VIDAS® Prolactin (PRL)

IVD

The VIDAS® Prolactin (PRL) Assay is intended for use on the instruments of the VIDAS family (VITEK® ImmunoDiagnostic Assay System) as an automated enzyme-linked fluorescent immunoassay (ELFA) for the quantitative determination of prolactin concentration in human serum or plasma (heparin). It is intended for use as an aid in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.

SUMMARY AND EXPLANATION OF THE TEST

Prolactin is a polypeptide hormone with a molecular weight of approximately 23, 000 daltons, consisting of 198 amino acids(1,4). Synthesized by the anterior pituitary, prolactin is secreted in a pulsating manner (every 20 minutes) and follows a circadian rhythm with highest levels reached during sleep(2,3).

Many factors control the secretion of prolactin. Physiologically, prolactin levels are controlled by the hypothalamus. Dopamine and GABA are the main inhibitory factors; and thyrotropin releasing hormone (TRH), serotonin, and vasoactive intestinal peptide (VIP) stimulate prolactin secretion(4). Exogenous factors such as stress, diet, hypoglycemia, and in particular breast feeding can cause an increase in prolactin levels(2).

The major physiological role of prolactin in women is in the initiation and maintenance of lactation(5). Prolactin is also involved in follicular maturation and development of the ovum. In males, prolactin affects gonadal function.

Hyperprolactinemia has been recognized as a cause of infertility problems in men and women(4). Three etiological forms of hyperprolactinemia are iatrogenic hyperprolactinemia associated with the use of certain medications (e.g. anti-depressants, tranquilizers, etc.), primary hyperprolactinemia associated with pituitary tumors, and secondary hyperprolactinemia associated with other conditions (e.g. hyperthyroidism, renal insufficiency, etc.)(6).

PRINCIPLE OF THE PROCEDURE

The VIDAS® Prolactin (PRL) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR®), serves as a solid phase for the assay as well as a pipetting device. The SPR is coated at the time of manufacture with mouse monoclonal anti-prolactin antibodies. The VIDAS Prolactin (PRL) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are located in the sealed Reagent Strips. The sample is transferred into the well containing anti-prolactin antibodies conjugated with alkaline phosphatase. The sample/conjugate mixture is cycled in and out of the SPR and the prolactin will bind to antibodies coated on the SPR and to the conjugate forming a "sandwich". Wash steps remove unbound conjugate.

A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument ; it is proportional to the prolactin concentration present in the sample.

When the VIDAS Prolactin (PRL) Assay is completed, the results are analyzed automatically by the instrument, and a report is printed for each sample.

KIT COMPOSITION (60 tests) :

60 PRL Reagent Strips	STR	Ready-to-use.
60 PRL SPRs (2 x 30)	SPR®	Ready-to-use. SPRs coated with mouse monoclonal anti-prolactin antibodies.
PRL Control (lyophilized) (1 x 3 ml)	C1	Reconstitute with 3 ml distilled water. Wait 5 to 10 minutes. Mix. Stable after reconstitution for 24 hours at 2-8°C or until expiration date on kit at -25 ± 6°C. Five freeze/thaw cycles are possible. Human serum* with prolactin and 0.02 % Bronidox. MLE data indicate the confidence interval in ng/mL (“Control C1 Dose Value Range”).
PRL Calibrator (lyophilized) (3 x 2 ml)	S1	Reconstitute with 2 ml distilled water. Wait 5 to 10 minutes. Mix. Stable after reconstitution for 24 hours at 2-8°C or until expiration date on kit at -25 ± 6°C. Five freeze/thaw cycles are possible. Human serum* with prolactin and 0.02 % Bronidox. MLE data indicate the concentration in ng/mL (“Calibrator (S1) Dose Value”) and the confidence interval in "Relative Fluorescence Value” (“Calibrator (S1) RFV Range”).
PRL Diluent (liquid) (1 x 3 ml)	R1	Ready-to-use. Human free Prolactin serum* with 1 g/L sodium azide.
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit, or • MLE bar codes printed on the box label.		
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 antigen, 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 monoclonal anti-prolactin immunoglobulins (mouse). Each SPR is identified by the "PRL" code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening**.

