17 אפריל, 2012

לקוחות נכבדים,

הנדון: **<u>השקת קיט חדש Vidas Anti HCV- מחברת bioMerieux</u>**

חברת אילקס שמחה להודיע על השקת ערכה חדשה בפאנל בדיקות הצהבת במכשיר ה- **Vidas**
בדיקת Anti HCV לבדיקת נוגדנים כנגד Hepatatis C Virus.

הקיט, 3rd Generation , מגלה נוגדנים כנגד 3 סוגים שונים של HCV Ag בדגימה:

- Nucleocapsid CORE
- NS3
- NS4

עם ההשקה אנו גאים להציג פאנל שלם לבדיקות הצהבת:

- הפטטיס A : IgG & IgM
- הפטטיס B : HBsAg, HBc IgM&IgG, HBe/Anti HBe, Anti HBs
- הפטטיס C : Anti HCV

יתרונות הערכה:

1. הרצת קליברטור בדופליקט פעם ב-28 יום.
2. נפח דגימה 100 ul
3. ריאגנטים בקיט : S1/C1 Ready To Use
4. הקיט ניתן לשימוש מיד עם הוצאתו מהמקרר
5. אינטרפרטציה של תוצאות:
   <1 → Negative
   ≥1 → Positive

להלן המק"ט להזמנה:

שם פריט	מק"ט אילקס
VIDAS ANTI HCV 60 TESTS	5-30308

מצ"ב מידע מחברת bioMerieux.

נשמח לסייע במידע נוסף שיידרש.

בברכה,

אורלי דויטש, 054-5686303
עילית ליזרמן, 054-6686183

VIDAS®, Designed to last

- Ease-of-use: Load and Go
- Robustness: MTBF > 700 days
- High Quality tests for reliable diagnosis
- Cost effective solution:
  - Single dose
  - All inclusive kits
  - Convenient packaging size

VIDAS and mini VIDAS
The adapted offer to your organization

VIDAS®, a Customized Solution for your Daily Workload

Routine Testing
- Up to 10 parameters in one run
- Comprehensive panels (Thyroid, Fertility, Cardiac Markers, Tumor Markers, HIV, Hepatitis, ToRC…)

Complementary and Specialized Testing
- Confirmatory testing (HIV DUO, Toxo Avidity, DD Exclusion, Prolactin…)
- Specialized testing: Lyme, Measles, Mumps, *H. pylori*, CD A/B, Chlamydia, Allergy…)
- Complementary Testing: large menu (> 90 parameters)

Emergency Testing
- 24/7 available
- Rapid results in compliance with Healthcare guidelines
- Emergency panel: TNIU, CK-MB, Myoglobin, NT-proBNP, DD Exclusion, PCT, Digoxin, hCG…

