VIDAS® HIV DUO Ultra (HIV5)

IVD

VIDAS HIV DUO Ultra is an automated HIV infection screening test for use on the VIDAS family instruments, for the combined detection of anti-HIV-1 (groups M and O) and anti-HIV-2 total immunoglobulins and HIV-1 p24 antigen in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).

SUMMARY AND EXPLANATION

Human immunodeficiency viruses (HIV) are RNA retroviruses transmitted via sexual contact, parenteral and perinatal pathways or the placenta. HIV-1 and HIV-2 were respectively isolated in 1983 and 1985 in patients infected by AIDS (Acquired Immunodeficiency Syndrome). Since then numerous genetic variants have been characterized. These mutations seemed to be without consequence for serological diagnosis until HIV-1 variants of group O (Outlier) were isolated, since they have only 50% homology at the *env* gene level with those of group M (Major) (1, 2, 3, 4, 5).
During 2007, 2.5 million individuals were newly infected by HIV. According to estimates, 33.2 million [30.6 – 36.1 million] people were living with HIV in 2007 (6).

Current diagnosis of HIV infection relies on the detection of anti-HIV serum antibodies using an ELISA method. However, there is a mean period of 3 weeks between contamination and the appearance of the first antibodies (7). During this period p24 antigen is present in most people infected by HIV-1 (8). Thus simultaneous detection of p24 antigenemia, anti-HIV-1 and anti-HIV-2 antibodies enables the time lapse between contamination and diagnosis of the infection to be decreased (9, 10). VIDAS HIV DUO Ultra is an automated test based on the combined detection of HIV-1 p24 antigen and anti-HIV-1 and anti-HIV-2 total immunogloblins, enabling a reduction of the seroconversion window.

Note: The use of VIDAS HIV DUO Ultra does not rule out the obligation of using a second technique in countries where legislation requires the use of two different screening tests.

PRINCIPLE

The principle of the test combines 2 enzyme immunoassay reactions with two final fluorescent detections (ELFA).
The Solid Phase Receptacle (SPR®), serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and are pre-dispensed in the sealed reagent strips.
All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.

The upper part of the SPR is coated with monoclonal anti-p24 antibodies for the detection of p24 antigen. The lower part of the SPR enables the detection of anti-HIV-1 and anti-HIV-2 antibodies: it is coated with an HIV-1 gp160 protein, and HIV-1 group O and HIV-2 specific synthetic peptides.

During preliminary incubation, the sample, the biotinylated anti-p24 antibody (rabbit) in the strip are cycled in and out of the SPR. Lysis of the virus occurs during incubation and the released p24 antigen binds to the monoclonal anti-p24 antibody coated on the SPR and is recognized by the biotinylated anti-p24 antibody. At the same time, the anti-HIV-1 and/or anti-HIV-2 antibodies bind to the gp160 and/or the peptides in the lower part of the SPR.

Two washing steps remove unbound components.

A second incubation with the biotinylated antigen in the strip (the same used in the solid phase) is only performed in the lower part of the SPR. The biotinylated antigen binds to any anti-HIV antibody coated in the lower part of the SPR.
Any excess reagent is eliminated by washing.

A third incubation is performed with alkaline phosphatase-labeled streptavidin. During this step, the streptavidin binds to the biotinylated anti-p24 antibody, if it is present in the upper part of the SPR, and to the biotinylated antigen, if it is present in the lower part of the SPR.

Any excess reagent is eliminated by washing.
The substrate (4-Methyl-umbelliferyl phosphate) is firstly incubated in the lower part of the SPR and the fluorescence is measured at 450 nm. The intensity of the fluorescence is proportional to the presence of anti-HIV antibody in the sample.
The substrate is then incubated in the complete SPR and a second fluorescence measurement is performed. The instrument calculates the intensity of the fluorescence in the upper part of the SPR. This intensity is proportional to the concentration of HIV-1 p24 antigen in the sample.
At the end of the assay, results are automatically calculated by the instrument in relation to the standard, and then printed out.

