VIDAS® *H. pylori* IgG (HPY)

℞ only IVD

VIDAS® *H. pylori* IgG (HPY) is an automated qualitative test for use on the instruments of the VIDAS® family, for the detection of anti-*Helicobacter pylori* IgG antibodies in human serum or plasma (EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® HPY assay is intended as an aid in diagnosis of *H. pylori* infection in an adult symptomatic population.

SUMMARY AND EXPLANATION

It has been shown that infection with *Helicobacter* (formerly *Campylobacter*) *pylori*, a spiral shaped microaerophilic bacillus, leads to inflammation of the stomach mucosa (gastritis) and in some infected persons, ulcers. The infection may also play a role in the development of stomach cancer (1, 2, 3). Symptomatic patients with *H. pylori* are considered infected, while asymptomatic people with *H. pylori* are considered colonized. Most people who are colonized with *H. pylori* never develop ulceration and remain asymptomatic despite colonization for years, probably even decades (4, 5).

There are invasive and non-invasive methods for determining presence of *H. pylori*. Biopsy by endoscopy has traditionally been used to obtain gastric or duodenal tissue specimens for subsequent stain, culture, and/or direct urease detection.

With biopsy, false negative results can occur in infected individuals due to non-uniform distribution of *H. pylori* in the sample or by obtaining tissue with non-viable or non-urease producing *H. pylori* (6). Also, invasive methods such as endoscopy involve patient discomfort, risk, and are costly to perform.

Non-invasive methods include urea breath tests and serological methods. Urea breath tests detect *H. pylori* presence via its highly active urease. Urea labeled with carbon-14 or carbon-13 is ingested by the patient, and presence of exhaled carbon dioxide is determined via scintillation or mass spectrometry. Patient exposure to radioisotopes and expensive equipment are drawbacks to urea breath testing (6, 7, 8).

Patients infected with *H. pylori* develop serum antibodies, which are correlated with the presence of histologically confirmed *H. pylori* infection.

Serological methods (such as enzyme immunoassays) are non-invasive, inexpensive, quick, easy to perform, and compared to invasive methods, the major advantage is that serological methods do not rely on the accuracy of the sampling (7, 9).

PRINCIPLE

The assay principle combines a 2-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA). All of the assay steps as well as the assay temperature are controlled automatically by the instrument. 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 pre-dispensed in the sealed reagent strips.

After preliminary wash and sample dilution steps, the sample is cycled in and out of the SPR® for a specified length of time. IgG antibodies to *H. pylori* present in the specimen will bind to the *H. pylori* antigen coating the interior of the SPR®. Unbound sample components are washed away.

Anti-human IgG antibodies conjugated with alkaline phosphatase are cycled in and out of the SPR® and will attach to any human IgG bound to the SPR® wall. A final wash step removes unbound anti-human antibody conjugate.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR®. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm. The intensity of fluorescence is measured by the optical scanner in the instrument. At the end of the assay, results are automatically calculated by the instrument, a test value is generated and a report is printed for each sample.

CONTENT OF THE KIT (30 TESTS):

30 HPY strips	STR	Ready-to-use.
30 HPY SPR®s (1 x 30)	SPR®	Ready-to-use. Interior of SPR®s coated with purified *H. pylori* antigen.
HPY Standard 1 x 2 mL (liquid)	S1	Ready-to-use. Human* serum containing anti-*H. pylori* antibodies + 1 g/L sodium azide. MLE data indicate the confidence interval in "Relative Fluorescence Value (RFV)" ("Standard (S1) RFV Range").
HPY Positive control 1 x 1.5 mL (liquid)	C1	Ready-to-use. Human* serum containing anti-*H. pylori* antibodies + 1 g/L sodium azide. MLE data indicate the Test Value (TV) range: Control C1 Test Value Range.
Negative control 1 x 1.9 mL (liquid)	C2	Ready-to-use. Phosphate buffer + protein stabilizer of animal origin + preservatives. MLE data indicate the Test Value (TV) range: Control C2 Test Value 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.		
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, 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 purified *H. pylori* antigens. Each SPR® is identified by the "HPY" code. Only remove the required number of SPR®s 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 strip