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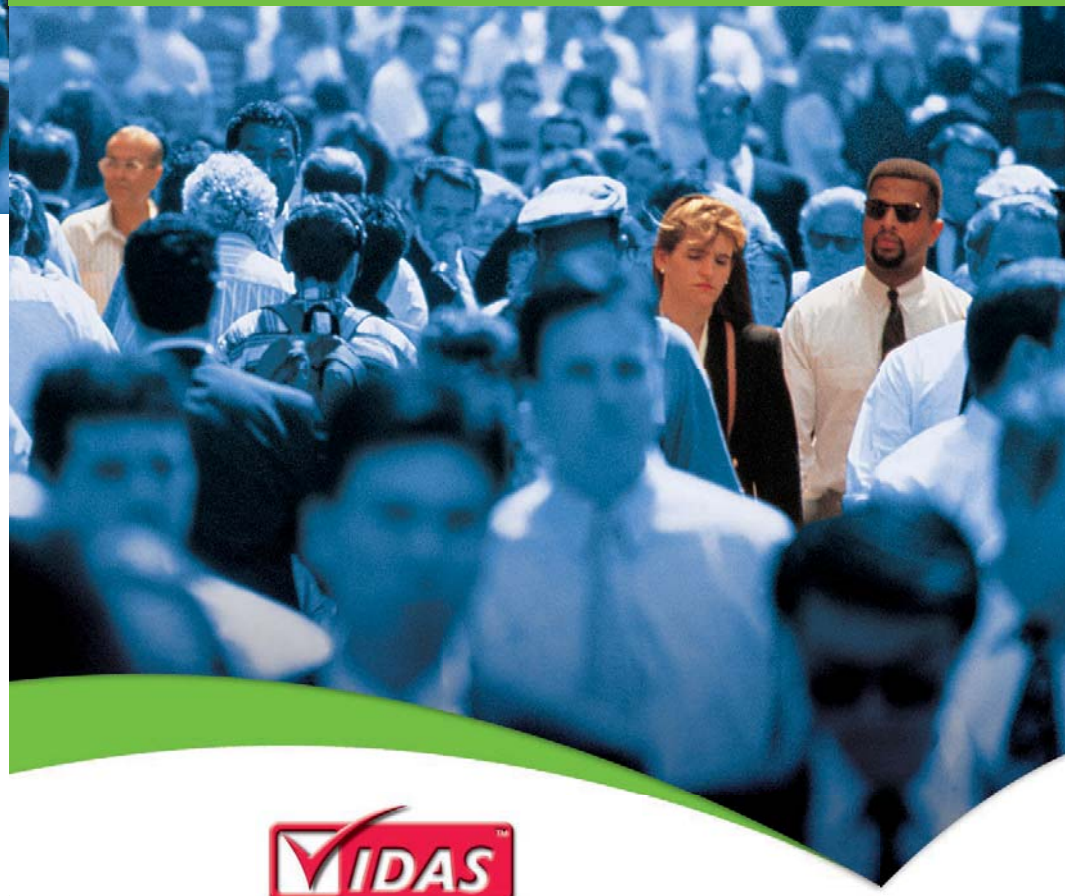
BIOMÉRIEUX

HEPATITIS C



VIDAS™

VIDAS® ANTI-HCV

For **C**lear and **C**onfident Diagnosis of **Hepatitis C**

BIOMÉRIEUX

The A, B, **C** 's of Hepatitis Testing

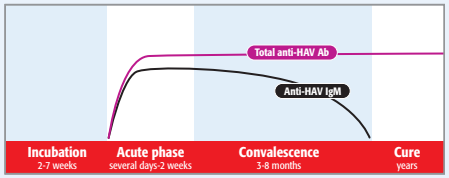
Viral hepatitis is a major global healthcare problem, responsible for significant morbidity and socio-economic losses, with an estimated 3% of the world's population infected with HCV alone. The VIDAS hepatitis panel now covers all the must have parameters for differential diagnosis of HAV, HBV and HCV, so you can provide:

➔ Adjusted treatment

➔ Better patient management

➔ Rapid results

Hepatitis A



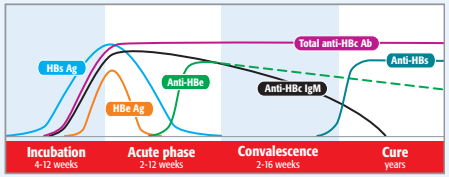
➔ Diagnosis of recent infection:
VIDAS HAV IgM

➔ Control of previous immunity or vaccination:
VIDAS Anti-HAV Total

VIDAS HEPATITIS PANEL
➔ THE FLEXIBILITY YOU NEED

Hepatitis A		
VIDAS HAV IgM	30 tests	ref. 30 307
VIDAS Anti-HAV total	30 tests	ref. 30 312
Hepatitis B		
VIDAS HBs Ag Ultra	60 tests	ref. 30 315
VIDAS HBs Ag Ultra Confirmation	30 tests	ref. 30 317
VIDAS Anti-HBs Total Quick	60 tests	ref. 30 238
VIDAS Anti-HBc Total II	60 tests	ref. 30 314
VIDAS HBc IgM II	30 tests	ref. 30 439
VIDAS HBe/Anti-HBe	30 tests	ref. 30 305
Hepatitis C		
VIDAS Anti-HCV	60 tests	ref. 30 308

Hepatitis B



➔ Diagnosis of recent infection:
VIDAS* HBs Ag Ultra
- Ultra sensitivity to:
  - Reduce the serological windows
  - Highlight hidden infections
  - Detect HBV variant/mutant

VIDAS HBc IgM II
- Sensitive and quantitative
- Can be used in treatment follow-up and as an indicator of viral reactivation

➔ Follow-up of Chronic Hepatitis:
VIDAS HBs Ag Ultra
VIDAS HBe/Anti-HBe

➔ Pre- or Post Vaccination Immunity Control:
VIDAS Anti-HBs Total Quick
- CV< 5% around the cut-off of 10 IU/ml.