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 Prolactin (PRL) Reagent Strip :

Wells	Reagents	
1	Sample well	
2-3-4-5	Empty wells	
6	Conjugate	Mouse monoclonal anti-prolactin antibodies conjugated to alkaline phosphatase with 1 g/L sodium azide (400 µl).
7-8	Wash buffer	Sodium phosphate (0.01 mol/l , pH 7.4) with 1 g/L sodium azide (600 µl)
9	Wash buffer	DEA* (1.1 mol/l or 11.5%, pH 9.8) with 0.01 g/L sodium azide (600 µl)
10	Reading Cuvette with substrate	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.
H373 : May cause damage to organs through prolonged or repeated exposure.
H315 : Causes skin irritation.
H302 : Harmful if swallowed.

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.
P309 + P311 : IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

** 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 Safety Data Sheet.

MATERIALS REQUIRED BUT NOT PROVIDED

- Pipettes with disposable tips which will dispense 2 ml, 3 ml and 200 µl.
- Powderless disposable gloves.
- For other specific materials, please refer to the Instrument Operator's Manual.
- Instrument of the VIDAS family.

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).
- Consider all patient specimens potentially infectious and observe routine biosafety precautions. Dispose of all used components and other contaminated materials by acceptable procedures for potentially biohazardous human blood products.
- Do not mix reagents or disposables from different lots.
- Kit reagents contain 1 g/L sodium azide which could 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.
- **Powderless** gloves are recommended as powder has been reported as a cause of false results in some enzyme immunoassays (7).
- The wash buffer (well 9) contains a harmful agent (11.5% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- The substrate (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 and a solution of household bleach containing at least 0.5 % sodium hypochlorite to inactivate infectious agents. See the Operator's Manual for cleaning spills on or in the instrument. Do not place solutions containing bleach in the autoclave.
- The instrument should be routinely cleaned and decontaminated. See the Operator's Manual for the appropriate procedures.

STORAGE AND HANDLING

- Store the VIDAS® Prolactin (PRL) kit at 2-8°C.
- **Do not freeze reagents.**
- Return unused components to 2-8°C.
- After opening the kit, check that the SPR® pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPRs and return the complete kit to 2-8°C.**
- All components are stable, when stored appropriately, until the expiration date printed on the label. Do not use components beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Acceptable specimens include serum or plasma (with heparin anticoagulant). Do not use serum collected with EDTA. The use of heat-inactivated sera has not been established for this test - do not heat sera. 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 for up to two months. Avoid repeated cycles of freezing and thawing. If necessary, clarify samples by centrifugation.

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 calibrator 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 calibrator, identified by S1, must be tested in **duplicate** (see the Operator Manual). The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

Assay Procedure

1. Remove necessary components from the kit and return all unused components to storage at 2-8°C.
2. Use one "PRL" strip and one "PRL" SPR for each sample, control or calibrator to be tested. **Make sure the storage pouch has been carefully resealed after the required SPRs have been removed**.
3. The test is identified by the "PRL" code on the instrument. The calibrator must be identified by "S1", and tested in **duplicate**. If the control is to be tested, it should be identified by "C1".
4. If needed, label the "PRL" Reagent Strips with the appropriate sample identification numbers.
5. Mix the calibrator, control and samples using a vortex-type mixer (for serum or plasma separated from the pellet).
6. **For this test, the calibrator, control, and sample test portion is 200 µl.**
7. Insert the "PRL" Reagent Strips and SPRs into appropriate position on 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 processing as directed in the Operator's Manual. All the assay steps are performed automatically by the instrument.
9. Reclose the vials and return them to the required temperature after pipetting.

10. The assay will be completed in approximately 40 minutes. 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

Two instrument readings for fluorescence in the Reagent Strip's reading cuvette are taken for each specimen tested. The first reading is a background reading of the cuvette and substrate before the SPR® is introduced into the substrate. The second reading is taken after the substrate has been exposed to the enzyme conjugate remaining on the interior of the SPR.
The background reading is subtracted from the final reading to give a Relative Fluorescence Value (RFV) for the test result.
The prolactin concentrations are expressed in ng/ml of the 3rd IS 84/500 (1ng = 21μIU). Results can be expressed in ng/ml of the 1st IRP 75/504 (1ng = 32 μIU) (see Operator's Manual).
The range of results for the VIDAS Prolactin (PRL) assay is 0.5 - 200 ng/ml. Samples with results less than 0.5ng/ml are reported as " < 0.5ng/ml".
Samples with results greater than 200 ng/ml must be diluted 1/10 (1 volume of sample and 9 volumes of PRL diluent (R1).) If the dilution factor has not been entered when the analysis has been requested (see Operator's Manual), multiply the result by the dilution factor to obtain the prolactin sample concentration.

