

Monolisa™ Anti-HCV PLUS Version 3

1 plate - ▽ 96

REF 72340

5 plates - ▽ 480

REF 72341

SCREENING KIT FOR ANTI-HCV ANTIBODIES (HEPATITIS C VIRUS) IN HUMAN PLASMA OR SERUM USING AN ENZYME IMMUNO-ASSAY TECHNIQUE



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1. INTENDED USE

Monolisa™ Anti-HCV PLUS Version 3 is an indirect qualitative enzyme immunoassay for the detection of infection by the hepatitis C virus (HCV) based on the detection of anti-HCV antibodies in serum or human plasma. This hepatitis C screening test can be used by diagnostic laboratories and blood banks.

2. SUMMARY AND EXPLANATION OF THE TEST

The hepatitis C virus (HCV) is an enveloped RNA positive-sense virus (9.5 kb) belonging to the Flaviviridae family. Isolated in 1989, six of the HCV's major genotypes have been identified. HCV is recognized as being the main cause of non-A and non-B viral hepatitis. HCV infection is characterized by an acute and chronic form that may lead to cirrhosis and hepatocellular carcinoma. First line hepatitis C screening uses a third-generation ELISA enzyme immunoassay for detecting anti-HCV antibodies.

3. PRINCIPLES OF THE PROCEDURE

Monolisa™ Anti-HCV PLUS Version 3 is based on the use of a solid phase prepared with purified antigens: three recombinant proteins of the non-structural region (NS3 and NS4), a peptide of the structural region (capsid) of the hepatitis C virus; and a liquid phase (conjugate) comprising mouse anti-human IgG antibodies coupled to peroxidase.

The assay procedure includes the following reaction steps:

- 1) The sample diluent (R6) and then the samples and controls (R3 and R4) are distributed in the wells of the microplate. If the antibodies to HCV are present, they will bind to the antigens fixed on the solid phase.
- 2) After incubation at 37°C during 1 hour and a washing step, the conjugate (R7) containing the peroxidase-labeled anti-human IgG antibodies is added. If human IgG is present, having reacted with the solid phase, the anti-human IgG conjugate binds to the human antibodies.
- 3) After 30 minutes of incubation at 37°C and elimination of the unbound enzymatic conjugate by washing, the presence of the peroxidase antigen-antibody complexes are revealed by adding the substrate.
- 4) After 30 minutes of incubation at laboratory temperature (18 - 30°C) and once the reaction has been stopped, the spectrophotometer reading is taken at 450/620-700 nm. The absorbance measured for a sample allows detection of the presence or absence of HCV antibodies of the hepatitis C in the sample. The colour intensity is proportional to the quantity of HCV antibodies bound onto the solid phase.

4. REAGENTS

4.1. Description

Identification on label		Description	Presentation/Preparation 72340 72341	
R1	Microplate	Microplate 12 strips of 8 wells each, coated with purified recombinant antigens (NS3, NS4) and a HCV capsid peptide. <i>Specific ID number = 94</i>	1 plate Ready to use	5 plates Ready to use
R2	Concentrated washing solution (20X)	Concentrated washing solution (20X) Tris NaCl buffer pH 7.4 Preservative: ProClin™ 300 (0.04%)	1 vial 70 ml To be diluted	1 vial 235 ml To be diluted
R3	Negative control	Negative control Tris HCl Buffer, containing BSA (Bovine Serum Albumin) Preservative: ProClin™ 300 (0.1%)	1 vial 1 ml Ready to use	1 vial 1 ml Ready to use
R4	Positive control	Positive control Human serum containing antibodies to HCV, negative for the HBs antigen and for anti HIV-1 and anti HIV-2 antibodies diluted in a Tris HCl buffer containing BSA, and photochemically inactivated Preservative: ProClin™ 300 (0.1%)	1 vial 1.5 ml Ready to use	1 vial 3 ml Ready to use
R6	Sample diluent	Sample diluent Citrate buffer; purple color Preservative: Sodium azide (<0.1%), Cosmocil® CQ (0.025%)	1 vial 15 ml Ready to use	2 vials 2 x 30 ml Ready to use
R7	Conjugate	Conjugate Mouse antibodies anti-human IgG / Peroxidase Green colour. Preservative: ProClin™ 300 (0.5 %)	1 vial 15 ml Ready to use	2 vials 2 x 30 ml Ready to use
R8	Substrate buffer	Substrate Citric acid and sodium acetate solution, pH 4.0, containing H ₂ O ₂ (0.015%) and dimethyl sulfoxide (DMSO) 4%	1 vial 60 ml To be reconstituted	2 vials 2 x 60 ml To be reconstituted
R9	Chromogen: TMB solution (11X)	Chromogen: TMB solution Solution containing 3,3', 5,5' tetramethylbenzidine (TMB)	1 vial 5 ml To be reconstituted	2 vials 2 x 5 ml To be reconstituted
R10	Stopping solution	Stopping solution Sulphuric acid solution 1N	1 vial 28 ml Ready to use	3 vials 3 x 28 ml Ready to use

4.2. Conditions of preservation and handling

The kit should be stored at +2-8°C. Each item of the kit preserved at +2-8°C can be used up to the expiry date mentioned on the package (unless otherwise indicated).

After opening and in the absence of contamination, the R2, R3, R4, R6, R7, R8, R9 and R10 reagents preserved at 2-8°C can be used up to the expiry date shown on the label.

Identification	Preservation
R1	After opening the vacuum-sealed bag, the microwell strips stored at +2-8°C can be used for 1 month in their carefully resealed original bag.
R2	The diluted washing solution can be stored at +2-30°C for 2 weeks. The concentrated washing solution (R2) can be stored at +2-30°C.
R8 + R9	After reconstitution, the reagents stored in the dark can be used for 6 hours at room temperature (18-30°C).

