of the test strips when aspirating.
- Make sure the entire strip is thoroughly washed by complete submersion in the washing solution.

- Adapt the speed of the shaker or rocker when necessary.

Directions for incubation

- All the incubation steps (sample, conjugate, substrate, and stop solution incubation) and also the washing steps should be performed on a shaker or rocker (**use rocker only for overnight sample incubation**).
- During incubation and washing steps, the strip surface should be completely submerged, with the membrane side facing upwards.
- The shaker or rocker should allow a reciprocal (to- and- fro) motion of the strips in the trough, and a movement of the liquid over the strips without spilling over the trough.
- The speeds generated by a shaker or rocker is critical in achieving even line staining and maximum sensitivity.

Recommendations for an orbital shaker:

- diameter of the circular motion should be equal or superior to 13 mm
- recommended speed for a 13 mm circular motion is 160 rpm
- recommended speed for a 24 mm circular motion is 90 rpm.

Recommendations for a rocker:

- the difference between highest and lowest point should not exceed 80 mm to avoid spilling of liquid
- recommended speed is 34 rpm.

Automated test procedure: *Auto-LIA*™

The LIA® test procedure can easily be automated using the *Auto-LIA*™ automate. This instrument is a walk-away system with automated aspiration, pipetting, and incubation. For more information on the *Auto-LIA*™, please contact Innogenetics® or your local distributor.

Please read Remarks and precautions before performing the test.

Detailed *Auto-LIA*™ procedures

- **16 hours sample incubation *Auto-LIA*™**
 1. DISP CH1 Stpos: Begin Endpos: Till end 1000 µl
 2. INC 1 min, shake speed 4
 3. PAUSE
 4. INC 960 min, shake speed 4
 5. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
 6. INC 6 min, shake speed 4
 7. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
 8. INC 6 min, shake speed 4
 9. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
 10. INC 6 min, shake speed 4
 11. ASP
 12. DISP CH4 Stpos: Begin Endpos: Till end 1000 µl
 13. INC 30 min, shake speed 4
 14. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
 15. INC 3 min, shake speed 4
 16. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl

17. INC 3 min, shake speed 4
18. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
19. INC 3 min, shake speed 4
20. ASP
21. DISP CH6 Stpos: Begin Endpos: Till end 1000 µl
22. INC 30 min; shake speed 4
23. ASP
24. DISP CH5 Stpos: Begin Endpos: Till end 1000 µl
25. INC 20 min, shake speed 4
26. ASP
27. END

- **3 hours sample incubation Auto-LIA™**

1. DISP CH1 Stpos: Begin Endpos: Till end 1000 µl
2. INC 1 min, shake speed 4
3. PAUSE
4. INC 180 min, shake speed 4
5. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
6. INC 6 min, shake speed 4
7. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
8. INC 6 min, shake speed 4
9. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
10. INC 6 min, shake speed 4
11. ASP
12. DISP CH4 Stpos: Begin Endpos: Till end 1000 µl
13. INC 30 min, shake speed 4
14. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
15. INC 3 min, shake speed 4
16. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
17. INC 3 min, shake speed 4
18. WASH CH2 Stpos: Begin Endpos: Till end 1000 µl
19. INC 3 min, shake speed 4
20. ASP
21. DISP CH6 Stpos: Begin Endpos: Till end 1000 µl
22. INC 30 min; shake speed 4
23. ASP
24. DISP CH5 Stpos: Begin Endpos: Till end 1000 µl
25. INC 20 min, shake speed 4
26. ASP
27. END

CH1 = Sample Diluent

CH2 = Wash Solution

CH4 = Conjugate

CH5 = Stop Solution

CH6 = Substrate

Results

Reading

The identity and location of the antigens and controls coated on the strip are as follows:

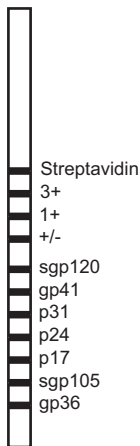


Figure 1: INNO-LIA™ HIV I/II Score test strip

The intensity of the reaction on the control lines on each strip is used to assign the reactivity ratings for each antigen on that strip:

Intensity of antigen line reaction (R)		Rating
Lower than ±	$R < \pm$	-
Equal to ±	$R = \pm$	±
Higher than ±, but lower or equal to 1+	$\pm < R \leq 1+$	1+
Higher than 1+ but lower than 3+	$1+ < R < 3+$	2+
Equal to 3+	$R = 3+$	3+
Higher than 3+	$R > 3+$	4+

A reactivity rating must be made separately for each strip. To facilitate the interpretation, a reading card is enclosed. The alignment of the developed strip with the 3+ control line on the reading card makes the identification of the lines easier.

Validation

Validation of the test run:

- The positive control strip must show a reaction of at least 1+ on sgp120, gp41, p31, p24 and gp36. The p17 and sgp105 antigen line may show a negative rating.
- The negative control strip must show a negative rating (no reaction at all or at least less than control level \pm) for all of the HIV antigen lines.

Validation of a single strip:

- The control levels \pm , 1+ and 3+ should be visible on all strips.
- The intensity of the control level 3+ should be greater than that of level 1+, and the intensity of the control level 1+ should be greater than that of level \pm .
- The streptavidin line should have a negative rating (the intensity is weaker than the \pm control line).

NOTE:

- The strip must be completely dried to avoid any misinterpretation due to faintly visible bands appearing after addition of stop solution.
- Do not place paper on top of the strips as long as they are wet.
- Weak control bands can be observed for samples containing high IgG levels (above the normal IgG range).

Interpretation of the results

Confirmation

Extensive evaluations have shown that results may be interpreted as follows:

A sample is **NEGATIVE** for HIV antibodies:

- if all lines are negative ($< \pm$)
- if one line has a rating of \pm , the other lines are negative.

A sample is **INDETERMINATE** for HIV antibodies:

- if two or more lines have a \pm rating
- if one line has a positive rating ($\geq 1+$), the other lines are negative or \pm
- if two or more lines have a positive rating ($\geq 1+$), but the conditions for HIV positivity, as described below are not fulfilled.

A sample is **POSITIVE** for HIV antibodies:

- if two lines have a rating $\geq 1+$:
 - Two envelope lines of the same HIV type (sgp120 + gp41 or sgp105 + gp36).
 - One envelope antigen (sgp120, gp41, sgp105 or gp36) and the p24 antigen line.
- if at least three lines have a rating of $\geq 1+$:
 - One of them must be an envelope antigen (sgp120, gp41, sgp105 or gp36).

When a result is interpreted as HIV positive (see the criteria described above), proceed to differentiation, see below.

Discrimination

Positive for HIV-1 antibodies:

- One HIV-1 antigen (sgp120 or gp41) is positive ($\geq 1+$): maximum reactivity of \pm is allowed on one HIV-2 line (sgp105 or gp36).
- Both HIV-1 (sgp120 and gp41) antigen lines are positive ($\geq 1+$): a maximum reactivity of 1+ is allowed on one HIV-2 line (sgp105 or gp36).

Positive for HIV-2 antibodies:

- One HIV-2 antigen (sgp105 or gp36) is positive ($\geq 1+$): maximum reactivity of \pm is allowed on one HIV-1 line (sgp120 or gp41).
- Both HIV-2 (sgp105 and gp36) antigen lines are positive ($\geq 1+$): a maximum reactivity of 1+ is allowed on one HIV-1 line (sgp120 or gp41).

Positive for HIV antibodies (untypable):

- Different combinations as the ones described above.

Summary of the interpretation criteria

A line is determined as being positive if a minimal rating of 1+ is observed.

