ORDIN DE PLATA NR.: 613 TIP.DOC. 1

DATA EMITERII:25 februarie 2021

PLATITI: 3700-00 LEI: Trei Mii Sapte Sute lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.
CONTUL DE PLATI/CODUL IBAN MD95ML0000000002251429243
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR BC"Moldindconbank"S.A. fil."Invest" Chisinau
CODUL BANCII: :MOLDMD2X329:

BENEFICIAR (R) Centrul pentru achizitii publice centralizate in sanatate
CONTUL DE PLATI/CODUL IBAN MD23TRPCCC518430B01859AA
CODUL FISCAL :1016601000212 /

PRESTATORUL BENEFICIAR Ministerul Finantelor - Trezoreria de Stat
CODUL BANCII: :TREZMD2X

DESTINATIA PLATII:/P102/3700,00 Pentru garantia pentru oferta la licitatia publica nr. ocds-b3wdp1-MD-1613650128830 din 26.02.2021

TIPUL TRANSFERULUI : NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:101:

DATA PRIMIRII:25/02/2021

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

L.S. (semnatura electronica)

CONDUCATOR: _____

(semnatura manuala)

CONTABIL-SEF: _____

(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

Digitally signed by Poiata Vitalie
Date: 2021.02.25 12:02:00 EET
Reason: MoldSign Signature
Location: Moldova

MOTIVUL REFUZULUI L.S.

BC "MOLDINDCONBANK" S.A.
Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000002251429243**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **14419** din **11.07.2016**

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**
Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat și codul fiscal: **1010600028048.**
Data înregistrării de stat: **12.08.2010.**
Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Activitatea farmaceutică;
2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;
3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;
4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;
5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;
6 Consultații în domeniul sistemelor de calcul.
Capitalul social: **5400** lei.
Administrator: POIATA VITALIE, IDNP 0983103892591,
Asociați:
1. POIATA VITALIE , IDNP 0983103892591
cota 1803.60 lei, ce constituie 33,4 %
2. NASEDCHIN ALEXANDR , IDNP 2002001070747
cota 1798.20 lei, ce constituie 33,3 %
3. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 1798.20 lei, ce constituie 33,3 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

A A 7 * E A * 0 3 7 0 4 3 1 E A

Date cu caracter personal. **Deținător:** Î.S. „Camera Înregistrării de Stat", **NUID (număr de identificare unic)** 0000151-001

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandru Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A2102242 **din** / от 16.02.2021

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 03.03.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Rîșcani
a DGAF mun.Chișinău
Funcția/Должность

Semnătura/Подпись

Viorica CĂUȘ
Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: **Claudia GOJAN**
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 16.02.2021 ora 14:09:46 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,44)

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Către Grupul de lucru pentru evaluarea
Procedurii de achiziție ocds-b3wdp1-MD-1613650128830
din 26 febr 2021, 11:30
din cadrul CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE

Declarație

Prin prezenta, SRL „Biosistem-mld", declara ca:

- Pentru produsele noi sau necunoscute, vor fi prezentate mostre in caz de solicitare, în termen de 5 zile de la solicitare
- Termenul de valabilitate restant (la momentul livrării) va constitui: nu mai puțin de 60% din cel inițial pentru produse cu o valabilitate de 2 ani şi mai mult şi de 80% din cel inițial pentru produse cu o valabilitate de până la 2 ani

_____Vitalie Poiata

L.Ş.

To: Whoever it may concern

18.02.2021

MANUFACTURERS DECLARATION

We, TURKLAB TIBBI MALZ. SAN VE TIC. A.S. located at ITOB 10017 Sk. No:2 Menderes-IZMIR/TURKEY manufacturer of Product code RTHC02 – RAPIDAN TESTER, Anti-HCV TEST, WB/S/P and Product code RTHB04 - RAPIDAN TESTER, HBsAg Test, WB/S/P, do hereby declare that:

The rapid tests from the offer for the tender *Nr. ocds-b3wdp1-MD-1613650128830 from 26.02.2021 organized by "CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE"*, submitted by our partner, *Biosistem mld SRL with business office at Albisoara 16/1street, office 7 , Chisinau, Republic of Moldova* are packed in boxes of 40 kits as follows: 40 tests, 40 pipettes, 40 sterile blood lancets, 40 alcohol pads and sufficient quantity of diluent for 40 tests.