CONTENT OF THE KIT (60 TESTS) – RECONSTITUTION OF REAGENTS:

60 HIV5 strips	STR	Ready-to-use.
60 HIV5 SPRs (2 x 30)	SPR	Ready-to-use. Interior of SPRs coated with gp160 (HIV-1) protein, HIV-1 group O and HIV-2 specific synthetic peptides, and monoclonal anti-p24 antibodies.
HIV5 positive antibody control (1 x 2.0 ml) (lyophilized)	C1	Reconstitute with 2 ml of distilled water. Leave for 5 to 10 minutes and then mix. After reconstitution, stable for 2 months at 2-8°C. Human serum* with anti-HIV-1 antibody + TRIS (0.1 mol/l, pH 7.4) + protein and chemical stabilizers + preservatives. MLE data indicate the confidence interval for the antibody result (Control C1 (+) Test Value Range).
HIV5 negative control (1 x 1.3 ml) (liquid)	C2	Ready-to-use. Human serum** + TRIS (0.1 mol/l, pH 7.4) + protein and chemical stabilizers + preservatives.
HIV5 positive antigen control (1 x 2.0 ml) (lyophilized)	C3	Reconstitute with 2 ml of distilled water. Leave for 5 to 10 minutes and then mix. After reconstitution, stable for 2 months at 2-8°C. Human serum** with inactivated HIV-1 viral lysate + TRIS (0.1 mol/l, pH 7.4) + protein and chemical stabilizers + preservatives. MLE data indicate the confidence interval for the antigen result (Control C3 (+) Test Value Range).
HIV5 antibody standard (1 x 2.0 ml) (lyophilized)	S1	Reconstitute with 2 ml of distilled water. Leave for 5 to 10 minutes and then mix. After reconstitution, stable for 2 months at 2-8°C. Human serum* with anti-HIV-1 antibody + TRIS (0.1 mol/l, pH 7.4) + protein and chemical stabilizers + preservatives. MLE data indicate the confidence interval in "Relative Fluorescence Value (RFV)" ("Standard (S1) RFV Range").
HIV5 p24 antigen standard 1 x 2.0 ml (lyophilized)	S2	Reconstitute with 2 ml of distilled water. Leave for 5 to 10 minutes and then mix. After reconstitution, stable for 2 months at 2-8°C. Human serum** + TRIS (0.1 mol/l, pH 7.4) + protein and chemical stabilizers + inactivated HIV-1 viral lysate + preservatives. MLE data indicate the confidence interval in "Relative Fluorescence Value (RFV)" ("Standard (S2) RFV Range").
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit, or • MLE bar code printed on the box label.		
Clip seal		
1 Package insert provided in the kit or downloadable from www.biomerieux.com/techlib		

* This product has been tested and shown to be negative for HBs surface antigen and antibodies to HCV. This product has been heat inactivated (30 minutes at 56°C). However, since no existing test method can totally guarantee their absence, this product must be treated as potentially infectious. Therefore, usual safety procedures should be observed when handling.

** This product has been tested and shown to be negative for HBs surface antigen, and antibodies to HIV1, HIV2 and HCV. However, since no existing test method can totally guarantee their absence, this product must be treated as potentially infectious. Therefore, usual safety procedures should be observed when handling.

The SPR

The interior of the SPR is coated during production with a gp160 protein and HIV-1 group O and HIV-2 specific synthetic peptides in the lower part, and monoclonal anti-p24 antibodies in the upper part. The antigens enable the capture of anti-HIV-1 and/or anti-HIV-2 antibodies, and the monoclonal antibodies enable the capture of HIV-1 p24 antigen.
Each SPR is identified by the HIV-5 code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening using the clip seal provided with the kit**.

The strip

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

Description of the VIDAS HIV DUO Ultra strip:

Wells	Reagents
1	Sample well.
2	HEPES buffer + biotin-labeled anti-p24 antibody (rabbit) + triton X100 + goat serum + protein and chemical stabilizers + 0.2 g/l gentamicin sulfate + 0.9 g/l sodium azide (300 µl).
3 - 5 - 6 - 8 - 9	Wash buffer: TRIS + protein and chemical stabilizers + 0.9 g/l sodium azide (600 µl).
4	HEPES buffer + gp160 protein and biotin-labeled synthetic peptides + skimmed milk + protein and chemical stabilizers + 0.2 g/l gentamicin sulfate + 0.9 g/l sodium azide (300 µl).
7	Tracer: alkaline phosphatase-labeled streptavidin + TRIS + skimmed milk + bovine albumin + triton X100 + protein and chemical stabilizers + 0.2 g/l gentamicin sulfate + 0.9 g/l sodium azide (400 µl).
10	Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/l) + diethanolamine (DEA*) (0.62 mol/l or 6.6 %, pH 9.2) + 1 g/l sodium azide (300 µl).

* Signal Word: **DANGER**

Hazard statement

H318 : Causes serious eye damage.

Precautionary statement

P280 :Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
For further information, refer to the Material Safety Data Sheet.

