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ORDIN DE PLATA NR.: 1917 TIP.DOC. 1 :
DATA EMITERII:6 martie 2023 :
=====:
PLATITI: 3300-00 LEI: Trei Mii Trei Sute lei 00 bani :
:
:
=====:
PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R) Centrul pen CONTUL DE PLATI/CODUL IBAN :
tru achizitii publice central MD23TRPCCC518430B01859AA :
izate in sanatate CODUL FISCAL :1016601000212 / :
:
:
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
Ministerul Finantelor - Trezoreria de Stat :TREZMD2X :
=====:
DESTINATIA PLATII:/Pl02/3300,00 Pentru g: TIPUL TRANSFERULUI :
arantia pentru oferta la procedura de ac: NORMAL/URGENT :N:
hizi?ie publica nr. ocds-b3wdpl-MD-1676: :
553791345 din 06.03.2023 :
:
:
: L.S. :
=====:
CODUL TRANZACTIEI:101: :
DATA PRIMIRII:06/03/2023 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONducator:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSq:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
L.S. (semnatura electronica) :
CONducator: (semnatura manuala) :
CONTABIL-SEF: (semnatura manuala) :
SEMnatura PRESTATORUL L.S. :
:-----:
MOTIVUL REFUZULUI : L.S. :
-----:

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2303137**

din
от **02.03.2023**

1. Destinația / Назначение

Pentru participarea la proceduri de achiziții 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 17.03.2023

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

Șef interimar DDF Rîșcani

Funcția/Dолжность

Digitally signed by Stoicov Ana
Date: 2023.03.02 15:31:39 EET
Reason: MoldSign Signature
Location: Moldova

Semnătura/Подпись



STOICOV Ana

Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

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

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 02.03.2023 ora 13:50:51
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,27)



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, 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. Московской, 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 în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

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*

A. Svirid
semnătura

MD 0101250





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

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.**

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,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

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: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

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

SITUAȚIILE FINANCIARE
pentru perioada 01.01.2021 - 31.12.2021

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIO: 40717392
Cod IDNO: 1010600028048

Sediul:
MD:
Raionul(municipiul): 106, DDF RISCANI
Cod CUATM: 0150, SEC.RISCANI
Strada: SECTORUL RISCANI STR.Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:
E-mail: zmii13@mail.ru
Numele și coordonatele al contabilului-șef: DI (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 3 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:	021		
	2.1. concesiuni, licențe și mărci			
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024		
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	2793637	3559998
	din care:	081		
	3.1. clădiri			
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	2791637	3533108
	3.4. mijloace de transport	084		

A.	3.5. inventar și mobilier	085		26890
	3.6. alte mijloace fixe	086	2000	
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120		1162136
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2793637	4722134
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140		
	2. Investiții financiare pe termen lung în părți afiliate, total	150		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
	2.2 împrumuturi acordate părților afiliate	152		
	2.3 împrumuturi acordate aferente intereselor de participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	2793637	4722134
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	51978	5346
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	7221203	9147976
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	7273181	9153322
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	3912218	2182471
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	74631	208171
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350	2	
	7. Alte active circulante	360	5756117	1608597
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	9742968	3999239
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		

	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	3942779	9861933
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	20958928	23014494
	TOTAL ACTIVE (rd.230 + rd.420)	430	23752565	27736628
	P A S I V			
C.	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	()	()
	3. Capital neînregistrat	460		
	4. Capital retras	470	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	20060126	16230339
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	10403995
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	20060126	26634334
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	20065526	26639734
D.	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:	641		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	din care:	721		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	3252667	343711
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	188105	355528
	6. Datorii față de personal	760	50	350
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	187676	150263
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	58541	247042
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	3687039	1096894
F.	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	23752565	27736628

SITUAȚIA DE PROFIT ȘI PIERDERE

de la pînă la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	25963175	38680547
din care:			
venituri din vânzarea produselor și mărfurilor	011	25044358	37724557
venituri din prestarea serviciilor și executarea lucrărilor	012	918817	951393
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016		4597
Costul vânzărilor, total	020	15186814	24434231
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	15186814	24433364
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		867
Profit brut (pierdere brută) (rd.010 - rd.020)	030	10776361	14246316
Alte venituri din activitatea operațională	040	247603	5189
Cheltuieli de distribuire	050	19740	6076
Cheltuieli administrative	060	1259776	1788732
Alte cheltuieli din activitatea operațională	070	640169	1870642
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	9104279	10586055

Venituri financiare, total	090	519239	1517765
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	25612	30619
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	493627	1487146
Cheltuieli financiare, total	100	597528	249562
din care:			
cheltuieli privind dobânzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	597528	249562
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-78289	1268203
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-78289	1268203
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	9025990	11854258
Cheltuieli privind impozitul pe venit	170	1051159	1450263
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	7974831	10403995

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
III.	Rezerve					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X			
	4. Profit utilizat al perioadei de gestiune	150	X	()	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	Rezerve din reevaluare	170				
VI.	Alte elemente de capital propriu	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190				

SITUAȚIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobînzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Расписка 2

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2021

Дата предоставления: 29.03.2022

Временная метка отчёта зарегистрированного в Информационной Системе НБС : 29.03.2022 17:25:45

National Bureau of Statistics (NBS) received the electronic version of the report, sent by you. The data provided is verified by NBS.