5. WARNING AND PRECAUTIONS

For *in vitro* diagnostic use by a health professional.

5.1. Health and Safety precautions:

- This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves, eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
- The test kit contains human blood components. Human source material used in the preparation of R4 reagent (Positive Control) has been tested and found non-reactive for hepatitis B surface antigen (HBs Ag) and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2 Ab) and positive for anti-HCV antibodies. The positive control R4 is inactivated by warming. No known test method can offer complete assurance that infectious agents are absent. Therefore, all human blood derivatives, reagents and human specimens, should be handled as if capable of transmitting infectious disease, following recommended Universal Precautions for blood borne pathogens as defined by local, regional and national regulations
- Biological spills: Human source material spills should be treated as potentially infectious. Spills not containing acid should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment, with an appropriate chemical disinfectant that is effective for the potential biohazards relative to the samples involved (commonly a 1:10 dilution of household bleach, 70-80% Ethanol or Isopropanol, an iodophor [such as 0.5% Wescodyne™ Plus, etc.), and wiped dry. Spills containing acid should be appropriately absorbed (wiped up) or neutralized, the area flushed with water and wiped dry; materials used to absorb the spill may require biohazardous waste disposal. Then the area should be decontaminated with one of the chemical disinfectants

NOTE: Do not place solutions containing bleach into the autoclave!

- Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or biohazardous wastes must be handled and discarded in accordance with all local, regional and national regulations.
- For hazard and precaution recommendations related to some chemical components in this test kit, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instructions for use. The Safety Data Sheet is available on www.bio-rad.com.

5.2. Precautions relating to the protocol

5.2.1. Preparing

The reliability of the results depends on correct implementation of the following Good Laboratory Practices:

- Do not use expired reagents.
- Do not mix or associate reagents from different lots within a test run.
- Before use wait for 30 minutes for the reagents to stabilize at room temperature (18-30°C).
- The name of the test, as well as a specific identification number for the test, is written on the frame of each microplate. This specific identification number is stated on each strip too.

Monolisa™ Anti-HCV PLUS Version 3: Specific ID number = 94

Verify the specific identification number before use. If the identification number is missing, or different from the stated number corresponding to the assay to be tested, the strip should not be used.

REMARK: For washing solution (R2, label identification: 20X coloured green), peroxidase substrate buffer (R8, label identification: TMB buffer, coloured blue), chromogen (R9, label identification: TMB 11X, coloured purple) and stopping solution (R10, label identification: 1N coloured red), it is possible to use other lots than those contained in the kit, provided the same lot is used within a given test run. These reagents can be used with some other products of our company. Contact our technical service for detailed information.

- Carefully reconstitute the reagents avoiding any contamination.
- Use glassware thoroughly washed and rinsed with deionized water or preferably, disposable material.
- Do not allow the microplate to dry between the end of the washing operation and the reagent distribution.
- The enzyme reaction is very sensitive to metal ions. Consequently, do not allow any metal element to come into contact with the various conjugate or substrate solutions.
- The development solution (substrate buffer + chromogen) must be coloured pink. The modification of this pink colour within a few minutes after reconstitution indicates that the reagent cannot be used and must be replaced.

Preparation of the development solution can be made in a clean disposable single use plastic tray or glass container that has first been pre-washed with 1N HCl and rinsed thoroughly with distilled water and dried. This reagent must be stored in the dark.

- Never use the same container to distribute conjugate and development solution.

5.2.2. Processing

- Do not change the assay procedure.
- Do not carry out the test in the presence of reactive vapors (acid, alkaline, aldehyde vapors) or dust that could alter the enzymatic activity of the conjugate.
- Use a new distribution tip for each sample.
- Well washing is a critical step in this procedure: respect the recommended number of washing cycles and make sure that all wells are completely filled and then completely emptied. Incorrect washing may lead to inaccurate results.
- Carefully follow the washing procedures described to obtain maximum test performance. With some instrument, it could be necessary to optimize the washing procedure (increase of number of cycle of washing step and/or volume of wash buffer for each cycle) to obtain an acceptable level of OD background for the negative sample.
- Contact our company for the adaptations and special procedures.

6. SPECIMENS

Collect a blood sample according to the current practices.

The tests should be performed on undiluted serum or plasma (collected on EDTA Lithium Heparinate, Sodium Citrate or ACD).

Specimens containing aggregates must be clarified by centrifugation before the test. Suspended fibrine particles or aggregates may produce false positive results.

The specimens will be stored at +2-8°C if the test is performed within 7 days or they may be deep-frozen at -20°C. Do not repeat more than 3 freeze/thaw cycles. The samples must be thawed at room temperature (18-30°C). It is recommended to homogenize them by inverting them before use. Samples containing up to 120 g/l of albumin, 200 mg/l of bilirubin, samples containing up to 33 g/l of triolein and samples containing up to 2 g/l of hemoglobin do not affect the results. However, it is not recommended to use contaminated hyperlipemic and hyperhemolysed samples.

If the specimens are to be shipped, they must be packaged in accordance with the regulations in force regarding the transport of etiological agents and preferably transport frozen.

It is not recommended to heat the samples.

7. PROCEDURE

7.1. Materials required but not provided

- Distilled water.
- Sodium hypochlorite (household bleach) and sodium bicarbonate.
- Absorbent paper.
- Adhesive films.
- Disposable gloves.
- Safety glasses.
- Disposable tubes.
- Automatic or semiautomatic, adjustable or preset pipettes or multipipettes to measure and dispense 50 µl, 80 µl, 100 µl, 200 µl and 1 ml.
- Graduated cylinders of 10 ml, 200 ml et 1,000 ml. Vortex mixer.
- Automatic, semi-automatic or manual microplate washing system.
- Water-bath, or equivalent microplate incubator, thermostatically set at 37°C ± 1°C (*).
- Container for biohazardous waste.
- Microplate reader equipped with 450, 490 nm and 620-700 nm filters (*).

