

CE Declaration of Conformity

We,
Atlas Medical GmbH
 Head office: Ludwig-Erhard-Ring 3
 15827 Blankenefelde-Mahlow Germany
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 Email: info@atlas-site.com

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 Amman 11512, Jordan
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Declare our responsibility that the following product:

Blood Grouping Reagents:
(Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent , Anti-AB Monoclonal Reagent and Anti-D IgG/IgG blend Reagent)
 see the attached list of variants

That are classified as Annex II, list A

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016
 EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,
 EN 13612:2002, EN 13641:2002 , EN 13975:2003,
 EN ISO 13485:2016, EN 62366-1:2020

And

Intended for In-Vitro Professional use only.

Conformity Assessment Route:

Annex IV.3 –Approval full Quality Assurance System.

Annex IV.4-EC Design Examination (of the product)

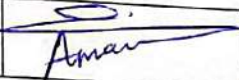
Notified Body:

G-MED	CE	0459
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GMED, Laboratoire national de métrologie et d'essais
 1 rue Gaston Boissier 75015 Paris
 Tél. : 01 40 43 37 00 , TVA:FR 28 839 022 522

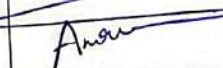
EC Certificates No.:

- CE Certificate of Approval full Quality Assurance System: 33540 rev4.
- CE Certificate Of EC Design Examination: 33544 rev3.

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09 th october 2017	26 th May 2025	Amani Al-habahbeh (RA Manager)		

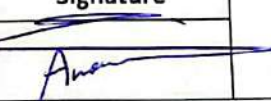


Product Code	Product Name	GMDN Code
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/Carton Box	52532
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 10 vials / Plastic Pack	52532
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 18 vials / Carton Box	52532
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, / Carton Box	52538
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials / Plastic Pack	52538
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials / Carton Box	52538
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/ Carton Box	46442
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials/Plastic Pack	46442
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials/Carton Box	46442
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 1 vial/ Carton Box	52647
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 10 vials / Plastic Pack	52647
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 18 vials / Carton Box	52647
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1 Vial/Carton Box	52532
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials / Plastic Pack	52532
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	52538
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials /Plastic Pack	52538
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)),3x10ml / plastic Pack	45308
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256), 2x10ml /Plastic Pack	52695
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	46442
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,10 vials /Plastic Pack	46442
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,18 vials / Carton Box	45308
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 1Vial/ Carton Box	52647
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 10 vials / Plastic Pack	52647

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature.	MRXDO10F.11 21.10.2013
	09 th october 2017	26 th May 2025	Amani Al-habahbeh (RA Manager)		

8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128)),3x10ml/Plastic Pack	45308
8.02.47.1.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Carton Box.	45308
8.02.47.3.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Plastic Pack	45308
8.02.47.5.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/128)), 3x10ml/Plastic Pack	45308
8.02.49.0.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64)), 4x10ml/Carton Box	45308
8.02.49.2.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/128)), 4 x 10ml, 4 vials/Plastic Pack	45308
8.02.53.0.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml/Plastic Pack	45308
8.02.53.1.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml, 4vials/Plastic Pack	45308
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box	52532
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1/1024) , 10 ml/vial ,1Vial/ Carton Box	52538
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1/1024) , 10 ml/vial , 1Vial/ Carton Box	45308
8.02.85.0.0010	Anti-D IgG/IgM Blend Reagent , Titer 1/256, 10ml/vial, 1Vial/ Carton Box	52647



Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09 th october 2017	26 th May 2025	Amani Al-habahbeh (RA Manager)		

Declaration Ref No: DC21-0035

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3
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Email: info@atlas-medical.com

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.

Tel.: +962 6 4026468

Fax: +962 6 4022588

Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
Certificate N°: 36655 rev 1
Expiry Date: October 8th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And

Intended for In-Vitro Professional use only.

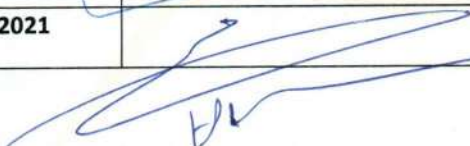
Manufacturer

Atlas Medical

Ludwig-Erhard-Ring 3

Blankenfelde-Mahlow , Germany.



Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10
	March.2021	09.03.2021		08.02.2011

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Product Description
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests
8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).
8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card, stirring sticks.
8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).



CE Declaration of Conformity

Name and address of Manufacturer	Atlas Medical GmbH Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com
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Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.00.19.0.0050	Atlas TPHA Kit , 50 Tests	51819
8.00.19.0.0100	Atlas TPHA Kit , 100 Tests	51819
8.00.19.0.0200	Atlas TPHA Kit , 200 Tests	51819

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
 And

EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
 EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
 EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	06.September.2021
Place	Atlas Medical GmbH
Signed by:	Amani AL-Habahbeh 
Position :	Regulatory Affairs Manager

Atlas Medical GmbH
 Ludwig - Erhard Ring 3
 15827 Blankenfelde - Mahlow
 Tel. (0049) 33708 - 355030

Date: 05/Jan/2023

STATEMENT


We, Atlas Medical having a registered office at Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL Sanmedico having a registered office at A. Corobceanu Street 7A, apt.9, Chisinau MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature: 

Date: 05.01.2023

Atlas Medical GmbH
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Regulatory Office: William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom
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Middle East Site: P.O Box 204, King Abdullah II Industrial Estate, Amman, 11512, Jordan
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ASO LATEX KIT

IVD For in-vitro diagnostic and professional use only



INTENDED USE

ATLAS ASO latex Test is used for the qualitative and semi-quantitative measurement of antibodies to Antistreptolysin-O in human serum.

INTRODUCTION

The group A β -hemolytic streptococci produce various toxins that can act as antigens. One of these exotoxins streptolysin-O, was discovered by Todd in 1932.

A person infected with group A hemolytic streptococci produces specific antibodies against these exotoxins, one of which is antistreptolysin-O. The quantity of this antibody in a patient's serum will establish the degree of infection due to the hemolytic streptococcal.

The usual procedure for the determination of the antistreptolysin titer is based on the inhibitory effect that the patient's serum produces on the hemolytic power of a pre-titrated and reduced streptolysin-O. However, the antigen-antibody reaction occurs independently of the hemolytic activity of streptolysin-O. This property enables the establishment of a qualitative and quantitative test for the determination of the antistreptolysin-O by agglutination of latex particles on slide.

PRINCIPLE

ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample. Visible agglutination occurs when increased antibody level is present in the test specimen.

MATERIALS

MATERIALS PROVIDED

- ASO Latex Reagent: Latex particles coated with streptolysin O, pH, 8.2. Preservative.
- ASO Positive Control (Red cap): Human serum with an ASO concentration > 200 IU/mL. Preservative.
- ASO Negative Control (Blue cap) Animal serum. Preservative
- Glass Slide.
- Stirring Sticks.

Note: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 μ L.
- Glycine Buffer=20x (1000 mmol/l); add one part to nineteen parts of distilled water before use.

Packaging contents

REF 8.00.02.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)

PRECAUTIONS

- All reagents contain 0.1 % (w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40 μ l). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

The ASO Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- DO NOT FREEZE.**
- The ASO Latex Reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagents deterioration: Presence of particles and turbidity.

SAMPLES

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- DO NOT USE PLASMA.**

PROCEDURE

Qualitative method

- Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
- Place (40 μ l) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
- Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (40 μ l) next to the sample to be tested.
- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
- Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

- Make serial two-fold dilutions of the sample in 9 g/L saline solution.

- Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

- Positive and Negative Controls should be included in each test batch.
- Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

CALCULATIONS

The approximate ASO concentration in the patient sample is calculated as follows:

$$200 \times \text{ASO Titer} = \text{IU/mL}$$

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL.

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

REFERENCE VALUES

Up to 200 IU/mL (adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

200 (\pm 50) IU/ml.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

SENSITIVITY

98%.

SPECIFICITY

97%.

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10 g/L)
- Bilirubin (20 mg/dL)
- Lipids (10 g/L)
- Rheumatoid factors (300 IU/mL)
- Other substances may interfere.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the ASO Latex Reagent will result in spontaneous agglutination.

- Intensity of agglutination is not necessarily indicative of relative ASO concentration; therefore, screening reactions should not be graded.
- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 2 years may cause false negative results. A single ASO determination does not produce much information about the actual state of the disease.
- Titration at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES

- Haffjee . Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
- Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.
- Spaun J et al. Bull Wild Hith Org 1961; 24: 271-279.
- The association of Clinical Pathologists 1961. Broadsheet 34.
- Picard B et al. La Presse Medicale 1983; 23: 2-6.
- Klein GC. Applied Microbiology 1971; 21: 999-1001.
- Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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PPI2325A01

Rev A (05.01.2023)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL	Positive control	CONTROL	Negative control

CRP LATEX KIT

IVD For *in-vitro* diagnostic and professional use only

2-8°C Store at 2-8°C.



INTENDED USE

CRP Latex kit is used to measure the CRP in human serum qualitatively and semi-quantitatively.

INTRODUCTION

C-reactive protein (CRP), the classic acute-phase of human serum, is synthesized by hepatocytes. Normally, it is present only in trace amounts in serum, but it can increase as much as 1,000-fold in response to injury or infection. The clinical measurement of CRP in serum therefore appears to be a valuable screening test for organic disease and a sensitive index of disease activity in inflammatory, infective and ischemic conditions. MacLeod and Avery found that antibody produced against purified CRP provided a more sensitive test than the C-polysaccharide assay. Since that time a number of immunological assays have been devised to measure CRP such as capillary precipitation, double immunodiffusion and radical immunodiffusion.

The CRP reagent kit is based on the principle of the latex agglutination assay described by Singer and Plotz. The major advantage of this method is the rapid two (2) minute reaction time.

PRINCIPLE

The CRP reagent kit is based on an immunological reaction between CRP Antiserum bound to biologically inert latex particles and CRP in the test specimen. When serum CRP equal or greater than the Reagent sensitivity (indicated on the label of the latex vial) the visible agglutination occurs.

MATERIALS

MATERIALS PROVIDED

- CRP Latex Reagent: Latex particles coated with goat IgG anti-human CRP (approximately 1%), pH 8.2 MIX WELL BEFORE USE.
- CRP Positive Control Serum (Red Cap): A stabilized pre-diluted human serum containing >20mg/L CRP.
- CRP Negative Control Serum (Blue Cap): A stabilized pre-diluted animal serum.
- Glass Slides.
- Stirring Sticks.
- Package Insert.

- Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.

The presence of agglutination indicates a CRP concentration equal or greater than the reagent sensitivity (mg/L CRP) (indicated on the label of the latex vial).

The titer, in semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate CRP concentration in the patient sample is calculated as follows:

Sensitivity (indicated on the label of the latex vial)
 \times CRP Titer = mg/L

INTERFERENCES

NONE INTERFERING SUBSTANCES:

- Hemoglobin (10 g/dl)
- Bilirubin (20 mg/dl)
- Lipids (10 g/L)
- Other substances interfere, such as RF (100IU/ml).

NOTE

- High CRP concentration samples may give negative results. Retest the sample again using a drop of 20 μ l.
- The strength of agglutination is not indicative of the CRP concentration in the samples tested.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds two (2) minutes, drying of the reaction mixture may cause false positive results.
- Freezing the CRP Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, screening reactions should not be graded.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 μ L.
- Glycine Buffer 20X (1000 mmol/L): add one part to nineteen parts of distilled water before use.

PACKAGING CONTENTS

REF 8.00.00.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)

PRECAUTIONS

- All reagents contain 0.1 % (w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For *In Vitro* diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40 μ l). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

- A false negative can be attributed to a prozone phenomenon (antigen excess). It is recommended, therefore, to check all negative sera by retesting at a 1:10 dilution with glycine buffer.