[Версия для печати](#)

[Сохранить](#)

Расписка

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2021

Дата предоставления: 29.03.2022

Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 29.03.2022 14:51:06

SOĞUK DAMGA VARDIR

TERCÜME

T.C.
TORBALI 6. NOTERLİĞİ
Tel: 0232 654 70 07 Fax: 0232 654 70 17



№ 09971

SERTİFİKA

No. M – 56/4/2020

İşbu sertifika ile;

TÜRKLAB Tıbbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No:2, Tekeli-Menderes
İzmir, Türkiye

ve sertifika ekinde listelenmiş

Lokasyon

Aşağıdaki faaliyetler kapsamında

EN ISO 13485:2016

ile uyumludur:

invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kendi kendine test ve profesyonel kullanım için tasarlanmış hızlı testler, kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri) ve EKG elektrotları

Polonya Test ve Sertifikasyon Merkezi tarafından yürütülen denetim, yukarıdaki kanıtları sağlamıştır. Bu Sertifika, Kuruluş tarafından yukarıdaki standarda uyulması kaydıyla geçerliliğini koruyacaktır.

Bu sertifikanın geçerlilik tarihi: 22.12.2020'den 21.12.2023'e kadar

Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020

Sertifika kararının tarihi: 14.10.2020

Sertifika, yetkili imzayı taşımaktadır.

Varşova, 15.10.2020

Anna <<Elektronik İmza>>
Malgorzata
Wyroba
Yönetim Kurulu Üyesi

POLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: pcbc@pcbc.gov.pl

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.

I hereby certify that this document has been translated from its English into Turkish truly and correctly by me. 03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

103 Aralık 2020





CERTIFICATE

No M - 56/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
rapid tests intended for self-testing and for professional use,
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

T.C.
TORBALI 6. NOTERİ
Selma ZİYEK

Anna
Małgorzata
Wyroba
Member of the Board

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.10.16
09:00:16 +02'00'



AC 019
QMS





№09971

SERTİFİKA EKİ**SADECE SERTİFİKA İLE BAĞLANTILI OLARAK GEÇERLİDİR****No. M – 56/4/2020**

İşbu sertifika, aşağıda yer alan faaliyetler kapsamında Lokasyonun tasdiki için hazırlanmıştır:

**Fabrika 2:ITOB 10031 Sokak No: 15,
Tekeli-Menderesizmir, Türkiye**

invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri), profesyonel kullanım IVD testleri ve EKG elektrotları

Sertifikada listelenen standardın gereksinimlerini karşılar.

Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020

Sertifika kararının tarihi: 14.10.2020

Sertifika, yetkili imzayı taşımaktadır.

Varşova, 15.10.2020

Anna <<Elektronik İmza>>

Malgorzata

Wyroba

Yönetim Kurulu ÜyesiPOLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: pcbc@pcbc.gov.pl

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.

I hereby certify that this document has been translated from its English into Turkish truly and correctly by me. 03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN**ERKAN ALTUNER**

03 Aralık 2020



ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

№ 09971

**Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents),
professional use IVD tests and ECG electrodes**

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020



AC 019
QMS



**Anna
Małgorzata
Wyroba**
Member of the Board

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.10.16
09:02:27 +02'00'





CERTIFICATE

No M - 56/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
rapid tests intended for self-testing and for professional use,
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **22.12.2020** to **21.12.2023**

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020



AC 019
QMS



Member of the Board



ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

**Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents),
professional use IVD tests and ECG electrodes**

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020



AC 019
QMS



Member of the Board



CERTIFICATE

No J - 2670/4/2020

This is to certify that:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey**

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
rapid tests intended for self-testing and for professional use,
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020



AC 019
QMS



Member of the Board



ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No J - 2670/4/2020

This is to certify that the following Location:

**Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents),
professional use IVD tests and ECG electrodes**

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020



AC 019
QMS



Member of the Board



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



Application No: 56/2019
Module: H6

Michał Pachowski, PhD
President



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



Application No: 56/2019
Module: H7

Michał Pachowski, PhD
President



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



CERTIFICATE

EC No 1434-IVDD-436/2019
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-HIV 1/2 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



Application No: 57/2019
Module: H6

Michał Pachowski, PhD
President



Certificate No **1434-IVDD-436/2019**
Issued under the Contract No **MD-31/2019**
Bears the PCBC hologram.
Warsaw, 29.08.2019



CERTIFICATE

EC No 1434-IVDD-437/2019
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-HIV 1/2 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



Application No: 57/2019
Module: H7


Michał Pachowski, PhD
President



Certificate No **1434-IVDD-437/2019**
Issued under the Contract No **MD-31/2019**
Bears the PCBC hologram.
Warsaw, 29.08.2019



Polish Centre for Testing and Certification

BM.433.0056.2019.1531.22.EP

Warsaw, 17.10.2022

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli – Menderes Izmir, Turkey

To Whom it May Concern,

Please be kindly informed that Polskie Centrum Badań i Certyfikacji S.A. (hereinafter "PCBC" or "Polish Centre for Testing and Certification") performed evaluation of the comparative study of IVD Device HBsAg Test, WB/S/P.