(*) Consult us for detailed information about the equipment recommended by our technical department.

7.2. Type of reagents

7.2.1. Ready for use reagents

Reagent 1 (R1): Microplate

Each frame support containing 12 strips is wrapped in a sealed aluminium bag. Cut the bag with scissors or a scalpel 0.5 to 1 cm above the sealing. Open the bag and take out the frame. Put the unused strips back into the bag. Close the bag carefully and put it back into storage at +2-8°C.

Reagent 6 (R6): Diluent sample

Homogenize by inverting before use.

Reagent 7: Conjugate (R7)

Homogenize by inverting before use.

7.2.2. Reagents to reconstitute

Reagent 2 (R2): Concentrated washing solution (20X)

Dilute 1:20 in distilled water to obtain the ready-for-use washing solution.

Prepare 800 ml for one plate of 12 strips.

Reagent 8 (R8) + Reagent 9 (R9): Enzyme development solution

Dilute 1:11 the chromogen (R9) in the Substrate Buffer (e.g. 1 ml reagent R9 + 10 ml of R8 reagent) given that 10 ml are necessary and sufficient to treat 12 strips. Homogenize.

7.3. Assay Procedure

Strictly follow the procedure.

Use negative and positive controls sera for each test in order to validate the test quality.

Follow the following Good Laboratory Practice:

1. Carefully establish the sample distribution and identification plan.
2. Prepare the diluted washing solution R2. (refer to § 7.2)
3. Take out from the protective packing the support frame and the necessary number of strips (R1). Put the unused strips back in their packing. Close the packing and replace it at +2-8°C.
4. Distribute in the well in the following order (advisable plate distribution):
 - 100 µl of sample diluent (R6) in each well then
 - 50 µl of negative control (R3) in A1,
 - 50 µl of positive control (R4) in B1, C1, D1,
 - 50 µl of the first sample in E1,
 - 50 µl of the second sample in F1, etc.

Homogenize the mixture with at least 3 aspirations or with a microplate shaker during 5 seconds. If the distribution of the samples takes more than 10 minutes, it is recommended to distribute the negative and positive controls after the samples that are to be tested.

Depending on the system used, you can adjust the position or the order of distribution of the controls.

REMARK: After the sample distribution, the well containing sample (or controls) turns purple to blue. It is possible to verify the presence of the sample in the wells by spectrophotometric reading at 620 nm (refer to § 7.7).

5. When possible, cover the plate with new adhesive film.
6. Incubate the microplate for 60 minutes (± 5 min.) at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
7. If necessary, remove the adhesive film. Aspirate the contents of all the wells in a liquid waste container and add a minimum of 0,370 ml of washing solution into each well. Aspirate again and repeat the washing a minimum of 4 times (5 washings carried out in total). The residual volume must be lower than 10 µl (if necessary, dry the strips by turning them upside down on absorbent paper).
If you have an automatic washer, follow the same operating cycle.
8. Distribute quickly 100 µl of the conjugate solution (R7) into each well within the plate. The conjugate must be shaken before use. Cover again with a new film if possible and incubate for 30 minutes (± 5 min.) at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$.

REMARK: The conjugate is coloured green. It is possible to verify the presence of conjugate in the wells by spectrophotometric reading at 620 nm (refer to § 7.7).

9. If necessary, remove the adhesive film, empty all the wells by aspiration and wash a minimum of 5 times as described above.
10. Prepare enzymatic development solution (reagent R8 + R9).
11. Quickly distribute 80 µl of prepared enzymatic development solution (R8 + R9) in all the wells. Allow the reaction to develop in the dark for 30 minutes (± 5 min.) at room temperature (18 - 30°C). Do not use adhesive film during this incubation.

REMARK: The distribution of the development solution, which is coloured pink, can be visually controlled. (Refer to § 7.7).

12. Add 100 µl of the stopping solution (R10) using the same sequence and same rate of distribution as for the development solution.

REMARK: Distribution of the colourless stopping solution can be visually controlled at this handling stage. The substrate colour, pink (for negative samples) or blue (for positive samples), fades from the wells, which become colourless (for negative samples) or yellow (for positive samples) after adding stopping solution.

13. Carefully wipe each plate bottom. Wait at least 4 minutes after the stopping solution addition and, within 30 minutes of stopping the reaction, read the optical density at 450/620-700 nm using a plate reader.
14. Check for agreement between the spectrophotometric and visual reading against the plate and sample distribution and identification plan.

7.4. Quality Control

Use positive controls (R4) and the negative control (R3) in each run of test to validate the assay. (Refer to §7.5).

7.5. Test validation criteria

This test is validated if the conditions below are respected:

1. For the negative control R3:

The measured absorbance value must be less than 60% of the cut off:

$$\text{O.D.} < \text{cut off} \times 0.6$$

2. For the antibodies positive control R4:

$$0,800 \leq \text{Mean O.D. R4} \leq 2,700$$

If one of the positive control R4 individual values differs by more than 30% from the mean value, disregard the value and carry out the calculation again with the two remaining positive control values.

7.6. Calculation/Interpretation of results

The cut-off is determined with the R4 positive control:

Calculate the mean measured absorbance value for the positive control R4.

Calculation of the cut off value (CO):

$$\text{CO} = \text{Mean OD R4} \times 0.4$$

The presence or absence of anti-HCV antibodies is determined by comparing the registered absorbency to the calculated cut-off value for each sample.