ENV1 = envelope line for HIV-1: sgp120 and gp41

ENV2 = envelope line for HIV-2: sgp105 and gp36

No lines positive	No line \pm	NEG
	1 line \pm	NEG
	2 or more lines \pm	IND
1 line positive ($\geq 1+$)		IND
2 lines positive ($\geq 1+$)	No ENV positive	IND
	1 ENV1 and p24	HIV-1 (*)
	2 ENV1	HIV-1 (*)
	1 ENV2 and p24	HIV-2 (**)
	2 ENV2	HIV-2 (**)
	Other combinations	IND
3 or more lines positive ($\geq 1+$)	No ENV positive	IND
	1 or 2 ENV1	HIV-1 (*)
	1 or 2 ENV2	HIV-2 (**)
	1 ENV1 and 1 ENV2	HIV
	2 ENV1 and 1 ENV2 (***)	
	ENV2 = 1+	HIV-1
	ENV2 > 1+	HIV
	1 ENV1 and 2 ENV2 (***)	
	ENV1 = 1+	HIV-2
	ENV1 > 1+	HIV
2 ENV1 and 2 ENV 2	HIV	

- (*) If a rating of \pm is obtained on both ENV2 lines, the sample is not typable.
In this case, the sample is determined as HIV positive.
- (**) If a rating of \pm is obtained on both ENV1 antigen lines, the sample is not typable.
In this case, the sample is determined as HIV positive.
- (***) If the remaining envelope line is \pm , the sample is untypable.
In this case, the sample is determined as HIV positive.

Interpretation software: LiRAS™ for infectious diseases

The LiRAS™ for infectious diseases software is designed to assist with the interpretation of the LIA® results. Please contact your local distributor to obtain the latest updated version.

WARNING:

- Do not use the automated interpretation without taking into account the limitation of the procedure as mentioned below.

Limitations of the procedure

- The protocol provided must be strictly followed to obtain optimal performance of the assay.
- A sample giving a positive reaction on the streptavidin control line may give cross-reactions with other HIV antigens lines and can not be determined as positive for HIV antibodies.
- If an indeterminate result is obtained, it is recommended to test an additional patient sample after a few weeks.
- Analysis of a follow-up sample is required, if designation of HIV positivity is based on the positive score of only 2 HIV-antigen bands.
- A negative result does not preclude the possibility of exposure to HIV or infection with the virus.
- The use of diluted samples may give erroneous results.

Test performance

Sensitivity

Seroconversion panels/low-titer panels

A total of 12 BBI seroconversion panels (PRB 903, 904, 908, 910, 912, 916, 919, 922, 923, 924, 925, 927) and 3 BBI low-titer panels (PRB 103 till 105) were analyzed internally on INNO-LIA™ HIV I/II Score using the *Auto-LIA™* 3-hour sample incubation procedure and the manual 16-hour procedure. These results were compared with Western blot and INNO-LIA™ HIV Confirmation results.

The INNO-LIA™ HIV I/II Score using both sample incubation procedures detected HIV antibodies earlier than Western blot in 2 panels, and at the same time as Western blot in 9 panels. One panel did not become positive with any of these tests. The INNO-LIA™ HIV I/II Score using both sample

incubation procedures detected HIV antibodies at the same time as the INNO-LIA™ HIV Confirmation in all 11 panels which became positive.

Of the 44 samples within the 3 BBI low-titer panels, 36, 38, and 38 samples were positive on INNO-LIA™ HIV I/II Score using the 3-hour and the 16-hour sample incubation procedures, and on INNO-LIA™ HIV Confirmation, respectively. Thirty-five of these samples were found to be positive on Western blot.

HIV-positive samples

A total of 273 HIV-1-positive and 120 HIV-2-positive samples that were found positive on Vironostika HIV Uni-Form II Ag/Ab and on INNO-LIA™ HIV Confirmation, were analyzed internally using the *Auto-LIA*™ 3-hour sample incubation procedure.

Of the 273 HIV-1-positive samples, 262 were identified as positive for HIV-1 antibodies, and the other 11 samples were positive for HIV antibodies but untypable, resulting in 100% sensitivity (273/273).