HBsAg Test can detect all subtypes of Hepatitis B virus surface antigens. Performance evaluation is indicated below:

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

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

The information in the IFU (version C08.RTHBG.02; date: 01.08.2019; Rev.9) for Rapidan Tester® brand had been reviewed and remain true and valid.

Test manufactured by TÜRKLAB Tibbi Mal. San. Tic. A.Ş. and covered by EC Certificates 1434-IVDD-435/2019 and 1434-IVDD-434/2019.

Yours Sincerely,

**Coordinator of In Vitro Diagnostic
Medical Device Certification Division**

1/1

Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw
Tel.: +48 22 46 45 200, Fax: +48 22 46 45 251
pcbc@pcbc.gov.pl

Branch PCBC in Gdansk
18A Jakuba Wejhera Street, 80-346 Gdańsk
Tel.: +48 663 130 693
gdansk@pcbc.gov.pl

Branch PCBC in Piła
11 Śniadeckich Street, 64-920 Piła
Tel.: +48 67 21 38 200, Fax: +48 67 21 38 384
pila@pcbc.gov.pl

NIP: 951-20-63-356

REGON: 015276609

KRS: 0000144813

INITIAL CAPITAL: 16.000.000 PLN (FULLY PAID)

Bank account: Bank Pekao SA, o/Warszawa, No 90 1240 6003 1111 0000 4946 7594
The company registered in the District Court for the Capital City of Warsaw, XIIIth Commercial Division



Polish Centre for Testing and Certification

BM.433.0057.2019.1539.22.EP

Warsaw, 19.10.2022

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli – Menderes Izmir, Turkey

To Whom it May Concern,

Please be kindly informed that Polskie Centrum Badań i Certyfikacji S.A. (hereinafter "PCBC" or "Polish Centre for Testing and Certification") performed evaluation of the comparative study of IVD Device Anti-HIV 1/2 Test, WB/S/P.

Anti-HIV 1/2 Test can detect antibodies (IgG, IgA and IgM) generated against all subtypes of Human Immunodeficiency Virus Type 1 (HIV-1) (including Group O) and Type 2 (HIV-2). Performance evaluation is indicated below:

Sample Status	Sample Anti-HIV Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Positive samples (including all available subtypes)	Positive	461	EIA	100 %	44	EIA	100 %
Blood donors	Negative	1045	EIA	100 %	-	-	-
Clinical samples	Negative	341	EIA	100 %	215	EIA	100 %
Pregnant women	Negative	280	EIA	100 %	30	EIA	100 %

Sensitivity: 100% [95% CI = 99,27% - 100%]; Specificity: 100% [95% CI= 99,81% - 100%]

The information in the IFU (version C08.RTHIV.02; date: 01.08.2019; Rev.9) for Rapidan Tester® brand had been reviewed and remain true and valid.

Test manufactured by TÜRKLAB Tibbi Mal. San. Tic. A.Ş. and covered by EC Certificates 1434-IVDD-436/2019 and 1434-IVDD-437/2019.

Yours Sincerely,

**Coordinator of In Vitro Diagnostic
Medical Device Certification Division**

1/1

Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw
Tel.: +48 22 46 45 200, Fax: +48 22 46 45 251
pcbc@pcbc.gov.pl

Branch PCBC in Gdansk
18A Jakuba Wejhera Street, 80-346 Gdańsk
Tel.: +48 663 130 693
gdansk@pcbc.gov.pl

Branch PCBC in Pila
11 Śniadeckich Street, 64-920 Piła
Tel.: +48 67 21 38 200, Fax: +48 67 21 38 384
pila@pcbc.gov.pl

NIP: 951-20-63-356

REGON: 015276609

KRS: 0000144813

INITIAL CAPITAL: 16.000.000 PLN (FULLY PAID)

Bank account: Bank Pekao SA, o/Warszawa, No 90 1240 6003 1111 0000 4946 7594
The company registered in the District Court for the Capital City of Warsaw, XIIIth Commercial Division

EC DECLARATION OF CONFORMITY

In vitro Diagnostic Medical Devices in accordance with Directive 98/79/EC

Manufacturer: Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side: ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product: Anti-HIV 1/2 Test
Brand: Rapidan® Tester, Toyo®, Info®, Labmen®
Classification: Annex II List A, 98/79/EC
Conformity Assessment Route: Annex IV

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied: EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

Notified Body: Polish Centre for Testing and Certification (PCBC),
ul. Klobucka 23a 02-699 Warszawa Poland
(Notified Body # 1434)

Start of CE Marking: 29.08.2008

Revision No: 7

Place, Date of Issue: Izmir, 08.03.2019

Signature Dr. Şahin Yağlıdere, Md
General Manager

TÜRKLAB

TIBBİ MALZ. SAN. VE TİC. A.Ş.

MERKEZ: İTOB OSB MAH. 10031 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. 879 000 6200

CE 1434

EC DECLARATION OF CONFORMITY

In vitro Diagnostic Medical Devices in accordance with Directive 98/79/EC

Manufacturer: Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - Turkey
Product: Anti-Syphilis Test
Brand: Rapidan® Tester, Toyo®, Info®, Labmen®
Classification: Professional Use IVD, 98/79/EC
Conformity Assessment Route: Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied: EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

Revision No: 5

Place, Date of Issue: İzmir, 08.03.2019

Signature Dr. Şahin Yağlıdere, Md
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 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



EC DECLARATION OF CONFORMITY

In vitro Diagnostic Medical Devices in accordance with Directive 98/79/EC

Manufacturer: Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - Turkey
Product: HBsAg Test
Brand: Rapidan® Tester, Toyo®, Info®, Labmen®
Classification: Annex II List A, 98/79/EC
Conformity Assessment Route: Annex IV

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied: EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

Notified Body: Polish Centre for Testing and Certification (PCBC),
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(Notified Body # 1434)

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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.