Wells	Reagents
1	Sample Well.
2	Sample Diluent: TRIS buffered saline (0.05 mol/L, pH 7.4) + protein stabilizers + 1 g/L sodium azide (600 µL).
3	Pre-wash buffer: TRIS buffered saline (0.05 mol/L, pH 7.4) + protein stabilizers + 1 g/L sodium azide (400 µL).
4 - 5 - 7	Wash buffer: TRIS buffered saline (0.05 mol/L) + detergent + 1g/L sodium azide (600 µL).
6	Conjugate: a titered mixture of alkaline phosphatase-labeled mouse monoclonal anti-human IgG + 1 g/L sodium azide (400 µL).
8	Wash buffer: DEA buffer (360 mmol/L) + 1g/L sodium azide (600 µL).
9	Sample diluent: TRIS buffer (0.05 mol/L, pH 7.4) + protein stabilizers + 1 g/L sodium azide (300 µL).
10	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 REQUIRED BUT NOT PROVIDED

- Pipette with disposable tip to dispense 100 µL.
- Powderless, disposable gloves.
- For other specific materials, refer to the Instrument Operator's Manual.
- Instrument of the VIDAS® family: VIDAS®, miniVIDAS® or VIDAS® 3.

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only.**
- **Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- **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, do not 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 (10-12).
- Do not use the SPR®s 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 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 Operator'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 Operator's Manual).

STORAGE CONDITIONS

- Store the VIDAS® HPY 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 SPR®s.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPR®s 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.

SPECIMENS

Specimen type and collection:

VIDAS® HPY test should be performed on sera or plasma (EDTA), that should not be hemolyzed or contaminated.
Do not heat the serum. Clarify samples containing particulate matter by centrifugation or filtration prior to testing.

Although data indicated no interference to hemoglobin (500 mg/dL), lipids (2.0 mg/mL), or bilirubin (30 mg/dL), use of hemolyzed, icteric, or lipemic specimens is not recommended. If possible, collect a new specimen.

Specimen stability

If a specimen is not tested on the day of collection, it can be stored at 2-8°C in stoppered tubes for up to 5 days; if longer storage is required, freeze the sera or plasma at -25 ± 6°C for up to 2 months. Do not exceed two freezing and thawing cycles. Do not test specimens with obvious microbial contamination.

INSTRUCTIONS FOR USE

For complete instructions, see the Operator'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 Operator's Manual).

Calibration

Calibration, using the standard 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 data and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.
The standard, identified by "S1", must be tested in **duplicate** (see Operator'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 "HPY" strip and one "HPY" SPR® for each sample, control or standard to be tested. **Make sure the storage pouch has been carefully resealed after the required SPR®s have been removed.**
3. The test is identified by the "HPY" code on the instrument. The standard must be identified by "S1", and tested in **duplicate**. If the positive control is to be tested, it should be identified by "C1". If the negative control needs to be tested, it should be identified by "C2".
4. Mix the standard, controls and samples using a vortex-type mixer (for serum or plasma separated from the pellet).
5. **For this test, the standard, control, and sample test portion is 100 µL.**
   NOTE: When manual pipetting is performed, check the sample wells for bubbles. If necessary, gently tap the strips to remove any bubbles present.
6. Insert the "HPY" SPR®s and "HPY" strips into the instrument. Check to make sure the color labels with the assay code on the SPR®s and the Reagent Strips match.
7. Initiate the assay as directed in the Operator's Manual. All the assay steps are performed automatically by the instrument.
8. Reclose the vials and return them to 2-8°C after pipetting.
9. The assay will be completed within approximately 35 minutes. After the assay is completed, remove the SPR®s and strips from the instrument.
10. Dispose of the used SPR®s and strips into an appropriate receptacle.