A report is printed which records :

- the type of test performed,
- the sample identification,
- the date and time,
- the lot number and the expiration date of the reagent kit being used,
- each sample's RFV and Prolactin (PRL) concentration.

QUALITY CONTROL

A positive control is included in each VIDAS Prolactin (PRL) kit. This control 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 this control. The instrument will only be able to check the control value if it is identified by C1.
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.

PERFORMANCE DATA

Immunological Specificity

The cross-reactivity percentage is the ratio between the compound concentration to be tested and the Prolactin (PRL) concentration to be tested for a signal of 50 RFV. No cross-reactivity in the VIDAS® Prolactin (PRL) Assay was observed with the substances tested

Tested compound	Cross-reactivity percentage
hCG (SCRIPPS ref. C0714, Lot 296264)	< 0.01
LH (SCRIPPS ref. L0815, Lot 399711)	< 0.01
FSH (SCRIPPS ref. F0615, Lot 312788)	< 0.01
TSH (SCRIPPS ref. T0115, Lot 148911)	< 0.01
hPL (SCRIPPS ref. L0114, Lot 683995)	< 0.01
hGH (SCRIPPS ref. G1615, Lot 4933xx)	< 0.01

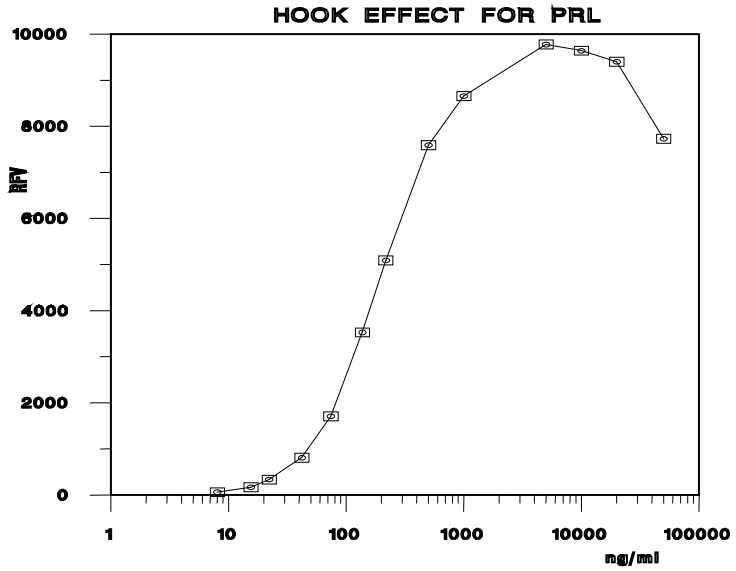
Immunological interference was tested by adding 1000 ng/ml of LH, FSH, or TSH; 10,000 ug/ml of hCG; or 100,000 ug/ml of hPL to two samples containing 58 ng/ml and 142 ng/ml of prolactin respectively. No interference was seen with any of the compounds tested.

Detection Limit

The detection limit (assay sensitivity) is defined as the lowest concentration that can be distinguished from zero with 95 % probability. The detection limit for the VIDAS® Prolactin (PRL) Assay is 0.5 ng/ml.

Hook Effect

The Hook effect was evaluated using prolactin solutions whose respective concentrations were from 0 to 50,000 ng/ml. No hook effect was seen up to 5,000 ng/ml.



<---------->
Calibration Range

Precision

Intra-assay reproducibility :

Five samples were tested for intra-assay precision. Thirty replicates of each sample were tested in the same run.

Sample	1	2	3	4	5
Mean concentration (ng/ml)	8.65	21.10	109.41	158.05	237.89
% CV	4.2	3.7	3.4	4.0	4.3

Inter-assay reproducibility on the same instrument:

Five samples were tested in 26 runs on the same instrument over an 8-week period (recalibration was performed every 14 days as described in the Operator's Manual).