The following ratio is calculated for each sample:

$$\text{Ratio} = \text{OD of the sample} / \text{CO Value}$$

Samples with an optical density lower than the cut off value are considered to be negative (ratio < 1) by the Monolisa™ Anti-HCV PLUS Version 3.

Results just below the cut-off value ($\text{CO} - 10\% < \text{O.D.} < \text{CO}$, ratio between 0.9 and 1) should however, be interpreted with caution. It is advisable to retest in duplicate the corresponding samples when the systems and laboratory procedures permit.

Samples with optical density greater or equal to the cut off (ratio ≥ 1) are considered to be initially positive by the Monolisa™ Anti-HCV PLUS Version 3. They should be retested in duplicate before final interpretation.

If after retesting the ratio value of at least one of the 2 duplicates is equal to or greater than 1, the initial result is repeatable and the sample is declared to be positive with the Monolisa™ Anti-HCV PLUS Version 3. The ratio values of the 2 duplicates are less than 1, the initial result is non-repeatable and the sample is declared to be negative.

The samples which have been retested twice and found negative with Monolisa™ Anti-HCV PLUS Version 3, but with one value near the cut-off value (ratio between 0.9 and 1) should be considered with care. It is advised to retest the patient with another method or on another sample.

In case of very low optical density for tested samples (negative OD) and when the presence of samples as well as of reagent is controlled, the results can be interpreted as negative.

It is recommended to confirm the positive samples following the current national recommendations and algorithms.

7.7. Spectrophotometric verification of the sample and conjugate pipetting (optional)

Sample diluent (R6) and sample pipetting verification during the first step

The simultaneous presence of (R6) and the sample (or control) may be checked by a spectrophotometric reading at 620 nm.

Each well containing simultaneously (R6) and a sample (or a control) must have an optical density greater than 0.800.

REMARK: after sample addition, the (R6) turns purple to blue.

Conjugate (R7) pipetting verification during the second step

Remark: the conjugate (R7) is coloured green.

The presence of the conjugate (R7) in the wells can be controlled by automatic reading at 620 nm. The OD value of each well must be greater than 0.300 (a value lower than this normally indicates a poor dispensing of the conjugate).

Development solution pipetting verification

It is possible to verify the presence of pink development solution into the well by automatic reading at 490 nm.

A well with development solution must have an optical density greater than 0.100 (a lower OD indicates a poor dispensing of the development solution).

There is a significant colour change for the empty wells from uncoloured to pink after addition of prepared substrate chromogen solution.

8. TEST LIMITATION

Due to the diverse immunological responses of patients infected by the hepatitis C virus (especially during seroconversions), some differences of detection can be observed between tests depending on the type of antigenic proteins used. A negative result during a screening test does not therefore exclude the possibility of exposure to or infection by the hepatitis C virus.

According to the literature, HCV carriers undergoing immunosuppression treatment or coinfecting with HIV-HCV may have particularly low antibody levels, below the detection limit of the HCV tests. Any ELISA technique may produce false positive reactions. It is recommended to check the specificity of the reaction of any sample found to be a repeatable positive, according to the interpretation criteria of the Monolisa™ Anti-HCV PLUS Version 3 kit, using a suitable method: using an ELISA anti-HCV antibody screening test on its own or with an immunoblot anti-HCV antibody detection test to prove the presence of anti-HCV antibodies. If necessary, use a molecular biology test to screen for the HCV genome.

The colorimetric method to check for the deposition of samples and/or conjugate and/or the development solution does not allow the accuracy of the distributed volumes to be checked and only reveals the presence of the sample and/or conjugate and/or the development solution. The rate

of wrong answers with this method is closely linked to the accuracy of the utilized system (accumulated pipetting CVs and readings above 10% may significantly reduce the quality of the verification).

The use of the Monolisa™ Anti-HCV PLUS Version 3 test is not approved for pools of samples or diluted samples.

Fine particles could be seen exceptionally in the sample diluent (R6), their presence in any case not altering the quality of the reagent.

9. PERFORMANCES CHARACTERISTICS

9.1. Precision Measurement

The reproducibility and intermediate precision have been determined using samples with different concentrations of anti-HCV antibodies. The samples were tested 30 times during the same series of tests to determine the repeatability.

The samples were also duplicate tested for 20 days at a rate of 2 tests a day.

The ratio means, standard deviations and Coefficients of Variation (CV) were calculated.

9.1.1. Repeatability

Samples	N	Mean of ratios	Standard deviation	CV %
Negative	30	0.12	0.006	4.5
Weakly positive anti-HCV	30	1.29	0.059	4.6
Weakly positive anti-HCV	30	1.33	0.112	8.4
Strongly positive anti-HCV	30	3.60	0.191	5.3

The CVs obtained on the positive samples are less than 10%.

9.1.2. Intermediate precision

Samples	N	Mean of ratio	Intra assay		Inter assay/operator		Inter day		Total reproducibility	
			SD	CV %	SD	CV %	SD	CV %	SD	CV %
Negative	120	0.13	0.009	7.3	0.011	8.5	0.005	3.9	0.015	11.8
Weakly positive anti-HCV	120	1.40	0.053	3.8	0.119	8.5	0*	N.A	0.130	9.3
Weakly positive anti-HCV	120	1.48	0.082	5.6	0.120	8.1	0*	N.A	0.145	9.8
Strongly positive anti-HCV	120	3.57	0.141	4.0	0.173	4.8	0*	N.A	0.223	6.2

* The negative variance value is estimated at 0.

The CVs obtained on the positive samples are less than 15%.

9.2. Clinical Performance

The performance of the Monolisa™ Anti-HCV PLUS Version 3 has been determined by testing samples from random blood donors, hospitalized patients, patients with acute and chronic infections of the hepatitis C virus, and patients with clinical signs unrelated to infection by the hepatitis C virus. The studies were carried out on 2 blood donor sites, on a hospital site and on the Bio-Rad site.