VIDAS Anti-HBc Total II
- Excellent sensitivity provided with the inhibition technique.

➔ Screening during Pregnancy:
VIDAS HBs Ag Ultra

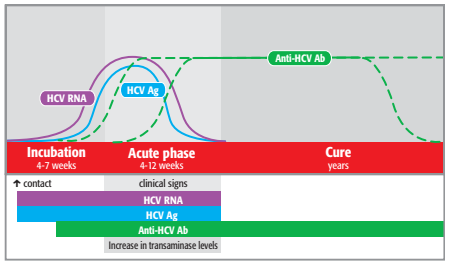
Hepatitis C

VIDAS anti-HCV to support you in Hepatitis C investigations

The VIDAS Anti-HCV assay combines a two-step enzyme immunoassay sandwich method with a final fluorescent detection. Proprietary recombinant Core, NS3 and NS4 antigens are used for the qualitative detection of anti-HCV antibodies in serum or plasma.

- Detects all 6 HCV genotypes
- For patients with clinical symptoms or at-risk populations

With all the benefits of VIDAS
- Easy to use
- Robust and reliable system
- Maximum flexibility
- Cost-effective 60 test packaging
- Ideal for routine, complementary or specialized testing



VIDAS Anti-HCV	
Detection	(Core, NS3, NS4) IgG
Principle	Sandwich, ELFA
Kit size	60 tests
Calibration	Every 28 days
Run time	Around 40 min
Result interpretation	< 1: negative ≥ 1.00: positive

VIDAS quality you can trust

The solid performance of the VIDAS Anti-HCV assay in clinical trials confirms the high level of quality you've come to expect from VIDAS, for your peace of mind and the patient's.

Diagnostic Specificity (95% Confidence Interval)	
Blood donor population (n=5,104)	**99.61%** [99.40% - 99.76%]
Clinical Specificity (95% Confidence Interval)	
Hospitalized patients (n=200)	**99.50%** [97.25% - 99.99%]

Diagnostic Sensitivity (95% Confidence Interval)	
HCV+ / HIV negative patients (n=254)	**100%** [98.56% - 100%]
HCV+ / HIV positive patients (n=61*)	**98.36%** [91.20% - 99.96%]
HCV+ / (HIV unknown) patients (n=124)	**100%** [97.07% - 100%]
Total population (n=439*)	**99.77%** [98.74% - 99.99%]

*1 patient who was not detected using VIDAS Anti-HCV either had a low antibody level or was not detected using equivalent method

VIDAS® Anti-HCV (HCV)

VIDAS Anti-HCV is an automated qualitative test for use on the instruments of the VIDAS family, for the detection of IgG antibodies to hepatitis C virus (anti-HCV) in human serum or plasma (heparin) using the ELFA technique (Enzyme Linked Fluorescent Assay). The detection of these specific antibodies, in conjunction with other clinical information, aids in the diagnosis of infection in persons with symptoms of hepatitis and in persons at risk for hepatitis C infection.

SUMMARY AND EXPLANATION

The Hepatitis C virus (HCV) discovered in 1989 using advanced molecular biology techniques, was rapidly found to account for the majority of those patients with non-A non-B hepatitis. HCV represents a major worldwide public health problem requiring global action for the diagnosis, treatment and prevention of this infection (1).
HCV is primarily parenterally transmitted through direct blood-to-blood contact between two people: use of unsterilized injection devices and transfusion of unscreened blood or blood products (2). The disease frequently progresses to chronic hepatitis C (80%), exposing patients to a greater risk of hepatic complications such as cirrhosis or hepatocellular carcinoma. (3).