Tests	Interpretation of the Hepatitis B Panel	
	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 (≥ 10 mIU/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 Hepatitis 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

- For professional and *in vitro* diagnostic use only.
- 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.
- The test is designed for whole blood / serum / plasma samples. Using other types of samples may cause invalid or false results.
- Do not use test kit beyond the indicated expiry date. The test device is single use. Do not reuse.
- 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.
- 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.
- Adequate lighting is required to read the test results.
- The test device should be discarded in a proper biohazard container after testing.
- 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.
- 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.
- 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.
- Do not use turbid, hemolyzed samples. Turbid test samples should be centrifuged.
- Hemolytic samples should not be used since they can lead to invalid or false results.
- 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.
- 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.
- 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.
- 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

- Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.
- 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.
- 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

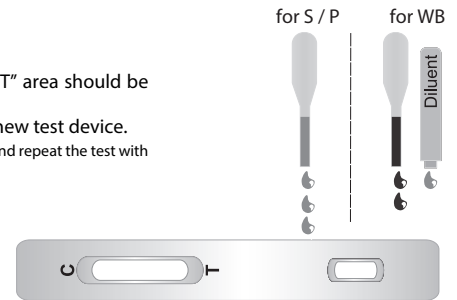
Negative: Only one colored line is visible in "C" area.

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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Manufacturer

Consult instruction for use



Attention, see instruction for use
In vitro diagnostic medical device



For single use only
Number of test



Storage temperature



Lot number
Expiry date

in vitro diagnostic test

Только для профессиональной диагностики *in vitro*

Код продукта: RTHIV02

Тест-кассета для определения антител к вирусу иммунодефицита человека.

ОБЩАЯ ИНФОРМАЦИЯ

ВИЧ/СПИД является самым губительным заболеванием в истории человечества. ВИЧ означает вирус иммунодефицита человека, вызывающий СПИД. ВИЧ разрушает определённые клетки крови, имеющие решающее значение в нормальном функционировании иммунной системы, которая защищает организм человека от болезней. СПИД означает синдром приобретённого иммунодефицита. Он проявляется тогда, когда иммунная система организма настолько ослаблена ВИЧ, что у человека развиваются различные заболевания или рак.

ВИЧ-инфекция чаще всего выявляется при тестировании проб крови, существуют и слюнные тесты. Если в пробе крови или слюне обнаруживаются антитела к ВИЧ — специальные белки, вырабатываемые организмом в ответ на встречу с возбудителем инфекцией, то человек является ВИЧ-положительным. Недавно был разработан экспресс-тест на ВИЧ для использования с пробами сыворотки и плазмы.

ВИЧ не выживает вне человеческого тела. Поэтому он не может передаваться при повседневном бытовом контакте. Комары и другие насекомые не переносят ВИЧ.

ВИЧ может передаваться при половом контакте с заражённым человеком, через инфицированные иглы и/или шприцы и/или другое инъекционное оборудование или, реже (и сейчас очень редко в странах, где кровь проверяется на наличие антител к ВИЧ) при переливании инфицированной крови или факторов свертываемости крови, используемых для лечения гемофилии.

Ранняя лабораторная диагностика первичной ВИЧ-инфекции основана на выявлении вирусной РНК или антигена p24 в плазме или сыворотке крови человека до сероконверсии антител. Диагностическое окно ВИЧ-инфекции может быть сокращено на 4-5 дней за счёт выявления антигена p24.

НАЗНАЧЕНИЕ

Тест на антитела к ВИЧ-1 и ВИЧ-2 — быстрый иммуноанализ для качественного выявления антител (IgG, IgA и IgM), вырабатываемых против всех подтипов вируса иммунодефицита человека типа 1 (ВИЧ-1) (включая группу «О») и типа 2 (ВИЧ-2) в цельной крови, сыворотке или плазме человека.

РЕАГЕНТЫ

Рекombинантный антиген ВИЧ, моноклональные антитела к ВИЧ и рекombинантный антиген ВИЧ, конъюгированный с коллоидными частицами золота.