Sincerely yours,

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.
Headquarters / Factory I : ITOB 10017 Sokak No: 2 Tekeli - Menderes - Izmir / TURKEY
Factory II : ITOB 10031 Sokak No: 15 Tekeli - Menderes - Izmir / TURKEY
TEL: +90 232 376 80 81 FAX: +90 232 376 80 40 www.turklab.com.tr

CERTIFICATE

EC No 1434-IVDD-430/2019
EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

Anti-HCV Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

The date of the first issue of the Certificate: 29.08.2008

CE 1434

Michał Pachowski, PhD
President

Application No: 58/2019
Module: H6

Certificate No **1434-IVDD-430/2019**
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

CERTIFICATE

EC No 1434-IVDD-431/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices,
List A

Anti-HCV Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

The date of the first issue of the Certificate: 29.08.2008

CE 1434

Michał Pachowski, PhD
President

Application No: 58/2019
Module: H7

Certificate No **1434-IVDD-431/2019**
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

CERTIFICATE

EC No 1434-IVDD-434/2019
EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

HBsAg Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

The date of the first issue of the Certificate: 29.08.2008

CE 1434

Michał Pachowski, PhD
President

Application No: 56/2019
Module: H6

Certificate No **1434-IVDD-434/2019**
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

CERTIFICATE

EC No 1434-IVDD-435/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices,
List A

HBsAg Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

The date of the first issue of the Certificate: 29.08.2008

CE 1434

Michał Pachowski, PhD
President

Application No: 56/2019
Module: H7

Certificate No **1434-IVDD-435/2019**
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Rapidan® Tester

INSTRUCTION FOR USE
HBsAg Test, WB/S/P
HBsAg Detection in
Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: RTHB04

Hepatitis B Virus Surface Antigen Cassette Test

BACKGROUND INFORMATION
Hepatitis is a general term meaning inflammation of the liver and can be caused by a variety of different viruses such as hepatitis A, B, C, D and E. Of the many viral causes of human hepatitis few are of greater global importance than hepatitis B virus (HBV). Hepatitis B is a serious and common infectious disease of the liver, affecting millions of people throughout the world.
The severe pathological consequences of persistent HBV infections include the development of chronic hepatic insufficiency, cirrhosis, and hepatocellular carcinoma (HCC). In addition, HBV carriers can transmit the disease for many years. Infection occurs very often in early childhood when it is asymptomatic and often leads to the chronic carrier state. Detection of hepatitis B surface antigen (HBsAg) identifies individuals infected with the hepatitis B virus. Serum HBV DNA concentrations quantified by real-time polymerase chain reaction (PCR) correlate with disease progression and for decisions to treat and subsequent monitoring. HBsAg is typically detected by sensitive immunoassays that uses antibody to hepatitis B surface. Point-of-care testing offers significant advantages which include reduction of facility costs, rapid delivery of results, early diagnosis, nurses or technicians with a minimum of training, peripheral health care level and rapid initiation of treatment.

Interpretation of the Hepatitis B Panel		
Tests	Results	Interpretation
HBsAg, anti-HBc, anti-HBs	Negative, negative, negative	Susceptible
HBsAg, anti-HBc, anti-HBs	Negative, positive, positive	Immune due to natural infection
HBsAg, anti-HBc, anti-HBs	Negative, negative, positive	Immune due to hepatitis B vaccination **
HBsAg, anti-HBc, IgM anti-HBc, anti-HBs	Positive, positive, positive, negative	Acutely infected
HBsAg, anti-HBc, IgM anti-HBc, anti-HBs	Positive, positive, negative, negative	Chronically infected
HBsAg, anti-HBc, anti-HBs	Negative, positive, negative	Four interpretations possible *

* Four Interpretations: 1. Might be recovering from acute HBV infection. 2. Might be distantly immune and test not sensitive enough to detect very low level of anti-HBs in serum. 3. Might be susceptible with a false positive anti-HBc. 4. Might be undetectable level of HBsAg present in the serum and the person is actually chronically infected.
** Antibody response (anti-HBs) can be measured quantitatively or qualitatively. A protective antibody response is reported quantitatively as 10 or more milliinternational units (≥10mIU/mL) or qualitatively as positive. Post-vaccination testing should be completed 1-2 months after the third vaccine dose for results to be meaningful.