RESULTS AND INTERPRETATION

Once the assay is completed, results are analyzed automatically by the computer. Fluorescence is measured twice in the 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 taken after incubating the substrate with the enzyme remaining on the interior of the SPR®. The RFV (Relative Fluorescence Value) is calculated by subtracting the background reading from the final result. This calculation appears on the result sheet.

The Test Value is obtained by dividing the patient RFV by the standard RFV.

TV= Test Value = patient RFV / standard RFV

The Test Value is then compared to a threshold stored by the instrument and a final result is interpreted.
Interpretation of test results based on Test Value is as follows:
Results with test values less than the lower threshold indicate that the patient does not have detectable anti-*H. pylori* antibodies.

Thresholds and Interpretation of Results

Test Value Threshold	Interpretation
TV < 0.75	Negative
0.75 ≤ TV < 1.00	Equivocal
TV ≥ 1.00	Positive

A report is printed which records:
- the type of test performed,
- the sample identification,
- the date and time,
- the lot number and expiration date of the reagent kit being used,
- each sample's RFV, test value and interpreted result.

The imprecision inherent in any method implies a lack of confidence in samples with test values very close to the thresholds. Consequently, an equivocal zone is established between the thresholds based on a statistical understanding of this imprecision.
Samples with test values that are greater than or equal to the high threshold are reported as positive.
Samples with test values between 0.75 and 1.00 should be repeated with the original specimen, if available. If the original specimen is not available, obtain a fresh specimen and repeat the assay.
If the sample repeats as an equivocal, clinical information and other available laboratory tests should be considered.
Invalid results are reported when the background reading is above a predetermined cutoff (indicating low-level substrate contamination). In this case, repeat the assay with the original specimen.
An invalid result is also seen if there is no standard available for the lot number of the patient test strip. In this case, run a standard in duplicate in HPY strips with the same lot number as the invalid patient test. The patient test result can then be recalculated using the new stored standard.
(Refer to the Operator's Manual for a detailed explanation).

QUALITY CONTROL

One positive control and one negative control are included in each VIDAS® HPY 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 and C2. The positive and negative controls must be tested following Good Laboratory Practices.
Results cannot be validated if the control value deviates from the expected values.

The expected value range for the kit standard is entered into the system using the master lot entry (MLE) data. Out-of-range standard values will be flagged as invalid. The system is unable to calculate control and patient RFV and Test Value (TV).

Note

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

LIMITATIONS OF THE METHOD

1. The VIDAS® HPY assay should be used only to evaluate patients with clinical signs and symptoms of gastroduodenal disease and is not intended for use with asymptomatic patients.
2. As with any diagnostic test, results from the VIDAS® HPY IgG test should be interpreted in conjunction with other laboratory test results and clinical data available to the clinician.
3. A positive HPY assay result does not distinguish between active infection and colonization with *H. pylori*.
4. A positive HPY assay result only indicates presence of IgG antibodies to *H. pylori* and does not necessarily indicate that gastroduodenal disease is present.
5. A negative HPY assay result indicates either that IgG antibodies to *H. pylori* are not present or that they are at a level not detectable by the HPY assay.
6. Performance has not been demonstrated for monitoring the effects of antimicrobial therapy for treatment of *H. pylori*.
7. The assay has not been established for patients under 18 years of age.
8. 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's history, and the results of any other tests performed.

RANGE OF EXPECTED VALUES

H. pylori infection has been found worldwide, but geographical distribution of prevalence varies widely. It is always higher in developing countries (70 - 90%) than in industrialized countries (20 - 30%), higher prevalence being associated with low socio-economic levels. In Caucasian populations in the United States and other industrialized countries, *H. pylori* infection is infrequent in childhood but with each year of age the prevalence increases 0.5 - 2%, reaching about 50% in those who are 60 or older. Prevalence rates appear to be higher in blacks and Hispanics than in whites (13, 14). The frequency of *H. pylori* infection in patients diagnosed with duodenal ulcers is approximately 80% in all age groups (15).
In a random population of 200 apparently healthy blood donors tested using VIDAS® HPY, the positive rate was 27.5% with an equivocal rate of 5.5%.
Expected values for a given population should be determined for each laboratory. The positivity rate for any test may vary depending upon factors such as geographical location, age, sex of population studied, season of year, specimen collection and handling procedures, etc.