REFERENCE VALUES

Up to the reagent sensitivity (indicated on the label of the latex vial). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

- Sensitivity:** Refer to vial label.
- Prozone effect:** No prozone effect was detected up to 1600 mg/L
- Diagnostic sensitivity:** 95.6 %
- Diagnostic specificity:** 96.2 %

REFERENCES

- Pepys, M.B., Lancet 1:653 (1981).
- Werner, M., Clin.Chem. Acta 25:299 (1969).
- MacLeod, C.M., et. al., J. Exp. Med 73:191 (1941).
- Wood, H.F., et. al., J. Clin. Invest. 30: 616 (1951).
- Mancini, G., et. al. Immunochemistry 2:235 (1965).
- Singer, J.M., et. al., Am. J. Med 21: 888 (1956).
- Fischer, C.L., Gill, C.W., In Serum Protein Abnormalities. Boston, Little, Brown and Co., (1975).

REAGENT PREPARATION:

The CRP Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2 - 8°C).
- DO NOT FREEZE.**
- The CRP latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagents deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- Do not use plasma.

PROCEDURE

A. QUALITATIVE TEST:

- Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
- Place (40 μ L) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
- Mix the CRP-latex reagent vigorously or on a vortex mixer before using and add one drop (40 μ L) next to the samples to be tested.
- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
- Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

B. SEMI-QUANTITATIVE TEST:

- Make serial two-fold dilutions of the sample in 9 g/L saline solution.

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 Website: www.atlas-medical.com

PPI237A01
 Rev A (05.01.2023)

	Catalogue Number		Temperature limit
	<i>In Vitro</i> diagnostic medical device		Caution
	Contains sufficient for <math>n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
	Positive control		Negative control

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité / Effective date October 9th, 2023 (included)

Valable jusqu'au / Expiry date : October 8th, 2026 (included)

Etabli le / Issued on : October 9th, 2023

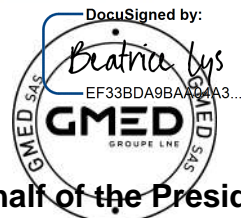


CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 36655-2

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-1



On behalf of the President
Béatrice LYS
Technical Director

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

**ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY**

French version:

Siège social, responsable de la mise sur le marché

English version:

Headquarter, legal manufacturer

**Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN**


French version:

Conception, fabrication et contrôle final

English version:

Design, manufacture and final control

2 sites / 2 sites

DocuSigned by:
Beatrice Lys
FF33BDA80AA04A3...


**On behalf of the President
Béatrice LYS
Technical Director**

Blood Grouping Reagents:

Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent, Anti-AB Monoclonal Reagent, Anti-D IgG/IgM blend Reagent, & Their variants SLIDE AND TUBE TESTS

IVD For In-Vitro and professional use only

Store at 2- 8°C

INTENDED USE

The blood grouping reagents are used to detect the presence or absence of A, B or Rhesus Antigens on the surface of human red blood cells based on hemagglutination using slide or tube test techniques in whole blood samples or anticoagulant blood samples collected in EDTA, citrate or heparin tubes.

INTRODUCTION & PRINCIPLES

Blood grouping reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines. The reagents are diluted with phosphate buffer containing sodium chloride, EDTA and bovine albumin to give reagents that are optimized for use in tube and slide procedures. **Anti-A monoclonal reagent is colored with acid blue (patent blue) dye, Anti-B monoclonal reagent is colored with acid yellow (tartrazine) dye, and Anti-AB monoclonal reagent is not colored.** The test procedure is based on hemagglutination principle, where red cells possessing the antigen agglutinate in the presence of the corresponding antibody indicating that the result is positive. The test is considered negative when no agglutination appears.

Anti-D IgG/IgM blend reagent is prepared from carefully blended human monoclonal IgM and IgG. Anti-D IgG/IgM blend reagent is suitable for slide and tube test procedures. The reagent will directly agglutinate Rh D positive cells, including majority of variants (but not D^{VI}) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D^{VI} and low grade weak D (D^{VI}) phenotypes by the indirect anti-globulin techniques.

Anti-D IgG/IgM blend reagent is diluted with a sodium chloride solution, sodium phosphate solution and bovine albumin (sodium caprylate free). Anti-D IgG/IgM blend reagent is not colored. The procedure is based on hemagglutination principle, where red cells' possessing the antigen agglutinates in the presence of the corresponding antibody in the reagent indicating that the result is positive. The test is considered negative when no agglutination appears.

MATERIALS

MATERIALS PROVIDED

Blood Grouping Reagents:

- Anti-A monoclonal reagent (10 ml/vial), Clone: (9113D10).
- Anti-B monoclonal reagent (10 ml/vial), Clone: (9621A8).
- Anti-AB monoclonal reagent (10ml/vial), Clone: (152D12+9113D10).
- Anti-D IgG/IgM Blend reagent (10 ml/vial), Clone: (P3X61 + P3X21223B10 + P3X290 + P3X35).

MATERIALS NEEDED BUT NOT PROVIDED

- Plastic test tube or glass.
- Isotonic saline solution (% 0.9) NaCl).
- Applicator sticks.
- Centrifuge (100-1200 (g) for tube test).
- Timer.
- Incubator
- Anti-Human Globulin Reagent (can be ordered from Atlas Medical).
- White or transparent glass slide.

PRECAUTIONS

- The reagents are intended for in vitro diagnostic use only.
- The test is for well trained professional healthy user not for lay user.
- These reagents are derived from animal and human sources, thus, appropriate care must be taken in the use and disposal of these reagents, as there are no known test methods that can guarantee absence of infectious agents.
- Do not use reagents if it is turbid or contain particles as this may indicate reagent deterioration or contamination.
- Protective clothing should be worn when handling the reagents.
- **The reagents contain (0.1-0.2%) Sodium Azide and 0.02% sodium arseniate which is toxic and can be absorbed through the skin. When drained, the drains should be thoroughly flushed with water.**
- The reagents should be used as supplied and in accordance to the procedure mentioned below. Don't use beyond expiration date.
- Avoid cross contamination of reagents or specimens.
- Visible signs of microbial growth in any reagent may indicate degradation and the use of such reagent should be discontinued.

- Don't use these reagents if the label is not available or damaged.
- Do not use dark glass slide.
- Don't use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and the test table top with water and soap once the testing is done.
- Hemolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well lit area with very good visibility.
- Failure to follow the procedure in this package insert may give false results or safety hazard.
- Close the vial tightly after each test.
- The reagent is considered toxic, so don't drink or eat beside it.
- If spillage of reagent occurs clean with disinfectant (disinfectant used could be irritable so handle with care).

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 - 8°C.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

REAGENT PREPARATION

- The reagents are intended for use as supplied, no prior preparation or dilution of the reagent is required.
- All reagents should be brought to room temperature before use.

SPECIMEN COLLECTION AND PREPARATION

- Blood collected with or without anticoagulant (EDTA, Heparin or Citrate) can be used for Antigen typing.

Note: Blood collected without anticoagulant should be tested immediately.

- The specimens should be tested as soon as possible after collection. If testing is delayed, the specimens should be stored at 2- 8 °C. Sample must be retained to room temperature prior to analysis. (Testing should be carried out within five days of collections).
- Insure that there is no sign of hemolysis.
- At the time of the test, centrifuge the blood sample at 1200 RCF for 3 minutes.
- Blood collection is to be done with great care.

PROCEDURES

A. DIRECT TUBE METHOD AT ROOM TEMPERATURE

1. Prepare a 5% suspension of red blood cells in isotonic solution.
2. Using the vial dropper, transfer a drop (40±10µl) of each reagent into a separate and appropriately marked tube.
3. Add 50 µl of red blood cell suspension prepared in step 1.
4. Shake to homogenize the mixture, then centrifuge at 500g for **1 minute**.
5. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
6. Read the reaction immediately.
7. For Anti-D tube, if the reaction is weak or negative, shake the tubes and incubate at 37°C for **15 minutes**.
8. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
9. Add one drop (50µl) of the AHG reagent into the tube. Mix and centrifuge at 120g for **1 minute**.
10. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
11. Read the reaction immediately.

B. ANTIGLOBULIN INDIRECT METHOD for ANTI-D

1. After immediately centrifuging and reading as above, if the reaction is weak or negative, shake the tubes and incubate at 37°C for 15 minutes.
2. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
3. Add one drop (40 µl ± 10 µl) of ANTI-HUMAN GLOBULIN to the tube. Mix and centrifuge at 120 (g) for **1 minute**.
4. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
5. Read the reaction immediately.

C. DIRECT SLIDE METHOD AT ROOM TEMPERATURE

1. Bring reagents and samples to room temperature (18-25°C).
2. Using the wax pen divide the slide into appropriate numbers of divisions.
3. Using the provided dropper, place one drop (40 µl ± 10 µl) of each reagent onto its correspondent division on the slide.
4. Add 25µl of the precipitated cells next to each drop of reagents.
5. Mix the reagent and the cells using a clean stirring stick over an area with a diameter of approximately 20-40mm.
6. Incubate the slide at room temperature (18-25°C) without stirring for **30 seconds**.
7. Hold the slide and gently rock the slide for **3 minutes** and observe macroscopically for any agglutination.
8. Read the reaction immediately.

READING THE RESULT

POSITIVE: If Agglutination appears.

NEGATIVE: If no agglutination is observed.

Use the below table to determine the blood group:

Result of each reaction				ABO Group
Anti-A monoclonal reagent	Anti-B monoclonal reagent	Anti-AB monoclonal reagent	Anti-D IgG/IgM blend reagent	
+	-	+	+	A+
+	-	+	-	A-
-	+	+	+	B+
-	+	+	-	B-
+	+	+	+	AB+
+	+	+	-	AB-
-	-	-	+	O+
-	-	-	-	O-

STABILITY OF THE REACTIONS

- ABO Blood Grouping Tube tests should be read immediately following centrifugation.
- Slide tests should be interpreted within three minutes to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of reagents.
- Delay in reading and interpreting results may result in weekly positive or falsely negative reactions. Slide tests should be interpreted at the end of the three minutes.

PROCEDURE LIMITATION

- False positive/ negative results may occur due to:
 - Contamination from test materials.
 - Improper storage, cells concentration, incubation time or temperature.
 - Improper or excessive centrifugation.
 - Deviation from the recommended technique.
 - Blood samples of weak A or B subgroups may give rise to false negative results or weak reactions when tested using slide test method. It is advisable to re-test weak subgroups using tube test method.
- Weaker reactions may be observed with stored blood than with fresh blood.
- ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
- ABO blood grouping interpretation on individuals greater than 6 months old should be confirmed by testing serum or plasma of the individual against group A and group B red cells (reverse grouping). If the results obtained with the serum do not correlate with the red cell test, further investigation is required.
- Return the kit to the agent if it does not function properly.
- Anti-D IgG/IgM blend Reagent tests conducted on particular weak-D phenotypes, while satisfactory, cannot ensure recognition of all weak variants, due to the variability of antigen patterns.

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

The following tables compare the results in slide and tube techniques of 3 lots of Atlas Medical reagents and the results of a CE marked device.

Slide Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
232	232	232	232	100%
Tube Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
212	212	212	212	100%

Slide Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				

CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%
Tube Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%

Slide Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
241	241	241	241	100%
Tube Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
243	243	243	243	100%

Slide Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
33	33	33	33	100%
Tube Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
24	24	24	24	100%

No inversion in diagnosis has been shown: from a qualitative point of view we have observed 100% compliance in direct group testing in slide and tube techniques for determination of A, B, AB and O groups for the three lots of Atlas Medical.

QUALITY CONTROL

The reactivity of all blood grouping reagents should be confirmed by testing known positive and negative red blood cells on each day of use. To confirm the specificity and sensitivity, Blood grouping reagents should be tested with antigen-positive and antigen-negative red blood cells.