9.2.1. Diagnostic Specificity

The study was carried out on serum and plasma EDTA samples collected at 2 donor centers on random donors.

A specificity study was also carried out on samples from hospitalized patients.

All the samples were tested with an anti-HCV test with the CE mark.

Table 1: Specificity Test

Population	Site	Type of sample	Number	Initially reactive samples (IR)	Repeated reactive samples (RR)	Specificity (%)	Confidence interval 95%
Blood donors	#1	serum*	2,641*	2	2	2,636/2,638	
	#2	serum	537	1	1	536/537	
		plasma	2002	4	1	2,001/2,002	
	#1 + #2		5,180*	7	4	99.92% 5,173/5,177	99.80 – 99.98
Hospitalized patients	#3	serum	502	0	0	100% 502/502	99.30 – 100.00

* 3 donors found to be indeterminate with the reference test were removed from the calculations.

9.2.2. Diagnostic Sensitivity

The diagnostic sensitivity was studied on 559 samples from patients infected by the hepatitis C virus of which 465 represented different genotypes (1, 2, 3, 4, 5, 6). Among these samples, 25 came from patients sampled in the 24 hours before analysis.

Table 2: Tested genotypes

Genotypes	1 (1, 1a, 1a/b, 1b)	2 (2, 2a/c, 2a, 2b, 2b/3)	3 (3, 3a, 3b, 3c)	4 (4, 4a, 4a/c, 4a/c/d, 4c, 4e, 4h, 4n, 4r)	5 (5, 5a)	6 (6, 6a, 6a/b, 6n)	Total
N	230	51	107	63	8	6	465

The diagnostic sensitivity over all the tested samples is 100% (559/559) with a confidence interval of 95% of [99.3-100%].

Samples from patients with an acute infection:

The clinical sensitivity was also studied on 38 commercial seroconversion panels (including 9 capsid profiles, 10 NS3 profiles and 19 multiple profiles) and compared to a CE-marked test taken as reference.

Among the 38 seroconversions, 1 panel was not detected with Monolisa™ Anti-HCV PLUS Version 3 assay and with the comparison assay.

On the 37 panels detected with Monolisa™ Anti-HCV PLUS Version 3, 11 seroconversions were detected earlier, 25 gave an equivalent detection and one had a late sample.

9.3. Analytical Specificity/Cross Reactivity Study

283 potentially interfering samples containing antibodies against pathogens that could lead to infectious illnesses (cytomegalovirus, Epstein Barr virus, VZV, measles virus, rubella virus, mumps virus, herpes virus, flu virus, hepatitis A virus, hepatitis B virus, HIV 1/2, HTLV 1/2, Syphilis, Toxoplasma gondii, Dengue, Chagas), samples from the at-risk group (dialysis patients, suffering non-hepatic cirrhosis, pregnant women, multiparous women) or samples from patients with immune system disorders (autoantibodies, rheumatoid factors, anti-mouse antibodies, and myelomas) were tested with the Monolisa™ Anti-HCV PLUS Version 3 test.

No sample was found positive with the Monolisa™ Anti-HCV PLUS Version 3 test. The specificity observed on this target population is 100% (283/283), was similar to the specificity of clinical samples.

9.4. Hook effect

The existence of a possible hook effect was studied by testing 5 samples with high titers at different dilutions. The equivalence of results observed among non-diluted and diluted samples indicates the absence of the hook effect.

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Evaluation of two commercial enzyme immunoassays for diagnosis of hepatitis C in the conditions of a virology laboratory.
Pathologie Biologie, 2004, 52 (2004): 511–516.

- (BG) • Този продукт съдържа човешки или животински компоненти. Бъдете внимателни при работа с него.
- (CZ) • Tento výrobek obsahuje lidské nebo zvířecí komponenty. Zacházejte s ním opatrně.
- (DE) • Dieses Produkt enthält Bestandteile menschlichen oder tierischen Ursprungs. Vorsichtig handhaben.
- (DK) • Dette produkt indeholder humane og animalske komponenter. Skal behandles med forsigtighed.
- (EE) • Käesolev toode sisaldab inim-või loomseid komponente. Käsitleda ettevaatlikult.
- (EN) • This product contains human or animal components. Handle with care.
- (ES) • Este producto contiene componentes humanos o animales. Manejar con cuidado.
- (FI) • Tässä tuotteessa on ihmisestä tai eläimestä peräisin olevia osia. Käsittele varovasti.
- (FR) • Ce produit contient des composants d'origine humaine ou animale. Manipuler avec précaution.
- (GR) • Αυτό το προϊόν περιέχει ανθρώπινα ή ζωικά στοιχεία. Χειριστείτε το με προσοχή.
- (HR) • Ovaj proizvod sadrži ljudske ili životinjske sastojke. Pažljivo rukovati.
- (HU) • A készítmény emberi vagy állati eredetű összetevőket tartalmaz. Óvatosan kezelendő.
- (IT) • Questo prodotto contiene componenti umane o animali. Maneggiare con cura.
- (LT) • Šiame produkto yra žmogiskosios arba gyvūninės kilmės sudėtiniai dalys. Elgtis atsargiai.
- (MT) • Dan il-prodott fih komponenti umani jew tal-annimali. Uża b'attenzjoni.
- (NL) • Dit product bevat menselijke of dierlijke bestanddelen. Breekbaar.
- (NO) • Dette produktet inneholder humane eller animalske komponenter. Håndteres med forsiktighet.
- (PL) • Niniejszy produkt zawiera składniki pochodzenia ludzkiego lub zwierzęcego. Należy obchodzić się z nim ostrożnie.
- (PT) • Este medicamento contém componentes de origem humana ou animal. Manuseie com cuidado.
- (RO) • Acest produs conține materiale de origine umană sau animală. Manevrați-l cu grijă.
- (SE) • Denna produkt innehåller beståndsdelar från människa eller djur. Hantera produkten varsamt.
- (SI) • Izdelek vsebuje človeške ali živalske sestavine. Rokujte previdno.
- (SK) • Tento výrobok obsahuje ľudské alebo zvieracie zložky. Narábajte s ním opatrne.