МЕТОДИКА АНАЛИЗА

Тест на антитела к ВИЧ-1 и ВИЧ-2 использует твёрдофазную иммунохроматографическую технологию для качественного выявления антител к ВИЧ в цельной крови, сыворотке или плазме человека. Тест представляет собой двухстадийный иммунометрический анализ, в котором используется сочетание моноклональных антител и рекombинантных антигенов для избирательного выявления антител к ВИЧ в пробах с высокой степенью чувствительности. Рекombинантные антигены ВИЧ (в том числе gp120, gp41, gp36, p24) иммобилизованы в тестовой области «Т», а моноклональные антитела к ВИЧ иммобилизованы в контрольной области «С» нитроцеллюлозной мембраны. Рекombинантные антигены ВИЧ (в том числе gp120, gp41, gp36, p24), конъюгированные с коллоидными частицами золота, высушены на подушке конъюгата. Проба вводится с площадки для пробы. Если проба содержит антитела к ВИЧ, то эти антитела связываются с подвижными рекombинантными антигенами ВИЧ, конъюгированными с коллоидными частицами золота. Вместе они перемещаются в тестовую область «Т». Молекулы антител к ВИЧ связываются с иммобилизованными рекombинантными антигенами ВИЧ. В результате этого, молекулы антител к ВИЧ, которые уже связаны с подвижными рекombинантными антигенами ВИЧ (конъюгированными с коллоидными частицами золота), иммобилизируются в тестовой области «Т», таким образом создавая визуальный цветной сигнал из-за накопления коллоидных золотых частиц в тестовой области «Т» (цветная тестовая линия). Это указывает на положительный результат анализа. Если в пробе нет антител к ВИЧ, то проба перемещается в тестовую область «Т» вместе с несвязанными (свободными) рекombинантными антигенами ВИЧ, конъюгированными с коллоидными частицами золота. Иммобилизованные рекombинантные антигены ВИЧ не могут связаться с подвижными рекombинантными антигенами ВИЧ, конъюгированными с коллоидными частицами золота, поэтому в тестовой области «Т» нет визуального цветного сигнала (нет цветной тестовой линии). Это указывает на отрицательный результат анализа. Вне зависимости от наличия или отсутствия антител к ВИЧ в исследуемой пробе, подвижные рекombинантные антигены ВИЧ, конъюгированные с коллоидными частицами золота, связываются с иммобилизованными моноклональными антителами к ВИЧ, когда жидкая проба проходит через контрольную область «С». Поэтому накопление коллоидных золотых частиц создаёт визуальный цветной сигнал в контрольной области «С» (цветная контрольная линия), указывая на достоверность результата анализа. Цветная линия должна быть видна в контрольной области «С» в любом случае; если цветная линия не видна в контрольной области «С», результат анализа следует признать недостоверным.

МЕРЫ ПРЕДОСТОРОЖНОСТИ И ОГРАНИЧЕНИЯ

1. Только для профессиональной диагностики *in vitro*.
2. Не использовать тест-набор после окончания срока его годности. Тест-кассета предназначена для однократного использования. Нельзя использовать тест-кассеты повторно.
3. Тест-кассета должна оставаться в оригинальной герметичной индивидуальной упаковке вплоть до момента использования. Нельзя использовать тест-кассету, если упаковка раскрыта или повреждена.
4. Во время проведения анализа надевайте одноразовые перчатки.
5. Используйте новую пипетку для каждой пробы.
6. После проведения анализа тест-кассета должна быть утилизирована в соответствующий контейнер для сбора биологического материала.
7. Все пробы пациентов должны рассматриваться как способные переносить заболевание. Во время проведения анализа соблюдайте все установленные меры предосторожности при риске заражения и следуйте стандартным инструкциям для правильной утилизации проб.
8. Нельзя многократно замораживать и размораживать пробы сыворотки или плазмы. Если это возможно, следует избегать использования замороженных и размороженных проб по причине возможного засорения мембраны.
9. Не использовать мутные, гемолизированные пробы. Мутные пробы следует отцентрифугировать.
10. Не использовать гемолитические образцы, поскольку они могут привести к недостоверным или ложным результатам анализа.
11. Этот тест укажет только на присутствие или отсутствие антител к ВИЧ в пробе, и он не может быть использован в качестве единственного критерия для постановки диагноза ВИЧ.

Как и в случае со всеми диагностическими анализами, следует иметь в виду, что постановка диагноза не может базироваться только на единственном результате анализа. Диагноз может быть поставлен только специалистом после оценки всех клинических и лабораторных результатов.

УСЛОВИЯ ХРАНЕНИЯ

Тест-кассеты следует хранить вдали от прямых солнечных лучей, источников влаги, тепла и излучения. Хранить при температуре от +4°C до +30°C (39-86°F). Не замораживать.

При соблюдении условий хранения тест-кассеты в оригинальной упаковке остаются стабильными вплоть до конца срока годности. Тест-кассеты должны быть использованы, максимум, в течение одного часа после вскрытия упаковки из фольги.

Состав набора: тест-кассеты, пипетки, растворители (только для проб цельной крови) и инструкция по применению.

Дополнительно необходимые, но не поставляемые материалы: пробирка для сбора проб, центрифуга и таймер.

Дополнительно рекомендуемые, но не поставляемые материалы: микропипетки для забора указанного объёма пробы в ходе процедуры анализа, отрицательные и положительные контрольные материалы.

ЗАБОР ПРОБЫ И ПОДГОТОВКА К АНАЛИЗУ

Анализ может быть выполнен с помощью цельной крови, сыворотки или плазмы. Чтобы избежать гемолиза, сыворотка или плазма должны быть как можно скорее отделены от крови.

Для проб цельной крови: Анализ следует проводить сразу после забора пробы цельной крови. В ином случае, чтобы избежать коагуляции, проба цельной крови может храниться при температуре от +2°C до +8°C с антикоагулянтами (ЭДТК, гепарином, цитратом натрия) в течение 2 дней после забора пробы и до момента проведения анализа.