REFERENCES

1. BCSH Blood Transfusion Task Force. Guidelines for microplate techniques in liquid-phase blood grouping and antibody screening. Clin. Lab. Haem 1990; 12, 437-460.
2. Issitt P. D. Applied Blood Group Serology, 3rd ed. Miami: Montgomery Scientific, 1985.
3. Kholer G., Milstein C. Continuous culture of fused cells secreting antibody of predefined specificity, 256, 495-497, 1975
4. Messeter L. et. al. Mouse monoclonal antibodies with anti-A, anti-B and anti-A,B specificities, some superior to human polyclonal ABO reagents, Vox Sang 46, 185-194, 1984
5. Race R.R. and Sanger R. Blood groups in man, 6th ed., Oxford: Blackwell Scientific, 1975.
6. Voak D. ET. al., Monoclonal anti-A and anti-B development as cost effective reagents. Med. Lab. Sci 39, 109-122. 1982.



LIST OF VARIANTS:

Product Code	Product Name
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/ Carton Box
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials / Plastic Pack
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials / Carton Box
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, / Carton Box
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials / Plastic Pack
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials / Carton Box
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/ Carton Box
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials/Plastic Pack
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials/ Carton Box
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 1 vial/ Carton Box
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 10 vials / Plastic Pack
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 18 vials / Carton Box
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1 Vial/ Carton Box
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials / Plastic Pack
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/ Carton Box
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials /Plastic Pack
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1 /256), Anti-D (1/64)), 3x10ml / plastic Pack
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1 /256), 2x10ml /Plastic Pack
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/ Carton Box
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials /Plastic Pack
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 18 vials / Carton Box
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 1Vial/ Carton Box
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 10 vials / Plastic Pack
8.02.47.0.0030	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-D (1 /128)), 3x10ml/Plastic Pack
8.02.47.1.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Carton Box.
8.02.47.3.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Plastic Pack
8.02.47.5.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /128)), 3x10ml/Plastic Pack
8.02.49.0.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /64)), 4x10ml/ Carton Box
8.02.49.2.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /128)), 4 x 10ml, 4 vials/Plastic Pack
8.02.53.0.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml/Plastic Pack
8.02.53.1.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml, 4vials/Plastic Pack
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial ,1Vial/ Carton Box
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial , 1Vial/ Carton Box
8.02.85.0.0010	Anti-D IgG/IgM Blend reagent (Titer 1 /256), 10ml/vial, 1Vial/ Carton Box

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

RF LATEX KIT

IVD For In-Vitro diagnostic and professional use only

Store at 2-8°C



INTENDED USE

Atlas RF latex test for the qualitative and semi-quantitative measurement of RF in human serum.

INTRODUCTION

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.

One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz. The major advantage of this method is rapid performance (2-minutes reaction time) and lack of heterophile antibody interference.

PRINCIPLE

The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs.

MATERIALS

MATERIALS PROVIDED

- RF Latex Reagent: Latex particles coated with human gamma-globulin, pH, 8.2. Preservative.
- RF Positive Control Serum (Red Cap): Human serum with a RF concentration > 30 IU/ML. Preservative.
- RF Negative Control Serum (Blue Cap): Animal serum. Preservative.
- Glass Slide
- Stirring sticks

NOTE: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.

- Pipettes 50 µL
- Glycine Buffer 20x (1000mmol/L): add one part to nineteen parts of distilled water before use.

Packaging contents

REF 8.00.04.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)

PRECAUTIONS

- All reagents contain 0.1 % (w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

- The RF Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- Do not freeze.

- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- The RF latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Reagents deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- Do not use PLASMA.

PROCEDURE

Qualitative method

- Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
- Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
- Mix the RF-latex reagent rigorously or on a vortex mixer before using and add one drop (40 µL) next to the sample to be tested.
- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
- Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

- Make serial two-fold dilutions of the sample in 9 g/L saline solution.
- Proceed for each dilution as in the qualitative method.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates a RF concentration equal or greater than 8 IU/mL (Note 1).

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate RF concentration in the patient sample is calculated as follows:

$$8 \times \text{RF Titer} = \text{IU/mL}$$

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10g/L)
- Bilirubin (20mg/dl)
- Lipids (10g/L)

Other substances may interfere.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

8 (6-16) IU/mL, under the described assay conditions.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/mL.

DIAGNOSTIC SENSITIVITY

100%.

DIAGNOSTIC SPECIFICITY

100%.

The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the RF Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.

- Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcoidosis, lupus erythematosus, Sjogren's syndrome.

- Certain patients with rheumatoid arthritis will not have the RF present in their serum.

- The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.

- Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

REFERENCE VALUES

Up to 8 IU/mL. Each laboratory should establish its own reference range.

NOTES

- Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

REFERENCES

- Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1 - 21.
- Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951-960.
- Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 - 534.
- Adalbert F. Schubart et al. The New England Journal of Medicine 1959; 261: 363 - 368.
- Charles M. Plotz 1956; American Journal of Medicine; 21:893 - 896.
- Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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PPI2326A01

Rev A (05.01.2023)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
V	Contains sufficient for \leq tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL	Positive control		Negative control

TPHA TEST KIT

For the detection of antibodies to *T.pallidum* in human Serum using micro haemagglutination.

IVD For In-Vitro diagnostic and professional use only

2°C 8°C
Store at 2° to 8° C

INTENDED USE

TPHA test kit is designed for the detection of antibodies to *Treponema pallidum* (IgG and IgM antibodies) in human serum or plasma based on the principle of passive haemagglutination.

INTRODUCTION

Syphilis is a venereal disease caused by the spirochaete micro-organism *Treponema pallidum*. As this organism cannot be cultured on artificial media the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody demonstrated by serological tests. Serological screening tests for syphilis using cardiolipin and lecithin as antigens are simple to perform but biological false positive (BFP) reactions occur frequently because the tests use non-treponemal antigens.

The TPI and FTA-ABS tests utilize pathogenic *Treponema pallidum* as the antigen but these tests present some difficulties for routine serodiagnosis. The TPI test requires living pathogenic *T.Pallidum* and the FTA-ABS test requires a fluorescence microscope. Both tests require a high level of expertise.

TPHA test kit has been shown to be a convenient and specific test for the diagnosis of treponemal infection, having specificity similar to that of the TPI test and sensitivity comparable to that of the FTA-ABS test. It requires minimum laboratory equipment and is very simple to perform. TPHA reagents are used to detect human serum antibody to *T.pallidum* by means of an indirect haemagglutination (IHA) method. Preserved avian erythrocytes are coated with antigenic components of pathogenic *T.pallidum* (Nichol's strain). These Test Cells agglutinate in the presence of specific antibodies to *T.pallidum*, and show characteristic patterns in microtitration plates.

Any non-specific reactions occurring are detected using the Control Cells, which are avian erythrocytes not coated with *T.pallidum* antigens. Non-specific reactions may also be absorbed out using these Control Cells. Antibodies to non-pathogenic treponemes are absorbed by an extract of Reiter's treponemes, included in the cell suspension. Test results are

obtained in 45-60 minutes and the cell agglutination patterns are both easily read and long lasting.

The test sample is diluted in absorbing diluent to remove possible cross-reacting heterophile antibody and to remove, block, or absorb potentially cross-reacting. Nonpathogenic treponemal antibodies.

MATERIALS

MATERIALS PROVIDED

- Test cells; preserved avian erythrocytes sensitised with *T.pallidum* antigen.
- Control cells; preserved avian erythrocyte.
- Diluent.
- Positive control serum; (prediluted 1:20), Use neat. This will give an equivalent titer of 1/640:/2560 in the quantitative test.
- Negative control serum; (prediluted 1:20), Use neat.
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Accurate pipettes for delivering 10:25:75 and 190 microlitres.
- U-Well microtitration plates.

PRECAUTIONS

The reagents and controls contain 0.1% sodium azide as a preservative. Avoid ingestion and contact with skin or mucus membrane. Normal laboratory precautions should be maintained while handling test reagents.

REAGENTS HANDLING

- All the reagents must be allowed to reach room temperature before use.
- Do not freeze any of the reagents.
- Do not use heamolysed, contaminated or lipaemic serum or plasma for testing as this will adversely affect the results.

REAGENTS STORAGE

- The kit should be stored at 2-8° C in an upright position at all times.
- Under these conditions, kit performance characteristics will be maintained for at least 15 or 18 months from date of manufacture. See expiry date on kit label.
- Reagents should be discarded if they become contaminated or do not demonstrate correct activity with the controls.
- The reagents in each kit have been standardized to produce the proper reaction and reagents should not be interchanged with those from other batches.

SAMPLE PREPARATION

- The test is designed for use with serum only.

- Plasma samples should not be used.
- The samples should be free from haemolysis and contamination.
- Serum samples may be stored at 2-8° C if a preservative is added prior to storage.
- For long term storage sera should be stored at -20° C Strictly avoid contaminating any of the reagents or serum dilutions with saliva. This will cause confusing patterns similar to positive results with specimens which should be negative.

PROCEDURES

QUALITATIVE METHOD

Each sample requires 3 wells of a microtitration plate.

1. Add 190µl of diluent to Well 1.
2. Add 10µl serum to Well 1. (Sample dilution 1:20).
3. Using a micropipette, mix contents of Well 1 and transfer 25µl to Wells 2 & 3.
4. Ensure that the Test and Control Cells are thoroughly resuspended. Add 75µl of control cells to Well 2. Add 75µl of Test Cells to Well 3.
5. Tap the plate gently to mix the contents thoroughly.
6. Incubate 45-60 minutes at room temperature.
7. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
8. Read results. Results are stable for 24hrs if the plate is covered and the above precautions are observed.

NOTE

Kit controls can be run in parallel and are diluted and ready for use.

QUANTITATIVE TEST

Each sample requires 8 Wells of a microtitration plate, Labeled A through to H.

1. Add 25µl of diluent to Wells B to H inclusive.
2. Transfer 25µl of 1:20 serum dilution from screening test to Wells A and B.
3. Take 25µl of diluted serum from Well B and serially dilute from Wells B to H inclusive in 25µl aliquots, discarding 25µl of diluted serum from Well H.
4. Ensure that the Test Cells are thoroughly resuspended. Add 75µl of Test cells to wells A to H inclusive. This will give a dilution of serum of 1/ 80 in well A through 1/ 10240 Well H.
5. Shake the plate gently to mix the contents thoroughly.
6. Incubate for 45-60 minutes at room temperature.
7. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
8. Read results. Results are stable for 24hrs. if the plate is covered and the above precautions are observed.

RESULTS

RESULTS	TEST CELLS	CONTROL CELLS
Strong Positive	Full cell pattern covering the bottom of the well.	No agglutination tight button
Weak Positive	Cell pattern covers approx. 1/3 of well bottom	No agglutination tight button
Indeterminate	Cell pattern shows a distinctly open center	No agglutination tight button
Negative	Cells settled to a compact bottom, typically with a small clear center.	No agglutination tight button
Non-specific *	Positive reaction	Positive reaction

Non-specific absorption *

1. Add 10µl to a small tube then add 190µl of Control Cells. Mix well and stand for 30 minutes.
2. Centrifuge for 15 minutes at 1000 rpm and test the supernatant by the qualitative method.

Note:

If the result is repeatedly non-specific the sample should be tested by another method eg. Reagin or FTA-ABS.

Although TPHA test is highly specific, **false positive results** have been known to occur in patients suffering from leprosy, infectious mononucleosis and connective tissue disorders. For confirmation FTA-ABS test should be used.

INTERPRETATION OF RESULTS.

Strong positive reactions may show some folding at the edge of the cell mat.

When the Test well is positive, the Control well should be observed. The Control cells should settle to a compact button. They should not be used as a comparison for Non-Reactive serum patterns since the Control Cells will give a more compact pattern than the Test Cells.

Weak positive may show partially not full cell pattern cover the well bottom

INVALID may show Agglutination in the Control well indicates the presence of non-specific agglutinins in the sample. A serum that gives this result may be absorbed using the Control Cells as detailed under Non-specific absorption.