PERFORMANCE

A total of 247 frozen serum specimens and 100 freshly collected serum samples were used to evaluate VIDAS® HPY sensitivity and specificity performance.

Two hundred and four frozen serum specimens were well characterized by culture. Ninety-nine specimens were considered negative for *H. pylori* and 105 specimens were considered positive.

Forty-three frozen serum specimens were defined by histology. Twenty-six specimens were considered negative and 17 specimens were considered positive.

The same 247 frozen serum specimens and 100 freshly collected serum specimens were also evaluated by a competitor EIA method.

Table 1

204 Culture defined serum samples

Table 1

		Culture	
		+	-
VIDAS® HPY	+	103	9
	E	0	1
	-	2	89

1 VIDAS® equivocal (not included in calculations)

Clinical Sensitivity	98.10%
95% CI	93.12% - 99.77%
Clinical Specificity	90.82%
95% CI	83.28% - 95.71%

CI: Confidence Interval

Table 2

43 Histology stain defined serum samples

Table 2

		Histology	
		+	-
VIDAS	+	17	0
HPY	-	0	26

Percent Positive Agreement	17/17	100%
Percent Negative Agreement	26/26	100%
Concordance of Results	43/43	100%

Table 3

247 Serum samples evaluated by a competitor EIA method.

Table 3

		EIA	
		+	-
VIDAS® HPY	+	118	11**
	E***	1	1
	-	2*	114

2 VIDAS® equivocals (not included in calculations)

Percent Positive Agreement	118/120	98.3%
Percent Negative Agreement	114/125	91.2%
Concordance of Results	232/245	94.7%

* Two serum specimens, competitor EIA positive/VIDAS® HPY negative, were negative by culture.

**Seven serum specimens, competitor EIA negative/VIDAS® HPY positive, were negative by culture. One serum specimen, competitor EIA negative/VIDAS® HPY positive, was positive by culture. Three serum specimens, competitor EIA negative/VIDAS® HPY positive, were positive by histology.

***One serum specimen, competitor EIA positive/VIDAS® HPY equivocal, was negative by culture. One serum specimen, competitor EIA negative/VIDAS® HPY equivocal, was negative by culture.

Table 4

100 Freshly collected serum samples defined by another EIA method

Table 4

		EIA	
		+	-
VIDAS® HPY	+	30	6
	E	1	0
	-	1	62

1 VIDAS® equivocal (not included in calculations)

Percent Positive Agreement	30/31	96.8%
Percent Negative Agreement	62/68	91.2%
Concordance of Results	92/99	92.9%

Discrepant results were not reevaluated by another *H. pylori* detection method.

REPRODUCIBILITY – VIDAS®/MINIVIDAS®

VIDAS® HPY reproducibility was demonstrated using a 6-member panel of pooled specimens, consisting of 2 negative, 2 low positive and 2 positive pools. This panel was run at three sites. Each pool was run 10 times in one instrument run over three days. The results of combined within run and total imprecision are shown in Table 5.

The VIDAS® test value (TV) was used. Coefficient of Variation (%CV) is not presented for the negative pools, instead the Standard Deviation (SD) is presented as the measure of variability. Results are presented according to the National Committee for Clinical Laboratory Standards (NCCLS).