H314 - H317

**P280 - P305+P351+P338 -
P301+P330+P331 -
P303+P361+P353 -
P333+P313 - P501**

(BG)

опасно

Причинава тежки изгаряния на кожата и сериозно увреждане на очите. Може да причини алергична кожна реакция.

Използвайте предпазни ръкавици/предпазно облекло/предпазни очила/предпазна маска за лице. ПРИ КОНТАКТ С ОЧИТЕ: Промийвайте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако има такива и доколкото това е възможно. Продължавайте да промивате. ПРИ ПОГЛЪЩАНЕ: изплакнете устата. НЕ предизвиквайте повръщане. ПРИ КОНТАКТ С КОЖАТА (или косата): Незабавно свалете цялото замърсено облекло. Облейте кожата с вода/вземете душ При поява на кожно дразнене или обрив на кожата: Потърсете медицински съвет/помощ. Изхвърлете съдържанието/контейнера в съответствие с местните/регионалните/националните/международните разпоредби.

(CZ)

Nebezpečí

Způsobuje těžké poleptání kůže a poškození očí. Může vyvolat alergickou kožní reakci.

Používejte ochranné rukavice/ochranný oděv/ochranné brýle/obličejový štít. Při ZASAŽENÍ OČÍ: Několik minut opatrně vyplachujte vodou. Vyměňte kontaktní čočky, jsou-li nasazeny a pokud je lze vyjmout snadno. Pokračujte ve vyplachování. Při POŽITÍ: Vypláchněte ústa. NEVYVOLÁVEJTE zvracení. Při STYKU S KÚŽÍ (nebo s vlasy): Veškeré kontaminované části oděvu okamžitě svlékněte. Opláchněte kůži vodou/osprchujte. Při podráždění kůže nebo vyrážce: Vyhleďte lékařskou pomoc/ošetření. Obsah/nádoba likvidujte v souladu s místními/regionálními/národními/mezinárodními předpisy.

(DE)

Gefahr

Verursacht schwere Verätzungen der Haut und schwere Augenschäden. Kann allergische Hautreaktionen verursachen. Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen. BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. BEI VERSCHLÜCKEN: Mund ausspülen. KEIN Erbrechen herbeiführen. BEI KONTAKT MIT DER HAUT (oder dem Haar): Alle beschmutzten, getränkten Kleidungsstücke sofort ausziehen. Haut mit Wasser abwaschen/duschen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. Entsorgung des Inhalts / des Behälters gemäß den örtlichen / regionalen / nationalen / internationalen Vorschriften.

(DK)

Fare

Forårsager svære forbrændinger af huden og øjenskader. Kan forårsage allergisk hudreaktion. Bær beskyttelseshandsker/beskyttelseshandsker/øjenskyttelse/ansigtsskyttelse VED KONTAKT MED ØJNE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning. I TILFÆLDE AF INDTAGELSE: Skyl munden. Fremkald IKKE

opkastning. VED KONTAKT MED HUDEN (eller håret): Tilmusket tøj tages straks af/fjernes. Skyl/brus huden med vand. Ved hudirritation eller udslæt: Søg lægehjælp. Bortskaffelse af indholdet/beholderen i henhold til de lokale/regionale/nationale/internationale forskrifter.

(EE)

Ettevaatus

Põhjustab rasket nahasöövitust ja silmakahjustusi. Võib põhjustada allergilist nahareaktsiooni.

Kanda kaitsekindaid/kaitserõivastust/kaitseprille/kaitsemaski. SILMA SATTUMISE KORRAL: loputada mitme minuti jooksul ettevõttelikult veega. Eemaldada kontaktläätsed, kui neid kasutatakse ja kui neid on kerge eemaldada. Loputada veel kord. ALLANEELAMISE KORRAL: loputada suud. MITTE kutsuda esile oksendamist. NAHALE (või juustele) SATTUMISE KORRAL: võtta viivitamata kõik saastunud rõivad seljast. Loputada nahka veega/loputada duši all. Nahaärrituse või _obe korral: pöörduda arsti poole. Sisu/konteineri kätlus vastavuses kohalike/regionaalsete/rahvuslike/rahvusvaheliste nõuetega.

(EN)

Danger

Causes severe skin burns and eye damage. May cause an allergic skin reaction.

Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. Dispose of contents/container in accordance with local/regional/national/international regulations.

(ES)

Peligro

Provoca quemaduras graves en la piel y lesiones oculares graves. Puede provocar una reacción alérgica en la piel. Llevar guantes que aislen del frío/gafas/máscara. EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. EN CASO DE INGESTIÓN: Enjuagarse la boca. NO provocar el vómito. EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitarle inmediatamente las prendas contaminadas. Aclararse la piel con agua o ducharse. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido o el recipiente conforme a la reglamentación local/regional/nacional/internacional.

(FI)

Vaara

Voimakkaasti ihoa syövyttävää ja silmiä vaurioittavaa. Voi aiheuttaa allergisen ihoreaktion.

Käytä suojakäsineitä/suojavaateusta/silmiensuojainta/kasvosuojainta. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Poista piilolinssit, _edical voi tehdä helposti. Jatka huuhtomista. JOS KEMIKAALIA ON NIELTY: Huuhdo suu. Ei saa oksennuttaa. JOS KEMIKAALIA JOUTUU IHOLLE (tai hiuksiin): Riisu saastunut vaatetus välittömästi. Huuhdo/suihkuta iho vedellä. Jos ilmenee ihoärsytystä tai ihottumaa: Hakeudu lääkäriin. Säilytä säiliö(t) noudattaen paikallisia/alueellisia/kansallisia/kansainvälisiä määräyksiä.