Sample	1	2	3	4	5
Mean concentration (ng/ml)	8.86	21.02	107.11	158.60	236.44
% CV	5.6	5.1	4.7	4.8	3.5

Inter-instrument and inter-assay reproducibility

Five samples were tested in singlet in 9 runs on different instruments.

Sample	1	2	3	4	5
Mean concentration (ng/ml)	8.96	20.98	107.71	156.73	234.62
% CV	4.3	2.7	3.9	4.0	4.3

Accuracy

Parallelism (Dilution tests):

Three samples were diluted in Prolactin (PRL) diluent and tested in singlet in 3 runs.

Sample	Dilution factor	Expected mean concentration (ng/ml)	Measured mean concentration (ng/ml)	Mean recovery percentage
1	1/1	68.89	68.89	100.0
	1/2	34.44	38.53	111.9
	1/4	17.22	18.28	106.1
	1/8	8.61	8.71	101.1
2	1/1	113.95	113.95	100.0
	1/2	56.97	62.01	108.8
	1/4	28.49	30.10	105.7
	1/8	14.24	14.29	100.3
3	1/1	141.43	141.43	100.0
	1/2	70.71	80.75	114.2
	1/4	35.36	36.13	102.2
	1/8	17.68	17.15	97.0

Recovery tests

Three samples were spiked with known quantities of prolactin (3rd IS 84/500) and tested in singlet in three instrument runs. The measured mean concentration compared to the expected mean concentration is shown below.

Sample	Amount spiked (ng/ml)	Expected mean concentration (ng/ml)	Measured mean concentration (ng/ml)	Mean recovery percentage
1	0	12.5	12.5	100.0
	2.5	15.00	14.99	99.9
	5.0	17.50	18.60	106.3
	12.5	25.00	25.16	100.6
	37.5	50.00	52.30	104.6
	75.0	87.50	91.99	105.1
2	0	33.7	33.7	100.0
	2.5	36.21	37.79	104.4
	5.0	38.71	39.17	101.2
	12.5	46.21	46.78	101.2
	37.5	71.21	76.67	107.7
	75.0	108.71	119.11	109.6
3	0	78.2	78.2	100.0
	2.5	80.70	77.40	95.9
	5.0	83.20	80.99	97.3
	12.5	90.70	89.07	98.2
	37.5	115.70	120.27	104.0
	75.0	153.20	154.77	101.0

INFLUENCE OF SPECIMEN COLLECTION

Blood samples were collected from fourteen patients. For each patient, 3 specimens were collected at the same time: in a dry glass tube; in a tube with separating gel; and in a heparinized tube. Each sample collected was tested in duplicate and sera from the same donor were tested in the same run. The dry glass tube was the reference to which the other tubes were compared.

Collection tube	Equation of the line	Correlation coefficient
Tube with separating gel	0.98x + 0.11	0.99
Tube with heparin (lithium)	0.96 x + 0.19	0.99

INTERFERENCE STUDIES

Heparin

Two pools of human sera were spiked with increasing quantities of heparin.

		Amount of heparin spiked (U/ml)			
		0	0.5	5	50
PRL	Pool 1	6.8	7.1	7.1	7.1
(ng/ml)	Pool 2	93.0	89.0	93.0	92.0

EDTA

Two pools of human sera were spiked with increasing quantities of EDTA.

		Amount of EDTA spiked (mg/ml)			
		0	1	5	10
PRL	Pool 1	6.8	6.9	3.1	0.6
(ng/ml)	Pool 2	93.0	92.0	41.0	20.0

A decrease in values is seen with EDTA. Do not use EDTA plasma in the VIDAS® Prolactin (PRL) assay.

Hemoglobin

Two pools of human sera were spiked with increasing quantities of hemoglobin obtained from a lysate of human red blood cells.

		Amount of hemoglobin spiked (µmol/l)						
		0	15	30	60	150	210	300
PRL	Pool 1	18.7	19.4	19.3	19.8	20.4	20.0	19.1
(ng/ml)	Pool 2	145	145	145	146	158	153	148

Turbidity

Two pools of human sera were spiked with increasing quantities of a lipid solution.