INDETERMINATE may show a doubtful reaction with Test Cells This result may indicate a low level of antibody in early primary syphilis or yaws. This sample should be first retested in the qualitative test then a further sample should be tested at a later date to determine whether or

not there is a rising titer. It is also advisable to perform a regain test and/or another confirmation test (FTA-ABS) to complete the profile of the test serum.

Negative may show cells settled as a dot at the bottom of the well

PERFORMANCE

SENSITIVITY

With clinical samples when compared to FTA-ABS and/or clinical diagnosis was 99.7% (298/299)

SPECIFICITY

With clinical samples was 99.3% (301/303).

CROSS REACTIVITY

Reactive results may indicate an active or successfully treated infection. The following have all been shown not to interfere with the test results (10 clinical samples of each)

- Rheumatoid Factor.
- Post Hepatitis B vaccination.
- Genital Herpes.
- Leptospirosis.
- EBV Infection.
- SLE.
- Lyme's Disease.

REFERENCES:

1. Rathlev T. - Haemagglutination tests utilizing antigens from pathogenic and apathogenic Treponema pallidum WHO/VDT/RES 1965 ; 77 : 65.
2. Tomizawa T, Kasamatsu S. - Haemagglutination tests for diagnosis of syphilis. A preliminary report. Japan. J. Med. Sci. Biol. 19, 305-308, 1966.
3. Rathlev T. - Haemagglutination test utilizing pathogenic Treponema pallidum for the serodiagnosis of syphilis. Br J Vener Dis 1967 ; 43 : 181-5.
4. Tomizawa T. Kasamatsu S. Yamaya S. - Usefulness of the haemagglutination test using Treponema pallidum antigen (TPHA) for the serodiagnosis of syphilis. Jap J Med Sci Biol 1969; 22: 341-50.
5. Sequeira P, J, L. Eldridge A, E. – Treponemal Haemagglutination test. Br J Vener Dis 1973; 49: 242-8.
6. Larsen S.A., Hambie E.A., et coll., Specificity, sensitivity and reproducibility among the fluorescent treponemal antibody absorption test, the microhemagglutination assay for Treponema pallidum antibodies, and the hemagglutination treponemal test for syphilis. J. Clin. Microbiol., 1981 ; 14 : 441 – 445.
7. Houg H. - Syphilis: new diagnostic directions. Intern. J. STD and AIDS 1992; 3: 391-413.
8. Sluis J.J. Van Der. - Laboratory Techniques in the diagnosis of syphilis: a review. Genitourin Med. 1992; 68 : 413-9.



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PPI080A01

Rev F (09.06.2016)

REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		



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bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 092378 0009 Rev. 00

Manufacturer:

**Healgen Scientific Limited
Liability Company**

3818 Fuqua Street
Houston TX 77047
USA

Product:

Screening test for Hepatitis C marker

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7_092378_0009_Rev.00

Report No.:

713234651

Valid from:

2022-04-22

Valid until:

2025-05-26

Date,

2022-04-22

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
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 www.zlg.de
 ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate
 Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 092378 0009 Rev. 00

Model(s):	HCV Hepatitis C Virus Rapid Test	
Facility(ies):	Zhejiang Orient Gene Biotech Co., Ltd. 3787#, East Yangguang Avenue, Dipu Street Anji, 313300 Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA	
Parameters:	Model Name:	Model No.:
	--	
	HCV Hepatitis C Virus Rapid Test (Serum / Plasma) (Cassette)	GCHCV-302a
	HCV Hepatitis C Virus Rapid Test (Whole Blood /Serum / Plasma) (Cassette)	GCHCV-402a



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG038
Version 2.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402a
Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: *Shanghai International Holding Corp. GmbH (Europe)*

EC Representative's Address: *Eiffestrasse 80, 20537 Hamburg, Germany*

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: August 11, 2020

Name of authorized signatory: *Joyce Pang*
Position held in the company: *Vice-President*



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG039
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

H. pylori Ag Rapid Test Strip (Feces)	GCHP-601a
H. pylori Ag Rapid Test Cassette (Feces)	GCHP-602a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President



Certificate

No. Q5 092305 0001 Rev. 01

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_092305_0001_Rev_01)

Report No.: SH2198802

Valid from: 2022-04-11

Valid until: 2024-03-16

Date, 2022-04-11



Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Troponin I

Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.¹ Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.² After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.³ cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.⁴ Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.⁵

PRINCIPLE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region. During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane.

Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

- For professional In Vitro diagnostic use only.
- Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Do not use it if the tube/pouch is damaged or broken.
- Test is for single use only. Do not re-use under any circumstances.
- Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolyzed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Disposable Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Clock or Timer

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.

- Transfer 2 drops of serum or plasma to the specimen well of the device with a disposable pipette provided in the kit, and then start the timer.

OR

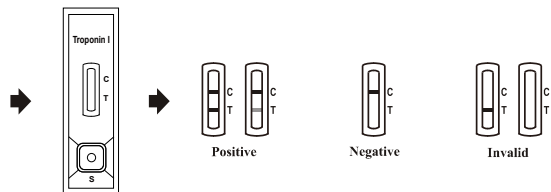
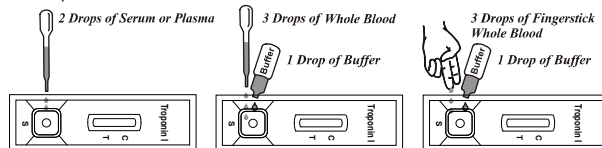
Transfer 3 drops of whole blood specimen to the specimen well of the device with a disposable pipette provided in the kit, then add 1 drop of buffer, and start the timer.

OR

Allow 3 hanging drops of fingerstick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer, and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane.

- Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded.

Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
- Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.
- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of tuberculosis.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
- Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Test vs. EIA

Method	Troponin I Rapid Test Device		Total Results	
	Results	Positive		Negative
EIA	Positive	138	2	140
	Negative	1	315	316
Total Results		139	317	456

Relative Sensitivity: 98.6% (94.9%-99.8%)*

Relative Specificity: 99.7% (98.3%-99.9%)*

Overall Agreement: 99.3% (98.1%-99.9%)*

*95% Confidence Interval

BIBLIOGRAPHY

- Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88: 750-763, 1993.
- Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
- Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
- Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
- Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.

H. pylori Ag Rapid Test Cassette (Feces)



INTENDED USE

H. pylori Ag Rapid Test Cassette (Feces) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of H. Pylori antigen in feces. It is for professional *in vitro* diagnostic use only.

INTRODUCTION

H. Pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis.^{1,2} The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer.³ H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses^{4,5,6} which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence.⁷

PRINCIPLE

H. pylori Ag Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antibodies conjugated with color particles (H. Pylori conjugates). 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. Pylori antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antigen of H. Pylori if present in the specimen will bind to the H. Pylori antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibodies, forming a burgundy colored T band, indicating a H. Pylori antigen positive test result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRODUCT CONTENTS

H. pylori Ag Rapid Test Cassette (Feces) containing anti- H. pylori antibodies particles and anti-H. pylori antibodies coated on the membrane.

MATERIALS SUPPLIED

- 20 Sealed pouches each containing a test cassette and a desiccant
- 20 Specimen collection tubes with extraction buffer, 2.0 mL
- 1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Specimen collection containers.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use it if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Humidity and temperature can adversely affect results

SPECIMEN COLLECTION

Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

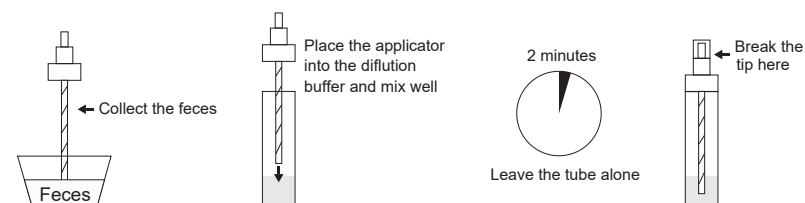
To process fecal specimens:

• For Solid Specimens:

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

• For Liquid Specimens:

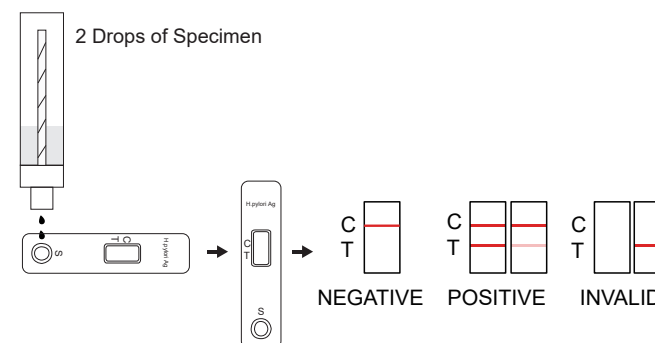
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.



TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 2 drops (~80 µL) of the sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results in 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS



H. pylori Ag Rapid Test Cassette (Feces)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of H. Pylori antigen in feces from individual subjects. Failure to follow the procedure may give inaccurate results.

2. H. pylori Ag Rapid Test Cassette (Feces) is limited to the qualitative detection of H. Pylori antigen in feces. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.

3. A negative result for an individual subject indicates absence of detectable H. Pylori antigen. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.

4. A negative result can occur if the quantity of the H. Pylori antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.

5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

A study was performed with 165 patient feces samples including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal feces samples. Comparison for all subjects with H. pylori Ag Rapid Test Cassette (Feces) and reference ELISA kit is showed in the following table:

Method		EIA		Total Results
H.P Test Cassette	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative sensitivity: 98.8%

Relative specificity: 100%

Accuracy:98.9%

REFERENCE

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia.149:439-44, 1985.

2. Marshall,B.J.et.al. Prospective double-blind trial of duodenal ulcer relapse after eradication of Campylobacter pylori. Lancet. Dec.1437-42,1988.

3. Megraud,F.et.al. Seroepidemiology of Campylobacter pylori infection in virious populations J.Clin.Microbiology. 27:1870-3,1989.

4. Soll,A.H. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.322:909-916,1990.

5. Parsonnet,J.et.al. Helicobacter pylori infection and the risk of gastric carcinoma. New England J.Med. 325:1127-31,1991.

6. Ansong,R. et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J.Clin.Micro. 29:51-53,1991.

7. Pronovost,A.P.et.al. Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J.Clin.Microbiol.32:46-50,1994.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#



Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China.
TEL: +86-572-5226111 FAX: +86-572-5226222
Website: www.orientgene.com

Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

GCHP-602a

Revision Date: 2022-03-08
B20435-03

HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)

INTENDED USE

The HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- Hepatitis C virus (HCV) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the HCV Ab Rapid Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens^(1, 2). Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests^(3, 4).

HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in whole blood, serum or plasma.

PRINCIPLE

The HCV Ab Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antigen-sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated HCV antigens, forming a burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRODUCT CONTENTS

HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) containing HCV antigen coated particles and HCV antigen coated on the membrane.

MATERIALS SUPPLIED

1. Test Strip 2. Pipette Dropper 3. Desiccant 4. Buffer 5. Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only) 4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to

prevent azide build-up.

3. Do not use it if the tube/pouch is damaged or broken.

4. Test is for single use only. Do not re-use under any circumstances.

5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.

6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

7. Humidity and temperature can adversely affect results .

SPECIMEN COLLECTION

1. The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

2. To collect Fingerstick Whole Blood specimens:

• Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.

• Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

• Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.

• Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

• Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:

• Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.

• Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.

• Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:

• Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.

• Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device or, move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).

3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test device on a clean and level surface.