Для проб сыворотки: Внесите пробу крови в пробирку без антикоагулянта, оставьте на 30 минут для свёртывания крови, а затем отправьте кровь на центрифугирование. В конце периода центрифугирования оставшийся супернатант используется в качестве сыворотки. (Время и скорость центрифугирования: 2300-2880 x g в течение 10 минут)

Для проб плазмы: Внесите пробу крови в пробирку с антикоагулянтами (ЭДТК, гепарином, цитратом натрия), чтобы избежать коагуляции пробы крови, а затем отправьте кровь на центрифугирование. В конце периода центрифугирования оставшийся супернатант используется в качестве плазмы. (Время и скорость центрифугирования: 2300-2880 x g в течение 10 минут).

Не использовать мутные, гемолизированные пробы. Если тестирование нельзя провести в день забора, то пробы сыворотки или плазмы можно хранить в холодильнике или морозильнике. Нельзя многократно замораживать и размораживать пробы сыворотки или плазмы. Не замораживать пробы цельной крови. Перед проведением анализа доведите пробы до комнатной температуры. Замороженные пробы должны полностью оттаять, а перед анализом их необходимо хорошо перемешать. Мутные пробы следует отцентрифугировать. Если это возможно, следует избегать использования замороженных и размороженных проб по причине возможного засорения мембраны.

ПРОЦЕДУРА ПРОВЕДЕНИЯ АНАЛИЗА

1. Довести тест-кассету и пробы цельной крови, сыворотки или плазмы до комнатной температуры. Извлечь тест-кассету из индивидуальной упаковки.
 2. **Для проб цельной крови:** Набрать цельную кровь в пипетку и поместить 1 каплю (30 мкл) в лунку для пробы на тест-кассете. Сразу после этого добавить в лунку для пробы 1 каплю разбавителя и дать впитаться.
 3. **Для проб сыворотки/плазмы:** Набрать сыворотку/плазму в пипетку и поместить 2 капли (50 мкл) в лунку для пробы на тест-кассете. Не использовать растворители для проб сыворотки или плазмы.
- Избегать образования пузырьков воздуха.
3. В зависимости от концентрации антител к ВИЧ в пробе, тест может отреагировать уже через 5 минут. Как показано ниже, результаты следует интерпретировать через 15 минут. Нельзя интерпретировать результаты после 20 минут. Результаты после 20 минут следует интерпретировать как недостоверные.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ ТЕСТА

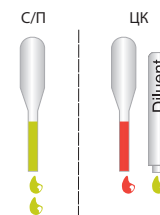
Отрицательный: Одна цветная линия появляется в области контроля «С», указывая на отсутствие антител к ВИЧ в пробе.

Положительный: Две цветные линии появляются в контрольной области «С» и в тестовой области «Т», указывая на наличие антител к ВИЧ в пробе.

Низкая концентрация антител к ВИЧ в пробе может привести к слабо выраженной линии в области «Т». Однако даже такую линию с низкой интенсивностью окрашивания в области «Т» следует рассматривать как «положительный» результат.

Недостоверный: Цветная линия не появляется или появляется только в тестовой области «Т». Следует повторить анализ с помощью новой тест-кассеты.

Недостаточный объем пробы или неправильные процедурные методы являются наиболее вероятными причинами проблем в работе контрольной линии. Пересмотрите процедуру проведения анализа и повторите тест с помощью нового тестового устройства. Если проблема не устранена, немедленно прекратите использование набора тестов и обратитесь к местному дистрибьютору.



КОНТРОЛЬ КАЧЕСТВА

В тест-кассету включён внутренний контроль процедуры анализа. При завершении анализа пользователь увидит цветную линию в контрольной области «С» на отрицательных пробах и цветную линию в тестовой области «Т» и контрольной области «С» на положительных пробах. Наличие контрольной линии «С» рассматривается как внутренний контроль процедуры анализа. Эта линия подтверждает внесение достаточного объема пробы и достоверность самого результата анализа. Рекомендуется тестировать заведомо отрицательные и положительные образцы для внешней проверки правильности выполнения анализа. Пользователи должны придерживаться государственных, региональных и местных рекомендаций, касающихся внешнего контроля качества.

ОЦЕНКА ЭФФЕКТИВНОСТИ

Тест на антитела к ВИЧ-1 и ВИЧ-2 может выявить антитела IgG, IgA и IgM, вырабатываемые против всех подтипов вируса иммунодефицита человека типа 1 (ВИЧ-1) (включая группу «О») и типа 2 (ВИЧ-2).