The current standard of treatment for HCV is a combination of two drugs: pegylated interferon and ribavirin, but due to the high genetic variability of HCV (4), it is still only partially effective: viral eradication in less than 50% of patients infected with genotype 1 hepatitis C virus against approximately 80% of patients infected with genotype 2 or 3. New therapeutic options are under study to offer more effective and safer personalized treatments (5,6).

Diagnosis of patients infected with HCV can be performed using two categories of virological tests: indirect tests, and direct tests (7). Indirect serological tests are third-generation enzyme immunoassays that detect antibodies to HCV. The antigens used in the tests to detect antibodies are from the structural and non-structural regions of the HCV (8) (capsid, protein, cofactors, polymerase, etc.). The presence of anti-HCV antibodies indicates that an individual may have been infected with HCV in the past or may have an ongoing HCV infection. To confirm the presence of active HCV infection, a positive serological test can be completed using direct tests (e.g.: molecular assays that detect RNA genomes). The results will be used to guide patient management and determine the optimal duration of treatment.

The VIDAS Anti-HCV assay is a third-generation test using antigens corresponding to the HCV core, NS3 and NS4 proteins for the qualitative detection of anti-HCV antibodies.

PRINCIPLE

The assay principle combines a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA).
The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device. 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.

During the first step, the sample is diluted, and then cycled in and out of the SPR several times. The anti-HCV antibodies present in the sample will bind to the antigens representing the HCV core, NS3 and NS4 proteins coated on the interior of the SPR. Unbound sample components are washed away.
During the second step, mouse monoclonal anti-human IgG antibodies in Fab form, conjugated to recombinant alkaline phosphatase (yeast) are cycled in and out of the SPR several times and will bind to the human Ig bound to the molecules on the solid phase. Further wash steps remove unbound components.
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 the fluorescence is proportional to the concentration of antibody present in the sample. At the end of the assay, the results are automatically calculated by the instrument in relation to the Standard S1 stored in memory, and then printed out.

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

60 Strips HCV	STR	Ready-to-use.
60 SPRs HCV (2 x 30)	SPR®	Ready-to-use. Interior of SPRs coated with antigens representing the HCV core, NS3 and NS4 proteins.
HCV Positive control 1 x 1.9 ml (liquid)	C 1	Pooled human serum or plasma* containing anti-HCV IgG in a phosphate buffer + BSA + preservatives Index: The confidence interval is indicated on the MLE card after the following mention: "Control C1 (+) Test Value Range".
HCV Negative control 1 x 1.9 ml (liquid)	C 2	Phosphate buffer + BSA + preservatives Index: The confidence interval is indicated on the MLE card after the following mention: "Control C2 (-) Test Value Range".
Standard 1 x 1.9 ml (liquid)	S 1	Pooled human serum or plasma* containing anti-HCV IgG in a phosphate buffer + BSA + preservatives The confidence interval in "Relative Fluorescence Value (RFV)" is indicated on the MLE card after the following mention: "Standard (S1) RFV Range".
1 MLE card (Master Lot Entry)		Specifications for the factory master data required to calibrate the test: to read the MLE data, please refer to the User's Manual
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 HIV1 and HIV2. The product has been inactivated. 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 the antigens representing the HCV core, NS3 and NS4 proteins. Each SPR is identified by the code "HCV". 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 HCV strip

Wells	Reagents
1	Sample well.
2	Sample diluent: TRIS buffered saline + Tween 20 + BSA + preservatives (600 µl)
3 – 4 – 5 – 7 - 8	Wash buffer: TRIS buffered saline + Tween 20 + preservatives (600 µl)
6	Conjugate: mouse monoclonal anti-human IgG antibodies conjugated to recombinant ALP in Phosphate buffered saline + protein stabilizer + preservatives (400 µl)
9	Reactive diluent: Phosphate buffered saline + preservative (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).

*** IRRITANT reagent:**
- **R 36:** Irritating to eyes.
- **S 26:** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

For further information, refer to the Safety Data Sheet available on request.

MATERIALS AND DISPOSABLES REQUIRED BUT NOT PROVIDED

- Pipette with disposable tip to dispense 100 µl.
- Powderless, disposable gloves.
- For other specific materials and disposables, please refer to the Instrument User'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).
- 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 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 risk phrase "R" and the precautions "S" 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 Anti-HCV 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 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

Human serum or plasma

Types of tubes validated:

– Plain tube,
– Tube with lithium heparin,
– Tube with sodium heparin,
– Tube with lithium heparin and separation gel,
– Plastic tube with clot activator,
– Plastic tube with clot activator and separation gel.