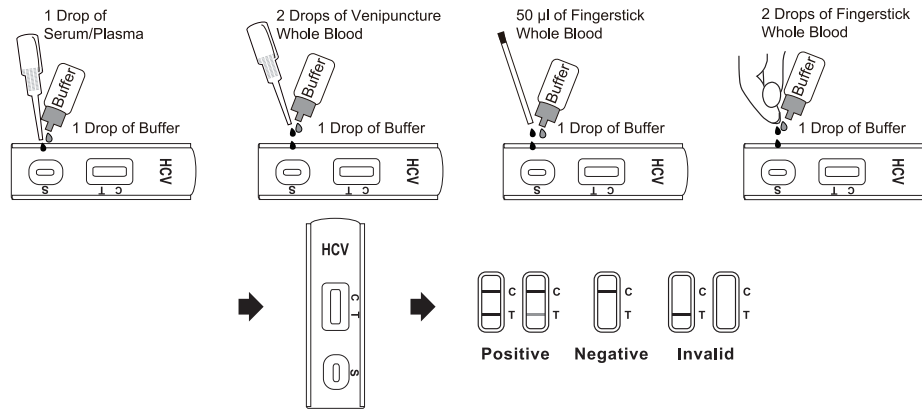
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

(please refer to the illustration above)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative: One colored line appears in the control line region (C). No line appears in the test line region (T).

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The HCV Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.
2. The HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.
5. A negative result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

PERFORMANCE CHARACTERISTICS

Sensitivity: HCV Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) has passed a seroconversion panel and compared with leading commercial HCV EIA test using clinical specimens.

Specificity: The recombinant antigens used for HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) are encoded by genes for both structural (nucleocapsid) and non-structural proteins. HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is highly specific for antibodies to Hepatitis C Virus compared with a leading

commercial HCV EIA test.

The HCV Ab Rapid Test Cassette vs EIA test

Method		EIA		Total Results
		Positive	Negative	
HCV Ab RapidTest	Results			
	Positive	105	19	124
	Negative	2	1760	1762
Total Results		107	1779	1886

Relative sensitivity: 98.1%

Relative specificity: 98.9%

Accuracy: 98.9%

REFERENCE

1. Choo, Q.L., G.Kuo,A.J. Weiner, L.R. Overby,D.W. Bradley, andM. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome Science 189;244:359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiolog Virus of human non-A, non-B hepatitis. Science 1989; 244:362.
3. Van der Poel, C.L., H.T.M. Cuyper, H.W. Reesink, and P.N. Lelie .Confirmation of hepatitis C Virus infection by new four- antigen recombinant immunoblot assay. Lancet 1991;337:317
4. Wilber, J.C.Development and use of laboratory tests for hepatitis C infection: a review.J. Clin. Immunoassy 1993;16:204.

DICHIARAZIONE DI CONFORMITA'
Conformity declaration



Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/manufacturer

SYNTESYS S.a.s. di Rinaldo R. & C.

indirizzo/address

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

o rappresentante il mandatario autorizzato entro la Unione Europea
or representing the authorized mandatary within the European Community

Mandatario autorizzato/authorized mandatary

indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsibility that the product:*

Denominazione/Description

Padella per ammelati, urinali uomo e donna, speculum vaginali, tamponcini cotonati, tamponi sterili in provetta, tamponi sterili con terreno Amies e Stuart in provetta/ *Bed pan, Urinal's man and woman, Vaginal speculum, Cotton swab, Sterile swab in test tube, Sterile swab with medium Amies or Stuart in test tube*

Materiale/Material

Polipropilene, Polietilene, Legno/ *Polypropylene, Polyethylene, Wood*

È conforme alle disposizioni della direttiva 93/42/CE e s.m.i. concernente i dispositivi medici ed al Decreto Legislativo di recepimento con D.lgs. del 24/02/1997 n° 46/97 e soddisfa a tutti i requisiti specificati.

Il dispositivo è stato classificato appartenente alla classe I° secondo i criteri stabiliti in base a quanto previsto dall'Art. 9 ed allegato IX della direttiva sopra citata /*It meets the EC Directive 93/42 about Medical Device, specifications established by the Italian law n 46/97, dated 24th February 1997. The device was classified as belonging to the 1st class, according to the specifications of the established by the art.9, IX enclosure of the above mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/ *declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07.01.2016
Issued on January 7th 2016

SYNTESYS S.A.S.
Il legale rappresentante
Rinaldo Ruggero



SYNTESYS



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DICHIARAZIONE DI CONFORMITA'
Conformity declaration



Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/manufacturer

SYNTESYS S.a.s. di Rinaldo Ruggero & C.
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indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsibility that the product:*

Denominazione degli
articoli
prodotti/*Description of
Manufacturer*

Contenitori per urina, contenitori per feci,
contenitori universali, Pipette Pasteur, Piastre di
Petri, Anse Sterili per batteriologia, Aste a "L",
Puntali Eppendorf gialli e blue, cuvette per
spettrofotometro, tazzine per campionamento siero,
bacchette per distacco ed estrazione del coagulo,
pinzette in polistirolo monouso, provette monouso in
plastica, tappi alettati per provette diam. 12 mm e
16mm, provette con granuli ed acceleratore, provette
sottovuoto per prelievo, Sistema SEDIPLAST,
Microprovette, Portavetrini, Vetrini precolorati,
Portaprovette, supporti per microprovette, bottiglie
per raccolta urine.

*Urine container, faeces container, universal
container, Pasteur pipette, Petri dishes, Sterile
loops, Sterile loops open "L", Eppendorf tips yellow
and blue, cuvettes for spectrophotometer, samples
cups, Rod to detach clot, disposable forceps,
Disposable plastic tubes, winged stoppers for tubes
diam. 12mm & 16mm, Test tube with granules and clot
activator, vacuum test tube, SEDIPLAST system,
micro test tubes, Slides Mailer, "TESTSIMPLETS" slide
rack for test tubes, rack for micro test tubes,
Bottles for urine collection.*



SYNTESYS



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Materiale/Material

**Polipropilene, Polistirolo, Polietilene e
Polimetilmetacrilato**

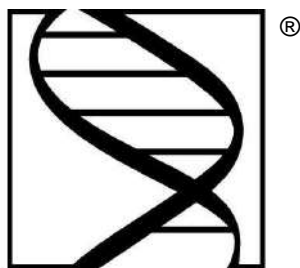
***Polypropylene, Polystyrene, Polyethylene and
Polymethylmetacrylate***

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnostic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/declares that all technical documents attached to this conformity statement are filed in our company and can be consulted by any authorized body on demand.

Data 07/01/2016
Issued on January 7th 2016

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero



SYNTESSYS



Cert. N.7111/3



Cert. N.6574/3



SYNTESSYS S.R.L. UNIPERSONALE

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PEC POSTA@PEC.SYNTESSYS.IT

DICHIARAZIONE DI CONFORMITA' UE
EU Declaration of conformity



Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

fabbricante/manufacturer

SYNTESSYS S.r.l.

indirizzo/address

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O rappresentante il mandatario autorizzato entro la Unione Europea
or representing the authorized mandatary within the European Community

Mandatario autorizzato/authorized mandatary

indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsibility that the product:*

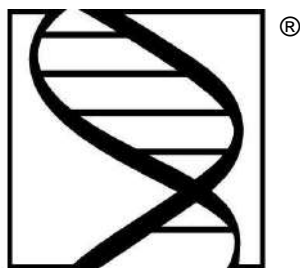
Denominazione/ <i>Description</i>	Puntali azzurri tipo Eppendorf da 201 a 1000 µl / Blue tips EPPENDORF type 201-1000 µl
Codice/ <i>Code</i>	318172
Classe di rischio / <i>Risk class</i>	Classe A / Class A
Numero di registrazione unico (SRN) / <i>Unique registration number (SRN)</i>	IT-MF-000027856
UDI-DI di base / <i>Basic UDI-DI</i>	805414149PUNTALITY

È conforme secondo il Regolamento (UE) 2017/746 concernente i Dispositivi Medico-Diagnostici in vitro e soddisfa tutti i requisiti specificati. Il dispositivo è stato classificato appartenente alla Classe A secondo la Regola 5 dell' Allegato VIII /
It complies with the Regulation (EU) 2017/746 concerning In Vitro Diagnostic Medical Devices and meets all the specified requirements. The device has been classified as belonging to Class A according to Rule 5 of Annex VIII.

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà messa a disposizione delle autorità competenti secondo quanto prescritto dall'Art. 10 punto 7 del Regolamento. / *It also declares that the technical documentation supporting this declaration of conformity is kept at the company offices and will be made available to the competent authorities in accordance with the provisions of Art. 10 point 7 of the Regulations.*

Teolo (PD), 26.05.2022

SYNTESSYS S.R.L.
UNIPERSONALE
Il Legale Rappresentante
Rinaldo Ruggero



SYNTESYS



Cert. N.7111/2



Cert. N.6574/2



SYNTESYS S.R.L. UNIPERSONALE

VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
C.F./P.I./N.REG.IMP. PADOVA 03573950288
REA PD-320123 - CAP.SOC. 20.700,00€
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT
PEC POSTA@PEC.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'

Conformity declaration



Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/manufacturer

SYNTESYS S.r.l.

indirizzo/address

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea
or representing the authorized mandatary within the European Community

Mandatario autorizzato/authorized mandatary

indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsibility that the product:*

Denominazione/Description	Microprovette tipo Eppendorf in polipr. coniche graduate 1,5 ml c/tappo /Polypropylene microtubes Eppendorf type conical graduated with cap vol. 1,5 ml	
Lotto/Lot	21184378	Data di scadenza/expiry date 06.2026
Codice/Code	318766	
Materiale/Material	Polipropilene/ Polypropylene	
Confezione/Pack	10.000 pezzi/10.000 pcs.	

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnostic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/ *declares that all technical documents attached to this conformity statement are filed in our company and can be consulted by any authorized body on demand.*

Data 09.09.2021

SYNTESYS S.R.L.
UNIPERSONALE
Il Legale Rappresentante
Rinaldo Ruggero

Certificate

CISQ/ICIM S.P.A. has issued an IQNet recognized certificate that the organization:

SYNTESYS S.R.L.

Head Office and Operative Unit

Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)

Operative Units

Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)

Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD)

Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a/an

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **2022-06-05**

First issued on: **2013-06-05**

Expires on: **2025-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: **IT-83562**



Alex Stoichitoiu
President of IQNET



Mario Romersi
President of CISQ



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IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
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Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea
LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Certificate

CISQ/ICIM S.P.A. has issued an IQNet recognized certificate that the organization:

SYNTESYS S.R.L.

Head Office and Operative Unit

Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)

Operative Units

Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)

Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD)

Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a/an

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2022-06-05**

First issued on: **2014-06-21**

Expires on: **2025-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: **IT-93779**



Alex Stoichitoiu
President of IQNET



Mario Romersi
President of CISQ



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea
LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



Zhejiang Orient Gene Biotech Co., LTD

CERTIFICATE OF ANALYSIS

Product Name: H. pylori Ag Cassette (Feces) (Cassette)

Catalog NO.: GCHP-602a

Purchase NO.: 2023-IEU078#

Lot NO.: 2305067

Quantity: 4000 pcs

Expiration Date: 2025 04

CONTROLS	SPECIFICATION	TEST RESULT	CONCLUSION
Negative Specimens	Negative	Negative	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Specimens	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail



Conclusion: Pass: All results meet QC standard.