DEFINITIONS
* Hepatitis B Surface Antigen (HBsAg): A serologic marker on the surface of HBV. It can be detected in high levels in serum during acute or chronic hepatitis. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection.
* Hepatitis B Surface Antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.
* Total Hepatitis B Core Antibody (anti-HBc): Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus (HBV) in an undefined time frame.
* IgM Antibody to Hepatits B Core Antigen (IgM anti-HBc): This antibody appears during acute or recent HBV infection and is present for about 6 months.

INTENDED USE
HBsAg Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human whole blood / serum / plasma.

REAGENTS
Anti-HBs monoclonal antibody, goat anti-mouse IgG polyclonal antibody and anti-HBs monoclonal antibody conjugated with colored particles.

METHOD
HBsAg Test uses immunochromatographic technology for the qualitative detection of HBsAg in human whole blood / serum / plasma. Sample is introduced from sampling pad. If there is HBsAg in the sample at detectable level, HBsAg binds to the mobile anti-HBs monoclonal antibodies conjugated with colored particles. Together they move to the test area "T". A visible colored signal due to the accumulation of colored particles in the test area "T" (a colored test line) indicates positive test result. If there is no HBsAg in the sample at detectable level then sample moves to the test area "T" together with unbound anti-HBs monoclonal antibodies conjugated with colored particles. Therefore, there is no visible colored signal in the test area "T" (no colored test line) be obtained, indicating negative test result. Regardless of HBsAg content of the liquid sample, accumulation of colored particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line always appears in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS
1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. The test is designed for whole blood / serum / plasma samples. Using other types of samples may cause invalid or false results.
4. Do not use test kit beyond the indicated expiry date. The test device is single use. Do not reuse.
5. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
6. Use a new pipette for each sample. Close the buffer bottle cap after using. Buffer is stable until expiry date after the first use in routine.
7. Adequate lighting is required to read the test results.
8. The test device should be discarded in a proper biohazard container after testing.
9. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
10. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
11. Do not freeze and thaw the serum, plasma samples repeatedly. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.
12. Do not use turbid, hemolyzed samples. Turbid test samples should be centrifuged.
13. Hemolytic samples should not be used since they can lead to invalid or false results.
14. A negative result does not exclude the possibility of HBV infection. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is required.
15. A false negative result can occur in the following a recent exposure to HBV; the recent exposure may take several months to reach detectable levels due to recent infection. In exceptional cases; presence of mutant virus and infection with a variant of the virus may lead to observation of false negative results.
16. Positive samples should be retested using another method and the results should not be used as the only basis for the diagnosis of hepatitis viral infection.
17. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE
Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze. The test in the original packaging retains stable until expiry date at storage conditions.
The test device should be used in maximum one hour after the foil is opened.
Kit components : Test cassettes, pipettes, diluents (for whole blood samples only) and instructions for use.
Additional materials required but not provided : Sample collection tube, centrifuge, timer, for fingerstick whole blood: sterile lancet and capillary tubes.
Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION
The test can be performed using whole blood (venous blood and capillary blood), serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible and tested immediately after collection. If the sample cannot be tested on the day of collection, serum or plasma samples should be refrigerated at 2 to 8°C for up to 3 days prior to testing. If testing within 3 days is not possible, serum or plasma samples should be frozen at -20°C or colder. Frozen serum, plasma samples must be completely thawed and mixed well prior to testing. Bring the samples to room temperature before testing.
Plasma and venous blood can be collected with the following anticoagulants: K3EDTA, K2EDTA, sodium citrate (3,2%), sodium citrate (3,8%), lithium heparin, sodium heparin.
Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).
Plasma Samples: Collect blood into a collection tube with anticoagulants to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).
Whole Blood Samples: Collect venous blood into a collection tube with anticoagulants to avoid coagulation, test should preferably be performed immediately. Otherwise, whole blood samples should be stored at 2 - 8 °C until they are being tested in a period of 2 days after collection. Do not freeze whole blood sample.
For Capillary Blood; according to the laboratory practice, use a sterile lancet and an appropriate capillary tube to collect blood by capillary action. Test should be performed immediately.

TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.
2. **For Serum / Plasma Samples:** Draw serum / plasma into pipette and put 3 drops (75 µl) into the sample well of the cassette. Do not use diluent for serum / plasma samples.

For Whole Blood Samples: Draw whole blood into pipette and put 2 drops (50 µl) into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.

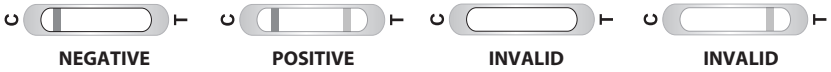
When using Capillary Blood Samples: Collect 50 µl of fingerstick whole blood using the capillary tube (not provided) and transfer it into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.

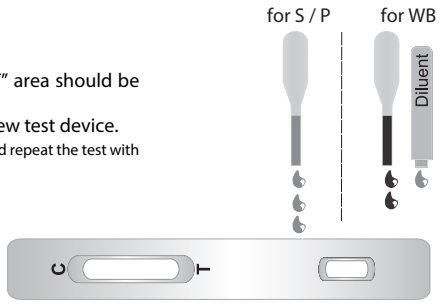
Avoid the formation of any air bubbles.

3. Results should be read at 15 minutes as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in "C" area.
Positive: Two colored lines are visible in "C" and "T" areas.
Low concentration of hepatitis B surface antigen may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid: No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.
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

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

HBsAg Test can detect all subtypes of hepatitis B virus surface antigens.

Sample Status	Sample HBsAg Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Naturally acute or chronic infected	Positive	536	EIA	100 %	411	EIA	100 %
Blood donors	Negative	1041	EIA	99,8 %	-	-	-
Clinical samples	Negative	225	EIA	100 %	225	EIA	100 %
Pregnant women	Negative	280	EIA	100 %	30	EIA	100 %

Sensitivity and Specificity

Using results of positive samples (947/947) and negative samples (1799/1801); sensitivity, specificity with the 95% confidence interval values are calculated as;

Sensitivity : 100 % [95% CI = 99,61% - 100%] Specificity : 99,89 % [95% CI = 99,60% - 99,99%]

Analytical Sensitivity Cut-off: 0,26 IU/mL

Seroconversion panels: 30 seroconversion panels were studied with Türklab HBsAg Test and compared to results from CE Marked EIAs as reference assays. Türklab HBsAg Test was capable of detecting antigens of HBsAg in a similar manner of the CE Marked EIA tests.

Interferences: Following potentially interfering substances were tested with HBsAg Test: Hemoglobin, Bilirubin, Triglycerides, Rheumatoid Factor (RF). No interference was observed.

Hemolytic samples should not be used since they can lead to invalid or false results.

Cross Reactivity: Cross reactivity has been tested with below samples, no cross reactivity was found with the HBsAg Test.
- Anti-HCV serum / plasma samples,
- Anti-HBs serum / plasma samples,
- Whole blood / serum / plasma samples from pregnant women.

Capillary Blood: Positive and negative capillary whole blood specimens collected by fingerstick were performed with HBsAg Test. The results showed that there was a good correlation of testing results between venous whole blood and capillary blood.