The use of heat-inactivated sera has not been validate.

Note: Depending on the manufacturer, blood collection tubes may contain materials and additives that could generate different test results.
It is the responsibility of each laboratory to validate use of these tubes in accordance with the manufacturer's recommendations for use.

Specimen preparation

Plain tubes: wait for samples to coagulate and **centrifuge** according to the tube manufacturer's recommendations to eliminate fibrin.
Other tubes: follow the tube manufacturer's recommendations for use.
Frozen-stored samples: after thawing, these samples must be homogenized before analysis.

Sample-related interference

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 mmol/l equivalent in triglycerides),
- bilirubinemia (after spiking samples with bilirubin: 0 to 220 mg/ml or 376 µmol/l).

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

Specimen stability

Serum and plasma samples separated from the clot, can be stored at 2-8 °C in stoppered tubes for 7 days; if longer storage is required, freeze the sera or plasma at -25 ± 6°C.
Do not exceed 3 freeze/thaw cycles.
A study performed on samples frozen for 12 months, showed that the quality of results is not affected.

INSTRUCTIONS FOR USE

For complete instructions, see the User's Manual.

VIDAS PTC protocol data entry

When using the assay for the first time, **and before reading the MLE data**, scan the bar code(s) (at the end of the package insert) using the instrument's external bar code reader. This reading will allow VIDAS PTC protocol data to be transferred to the instrument software for its update. These data should only be read the first time the assay is used.

Master lot data entry

Note: When using the assay for the first time, enter the VIDAS PTC protocol (bar codes at the end of the package insert) before reading the MLE data. If the MLE data have been read before the VIDAS PTC protocol, read the MLE data again.
Before each new lot of reagents is used, specifications (or factory master calibration data) must be entered into the instrument using the MLE data. If this operation is not performed **before initiating the tests**, the instrument will not be able to print results. 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 standard provided in the kit, must be performed upon receipt of a new lot of reagents after the master lot data have been entered. Calibration should then be performed every 28 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 standard, identified by "S1", 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. They can be used immediately.**
2. Use one "HCV" strip and one "HCV" SPR for each sample, control or standard 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 "HCV" 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 is to be tested, it should be identified by "C2".
4. If necessary, clarify samples by centrifugation.
5. Mix the standard, controls and samples using a vortex-type mixer (for serum or plasma separated from the pellet).
6. **For this test, the standard, control, and sample test portion is 100 µl.**
7. Insert the "HCV" SPRs and the "HCV" 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 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

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 results are automatically calculated by the instrument.
The patient RFV is interpreted as follows:
Test value = (patient RFV / standard RFV).
This test value and the interpretation are also included on the result sheet. The interpretation depending on the test value is as follows:

Test value (TV)	Interpretation
<1.00	negative
≥1.00	positive

All positive patient results must be verified in duplicate. If at least one of the repeat values is positive, the patient result is considered as positive. In that case, additional tests should be performed (another immunoassay or HCV marker) on the same sample or on a second one.

Note: In all cases, refer to current national guidelines concerning HCV diagnosis.

Interpretation of VIDAS Anti-HCV test results should be made taking into consideration the patient history and the results of any other tests or hepatitis C markers.

QUALITY CONTROL

One positive control and one negative control are included in each VIDAS Anti-HCV 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.
Results cannot be validated if the control values deviate 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

For the diagnosis of HCV infection, the serological results should be used and interpreted taking into account the patient history, the clinical record, and further tests.

A negative test result does not exclude the possibility of exposure to HCV or infection with HCV. Anti-HCV antibodies may be undetectable in some stages of the infection (acute phase of hepatitis or presence of a serological scar) and in some clinical conditions (immunosuppression) (7,9).

Interference may be encountered with certain sera containing antibodies against reagent components.

This test has not been validated for use with any specimen matrices other than human serum or plasma.