MATERIALS AND DISPOSABLES REQUIRED BUT NOT PROVIDED

- Pipette with disposable tip to dispense 2 ml and 200 µl.
- Powderless, disposable gloves.
- For other specific materials and disposables, please refer to the Instrument User's Manual.
- VIDAS family instrument.

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only.**
- **For professional use only.**
- **This kit contains products of human origin. No known analysis method can totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (see Laboratory biosafety manual - WHO - Geneva - Latest edition).**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
- Do not use the SPRs if the pouch is pierced.
- Do not use visibly deteriorated STRs (damaged foil or plastic).
- Do not use reagents after the expiration date indicated on the box label.
- Do not mix reagents (or disposables) from different lots.
- Use **powderless** gloves, as powder has been reported to cause false results for certain enzyme immunoassay tests.

- Kit reagents contain sodium azide which can react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- The substrate in well 10 contains an irritant agent (6.6% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped up thoroughly after treatment with liquid detergent or a solution of household bleach containing at least 0.5% sodium hypochlorite. See the User's Manual for cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
- The instrument should be regularly cleaned and decontaminated (see the User's Manual).

STORAGE CONDITIONS

- Store the VIDAS HIV DUO Ultra kit at 2-8°C.
- **Do not freeze reagents.**
- **Store all unused reagents at 2-8°C.**
- After opening the kit, check that the SPR pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- **To maintain stability of the remaining SPRs, carefully reseal the pouch after use with the desiccant inside using the clip seal provided, and return the complete kit to 2-8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label. Refer to the kit composition table for special storage conditions.

SPECIMENS

Specimen type and collection

Human serum or plasma (collected in lithium heparin or EDTA).

Do not use recalcified plasma.

It is recommended that each laboratory checks the compatibility of collection tubes used.

Do not inactivate specimens.

None of the following factors have been found to significantly influence this assay.

- hemolysis (after spiking samples with hemoglobin: 0 to 300 µmol/l (monomer)).
- lipemia (after spiking samples with lipids: 0 to 30 mg/ml equivalent in triglycerides)
- bilirubinemia (after spiking samples with bilirubin: 0 to 200 mg/l

However, it is recommended not to use samples that are clearly hemolyzed, lipemic or icteric and, if possible, to collect a new sample.

Specimen stability

Samples can be stored at 2-8 °C in stoppered tubes for up to 2 days. If longer storage is required, freeze the sera or plasma at -25 ± 6°C.

Avoid successive freezing and thawing.

A study performed on samples frozen for 2 months, showed that the quality of results is not affected.instructions for use

For complete instructions, see the User's Manual.

INSTRUCTIONS FOR USE

For complete instructions, see the User's Manual.

Reading Master lot data

Before each new lot of reagents is used, enter the specifications (or factory master data) into the instrument using the master lot entry (MLE) data.

If this operation is not performed **before initiating the tests**, the instrument will not be able to print results.

Note: the master lot data need only be entered once for each lot.

It is possible to enter MLE data **manually or automatically** depending on the instrument (refer to the User's Manual).

Calibration

Calibration, using the standards S1 and S2 provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.

The standards, identified by S1 and S2, must be tested in **duplicate** (see User's Manual). The standard value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

Procedure

1. **Only remove the required reagents from the refrigerator and allow them to come to room temperature for at least 30 minutes.**
2. Use one "HIV5" strip and one "HIV5" SPR for each sample, control or standard to be tested. **Make sure the storage pouch has been carefully resealed with the clip seal after the required SPRs have been removed.**
3. The test is identified by the "HIV5" code on the instrument.. The standards must be identified by "S1" and "S2", and tested in **duplicate**. If the positive controls are to be tested, they should be identified by "C1" and "C3". If the negative control needs to be tested, it should be identified by "C2".
4. If necessary, clarify samples by centrifugation.
5. Mix the standards, controls and samples using a vortex-type mixer (for serum or plasma separated from the pellet) in order to improve result reproducibility.
6. **For this test, the standard, control, and sample test portion is precisely 200 µl. The test portion is pipetted into the sample well, which is used as the reaction cuvette for this test**
7. Insert the "HIV5" SPRs and "HIV5" strips into the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.
8. Initiate the assay as directed in the User's Manual. All the assay steps are performed automatically by the instrument.
9. Restopper the vials and return them to 2–8°C after pipetting.
10. The assay will be completed within approximately 2 hours. After the assay is completed, remove the SPRs and strips from the instrument.
11. Dispose of the used SPRs and strips into an appropriate recipient.