Fail

Test by :

QC Supervisor:

Date: 2023.05.10



文件复审批准日期
2020年09月14日

文件复审批准日期
2022年08月25日

文件编号/Doc. No. :QC-M0111F-01

版本号/Version:2.0

生效日期/Effective Date:2018年10月25日

Page 1 of 1

HCV Hepatitis C Virus Rapid Test (whole blood/serum/plasma)(Cassette) (CE)
Final Products inspection Report (Certificate of Analysis)

Item	HCV Hepatitis C Virus Rapid Test(whole blood/serum/plasma) (Cassette) Catalog No:GCHCV-402a	Specification	Cassette
Lot No.	2305069	Quantity	1500 tests
Source From	Workshop	Inspection Basis	HCV Hepatitis C Virus Rapid Test(whole blood/serum/plasma)(Cassette)Finished Product Quality Standards and Inspection SOP(CE)
Validity Date	2025.04	Date of Sampling	2023.05.10

Inspection Item		Acceptance Standard	Results
Functional Requirement : S-1 (AQL:2.5)	P1(20-22)	T line should be $\geq G7$ at 15 min.	Conformity <input checked="" type="checkbox"/> / Non-Conformity <input type="checkbox"/>
	P2(12-14)	T line should be $\geq G6$ at 15 min.	Conformity <input checked="" type="checkbox"/> / Non-Conformity <input type="checkbox"/>
	P3(6-8)	T line should be $\geq G5$ at 15 min.	Conformity <input checked="" type="checkbox"/> / Non-Conformity <input type="checkbox"/>
	P4(1-3)	T line signal should be $G4 \leq T \leq G6$ at 15 min.	Conformity <input checked="" type="checkbox"/> / Non-Conformity <input type="checkbox"/>
Functional Requirement : / 100 negative serum		T line should be $\leq G2$ at 15 min. C line should be visible $\geq G3$ within 3 min,and should be $\geq G7$ at 15 min. Note: when negative Serum/Plasma moving over T line, T line should be $< G5$ and fade within 3 min. If doing this, it is qualified. If not, it is unqualified	Conformity <input checked="" type="checkbox"/> / Non-Conformity <input type="checkbox"/>
Functional Requirement: S-2 AQL:1.0 clinical whole blood specimens		Membrane background is clean at 15min, not impacting reading results.	Conformity <input checked="" type="checkbox"/> / Non-Conformity <input type="checkbox"/>
Pouch Leakage tightness S-2 (AQL=0.65) Remarks:N/A		Leakage tightness is good	Conformity <input checked="" type="checkbox"/> / Non-Conformity <input type="checkbox"/>
Conclusion: Conformity <input checked="" type="checkbox"/> / Non-Conformity <input type="checkbox"/>			
Tester/Date: 查妍 2023.05.10		Reviewer/Date: 雷伙愚 2023.05.10	



Certificate of Analysis for Blood Grouping Kit

1- Product Identification:

Product Name : Anti-A Reagent	Catalog No. (Variant Code) : 8.02.04.5.0010	Item Dispense #:484	Minimal Titer Accepted: (1/256)
Lot #: 23012910	Mfg. Date: NA	Exp. Date: 01.2025	

2- Sampling Plan:

Date	QC Test Method Used	Inspection level	AQL	Determine the following by referring to Sampling Plan Sheet			
				Sample Size Code Letter	Sample Size (Test QTY)	Accepted	Rejected
02.02.2023	F13D	Physical Inspection: S-I	1.0	B	3	0	1
02.02.2023	F13D	Biochemical Inspection: One sample	Not Applicable				

3- Physical Check:

Applicable Test Type	Inspected Item and/or Criteria	Inspection Results
➤ Kit Assembly:	All components of the kit are present according to the outer label	■ Pass □ Fail
➤ Item Color & Status:	Anti-A: Blue – Liquid	■ Pass □ Fail
	Anti-B: Yellow – Liquid	□ Pass □ Fail
	Anti-D: Yellowish – Liquid	□ Pass □ Fail
	Anti-AB: Yellowish – Liquid	□ Pass □ Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A 10 ml	■ Pass □ Fail
	Anti-B	□ Pass □ Fail
	Anti-D	□ Pass □ Fail
	Anti-AB	□ Pass □ Fail
➤ Labels:	Correct label orientation	■ Pass □ Fail
	Correct label position	■ Pass □ Fail
	Clear printing	■ Pass □ Fail
➤ Package Insert:	Clear printing and correct folding	■ Pass □ Fail
	Correct code, version and brand as mentioned in Item Dispense	■ Pass □ Fail
	Address as mentioned on box design	■ Pass □ Fail
➤ Closing Cap:	No leakage and closed well	■ Pass □ Fail
➤ Dropper Coloring / Titer (CE Blood Grouping):	Anti A (High titer (1/512): Blue cap with black bulb	□ Pass □ Fail
	Anti A (Low titer (1/256): Blue cap with grey bulb	□ Pass □ Fail
	Anti B (High titer (1/512): Yellow cap with black bulb	□ Pass □ Fail
	Anti B (Low titer (1/256): Yellow cap with grey bulb	□ Pass □ Fail
	Anti AB (High titer (1/512): Grey cap with black bulb	□ Pass □ Fail

	Anti AB (Low titer (1/256): Grey cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Black cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (None CE Blood Grouping):	Anti A (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): White cap with white bulb	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Gray cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (Real Titer (256) / Non CE Blood Grouping):	Anti A (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Function:	Able to withdraw the reagent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: ...(2/1).....	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify	
Done by QC Officer/Supervisor (Sign.): ... <i>razan</i> Date: ...02.02.2023 Time: 10:22.....		

4- Biochemical Check:

A. Direct Slide Method: Interpret the results by referring to Table (01)

Pipette #:138				Pipette Code: E20PIQ138			
Anti A		Anti -B		Anti-AB		Anti-D	
A (lot No:731000		B (Lot no:))		AB (Lot no:))		O+(Lot no:))	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
1 sec	+4						
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify					
Done by QC Officer/Supervisor (Sign.): ... <i>razan</i> Date: .02.02.2023..... Time: 10:13.....							

B. Sensitivity test

Pipette #: 139			Pipette Code:E20PIQ139							
Type of Test			Anti-A		Anti-B		Anti-AB		Anti-D	
Sensitivity	Tube Test Method	Type of Cell Suspension	A (Lot no: 730000)		B (Lot no:))		A (Lot no:)) B (Lot no))		O+ (Lot no:))	
		Result	1:2	+4	1:2		1:2		1:2	
			1:4	+3	1:4		1:4		1:4	
			1:8	+3	1:8		1:8		1:8	
			1:16	+2	1:16		1:16		1:16	
			1:32	+2	1:32		1:32		1:32	
			1:64	+2	1:64		1:64		1:64	

			1:128	+1	1:128		1:128		1:128	
			1:256	+1	1:256		1:256		1:256	
			1:512	-ve	1:512		1:512		1:512	
			1:1024	-ve	1:1024		1:1024			

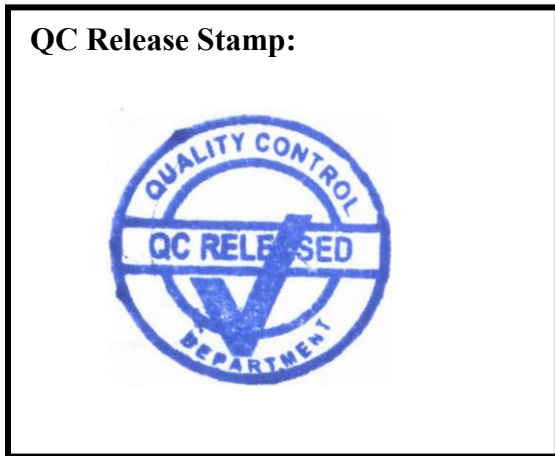
➤ Final Result: Pass Fail; justify

Done by QC Officer/Supervisor (Sign.): *razan* Date: 02.02.2023 Time: 10:15

Table (01)			
Blood Grouping Reagents	Control Cell	Reaction Time	Agglutination Strength
Anti-A	A - Cell	Up to 3 second	+4
Anti-B	B-Cell	Up to 3 second	+4
Anti-AB	A B-Cell	Up to 3 second	+3/+4
Anti -D	O RH positive cell	Up to 5 second	+3

Final Conclusion: Pass Fail

Final QC Manager Approval (Signature): *Tasneem* **Date:** 02.02.2023



Certificate of Analysis for Blood Grouping Kit

1- Product Identification:

Product Name : Anti-AB Reagent	Catalog No. (Variant Code) : 8.02.06.1.0010	Item Dispense #:1070	Minimal Titer Accepted: (1/256)
Lot #: 23031513	Mfg. Date: NA	Exp. Date: 03.2025	

2- Sampling Plan:

Date	QC Test Method Used	Inspection level	AQL	Determine the following by referring to Sampling Plan Sheet			
				Sample Size Code Letter	Sample Size (Test QTY)	Accepted	Rejected
22.03.2023	F13D	Physical Inspection: S-I	1.0	B	3	0	1
22.03.2023	F13D	Biochemical Inspection: One sample	Not Applicable				

3- Physical Check:

Applicable Test Type	Inspected Item and/or Criteria	Inspection Results
➤ Kit Assembly:	All components of the kit are present according to the outer label	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status:	Anti-A: Blue – Liquid NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B: Yellow – Liquid NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D: Yellowish – Liquid NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB: Yellowish – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-B NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D NA	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-AB 10 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in Item Dispense	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (CE Blood Grouping):	Anti A (High titer (1/512): Blue cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): Blue cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): Yellow cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): Yellow cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (High titer (1/512): Grey cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

	Anti AB (Low titer (1/256): Grey cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Black cap with grey bulb	<input type="checkbox"/> Pass <input checked="" type="checkbox"/> Fail
➤ Dropper Coloring / Titer (None CE Blood Grouping):	Anti A (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): White cap with black bulb	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): White cap with white bulb	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Gray cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (Real Titer (256) / Non CE Blood Grouping):	Anti A (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Function:	Able to withdraw the reagent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: ...(2/1).....	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify	
Done by QC Officer/Supervisor (Sign.): <i>Foga</i> Date: 22.03.2023.. Time: 14:10.....		

4- Biochemical Check:

A. Direct Slide Method: Interpret the results by referring to Table (01)

Pipette #:138				Pipette Code: E20PIQ138			
Anti A		Anti -B		Anti-AB		Anti-D	
A (lot No:)		B (Lot no:)		AB (Lot no: 734000)		O+(Lot no:)	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
NA	NA	NA	NA	2 sec	+3	NA	NA
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify					
Done by QC Officer/Supervisor (Sign.): <i>razan</i> Date: 22.03.2023..... Time: 14:03.....							

B. Sensitivity test

Pipette #: 139			Pipette Code:E20PIQ139							
Type of Test			Anti-A		Anti-B		Anti-AB		Anti-D	
Sensitivity	Tube Test Method	Type of Cell Suspension	A (Lot no:)		B (Lot no:)		A (Lot no: 733000) B (Lot no:)		O+ (Lot no:)	
		Result	1:2	NA	1:2	NA	1:2	+4	1:2	NA
			1:4	NA	1:4	NA	1:4	+3	1:4	NA
			1:8	NA	1:8	NA	1:8	+3	1:8	NA
			1:16	NA	1:16	NA	1:16	+2	1:16	NA
			1:32	NA	1:32	NA	1:32	+2	1:32	NA
			1:64	NA	1:64	NA	1:64	+2	1:64	NA

			1:128	NA	1:128	NA	1:128	+1	1:128	NA
			1:256	NA	1:256	NA	1:256	+1	1:256	NA
			1:512	NA	1:512	NA	1:512	-ve	1:512	NA
			1:1024	NA	1:1024	NA	1:1024	-ve		

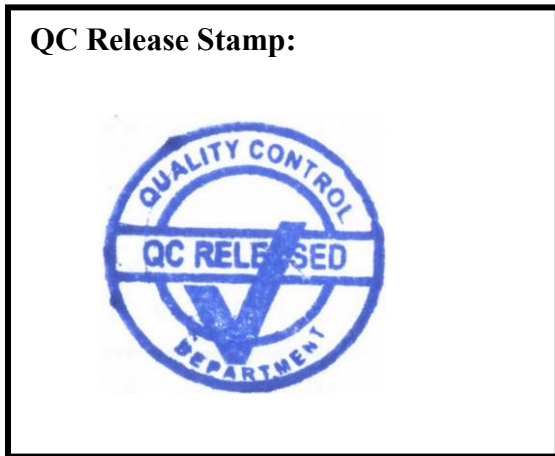
➤ Final Result: Pass Fail; justify

Done by QC Officer/Supervisor (Sign.): *razan* Date: 22.03.2023 Time: 14:05

Table (01)			
Blood Grouping Reagents	Control Cell	Reaction Time	Agglutination Strength
Anti-A	A - Cell	Up to 3 second	+4
Anti-B	B-Cell	Up to 3 second	+4
Anti-AB	A B-Cell	Up to 3 second	+3/+4
Anti -D	O RH positive cell	Up to 5 second	+3