RANGE OF EXPECTED VALUES(1)

Hepatitis C has a worldwide prevalence of 2-3% that varies according to country:

Region of the world	Anti-HCV prevalence (%)
Europe	2.3
Africa	3.2
Americas	1.5
Australia & Oceania	1.2
Asia	2.1
Middle East	4.7
Total	2.4

PERFORMANCE

The following study results demonstrate the conformity of VIDAS Anti-HCV to the Common Technical Specifications of 98/79/CE Directive:

1. Specificity for blood donor population:

5104 blood donor samples (including 2904 fresh samples with a negative status collected ≤ 24 hours previously) obtained from 2 blood transfusion centers, were tested using the VIDAS Anti-HCV assay.

	Status	
VIDAS Anti-HCV	Positive	Negative
Positive	0	20
Negative	0	5084

Diagnostic specificity of the VIDAS Anti-HCV assay on this population: 99.61%
(95% confidence interval: 99.40% - 99.76%)

2. Clinical specificity for hospitalized patients

200 samples with a negative status were tested using the VIDAS Anti-HCV assay.

Diagnostic specificity of the VIDAS Anti-HCV assay on this population: 99.50%.

(95% confidence interval: 97.25% - 99.99%)

3. Diagnostic sensitivity

439 samples with a positive status, including 102 fresh samples (collected ≤ 24 hours previously), were tested using the VIDAS Anti-HCV assay.

Genotypes 1 to 6 were tested:

Genotype	Number tested
1	21
2	21
3	23
4 (including non-a sub-types)	22
5	6
6	2

Results on tested populations:

Population	Positive VIDAS Anti-HCV /total tested	Diagnostic sensitivity observed (95% confidence interval)
HCV/HIV-negative patient	254/254	100% [98.56% - 100%]
HCV/HIV-positive patient	60/61*	98.36% [91.20% - 99.96%]
Patient with unknown HCV/HIV status	124/124	100% [97.07% - 100%]
Total HCV population	438/439*	99.77% [98.74% – 99.99%]

* The patient who was not detected using VIDAS Anti-HCV either had a low antibody level or was not detected using equivalent methods.

4. Sensitivity for seroconversion panels

Testing of 30 seroconversion panels demonstrated the precocity of detection of the VIDAS Anti-HCV assay.The results are comparable to those obtained using the most sensitive methods.

5. Precision

The repeatability and reproducibility were determined at two sites and calculated according to the recommendations of the CLSI® documents EP5-A2 / EP12-A2.
Four human samples were tested in duplicate using two lots of reagents. Testing was performed twice a day for 10 days on three instruments at one experimental site (N=120). Each reagent lot used a single calibration curve throughout the study. Data from this study are summarized in the following table:

Sample ID / Target value	Sample 1		Sample 2		Sample 3		Sample 4	
	0.26		0.93		1.08		1.19	
	Standard deviation	CV (%)	Standard deviation	CV (%)	Standard deviation	CV (%)	Standard deviation	CV (%)
Repeatability	0.01	5.6	0.04	4.3	0.05	4.8	0.06	4.7
Reproducibility	0.07	26.9	0.05	5.9	0.07	6.3	0.07	5.8

6. Cross-reactivity

273 samples from patients with a physiological status that can potentially interfere with the detection of hepatitis C antibodies, were tested using VIDAS Anti-HCV. All of the samples were found to be negative with another EIA method (except one CMV IgG+ sample). No disease-related interference was observed for VIDAS Anti-HCV.

	VIDAS Anti-HCV
HSV +	0/10
VZV +	0/10
EBV +	0/10
HIV +	0/10
CMV IgG +	1/11*
LYME Ig+	0/10
HAV IgG +	0/10
HVB (HBcT +)	0/8
HVB (Ag HBs +)	0/10
Syphilis	0/10
Rubella IgG +	0/10
Toxoplasmosis IgG +	0/10
Rheumatoid factor	0/10
Anti-Nuclear Antibody	0/10
Anti-E. coli antibody	0/10
Anti-Pichia Antibody	0/10
Pregnant women**	0/114

* The reference EIA method also showed one false positive sample, but on a different sample.
** including 10 multipara.

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.

REFERENCES BIBLIOGRAPHIQUES

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests

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