Table 5 (All Sites)

		Negative		Low positive		High positive	
N		90	90	90	90	90	90
Mean TV		0.32	0.22	1.75	1.33	9.39	5.39
With-in run	**SD**	0.02	0.01	0.07	0.06	0.25	0.20
	%CV	5.8	6.3	3.9	4.7	2.7	3.8
Between	**SD**	0.05	0.02	0.08	0.08	0.44	0.78
Day	**%CV**	16.1	11.0	4.5	6.0	4.6	14.4
Total imprecision	**SD**	0.05	0.12	0.25	0.21	1.67	0.78
Between sites	**%CV**	NA	NA	14.2	15.5	17.8	14.4

NA=Not applicable

CROSS REACTIVITY

	VIDAS® HPY
R.F. +	1/18
A.N.A.+	2/14
MNI +	0/19
Influenza +	0/11
HSV +	1/16
Toxoplasmosis IgG +	0/14
Syphilis +	0/10
CMV IgG +	0/12
Lupus erythematosus +	0/3

A total of 122 samples negative for anti- *H. pylori* antibodies (using a competitor EIA method) were tested: 5 equivocal VIDAS® HPY results were excluded from the table (1 equivocal RF +, 2 equivocal ANA +, 1 equivocal influenza +, 1 equivocal toxoplasmosis IgG +).

ASSAY SPECIFICITY

To test for assay specificity, test organisms were pre-incubated in a pool of human anti-*H. pylor*i positive serum and tested in triplicate.
The tested organisms are listed below and showed no unexpected results in the VIDAS® HPY assay. The seropositive serum remained positive after absorption with every organism except the *H. pylori* strain.

Bacteroides fragilis
Campylobacter coli
Campylobacter fetus fetus
Campylobacter fetus venerealis
Campylobacter hyointestinalis
Campylobacter jejuni
Campylobacter lari
Campylobacter rectus
Candida albicans
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Enterococcus faecalis
Escherichia coli
Helicobacter cinaedi
Helicobacter pylori
Klebsiella pneumoniae
Proteus vulgaris
Pseudomonas aeruginosa
Pseudomonas fluorescens
Salmonella minnesota
Serratia liquefaciens
Shigella flexneri
Shigella sonnei
Staphylococcus aureus
Wolinella succinogenes
Yersinia enterocolitica

METHOD COMPARISON – VIDAS® 3

A study was conducted to verify the correlation of the VIDAS® *H. pylori* IgG assay on the VIDAS® 3 to the VIDAS® *H. pylori* IgG assay on the VIDAS®. One reagent lot, one of each instrument and 250 serum samples including positive, equivocal and negative samples were used, and results were evaluated according to CLSI® EP12-A2:

Contingency Table:

		VIDAS®			
		Positive	**Equivocal**	**Negative**	**Total**
VIDAS® 3	**Positive**	122	3	0	125
	Equivocal	0	6	4	10
	Negative	0	2	113	115
	Total	122	11	117	250

Associated percent agreements and their 95% two-sided score confidence intervals (CI) are calculated below:

Category	**Samples of interest/Total**	**Percent Agreement 2-sided 95% CI**
Negative	113/117	96.6% [91.5 ; 98.7] %
Positive	122/122	100% [96.9 ; 100.0] %

PRECISION – VIDAS® 3

Three serum samples with samples close to the assay cut-off and moderate positive samples were tested in triplicate (3 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 108). The results were calculated according to CLSI EP5-A2 and were as follows:

		Sample 1	**Sample 2**	**Sample 3**
N		108	108	108
Mean Test Value (TV)		0.76	1.26	2.23
With-in Run	**SD**	0.06	0.08	0.12
	%CV	7.7	6.2	5.2
Between Day	**SD**	0.00	0.00	0.05
	%CV	0.0	0.0	2.4
Total Between	**SD**	0.08	0.09	0.15
Instrument	**%CV**	10.1	7.2	6.8

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

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
Rx only	Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner
	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
2015/10	9311312A	N/A	FIRST PUBLICATION
2016/09	9311312B	Technical	CONTENT OF THE KIT (30 TESTS)
2017/03	9311312C	Technical	ASSAY SPECIFICITY

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