RESULTS AND INTERPRETATION

Once the assay is completed, results are analyzed automatically by the computer. Fluorescence is measured twice in each Reagent Strip's reading cuvette for each sample tested.
The first reading is a background reading of the substrate cuvette before the SPR is introduced into the substrate.
The second reading is performed for the detection of anti-HIV antibodies after the substrate has been incubated with the enzyme in the lower part of the SPR.
The third reading is performed for the detection of HIV-1 p24 antigen after the substrate has been incubated with the enzyme covering the interior of the SPR.

The RFVs appear on the result sheet.

The test values are calculated for each of the antibody (AB on the result sheet) and antigen (AG on the result sheet) results, by the VIDAS system as follows:

Test value = patient RFV of the specific result/ specific standard RFV

The interpreted result for each sample (HIV5 on the result sheet) is calculated according to the antigen and antibody test value as follows:

Test value	Interpreted result
< 0.25 (for antigen **and** antibody detection)	Negative
≥ 0.25 (for antigen or antibody detection)	Positive

High RFVs obtained for antibody detection may mask the antigen result, and vice versa. The test value is not displayed for the masked result, and the message N.D. "**Not Determinable**" appears instead. In this case, interpretation is valid.

For some negative samples, the antibody test value may be associated with an antigen test value that is ND "**Not Determinable**" due to an antigen result that cannot be calculated by the VIDAS software but which is nonetheless below the threshold value. Refer to the negative test interpretation.
If the message "**Invalid**" is generated for the sample, the result is invalid. In this case, the sample should be retested.
Samples with a negative test value are considered to be negative, within the performance limitations of the reagent. In cases of suspected primary infection, values ≅ 0.25 must be interpreted with caution.
Samples with a positive test value should be retested in duplicate:

- Non repeatable positive samples (two negative reactions for three tests) are considered to be negative, within the performance limitations of the reagent.
- Repeatable positive samples (at least two positive reactions for three tests) should be confirmed using additional techniques.

If one of the two results is positive, this facilitates the choice of an additional technique:

- If the test value for antibody detection is ≥ 0.25, the additional technique can be Western Blot and/or a second screening test for detection of anti-HIV antibodies.

If these additional tests are negative, it is strongly recommended to test a second sample collected a few days later, particularly in the presence of clinical symptoms and/or risk factors.

- If the test value for antigen detection is ≥ 0.25, the additional technique should be based on p24 antigen detection and/or the determination of viral load.

Note: country-specific requirements for HIV diagnostics must be taken into account if necessary.

Interpretation of test results should be made taking into consideration the patient history, and the results of any other tests performed.

QUALITY CONTROL

A positive antibody control, a positive antigen control, and a negative control are included in each VIDAS HIV DUO Ultra kit. These controls must be performed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using these controls. The instrument will only be able to check the control values if they are identified by C1, C2 and C3.

Whatever the value of the antibody result for the C3 positive antigen control, only the Ag result validates this control.
Results cannot be validated if the control value deviates from the expected values.

Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

LIMITATIONS OF THE METHOD

VIDAS HIV DUO Ultra is an HIV infection screening test. **It should not be used as a specific test for the detection of HIV-1 p24 antigenemia**. **VIDAS HIV DUO Ultra must not be used as a supplementary test for VIDAS HIV DUO Quick.**

- This test has been validated for use with serum or plasma but not with other body fluids such as saliva, CSF or urine.
- Since the use of recalcified plasma may generate false positive results, this type of sample must not be used.
- In exceptional cases where the p24 antigen concentration is very high, the antigen result may be displayed as N.D (Not Determinable) and the signal for the antibody result may be over-evaluated. The final interpretation of the test is positive.

Do not use a mixture of samples.

Interference may be encountered with certain sera containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient history, and the results of any other tests performed.

PERFORMANCE

Studies performed using VIDAS HIV DUO ultra gave the following results

1. Specificity on a blood donor population:

5008 blood donor samples from 3 blood banks were tested.

	Final interpretation	
VIDAS HIV DUO Ultra	Positive	Negative
Positive	0	6
Negative	0	5002

Specificity of the VIDAS HIV DUO Ultra reagent on this population: 99.88%
(95% confidence interval: 99.73% - 99.95%.)

2. Specificity on hospitalized patients:

No false positive results were found for the 200 samples tested.

Specificity of the VIDAS HIV DUO Ultra reagent on this population: 100.00%.