Статус пробы	Проба на антитела к ВИЧ-1 и ВИЧ-2	Тип пробы сыворотка/плазма			Тип пробы цельная кровь		
		Номер исследования	Используемая сравнительная проверка	Результат	Номер исследования	Используемая сравнительная проверка	Результат
Положительные пробы (все доступные генотипы)	Положительная	500	EIA	100 %	500	EIA	100 %
Доноры крови	Отрицательная	1058	EIA	100 %	1011	EIA	100 %
Клинический	Отрицательная	250	EIA	100 %	210	EIA	100 %
Беременные женщины	Отрицательная	212	EIA	100 %	212	EIA	100 %
Ревматоидный фактор	Отрицательная	150	EIA	100 %	150	EIA	100 %
Антитела к ВГС	Отрицательная	20	EIA	100 %	10	EIA	100 %
Билирубин	Отрицательная	10	EIA	100 %	-	-	-
Гемоглобин	Отрицательная	10	EIA	100 %	-	-	-
Триглицериды	Отрицательная	10	EIA	100 %	-	-	-

Чувствительность и специфичность теста

Для проб сыворотки/плазмы используются результаты положительных проб (500/500), отрицательных проб доноров крови (1058/1058) и клинических проб (250/250). Используя эти результаты чувствительность, специфичность, прогностическая ценность положительного и отрицательного результатов рассчитываются следующим образом:

Чувствительность: 100%

Прогностическая ценность положительного результата: 100%

Специфичность: 100%

Прогностическая ценность отрицательного результата: 100%

Для проб цельной крови используются результаты положительных проб (500/500), отрицательных проб доноров крови (1011/1011) и клинических проб (210/210). Используя эти результаты чувствительность, специфичность, прогностическая ценность положительного и отрицательного результатов рассчитываются следующим образом:

Чувствительность: 100%

Прогностическая ценность положительного результата: 100%

Специфичность: 100%

Прогностическая ценность отрицательного результата: 100%

Сероконверсионные панели: Сорок сероконверсионных панелей были протестированы параллельно с помощью теста на антитела к ВИЧ-1 и ВИЧ-2 производства «Türklab» и иммуноферментного анализа (ИФА) в качестве референтного. Все 40 сероконверсионных панелей были правильно выявлены тестом на антитела к ВИЧ-1 и ВИЧ-2 производства «Türklab», который отреагировал появлением линии в контрольной области «С» и другой линии «Т» в тестовой области пробы. Эталонный анализ ИФА также выявил сероконверсию всех 40 панелей. Данный анализ указывает, что тест на антитела к ВИЧ-1 и ВИЧ-2 производства «Türklab» продемонстрировал аналогичную результативность диагностической чувствительности в сравнении с ИФА анализом с «СЕ» маркировкой.

Перекры́стная реактивность: Перекры́стная реактивность была протестирована с указанными ниже пробами. Перекры́стная реактивность с тестом на антитела к ВИЧ-1 и ВИЧ-2 не обнаружена.

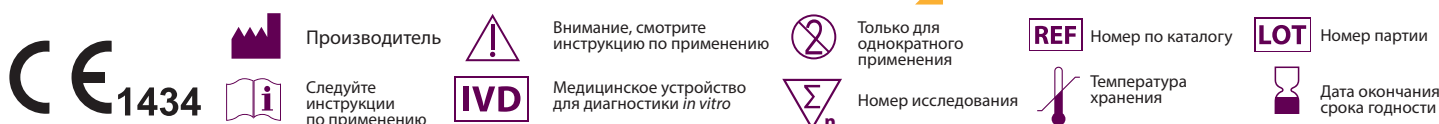
- Пробы цельной крови, сыворотки, плазмы содержащие и не содержащие антитела к ВГС.
- Пробы цельной крови, сыворотки, плазмы беременных женщин.

Интерференция: Следующие потенциально мешающие вещества были протестированы с тестом на антитела к ВИЧ-1 и ВИЧ-2: гемоглобин, билирубин, триглицериды, ревматоидный фактор. Никакой интерференции не обнаружено.

Не использовать гемолизические образцы, поскольку они могут привести к недостоверным или ложным результатам анализа.

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Product Code: RTP02

BACKGROUND INFORMATION

In spite of the development of efficient treatment methods, Syphilis still persists as a common Sexually Transmitted Disease in many regions of the world. This disease is caused by *Treponema pallidum*, which is a member of Spirochaetaceae family. Infection of *Treponema* type is transmitted by direct contact with active lesion. The primary and secondary lesions of sexually transmitted syphilis are highly infectious, and contain a high amount of organism until the healing period. Congenital syphilis occurs when the *Treponema pallidum* is transmitted from a pregnant woman with syphilis to her fetus, during the later phases of pregnancy. The immune response to syphilis involves production of antibodies to a broad range of antigens, including non-specific antibodies and specific treponemal antibodies. The first demonstrable response to infection is the production of specific anti-treponemal IgM, which may be detected towards the end of the second week of infection; anti-treponemal IgG appears later, at about four weeks. By the time that symptoms develop, most patients have detectable IgG and IgM. Use of this rapid diagnostic test is highly advantageous, due to the corresponding technical application difficulties and high cost of many other treponemal tests.

INTENDED USE

Anti-Syphilis Test is a rapid and immunochromatographic procedure for the qualitative detection of Treponemal antibodies (IgA, IgM, IgG) generated against *Treponema pallidum* antigens (17 kDa, 15 kDa, 47 kDa) in human whole blood / serum / plasma with high sensitivity and specificity. This test can be used even in detection of congenital syphilis with the same accuracy.

REAGENTS

Recombinant *Treponema pallidum* antigens, monoclonal goat anti-*Treponema pallidum*, recombinant *Treponema pallidum* antigens (17 kDa, 15 kDa, 47 kDa) conjugated with colloidal gold particles.