(FR)

Danger

Provoque des brûlures de la peau et des lésions oculaires graves. Peut provoquer une allergie cutanée.

Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. EN CAS D'INGESTION: rincer la bouche. NE PAS faire vomir. EN CAS DE CONTACT AVEC LA PEAU (ou les cheveux): enlever immédiatement les vêtements contaminés. Rincer la peau à l'eau/se doucher. En cas d'irritation ou d'éruption cutanée: consulter un médecin. Éliminer le contenu/récipient conformément à la réglementation locale/régionale/nationale/internationale.

(GR)

Κίνδυνος

Προκαλεί σοβαρά δερματικά εγκαύματα και οφθαλμικές βλάβες. Μπορεί να προκαλέσει αλλεργική δερματική αντίδραση.

Να φοράτε προστατευτικά γάντια/προστατευτικά ενδύματα/μέσα ατομικής προστασίας για ταμάρτια/πρόσωπο. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΑ ΜΑΤΙΑ: Ξεπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχουν φακοί επαφής, αφαιρέστε τους, εφόσον είναι εύκολο. Συνεχίστε να ξεπλένετε. ΣΕ ΠΕΡΙΠΤΩΣΗ ΚΑΤΑΠΟΙΗΣΗΣ: Ξεπλύνετε το στόμα. ΜΗΝ προκαλέσετε εμετό. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΟ ΔΕΡΜΑ (ή με τα μαλλιά): Αφαιρέστε αμέσως όλα τα μολυσμένα ενδύματα. Ξεπλύνετε το δέρμα με νερό/στο ντους. Εάν παρατηρηθεί ερεθισμός του δέρματος ή εμφανιστεί εξάνθημα: Συμβουλευθείτε/Επισκεφθείτε/επικοινωνήστε με τον γιατρό. Απορρίψτε τα περιεχόμενα/δοχείο σύμφωνα με τους τοπικούς/εθνικούς/διεθνείς κανονισμούς.

(HR)

Pasnost

Uzrokuje teške opекline kože i ozljede oka. Може izazvati алергичку реакцију на кожи.

Nositi заштитне rukavice/заштитну одјелу/заштиту за очи/заштиту за lice. U SLUČAJU DODIRA S OČIMA: опрезно ispirati vodom nekoliko minuta. Ukloniti kontaktne леће ukoliko ih nosite i ako се one lako uklanjaju. Nastaviti ispiranje. AKO SE PROGUTA: ispirati usta. NE izazivati povраćanje. U SLUČAJU DODIRA S KOŽOM (ili kosom): odmah ukloniti/skinuti svu zaganenu одјелу. Isprati коžu vodom/tuširanjem. U slučaju nadražaja ili osipa na koži: zatražiti savjet/pomoć liječnika. Odložite sadržaje /spremnike u skladu s lokalnim/regionalnim/nacionalni/međunarodnim odredbama.

(HU)

Veszély

Smarkiai nudegina odą ir pažeidžia akis. Alergiás bőrreakciót válthat ki.

Védőkesztyű/védőruha/szemvédő/arcvédő használatra kötelező. SZEMBE KERÜLÉS esetén: Több percig tartó óvatos öblítés vízzel. Adott esetben a kontaktlencsék eltávolítása, ha könnyen megoldható. Az öblítés folytatása. LENYELÉS ESETÉN: a szájat ki kell öblíteni. TILOS hánytatni. HA BŐRRE (vagy hajra) KERÜL: Az összes szennyezett ruhadarabot azonnal el kell távolítani/le kell vetni. A bőrt le kell öblíteni vízzel/zuhanyozás. Bőrirritáció vagy kiütések megjelenése esetén: orvosi ellátást kell kérni. Az edény tartalmát / a tartályt a helyi/regionális/nemzeti/nemzetközi szabályozásoknak megfelelően kell hulladékként elhelyezni.

(IT)

Pericolo

Provoca gravi ustioni cutanee e gravi lesioni oculari. Può provocare una reazione allergica cutanea.

Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso. IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. IN CASO DI INGESTIONE: sciacquare la bocca. NON provocare il vomito. IN CASO DI CONTATTO CON LA PELLE (o con i capelli): togliersi di dosso immediatamente tutti gli indumenti contaminati. Sciacquare la pelle/fare una doccia. In caso di irritazione o eruzione della pelle: consultare un medico. Smettere il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

(LT)

Pavojinga

Smarkiai nudegina odą ir pažeidžia akis. Gali sukelti alerginę odos reakciją.

Mūvēti apsauginius pirštines/dėvėti apsauginius drabužius/ naudoti akių (veido) apsaugos priemonės. PATEKUS Į AKIS: Kelias minutes atsargiai plauti vandeniu. Išimti kontaktinius lęšius, jeigu jie yra ir jeigu lengvai galima tai padaryti. Toliau plauti akis. PRARIJUS: išskalauti burną. NESKATINTI vėmimo. PATEKUS ANT ODOS (arba plaukų): Nedelsiant nuvilkti/pašalinti visus užterštus drabužius. Odą nuplauti vandeniu/čiurkšle. Jeigu sudirginama oda arba ją išberia: kreiptis į gydytoją. Turinį/talpą išpilti (išmesti) - šalinti pagal vietines / regionines / nacionalines / tarptautines taisykles.

(NL)

Gevaar

Verouorzaakt ernstige brandwonden en oogletsel. Kan een allergische huidreactie veroorzaken.

Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen. NA INSLIKKEN: de mond spoelen — GEEN braken opwekken. BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken — huid met water afspoelen/afdouchen. Bij huidirritatie of uitslag: een arts raadplegen. De inhoud en de verpakking verwerken volgens de plaatselijke/regionale/nationale/internationale voorschriften.

(NO)

Fare

Forårsaker alvorlige hudforbrenninger og øyeskader. Kan forårsake allergiske hudreaksjoner.

Bruk vernehansker/verneklær/vernebriller/ansiktsskjerm. VED KONTAKT MED ØYNENE: Skyll forsiktig med vann i opptil flere minutter. Fjern evt. kontaktlinser såfremt dette er lett mulig. Fortsett skyllingen. VED SVELGING: Skyll munnen. IKKE fremkall brekninger. VED HUDKONTAKT (eller kontakt med hår): Alle tilsolte klær må fjernes straks. Vask/dusj huden med vann. Ved hudirritasjon eller -utslett: Kontakt / tilkall lege. Innholdet / emballasjen skal avhendes i henhold til de lokale / regionale / nasjonale / internasjonale forskrifter.

(PL)**Niebezpieczeństwo**

Powoduje poważne oparzenia skóry oraz uszkodzenia oczu .
Może powodować reakcję alergiczną skóry.

Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W PRZYPADKU POŁKNIECIA: wypłukać usta. NIE wywoływać wymiotów. W PRZYPADKU KONTAKTU ZE SKÓRĄ (lub z włosami): Natychmiast usunąć/zdjąć całą zanieczyszczoną odzież. Spłukać skórę pod strumieniem wody/prysznicem. W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza. Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi.

(PT)**Perigo**

Provoca queimaduras na pele e lesões oculares graves. Pode provocar uma reacção alérgica cutânea.

Usar luvas de protecção/vestuário de protecção/protecção ocular/protecção facial. SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continuar a enxaguar. EM CASO DE INGESTÃO: enxaguar a boca. NÃO provocar o vómito. SE ENTRAR EM CONTACTO COM A PELE (ou o cabelo): despir/retirar imediatamente toda a roupa contaminada. Enxaguar a pele com água/tomar um duche. Em caso de irritação ou erupção cutânea: consulte um médico. Eliminar o conteúdo/recipiente de acordo com a legislação local/regional/nacional/ internacional.

(RO)**Pericol**

Provoacă arsuri grave ale pielii și lezarea ochilor. Poate provoca o reacție alergică a pielii.

Purtați mănuși de protecție/îmbrăcămintă de protecție/echipament de protecție a ochilor/ chipament de protecție a feței. ÎN CAZ DE CONTACT CU OCHIL: clătiți cu atenție cu apă timp de mai multe minute. Scoateți lentilele de contact, dacă este cazul și dacă acest lucru se poate face cu ușurință. Continuați să clătiți. ÎN CAZ DE ÎNGHIȚIRE: clătiți gura. NU provocați vomă. ÎN CAZ DE CONTACT CU PIELEA (sau părul): scoateți imediat toată îmbrăcămintea contaminată. Clătiți pielea cu apă/faceți duș. În caz de iritare a pielii sau de erupție cutanată: consultați medicul. Aruncați conținutul/containerul în acord cu regulamentele locale/regionale/naționale/internaționale.

(SE)**Fara**

Orsakar allvariga frätskador på hud och ögon. Kan orsaka allergisk hudreaktion.

Använd skyddshandskar/skyddskläder/ögonskydd/ansiktsskydd. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja. VID FÖRTÄRING: Skölj munnen. Framkalla INTE kräkning. VID HUDKONTAKT (även håret): Ta omedelbart av alla nedstänkta kläder. Skölj huden med vatten/duscha. Vid hudirritation eller utslag: Sök läkarhjälp. Innehållet / behållaren avfallshanteras enligt lokala / regionala / nationella / internationella föreskrifter.

(SI)**Nevamo**

Povzroča hude opekline kože in poškodbe oči. Lahko povzroči alergijski odziv kože.

Nositi zaščitne rokavice/zaščitno obleko/zaščitno za oči/zaščitno za obraz. PRI STIKU Z OČMI: previdno izpirajte z vodo nekaj minut. Odstranite kontaktne leče, če jih imate in če to lahko storite brez težav. Nadaljujte z izpiranjem. PRI STIKU Z OČMI: previdno izpirajte z vodo nekaj minut. Odstranite kontaktne leče, če jih imate in če to lahko storite brez težav. Nadaljujte z izpiranjem. PRI STIKU S KOŽO (ali lasmi): takoj odstraniti/sleči vsa kontaminirana oblačila. Izprati kožo z vodo/prho. Če nastopi draženje kože ali se pojavi izpuščaj: poiščite zdravniško pomoč/oskrbo. Vsebinsko/vsebnik odstranite v skladu z lokalnimi/regionalnimi/narodnimi/mednarodnimi predpisi.

(SK)**Nebezpečnostvo**

Provoacă arsuri grave ale pielii și lezarea ochilor. Může vyvolať alergickou kožnou reakci.

Noste ochranné rukavice/ochranný odev/ochranné okuliare/ochranu tváře. PO POŽITÍ: vypláchněte ústa. Nevyvolávejte zvracení. PO POŽITÍ: vypláchněte ústa. Nevyvolávejte zvracení. PRI KONTAKTE S POKOŽKOU (alebo vlasmi): Odstráňte/vyzlečte všetky kontaminované časti odevu. Pokožku ihneď opláchnite vodou/sprchou. Ak sa prejaví podráždenie pokožky alebo sa vytvorí vyrážky: vyhľadajte lekársku pomoc/starostlivosť. Zneškodnenie obsahu/obalu v súlade s miestnymi/oblastnými/národnými/medzinárodnými nariadeniami.

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