Of the 120 HIV-2-positive samples, 97 samples were correctly identified as positive for HIV-2 antibodies, 21 samples were scored positive for HIV antibodies but untypable, and 2 samples were indeterminate. For this HIV-2 sample population, including the 2 indeterminate results, a sensitivity of 100% (120/120) was observed.

Specificity

Blood donors

A total of 300 blood-donor samples found negative for HIV antibodies were analyzed internally using the manual 16-hour sample incubation procedure. After initial testing, 290 samples were scored negative, 9 samples were indeterminate, and 1 sample scored positive for HIV-2 antibodies.

Upon repeated testing in duplicate, this initial positive blood sample scored positive for HIV-2 antibodies once, then indeterminate a second time, and was positive on INNO-LIA™ HIV Confirmation. This sample was found to be negative on Vironostika HIV Uni-Form II Ag/Ab and on Genelabs Diagnostics HIV Blot 2.2. Specificity calculated on this sample set was 96.7% (290/300).

Clinical samples

Two hundred six clinical samples were tested internally using the manual 16-hour sample incubation procedure. One hundred ninety-eight samples scored negative, 7 were indeterminate, and 1 scored positive. This latter sample was found to be positive upon repeated testing in duplicate and upon testing on the INNO-LIA™ HIV Confirmation, while a negative result was obtained on Vironostika HIV Uni-Form II Ag/Ab and on Genelabs Diagnostics HIV Blot 2.2. For this sample set, a specificity of 96.1% (198/206) was observed.

Potentially interfering samples

One hundred twenty-four potentially interfering samples were tested internally using the manual 16-hour sample incubation procedure. Of these, 117 were negative and 7 indeterminate. The specificity for this set of samples was 94.4% (117/124).

Reproducibility

A panel of 5 HIV-positive samples, as well as one positive and one negative control were tested on 2 different lots by 4 experimenters using the *Auto-LIA™* 3-hour sample incubation procedure. The use of different strip lots and performance by different experimenters resulted in the same test outcome, except for one sample for which an indeterminate result instead of an HIV-1-positive result was obtained in 1 of the 5 observations.

Français

But du test

Le test INNO-LIA™ HIV I/II Score est un test immunoenzymatique sur bandelette = Line Immuno Assay (LIA®) destiné à la détection des anticorps dirigés contre le virus de l'immunodéficience humaine de type 1 (incluant groupe O) et de type 2 dans le sérum ou le plasma humain. Ce test permet également de faire une différenciation entre les infections dues à HIV-1 ou HIV-2. Il est destiné à être utilisé à titre complémentaire, sur des échantillons de sérum ou de plasma humains qui se sont révélés positifs dans le cadre d'une procédure de dépistage des anticorps anti-HIV.

Principe du test

Des protéines recombinantes et des peptides synthétiques HIV-1 et HIV-2, ainsi qu'un peptide synthétique HIV-1 groupe O sont fixés sous forme de fines bandes sur une bandelette de nylon adhérent à un support plastique.

Cinq antigènes HIV-1 sont fixés: sgp120 et gp41 qui permettent la détection d'anticorps spécifiques anti-HIV-1, p31, p24 et p17 qui peuvent également donner une réaction croisée avec les anticorps anti-HIV-2. Le peptide HIV-1 groupe O est contenu dans la bande HIV-1 sgp120. Les antigènes gp36 et sgp105 sont utilisés pour la détection des anticorps anti-HIV-2.

Par ailleurs, 4 bandes de contrôle sont fixées sur chaque bandelette: anti-streptavidine, Contrôle Positif 3+ servant également de bande de contrôle d'addition de l'échantillon (anti-Ig humaines), Contrôle Positif 1+ (IgG humaines), et la bande limite ± (IgG humaines). Le test INNO-LIA™ HIV I/II Score est basé sur le principe des tests immunoenzymatiques (EIA). L'échantillon à tester est incubé dans un compartiment avec une bandelette sensibilisée avec l'ensemble des antigènes. Les anticorps anti-HIV éventuellement présents dans l'échantillon vont se lier aux différentes bandes d'antigènes HIV fixées