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7. WHO Guidelines on Hepatitis B and C Testing. Geneva: World Health Organization; 2017 Feb. ANNEX 4, *PICO Questions and Decision-Making Tables.*

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TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.
ITOB 10017 Sokak No: 2 Tekeli Menderes / Izmir / TURKEY
T: +90 232 376 80 81 • F: +90 232 376 80 40 • www.turklab.com.tr • info@turklab.com.tr

CE 1434

Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD *In vitro* diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date

Rapidan® Tester

INSTRUCTION FOR USE
Anti-HCV TEST, WB/S/P

Anti-HCV (HCVab) Detection in
Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: RTHC02
Hepatitis C Virus Antibody Cassette Test

BACKGROUND INFORMATION

Hepatitis C virus (HCV) is a major cause of chronic liver disease, frequently progressing to cirrhosis and increased risk of hepatocellular carcinoma. HCV is a positive, single-stranded RNA virus in the Flaviviridae family. The genome is approximately 10.000 nucleotides and encodes a single polyprotein of about 3.000 amino acids. The polyprotein is processed by host cell and viral proteases into three major structural proteins and several non-structural proteins necessary for viral replication. Several different genotypes of HCV with slightly different genomic sequences have since been identified that correlate with differences in response to treatment with interferon alpha.
HCV can be classified into six genetically distinct genotypes and further subdivided into at least 70 subtypes, which differ by approximately 30% and 15% at the nucleotide level, respectively. The different genotypes may exhibit differing phenotypic properties. Immunochromatographic membrane tests can be performed in a few minutes and the results are read visually and could be suitable for use in laboratories that have limited facilities. In addition, even if there is no prophylactic HCV treatment after a needle-stick injury, it can be important to know rapidly the HCV status of a source patient.

INTENDED USE

Anti-HCV Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies generated against proteins that are encoded by conserved sequences of CORE, NS3, NS4, NS5 parts of HCV genome in human whole blood / serum / plasma.

REAGENTS

Recombinant HCV antigens (CORE, NS3, NS4, NS5), anti-HCV monoclonal antibodies, colored particles conjugated recombinant HCV antigens (CORE, NS3, NS4, NS5).

METHOD

Anti-HCV Test uses immunochromatographic technology for the qualitative detection of antibodies against HCV antigens in human whole blood / serum / plasma. Sample is introduced from sampling pad. If there is anti-HCV in the sample at detectable level, anti-HCV binds to the mobile recombinant HCV antigens conjugated with colored particles. Together they move to the test area "T". A visible colored signal due to the accumulation of colored particles in the test area "T" (a colored test line) indicates positive test result. If there is no anti-HCV in the sample at detectable level then sample moves to the test area "T" together with unbound recombinant HCV antigens conjugated with colored particles. Therefore, there is no visible colored signal in test area "T" (no colored test line) be obtained, indicating negative test result. Regardless of anti-HCV content of the liquid sample, accumulation of colored particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line always appears in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. The test is designed for whole blood / serum / plasma samples. Using other types of samples may cause invalid or false results.
4. Do not use test kit beyond the indicated expiry date. The test device is single use. Do not reuse.
5. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
6. Use a new pipette for each sample. Close the buffer bottle cap after using. Buffer is stable until expiry date after the first use in routine.
7. Adequate lighting is required to read the test results.
8. The test device should be discarded in a proper biohazard container after testing.
9. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
10. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
11. Do not freeze and thaw the serum, plasma samples repeatedly. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.
12. Do not use turbid, hemolyzed samples. Turbid test samples should be centrifuged.
13. Hemolytic samples should not be used since they can lead to invalid or false results.
14. A negative result does not exclude the possibility of HCV infection. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is required.
15. A false negative result can occur in the following a recent exposure to HCV; an antibody response to recent exposure may take several months to reach detectable levels due to recent infection. In exceptional cases; presence of mutant virus and infection with a variant of the virus may lead to observation of false negative results.
16. Positive samples should be retested using another method and the results should not be used as the only basis for the diagnosis of hepatitis viral infection.
17. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze. The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.
Kit components: Test cassettes, pipettes, diluents and instructions for use.
Additional materials required but not provided: Sample collection tube, centrifuge, timer, for fingerstick whole blood: sterile lancet and capillary tubes.
Additional materials recommended but not provided: Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood (venous blood and capillary blood), serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible and tested immediately after collection. If the sample cannot be tested on the day of collection, serum or plasma samples should be refrigerated at 2 to 8°C for up to 3 days prior to testing. If testing within 3 days is not possible, serum or plasma samples should be frozen at -20°C or colder. Frozen serum, plasma samples must be completely thawed and mixed well prior to testing. Bring the samples to room temperature before testing.
Plasma and venous blood can be collected with the following anticoagulants: K3EDTA, K2EDTA, sodium citrate (3,2%), sodium citrate (3,8%), lithium heparin, sodium heparin.
Serum Samples : Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).
Plasma Samples : Collect blood into a collection tube with anticoagulants to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).
Whole Blood Samples : Collect venous blood into a collection tube with anticoagulants to avoid coagulation, test should preferably be performed immediately. Otherwise, whole blood samples should be stored at 2 - 8 °C until they are being tested in a period of 2 days after collection. Do not freeze whole blood sample.
For Capillary Blood; according to the laboratory practice, use a sterile lancet and an appropriate capillary tube to collect blood by capillary action. Test should be performed immediately.

TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.
2. **For Serum / Plasma Samples:** Draw serum / plasma into pipette and put 1 drop (25 µl) into the sample well of the cassette. Immediately after, 2 drops of diluent is added into the sample well and allowed to soak in.

For Whole Blood Samples: Draw whole blood into pipette and put 2 drops (50 µl) into the sample well of the cassette. Immediately after, 2 drops of diluent is added into the sample well and allowed to soak in.

When using Capillary Blood Samples: Collect 50 µl of fingerstick whole blood using the capillary tube (not provided) and transfer it into the sample well of the cassette. Immediately after, 2 drops of diluent is added into the sample well and allowed to soak in.

Avoid the formation of any air bubbles.

3. Results should be read at 15 minutes as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in "C" area.
Positive: Two colored lines are visible in "C" and "T" areas.
Low concentration of hepatitis C antibody may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
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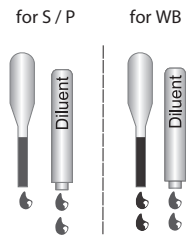

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PERFORMANCE EVALUATION

Anti-HCV Test can detect antibodies generated against proteins that are encoded by conserved sequences of CORE, NS3, NS4, NS5 parts of HCV genome.

Sample Status	Sample Anti-HCV Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Positive samples (including all available genotypes)	Positive	412	EIA	100 %	60	EIA	100 %
Blood donors	Negative	1045	EIA	100 %	-	-	-
Clinical samples	Negative	312	EIA	100 %	215	EIA	100 %
Pregnant women	Negative	280	EIA	100 %	30	EIA	100 %

Sensitivity and Specificity

Using results of positive samples (472/472) and negative samples (1882/ 1882); sensitivity, specificity with the 95% confidence interval values are calculated as;

Sensitivity : 100 % [95% CI = 99,22% - 100%] Specificity : 100 % [95% CI = 99,80% - 100%]

Seroconversion panels: 30 seroconversion panels were studied with Türklab Anti-HCV Test and compared to results from CE Marked EIAs as reference assays. Türklab Anti-HCV Test was capable of detecting antibodies to HCV in a similar manner of the CE Marked EIA tests.

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- Anti-HBs whole blood / serum / plasma samples,
- HBsAg whole blood / serum / plasma samples,
- Whole blood / serum / plasma samples from pregnant women.

Capillary Blood: Positive and negative capillary whole blood specimens collected by fingerstick were performed with Anti-HCV Test. The results showed that there was a good correlation of testing results between venous whole blood and capillary blood.

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TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.
ITOB 10017 Sokak No: 2 Tekeli Menderes / Izmir / TURKEY
T: +90 232 376 80 81 • F: +90 232 376 80 40 • www.turklab.com.tr • info@turklab.com.tr

CE 1434

Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD *In vitro* diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date