(95% confidence interval: 98.04% - 100.00%)

3. Specificity on high-risk behavior patients:

No false positive results were found for the 100 samples tested.
Specificity of the VIDAS HIV DUO Ultra reagent on this population: 100.00%.

(95% confidence interval: 96.38% - 100.00%)

4. Diagnostic sensitivity:

A study was performed using 440 samples presumed to be HIV-1 positive and 122 HIV-2 positive. All of the samples were found to be positive.

Sensitivity of the VIDAS HIV DUO Ultra reagent on this population: 100.00% (95% confidence interval: 99.29% - 100.00%).

In order to check the sensitivity of VIDAS HIV DUO Ultra on non-B subtypes, 40 group M samples (4A, 14B, 3C, 3D, 3F, 3G, 3H, 3CRF01-AE and 4 CRF02-AG) and 10 group O samples were tested. All were found to be positive.
31 fresh samples with a positive status (collection < 24 hours) were tested and found to be positive with VIDAS HIV DUO Ultra. 31 fresh samples with a negative status (collection < 24 hours) were tested and found to be negative with VIDAS HIV DUO Ultra.
In order to check the sensitivity of VIDAS HIV DUO Ultra on p24 antigen, at least 50 culture supernatants including different HIV-1 and HIV-2 subtypes and at least 50 p24 antigen-positive samples were tested. All were found to be positive.

5. Sensitivity on seroconversion panels

During different studies, 45 seroconversion panels were tested, demonstrating the early detection capabilities of VIDAS HIV DUO Ultra.

The dilutions of the 3 HIV-1 samples and the 2 HIV-2 samples of the EFS 96 panel were found to be positive.
The sensitivity of VIDAS HIV DUO Ultra, determined on the Ag HIV SFTS panel (subtype B), was estimated at 11.5 pg/ml of HIV-1 antigen. The sensitivity of VIDAS HIV DUO Ultra, determined using the international standard NIBSC 90/636 was estimated at 0.5 IU/ml of HIV-1 antigen.

At least 40 early HIV seroconversion samples were tested. The results are conform with the state of the art.

6. Precision

Intra-assay and inter-assay reproducibility, determined at two different sites, were calculated according to the recommendations of NCCLS document EP5-T2, volume 12-4.

Site 1

Sample	n	Mean index	Intra-assay reproducibility %	Inter-assay reproducibility %
Low positive antigen	40	3.19	2.28	2.54
Low positive antibody	40	4.54	4.13	5.71

Site 2

Sample	n	Mean index	Intra-assay reproducibility %	Inter-assay reproducibility %
Low positive antigen	40	3.08	2.95	4.92
Low positive antibody	40	4.18	6.97	8.33

Global analysis

Sample	n	Mean index	Inter-assay reproducibility %
Low positive antigen	80	3.13	4.51
Low positive antibody	80	4.37	9.03

In this analysis, the reproducibility takes into account within-run variability, and between-run and between-site dispersion.

7. Cross-reactivity

134 HIV negative samples from patients whose physiological status may interfere with the VIDAS HIV DUO Ultra assay, were tested. The following results were obtained:

	Positive VIDAS HIV DUO Ultra results
anti-HAV + antibody	0/10
anti-HCV + antibody	0/10
anti-HBV + antibody	0/10
anti-Gag + antibody	1/13
anti-EBV + antibody	0/10
anti-HSV + antibody	0/10
anti-CMV + antibody	0/10
anti-nuclear + antibody	0/10
anti-*Toxoplasma gondii* + antibody	0/6
anti-*Treponema pallidum* + antibody	0/5
Vaccinated against influenza	0/10
Vaccinated against hepatitis B	0/10
Rheumatoid factor +	0/10
Children under 15 years of age	0/10

Spiking of HIV positive and HIV negative samples with increasing concentrations of biotin (0 to 2 mg/l) did not affect the VIDAS HIV DUO Ultra result.

WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their type and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

WARRANTY

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REVISION HISTORY

Change type categories :

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Note: *Minor typographical, grammar, and formatting changes are not included in the revision history.*

Release date	Part Number	Change Type	Change Summary
2015/01	09691H	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	CONTENT OF THE KIT (60 TESTS) – RECONSTITUTION OF REAGENTS WARNINGS AND PRECAUTIONS
2015/06	09691I	Technical	CONTENT OF THE KIT (60 TESTS) – RECONSTITUTION OF REAGENTS INSTRUCTIONS FOR USE

BIOMÉRIEUX
bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Etoile - France
673 620 399 RCS LYON
Tél. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com

CE 0459