METHOD

Anti-Syphilis Test uses immunochromatographic, Ag-Ab-Ag sandwich method for qualitative detection of *Treponema pallidum* antibodies (IgG, IgM, IgA) in human whole blood/serum/plasma. Recombinant *Treponema pallidum* antigens were immobilized on the test area "T" and antibodies generated against *Treponema pallidum* were immobilized on the control area "C" of the nitrocellulose membrane. Other *Treponema pallidum* antigens (17 kDa, 15 kDa, 47 kDa) conjugated with colloidal gold particles were dried on a conjugate pad. Sample is introduced from sampling pad. If there are *Treponema pallidum* antibodies at detectable level in the sample, *Treponema pallidum* antibodies bind to the mobile recombinant *Treponema pallidum* antigens conjugated with colloidal gold particles. Together they move to the test area "T". *Treponema pallidum* antibodies that have already bound to mobile recombinant *Treponema pallidum* antigens conjugated to colloidal gold particles become immobilized in the test area "T" thus creating a visible colored signal due to the accumulation of colloidal gold particles in the test area "T" (a colored test line), indicating positive test result. If there are no *Treponema pallidum* antibodies at detectable level in the sample then sample moves to the test area "T" together with unbound (free) recombinant *Treponema pallidum* antigens conjugated to colloidal gold particles. Immobilized recombinant *Treponema pallidum* antigens can not bind to mobilized *Treponema pallidum* antigens conjugated to colloidal gold particles, therefore no visible colored signal in the test area "T" (no colored test line) can be obtained, indicating negative test result. Regardless of *Treponema pallidum* antibodies content of the liquid sample, *Treponema pallidum* antigens conjugated with colloidal gold particles, bind to the immobilized *Treponema pallidum* antibodies in the control area "C" while liquid sample is passing through the control area "C". Therefore accumulation of colloidal gold particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. The colored line should be visible in control area "C" in every case; if no visible colored line in control area "C", the test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
 2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
 3. 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.
 4. Wear disposable gloves while performing the test.
 5. Use a new pipette for each sample.
 6. 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.
 7. This test will indicate only the selectively total *Treponema pallidum* antibody in the sample, and should not be used as the only basis for the diagnosis of Syphilis.
- 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, diluent and instructions for use.

Additional materials required but not provided : Sample collection tube, centrifuge and timer.

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, serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.

For whole blood samples: Test should be performed immediately with whole blood samples. Otherwise, whole blood samples should be stored at 2 - 8 °C with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation until they are being tested in a period of 2 days after collection.

For 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).

For Plasma Samples: Collect blood into a collection tube with anticoagulants (EDTA, heparin, citrate should be used) 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).

Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. Do not freeze whole blood sample. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.

TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.
2. Draw whole blood / serum / plasma into pipette and put 1 drop (25 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.
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.

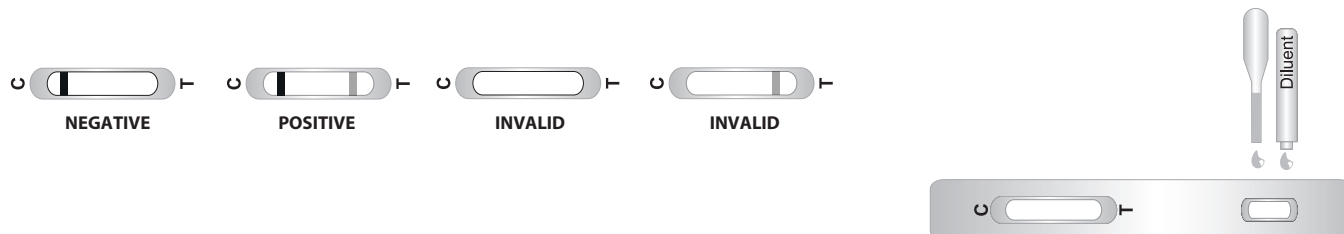
INTERPRETATION OF RESULTS

Negative : Only one colored line is visible in "C" area.

Positive : Two colored lines are visible in "C" and "T" areas.

Low concentration of *Treponema pallidum* antibody 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 in "C" and "T" areas or only one colored line is visible in "T" area; the test should be repeated using a new test device.



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

Study Number	Sample Status	Sample Anti- <i>T. Pallidum</i> Status	Comparative Assay Used	False Result
200	Positive samples	Positive	VDRL / TPHA	0
500	Blood donors	Negative	VDRL / TPHA	1
28	Clinical	Negative	VDRL / TPHA	0
50	Pregnant women	Negative	VDRL / TPHA	0
10	Bilirubin	Negative	VDRL / TPHA	0
10	Hemoglobin	Negative	VDRL / TPHA	0
10	Triglycerides	Negative	VDRL / TPHA	0
10	Anti-HBs	Negative	WHO Standard	0

Ultra Sensitive Anti-Syphilis Test can detect *Treponema pallidum* antibodies (IgA, IgM, IgG) generated against *Treponema pallidum* antigens (17 kDa, 15 kDa, 47 kDa)

Sensitivity : 99,9 % Specificity : 99,8 %
+ Predictive V : 99,5 % - Predictive V : 99,9 %

Cross Reactivity: Cross reactivity has been tested with below samples, no cross reactivity was found with the Anti-Syphilis Test.

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

Interferences: Following potentially interfering substances were tested with Anti-Syphilis Test: Hemoglobin, Bilirubin, Triglycerides. No interference was observed.

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

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