Final Conclusion: Pass Fail

Final QC Manager Approval (Signature): *Tasneem* **Date:** 22.03.2023



Certificate of Analysis for Blood Grouping Kit

1- Product Identification:

Product Name : Anti-B Reagent	Catalog No. (Variant Code) : 8.02.05.9.0100	Item Dispense #:551	Minimal Titer Accepted: (1/256)
Lot #: 23020110	Mfg. Date: NA	Exp. Date: 12.2024	

2- Sampling Plan:

Date	QC Test Method Used	Inspection level	AQL	Determine the following by referring to Sampling Plan Sheet			
				Sample Size Code Letter	Sample Size (Test QTY)	Accepted	Rejected
09.02.2023	F13D	Physical Inspection: S-I	1.0	A	2	0	1
09.02.2023	F13D	Biochemical Inspection: One sample	Not Applicable				

3- Physical Check:

Applicable Test Type	Inspected Item and/or Criteria	Inspection Results	
➤ Kit Assembly:	All components of the kit are present according to the outer label	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Item Color & Status:	Anti-A: Blue – Liquid	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti-B: Yellow – Liquid	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti-D: Yellowish – Liquid	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti-AB: Yellowish – Liquid	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Anti-A	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti-B	10 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti-D	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti-AB	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Labels:	Correct label orientation	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Correct label position	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Clear printing	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Package Insert:	Clear printing and correct folding	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Correct code, version and brand as mentioned in Item Dispense	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Address as mentioned on box design	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Closing Cap:	No leakage and closed well	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
➤ Dropper Coloring / Titer (CE Blood Grouping):	Anti A (High titer (1/512): Blue cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti A (Low titer (1/256): Blue cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti B (High titer (1/512): Yellow cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti B (Low titer (1/256): Yellow cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
	Anti AB (High titer (1/512): Grey cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	

	Anti AB (Low titer (1/256): Grey cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Black cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (None CE Blood Grouping):	Anti A (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): White cap with white bulb	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Gray cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (Real Titer (256) / Non CE Blood Grouping):	Anti A (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Function:	Able to withdraw the reagent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: ...(11/1).....	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify	
Done by QC Officer/Supervisor (Sign.): <i>Toga</i> Date: 09.02.2023.. Time: 12:45.....		

4- Biochemical Check:

A. Direct Slide Method: Interpret the results by referring to Table (01)

Pipette #:138				Pipette Code: E20PIQ138			
Anti A		Anti -B		Anti-AB		Anti-D	
A (lot No:)		B (Lot no: 731000)		AB (Lot no:)		O+(Lot no:)	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
		2 sec	+4				
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify					
Done by QC Officer/Supervisor (Sign.): <i>rajan</i> Date: 09.02.2023..... Time: 11:30.....							

B. Sensitivity test

Pipette #: 139			Pipette Code:E20PIQ139							
Type of Test			Anti-A		Anti-B		Anti-AB		Anti-D	
Sensitivity	Tube Test Method	Type of Cell Suspension	A (Lot no:)		B (Lot no:730000)		A (Lot no:) B (Lot no)		O+ (Lot no:)	
		Result	1:2		1:2	+4	1:2		1:2	
			1:4		1:4	+3	1:4		1:4	
			1:8		1:8	+3	1:8		1:8	
			1:16		1:16	+2	1:16		1:16	
			1:32		1:32	+2	1:32		1:32	
			1:64		1:64	+2	1:64		1:64	

			1:128		1:128	+1	1:128		1:128	
			1:256		1:256	+1	1:256		1:256	
			1:512		1:512	-ve	1:512		1:512	
			1:1024		1:1024	-ve	1:1024			

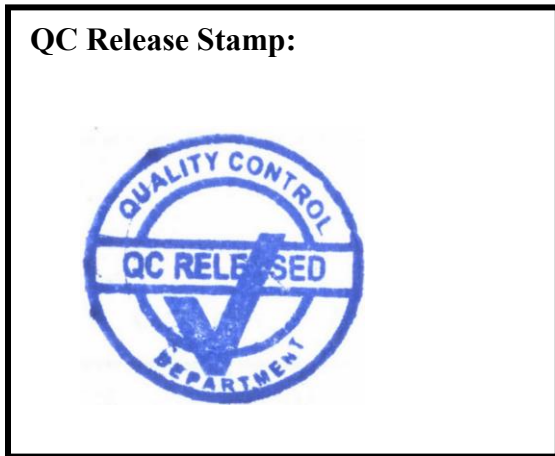
➤ Final Result: Pass Fail; justify

Done by QC Officer/Supervisor (Sign.): *raza* Date: ..09.02.2023..... Time: ..11:33.....

Table (01)			
Blood Grouping Reagents	Control Cell	Reaction Time	Agglutination Strength
Anti-A	A - Cell	Up to 3 second	+4
Anti-B	B-Cell	Up to 3 second	+4
Anti-AB	A B-Cell	Up to 3 second	+3/+4
Anti -D	O RH positive cell	Up to 5 second	+3

Final Conclusion: Pass Fail

Final QC Manager Approval (Signature): *Tasneem* **Date:** 09.02.2023



	Anti AB (Low titer (1/256): Grey cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Black cap with grey bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (None CE Blood Grouping):	Anti A (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti A (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (High titer (1/512): White cap with black bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (Low titer (1/256): White cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (High titer (1/128): Black cap with white bulb	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti D (Low titer (1/64): Gray cap with white bulb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Coloring / Titer (Real Titer (256) / Non CE Blood Grouping):	Anti A (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti B (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
	Anti AB (White cap with white bulb)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Dropper Function:	Able to withdraw the reagent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label • Record the QTY/Kit: ...(2/1).....	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify	
Done by QC Officer/Supervisor (Sign.): ... <i>razan</i> Date: .02.02.2023. Time: .10:28.....		

4- Biochemical Check:

A. Direct Slide Method: Interpret the results by referring to Table (01)

Pipette #:138				Pipette Code: E20PIQ138			
Anti A		Anti -B		Anti-AB		Anti-D	
A (lot No)		B (Lot no:)		AB (Lot no:)		O+(Lot no: 731000)	
Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength	Reaction time	Agglutination strength
						2 sec	+3
➤ Final Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify					
Done by QC Officer/Supervisor (Sign.): ... <i>razan</i> Date: .02.02.2023..... Time: .10:32.....							

B. Sensitivity test

Pipette #: 139			Pipette Code:E20PIQ139							
Type of Test			Anti-A		Anti-B		Anti-AB		Anti-D	
Sensitivity	Tube Test Method	Type of Cell Suspension	A (Lot no:)		B (Lot no:)		A (Lot no:) B (Lot no)		O+ (Lot no:730000)	
		Result	1:2		1:2		1:2		1:2	+3
			1:4		1:4		1:4		1:4	+2
			1:8		1:8		1:8		1:8	+2
			1:16		1:16		1:16		1:16	+2
			1:32		1:32		1:32		1:32	+1
			1:64		1:64		1:64		1:64	+1

			1:128		1:128		1:128		1:128	+1
			1:256		1:256		1:256		1:256	+/-
			1:512		1:512		1:512		1:512	-ve
			1:1024		1:1024		1:1024			

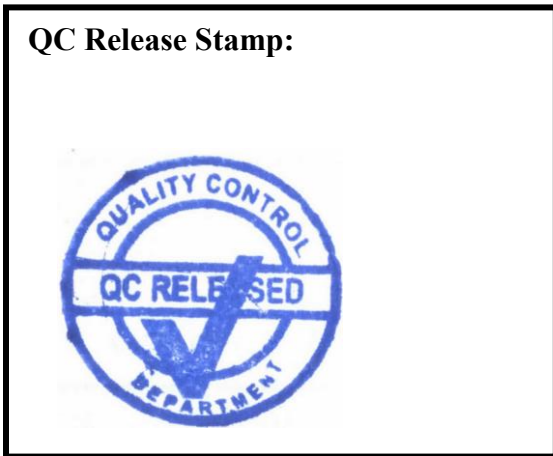
➤ Final Result: Pass Fail; justify

Done by QC Officer/Supervisor (Sign.): *razan* Date: 02.02.2023 Time: 10:35

Table (01)			
Blood Grouping Reagents	Control Cell	Reaction Time	Agglutination Strength
Anti-A	A - Cell	Up to 3 second	+4
Anti-B	B-Cell	Up to 3 second	+4
Anti-AB	A B-Cell	Up to 3 second	+3/+4
Anti -D	O RH positive cell	Up to 5 second	+3

Final Conclusion: Pass Fail

Final QC Manager Approval (Signature): *Tasneem* **Date:** 02.02.2023



Certificate of Analysis for Latex Kit

1- Product Identification:

Lot No	23010324
Product Name	ASO Latex Kit
Batch Size	20
QC Method No	F29D
EXP. Date	01.2025
Mfg. Date (if applicable)	NA

2- Physical Inspection:

Inspection level	AQL	Sample size code letter	Inspected quantity	Accepted	Rejected
S-1	1.0	A	2	0	1

Applicable test type	Inspected item / criteria	Acceptance criteria	Inspection results
➤ Kit Assembly:	All components of the kit are present according to the outer label		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status Based Color & Status are compatible with the specifications mentioned in the Product Specifications List (QRXQU07L):	Reagent:	White, (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Positive control :	Colorless/Yellowish (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Negative control :	Colorless/Yellowish (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Reagent :	4 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Positive control :	1 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Negative control :	1ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in the Item Dispense		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Stirring Sticks:	No breaking sticks and clean		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Glass Slide:	No scratch in test circles or edges		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clean		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label. • Record the QTY/Kit : 6/1		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail, justify:.....		
Done by (Signature): <i>rajan</i>	Date 07.01.2023	Time: 13:05	
QC Officer/Supervisor			

3- Biochemical Inspection: interpret the results by referring to tables (01)& (02)

Reagent Checking	RN No./ Lot No.	Agglutination Time	Agglutination Intensity	Sensitivity/ Titration	Sensitivity/ Titration Acceptance Criteria	Inspection results Pass/ Fail
Latex Reagent Check	23010324	2 min	+2/ -ve	150 (±)(IU/ml)	200 ± 50 (IU/ml)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Control Check	23010324	2 min	+2	1/8 (±), 1/16 (-ve)	1/8 (±), 1/16 (-ve)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Negative Control Check	23010324	2 min	-ve	N.A	N.A	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Normal Saline Check as a Negative Control (if applicable):	N.A	N.A	N.A	N.A	N.A	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Extraction working reagent in case of Streptococcus Latex/ as negative control	N.A	N.A	N.A	N.A	N.A	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail, justify:					
Done by (Signature): <i>rajan</i>	Date: 07.01.2023	Time: 13:10				
QC Officer/Supervisor						

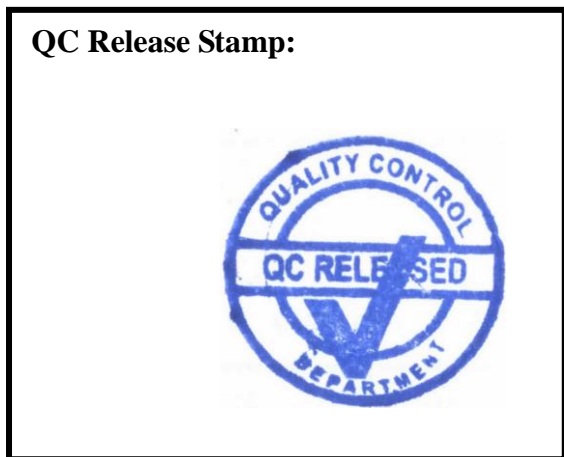
Table (01): Latex sensitivity

Latex Type	Positive	Negative
ASO Latex	200 ± 50 (IU/ml)	Less than 150 (IU/ml)
CRP Latex	5-10 (mg/L)	Less than 5 (mg/L)
RF Latex	8-12 (IU/ml)	Less than 8 (IU/ml)
HCG Latex	200 ± 50 (mIU/ml)	Less than 150 (mIU/ml)
D-Dimer Latex	200 ± 50 ng/ml for item (RLI129A00) 500 ± 50 ng/ml for item (RLI129A00BI)	Less than 150 ng/ml for item (RLI129A00) Less than 450 ng/ml for item (RLI129A00BI)