		Amount of triglycerides spiked (g/l)				
		0	0.25	0.5	1.0	2.0
PRL	Pool 1	19.2	18.8	18.3	19.0	18.8
(ng/ml)	Pool 2	146	141	145	137	137
Appearance		Clear	Opalescent		Turbid	

Bilirubin

Two pools of human sera were spiked with increasing quantities of bilirubin.

		Amount of bilirubin spiked (µmol/l)						
		0	29.4	52.4	100.0	238	378	450
PRL	Pool 1	18.4	18.9	18.8	18.8	20.8	21.5	22.2
(ng/ml)	Pool 2	139	145	141	145	152	161	170

Although interference linked to the presence of hemoglobin, bilirubin or to turbidity has not been observed, using hemolyzed, icteric or lipemic samples is not recommended. If possible, collect a new specimen.

RANGE OF EXPECTED VALUES (3RD IS 84/500)

Group	≤ 5 ng/ml	5-35 ng/ml	≥ 35 ng/ml
Normal menstruating women (N = 118)	2.6 %	93.4 %	4.0 %
Menopausal women (N = 123)	3.3 %	93.5 %	3.2 %
Group	≤ 3 ng/ml	3-25 ng/ml	≥ 25 ng/ml
Men (N = 120)	2.5 %	93.2 %	4.3 %

These figures are given as a guide; it is recommended that each laboratory establish its own reference values from a rigorously selected population.

CORRELATION

Four hundred and ninety five samples in the range of 0.5 - 200 ng/ml were tested using the VIDAS® Prolactin (PRL) Assay and a commercially available EIA. A summary of the results is shown below.

# of Samples	Slope	Intercept	Correlation coefficient
495	1.06	0.871	0.98

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 nature 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

1. Allolio, B., Hoeppener, U. Leonhartd, Deub, U., Winkelmann, W., 1987. Size heterogenity of immunoreactive prolactin in patients with prolactinoma". Acta Endocrinologica (Copenh). 114: 475-482.
2. L'Hermite, M., 1976. Hormone Assays and their Clinical Application. Edited by Loraine J.A. and Bell, E.T., Prolactin 4th Edition, Churchill Livingstone, Endinburg, 293-332.
3. Suh, Han K. and Frantz, Andrew G., 1974. Size heterogeneity of human prolactin in plasma and pituitary extracts. Department of Medicine, Columbia University College of Physicians and Surgeons, and Presbyterian Hospital, New York, 928-935.
4. Djiane, J. and Kelly, P.A., 1984. Medecine de la reproduction masculine. Edited by Schaison, G., Bouchard, P.,Mahoudeaux, J. and Labrie, F., Flammarion Medecine-Sciences, Presses de L'Universite de Montreal, 141-146.
5. Bjoro, T., Johansen, E., Frey, H.H., Turter, A., Torjensen, P.A., 1993. Different responses in little and bigbig prolactin to metoclopramide in subjects with hyperproactinemia due to 150-170 kD (bigbig) prolactin". Acta Endocrinologica, 128: 308-312.
6. Franks, S., 1983. Hormones in Blood. Edited by Gray, C.H., and James, V.H.T., Prolactin 3rd Edition, Academic Press, 109-136.
7. Lampe, A.S., H.J. Peiterse-Bruins, and J.C.R. Egtervan Wisserderke. 1988. Wearing gloves as cause of false negative HIV tests. Lancet ii 1140-1144.

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

bioMérieux, Inc. disclaims all warranties, express or implied, including any implied warranties of MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE. bioMérieux shall not be liable for any incidental or consequential damages. IN NO EVENT SHALL BIOMERIEUX'S LIABILITY TO CUSTOMER UNDER ANY CLAIM EXCEED A REFUND OF THE AMOUNT PAID TO BIOMERIEUX FOR THE PRODUCT OR SERVICE WHICH IS THE SUBJECT OF THE CLAIM.

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

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

Release date	Part Number	Change Type	Change Summary
2015/01	13705C	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	KIT COMPOSITION (60 tests) WARNINGS AND PRECAUTIONS
2015/06	13705D	Technical	KIT COMPOSITION (60 tests) INSTRUCTIONS FOR USE

BIOMÉRIEUX

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

Distributed by
bioMérieux, Inc.
100 Rodolphe Street
Durham, North Carolina 27712 - USA
www.biomerieux.com