Table (02): Positive control titration

Item Name	Positive	Positive	Negative
Toxo Latex Kit	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
SLE Latex	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
Rubella Latex	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
Rota Virus Latex	Give agglutination / Intensity ≥ +1	1/8 (+ve), 1/16 (±)	No agglutination
D-Dimer Latex	Give agglutination / Intensity ≥ +1	1/16 (+ve), 1/32 (±)	No agglutination
Waler Rose latex	Give agglutination / Intensity ≥ +1	1/4 (+ve), 1/8 (±)	No agglutination

IM Latex	Give agglutination / Intensity $\geq +1$		1/8 (\pm), 1/16 (-ve)	No agglutination
CRP Latex	Give agglutination / Intensity $\geq +1$		1/8 (\pm), 1/16 (-ve)	No agglutination
ASO Latex	Give agglutination / Intensity $\geq +1$		1/8 (\pm), 1/16 (-ve)	No agglutination
RF Latex	Give agglutination / Intensity $\geq +1$		1/8 (\pm), 1/16 (-ve)	No agglutination
E.coli Latex	Give agglutination / Intensity $\geq +1$		N/A	No Agglutination
Item Name	Positive		Positive	Negative
Staphylococcus Latex	Test Latex	Give agglutination / Intensity $\geq +1$	N/A	No Agglutination
	Control Latex	No agglutination		No Agglutination
Streptococcus Latex	Give agglutination / Intensity $\geq +1$		N/A	No Agglutination
Notes: <ul style="list-style-type: none"> ➤ Negative Control: to confirm that the latex will not give false positive result, test time must be extended 2 minutes than PI time record. ➤ If the titration (\pm) one titer is accepted; approve it, otherwise considered reject. 				
Final Conclusion: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail				
Final QC Manager Approval (Signature): <i>Tasneem</i>			Date: 07.01.2023	



Certificate of Analysis for Latex Kit

1- Product Identification:

Lot No	23010327
Product Name	CRP Latex Kit
Batch Size	30
QC Method No	F29D
EXP. Date	10.2024
Mfg. Date (if applicable)	N.A

2- Physical Inspection:

Inspection level	AQL	Sample size code letter	Inspected quantity	Accepted	Rejected
S-1	1.0	A	2	0	1

Applicable test type	Inspected item / criteria	Acceptance criteria	Inspection results
➤ Kit Assembly:	All components of the kit are present according to the outer label		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status Based Color & Status are compatible with the specifications mentioned in the Product Specifications List (QRXQU07L):	Reagent:	White, (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Positive control :	Colorless/Yellowish (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Negative control :	Colorless/Yellowish (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Reagent :	4 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Positive control :	1 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Negative control :	1 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in the Item Dispense		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Stirring Sticks:	No breaking sticks and clean		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Glass Slide:	No scratch in test circles or edges		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clean		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label. • Record the QTY/Kit:6/1		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail, justify:.....		
Done by (Signature): ... <i>razan</i>		Date: 09.01.2023	Time: 08:50
QC Officer/Supervisor			

3- Biochemical Inspection: interpret the results by referring to tables (01)& (02)

Reagent Checking	RN No./ Lot No.	Agglutination Time	Agglutination Intensity	Sensitivity/ Titration	Sensitivity/ Titration Acceptance Criteria	Inspection results Pass/ Fail
Latex Reagent Check	23010327	2 min	+2/ -ve	6 (±) (mg/L)	5-10 (mg/L)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Control Check	23010327	2 min	+2	1/8 (±), 1/16 (-ve)	1/8 (±), 1/16 (-ve)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Negative Control Check	23010327	2 min	-ve	N.A	N.A	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Normal Saline Check as a Negative Control (if applicable):	N.A	N.A	N.A	N.A	N.A	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Extraction working reagent in case of Streptococcus Latex/ as negative control	N.A	N.A	N.A	N.A	N.A	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail, justify:					
Done by (Signature): ... <i>razan</i>		Date: 09.01.2023		Time: 08:55		
QC Officer/Supervisor						

Table (01): Latex sensitivity

Latex Type	Positive	Negative
ASO Latex	200 ± 50 (IU/ml)	Less than 150 (IU/ml)
CRP Latex	5-10 (mg/L)	Less than 5 (mg/L)
RF Latex	8-12 (IU/ml)	Less than 8 (IU/ml)
HCG Latex	200 ± 50 (mIU/ml)	Less than 150 (mIU/ml)
D-Dimer Latex	200 ± 50 ng/ml for item (RLI129A00) 500 ± 50 ng/ml for item (RLI129A00BI)	Less than 150 ng/ml for item (RLI129A00) Less than 450 ng/ml for item (RLI129A00BI)

Table (02): Positive control titration

Item Name	Positive	Positive	Negative
Toxo Latex Kit	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
SLE Latex	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
Rubella Latex	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
Rota Virus Latex	Give agglutination / Intensity ≥ +1	1/8 (+ve), 1/16 (±)	No agglutination
D-Dimer Latex	Give agglutination / Intensity ≥ +1	1/16 (+ve), 1/32 (±)	No agglutination
Waler Rose latex	Give agglutination / Intensity ≥ +1	1/4 (+ve), 1/8 (±)	No agglutination

IM Latex	Give agglutination / Intensity $\geq +1$		1/8 (\pm), 1/16 (-ve)	No agglutination
CRP Latex	Give agglutination / Intensity $\geq +1$		1/8 (\pm), 1/16 (-ve)	No agglutination
ASO Latex	Give agglutination / Intensity $\geq +1$		1/8 (\pm), 1/16 (-ve)	No agglutination
RF Latex	Give agglutination / Intensity $\geq +1$		1/8 (\pm), 1/16 (-ve)	No agglutination
E.coli Latex	Give agglutination / Intensity $\geq +1$		N/A	No Agglutination
Item Name	Positive		Positive	Negative
Staphylococcus Latex	Test Latex	Give agglutination / Intensity $\geq +1$	N/A	No Agglutination
	Control Latex	No agglutination		No Agglutination
Streptococcus Latex	Give agglutination / Intensity $\geq +1$		N/A	No Agglutination
Notes: <ul style="list-style-type: none"> ➤ Negative Control: to confirm that the latex will not give false positive result, test time must be extended 2 minutes than PI time record. ➤ If the titration (\pm) one titer is accepted; approve it, otherwise considered reject. 				
Final Conclusion: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail				
Final QC Manager Approval (Signature): <i>Tasneem</i>			Date: 09.01.2023	



Certificate of Analysis for Latex Kit

1- Product Identification:

Lot No	23010326
Product Name	RF Latex Kit
Batch Size	30
QC Method No	F29D
EXP. Date	01.2025
Mfg. Date (if applicable)	NA

2- Physical Inspection:

Inspection level	AQL	Sample size code letter	Inspected quantity	Accepted	Rejected
S-1	1.0	A	2	0	1

Applicable test type	Inspected item / criteria	Acceptance criteria	Inspection results
➤ Kit Assembly:	All components of the kit are present according to the outer label		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Color & Status Based Color & Status are compatible with the specifications mentioned in the Product Specifications List (QRXQU07L):	Reagent:	White, (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Positive control :	Colorless/yellowish, (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Negative control:	Colorless/yellowish, (liquid)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Reagent :	4 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Positive control :	1 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Negative control:	1 ml	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Labels:	Correct label orientation		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct label position		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clear printing		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Package Insert:	Clear printing and correct folding		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Correct code, version and brand as mentioned in the Item Dispense		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Address as mentioned on box design		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Closing Cap:	No leakage and closed well		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Stirring Sticks:	No breaking sticks and clean		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Glass Slide:	No scratch in test circles or edges		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Clean		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

➤ Quantity/Kit:	Compatible with the quantity mentioned in the outer label. • Record the QTY/Kit:(6/1).....		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail, justify:.....		
Done by (Signature): <i>razan</i>		Date 09.01.2023	Time: 09:00
QC Officer/Supervisor			

3- Biochemical Inspection: interpret the results by referring to tables (01)& (02)

Reagent Checking	RN No./ Lot No.	Agglutination Time	Agglutination Intensity	Sensitivity/ Titration	Sensitivity/ Titration Acceptance Criteria	Inspection results Pass/ Fail
Latex Reagent Check	23010326	2 min	+2/ -ve	8(±)(IU/ml)	8-12 (IU/ml)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Control Check	23010326	2 min	+2	1/8 (±), 1/16 (-ve)	1/8 (±), 1/16 (-ve)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Negative Control Check	23010326	2 min	-ve	N.A	N.A	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Normal Saline Check as a Negative Control (if applicable):	N.A	N.A	N.A	N.A	N.A	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Extraction working reagent in case of Streptococcus Latex/ as negative control	N.A	N.A	N.A	N.A	N.A	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
➤ Final Result:	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail, justify:					
Done by (Signature): <i>razan</i>		Date: 09.01.2023		Time: 09:05		
QC Officer/Supervisor						

Table (01): Latex sensitivity

Latex Type	Positive	Negative
ASO Latex	200 ± 50 (IU/ml)	Less than 150 (IU/ml)
CRP Latex	5-10 (mg/L)	Less than 5 (mg/L)
RF Latex	8-12 (IU/ml)	Less than 8 (IU/ml)
HCG Latex	200 ± 50 (mIU/ml)	Less than 150 (mIU/ml)
D-Dimer Latex	200 ± 50 ng/ml for item (RLI129A00) 500 ± 50 ng/ml for item (RLI129A00BI)	Less than 150 ng/ml for item (RLI129A00) Less than 450 ng/ml for item (RLI129A00BI)

Table (02): Positive control titration

Item Name	Positive	Positive	Negative
Toxo Latex Kit	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
SLE Latex	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
Rubella Latex	Give agglutination / Intensity ≥ +1	1/8 (±), 1/16 (-ve)	No agglutination
Rota Virus Latex	Give agglutination / Intensity ≥ +1	1/8 (+ve), 1/16 (±)	No agglutination
D-Dimer Latex	Give agglutination / Intensity ≥ +1	1/16 (+ve), 1/32 (±)	No agglutination
Waler Rose latex	Give agglutination / Intensity ≥ +1	1/4 (+ve), 1/8 (±)	No agglutination

IM Latex	Give agglutination / Intensity $\geq +1$	1/8 (\pm), 1/16 (-ve)	No agglutination
CRP Latex	Give agglutination / Intensity $\geq +1$	1/8 (\pm), 1/16 (-ve)	No agglutination
ASO Latex	Give agglutination / Intensity $\geq +1$	1/8 (\pm), 1/16 (-ve)	No agglutination
RF Latex	Give agglutination / Intensity $\geq +1$	1/8 (\pm), 1/16 (-ve)	No agglutination
E.coli Latex	Give agglutination / Intensity $\geq +1$	N/A	No Agglutination
Item Name	Positive	Positive	Negative
Staphylococcus Latex	Test Latex	Give agglutination / Intensity $\geq +1$	No Agglutination
	Control Latex	No agglutination	No Agglutination
Streptococcus Latex	Give agglutination / Intensity $\geq +1$	N/A	No Agglutination

Notes:

- **Negative Control: to confirm that the latex will not give false positive result, test time must be extended 2 minutes than PI time record.**
- **If the titration (\pm) one titer is accepted; approve it, otherwise considered reject.**

Final Conclusion: Pass Fail

Final QC Manager Approval (Signature): *Tasneem*

Date: 09.01.2023

QC Release Stamp:

