ORDIN DE PLATA NR.: 562 TIP.DOC. 1

DATA EMITERII:28 ianuarie 2021

PLATITI: 520-00 LEI: Cinci Sute Douazeci lei 00 ban
i

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 pen tru achizitii publice central izate in sanatate
CONTUL DE PLATI/CODUL IBAN MD23TRPCCC518430B01859AA
CODUL FISCAL :1016601000212 /

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

DESTINATIA PLATII:/P102/520,00 Garantie pentru oferta pentru LP ocds-b3wdp1-MD-1: 610694912358 din 29.01.2021

TIPUL TRANSFERULUI : NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:101:

DATA PRIMIRII:28/01/2021

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTEQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxFzA

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT

L.S. (semnatura electronica)

CONDUCATOR: _____
(semnatura manuala)

CONTABIL-SEF: _____
(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

Digitally signed by Poiata Vitalie
Date: 2021.01.28 10:16:51 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

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

Data prezentării 21.05.2020 10:13:29
SITUATIILE FINANCIARE

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

2019 pentru perioada 01.01.2019 - 31.12.2019 de lichidare
BIROUL NAŢIONAL DE STATISTICĂ

Entitatea: BIOSISTEM MLD S.R.L.
Sediul:SEC.RISCANI, STR.ALBISOARA NR.16 BL.1 OF.7
Raionul(municipiul):106, DDF RISCANI
Satul(comuna):
Strada:SEC.RISCANI, STR.ALBISOARA NR.16 BL.1 OF.7
Cod postal:2001
Cod CUATM:0150, SEC.RISCANI
Activitatea principala:G4646, Comert cu ridicata al produselor farmaceutice
Forma proprietate:16, Proprietate colectivă
Forma organizatorico-juridica:530, Societăţi cu răspundere limitată
Cod CUÍÒ: 40717392
Codul fiscal:1010600028048
WEB:
Numele si coordonatele al contabilului-sef:Nasedchin Alexandr
Telefon:+37322808719
Numărul mediu scriptic al personalului în perioada precedentă: 6 persoane.

Unitatea de masura: leu

Notă informativă privind veniturile şi cheltuielile clasificate după natură

Anexa 8

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010		
Alte venituri din activitatea operationala	020		
Venituri din alte activitati	030		
Total venituri (rd.010 + rd.020 + rd.030)	040		
Variatia stocurilor	050		
Costul vinzarilor mărfurilor vândute	060		
Cheltuieli privind stocurile	070		
Cheltuieli cu personalul privind remunerarea muncii	080		
Contributii de asigurari sociale de stat obligatorii si prime de asigurare obligatorie de asistenta medicala	090		
Cheltuieli cu amortizarea si deprecierea activelor imobilizate	100		
Alte cheltuieli	110		
Cheltuieli din alte activitati	120		
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130		
Profit (pierdere) pina la impozitare (rd.040 – rd.130)	140		
Cheltuieli privind impozitul pe venit	150		
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160		

BILANŢUL
la

Anexa 1

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
1.	**Active imobilizate**			
	Imobilizari necorporale	010	1137	487
	Imobilizari corporale in curs de executie	020		
	Terenuri	030		
	Mijloace fixe	040	938614	2208593
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investitii financiare pe termen lung in parti neafiliate	070		
	Investitii financiare pe termen lung in parti afiliate	080		
	Investitii imobiliare	090		
	Creante pe termen lung	100		
	Avansuri acordate pe termen lung	110		
	Alte active imobilizate	120		
	Total active imobilizate(rd.010 + rd.020 + rd.030 + rd.040 + rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	939751	2209080
	Active circulante			
	Materiale	140		6209

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
2.	Active biologice circulante	150		
	Obiecte de mica valoare si scurta durata	160	51520	47842
	Productia in curs de executie si produse	170		
	Marfuri	180	4809995	5710647
	Creante comerciale	190	5528804	4337729
	Creante ale partilor afiliate	200		
	Avansuri acordate curente	210	2496545	1647170
	Creante ale bugetului	220	26401	166486
	Creante ale personalului	230		
	Alte creante curente	240		
	Numerar in casierie si la conturi curente	250	9066228	8911899
	Alte elemente de numerar	260		
	Investitii financiare curente in parti neafiliate	270		
	Investitii financiare curente in parti afiliate	280		
	Alte active circulante	290	3712	742
	Total active circulante (rd.140 + rd.150 + rd.160 + rd.170 + rd.180 + rd.190 + rd.200 + rd.210 + rd.220 + rd.230 + rd.240 + rd.250 + rd.260 + rd.270 + rd.280 + rd.290)	300	21983205	20828724
	Total active (rd.130 + rd.300)	310	22922956	23037804
3.	**Capital propriu**			
	Capital social si suplimentar	320	5400	5400
	Rezerve	330		
	Corectii ale rezultatelor anilor precedenti	340	x	
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	350	18182879	12119049
	Profit net (pierdere neta) al perioadei de gestiune	360	x	8902416
	Profit utilizat al perioadei de gestiune	370	x	
	Alte elemente de capital propriu	380		
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	18188279	21026865
4.	**Datorii pe termen lung**			
	Credite bancare pe termen lung	400		
	Imprumuturi pe termen lung	410		
	Datorii pe termen lung privind leasingul financiar	420		
	Alte datorii pe termen lung	430		
	Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)	440		
5.	**Datorii curente**			
	Credite bancare pe termen scurt	450		
	Imprumuturi pe termen scurt	460		
	Datorii comerciale	470	3883519	1331928
	Datorii fata de partile afiliate	480		
	Avansuri primite curente	490	135390	159545
	Datorii fata de personal	500	152404	2913
	Datorii privind asigurarile sociale si medicale	510		
	Datorii fata de buget	520	492060	434590
	Venituri anticipate curente	530		
	Datorii fata de proprietari	540		
	Finantari si incasari cu destinatie speciala curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	71304	81963
	Total datorii curente (rd.450 + rd.460 + rd.470 + rd.480 + rd.490 + rd.500 + rd.510 + rd.520 + rd.530 + rd.540 + rd.550 + rd.560 + rd.570)	580	4734677	2010939
	Total pasive (rd.390 + rd.440 + rd.580)	590	22922956	23037804

SITUATIA DE PROFIT SI PIERDERE

de la pina la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010	27523075	27319617
Costul vinzarilor	020	15709392	15672962
Profit brut (pierdere bruta) (rd.010 – rd.020)	030	11813683	11646655
Alte venituri din activitatea operationala	040		28586
Cheltuieli de distribuire	050	46862	16306
Cheltuieli administrative	060	729327	964136

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Alte cheltuieli din activitatea operationala	070	384100	417394
Rezultatul din activitatea operationala: profit (pierdere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	10653394	10277405
Rezultatul din alte activitati: profit (pierdere)	090	10777	-195996
Profit (pierdere) pina la impozitare (rd.080 + rd.090)	100	10664171	10081409
Cheltuieli privind impozitul pe venit	110	1291160	1178993
Profit net (pierdere neta) al perioadei de gestiune (rd.100 – rd.110)	120	9373011	8902416

SITUATIA MODIFICARILOR CAPITALULUI PROPRIU

de la pina la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la inceputul perioadei de gestiune	Majorari	Diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6	7
1	**Capital social si suplimentar**					
	Capital social	010				
	Capital suplimentar	020				
	Capital nevarsat	030	()	()	()	()
	Capital neinregistrat	040				
	Capital retras	050	()	()	()	()
	Total capital social si suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
2	**Rezerve**					
	Capital de rezerva	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total reserve (rd.070 + rd.080 + rd.090)	100				
3	**Profit nerepartizat (pierdere neacoperita)**					
	Corectii ale rezultatelor anilor precedenti	110	X			
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	120				
	Profit net (pierdere neta) al perioadei de gestiune	130	X			
	Profit utilizat al perioadei de gestiune	140	X			
	Rezultatul din tranzitia la noile reglementari contabile	150				
	Total profit nerepartizat (pierdere neacoperita) (rd.110 + rd.120 + rd.130 - rd.140 + rd.150)	160				
4	**Alte elemente de capital propriu, din care**	170				
	Diferente din reevaluare	171				
	Subventii entitatilor cu proprietate publica	172				
	Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180				

SITUATIA FLUXURILOR DE NUMERAR

de la pina la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxuri de numerar din activitatea operationala			
Incasari din vinzari	010		
Plati pentru stocuri si servicii procurate	020		
Plati catre angajati si organe de asigurare sociala si medicala	030		
Dobinzi platite	040		
Plata impozitului pe venit	050		
Alte incasari	060		
Alte plati	070		
Fluxul net de numerar din activitatea operationala (rd.010 – rd.020 – rd.030 – rd.040 – rd.050 + rd.060 – rd.070)	080		
Fluxuri de numerar din activitatea de investitii			
Incasari din vinzarea activelor imobilizate	090		
Plati aferente intrarilor de active imobilizate	100		
Dobinzi incasate	110		
Dividende incasate	120		
Alte incasari (plati)	130		

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxul net de numerar din activitatea de investitii (rd.090 – rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiara			
Incasari sub forma de credite si imprumuturi	150		
Plati aferente rambursarii creditelor si imprumuturilor	160		
Dividende platite	170		
Incasari din operatiuni de capital	180		
Alte incasari (plati)	190		
Fluxul net de numerar din activitatea financiara (rd.150 – rd.160 – rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferente de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la inceputul perioadei de gestiune	230		
Sold de numerar la sfirsitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Date generale

Anexa 6

1. Certificat de inregistrare a entitatii, eliberat de Camera Inregistrarii de Stat.
   Numar de inregistrare Data inregistrarii Seria Numar
2. Capital social inregistrat de Camera Inregistrarii de Stat:
   data , suma lei, inclusiv:
   1) cota statului lei,
   2) cota detinatorilor a cel putin 20% Increase lei.
   Modificari ulterioare:
   a) , suma lei, inclusiv cota statului lei,
   b) , suma lei, inclusiv cota statului lei.
3. Entitatile, activitatea carora necesita licenta, indica:
   Licenta in vigoare:

Nr. Ord.	Numar	Data eliberarii	Termen de valabilitate	Tipul de activitate	Organul care a eliberat licenta
1					

4. Numarul mediu scriptic al personalului in perioada de gestiune 6 persoane, inclusiv pe categorii:
   1) personal administrativ 6 persoane,
   2) muncitori persoane.
5. Numarul personalului la 31 decembrie 2019 6 persoane.
6. Remunerarea personalului entitatii in perioada de gestiune 326523 lei.
7. Remunerarea membrilor organelor de administrare, de conducere si supraveghere si alte angajamente aparute sau asumate in legatura cu pensiile membrilor actuali sau ale fostilor membri ai acestor organe, pe categorii lei.
8. Avansurile si creditele acordate membrilor organelor specificate la pct.7 lei, inclusiv rambursate lei.
9. Valoarea activelor imobilizate si circulante, inregistrate in calitate de gaj
   1) valoarea de gaj lei,
   2) valoarea contabila lei.
10. Numarul actiunilor ordinare la finele perioadei de gestiune unitati.
11. Profit net (pierdere neta) a perioadei de gestiune pentru o actiune ordinara:
    1) profit lei,
    2) pierdere lei.
12. Dividende calculate pentru o actiune ordinara pentru perioada de gestiune:
    1) platite lei,
    2) planificate pentru plata lei.
13. Valuta straina disponibila, recalculata in moneda nationala a Republicii Moldova – total lei,
    inclusiv (lei, denumirea si codul valutei):

Nr. Ord.	lei	denumirea	codul valutei
1			

14. Numerar legat – total lei.
    In rindurile, in care se inscriu sumele de gaj, in toate coloanele prin fractie se reflecta:
    a) la numarator – valoarea de gaj;
    b) la numitor – valoarea contabila

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 1

Creante, investitii financiare si datorii pe termen lung aferente fondatorilor nerezidenti

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung – total	010					
Creante comerciale, *inclusiv pe tari:*	020					

1	2	3	4	5	6	7

1	2	3	4	5	6	7
Avansuri acordate, *inclusiv pe tari:*	030					

1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040					

1	2	3	4	5	6	7
Alte creante si investitii financiare, *inclusiv pe tari:*	050					

1	2	3	4	5	6	7
Datorii pe termen lung – total	060					
Datorii comerciale, *inclusiv pe tari:*	070					

1	2	3	4	5	6	7
Avansuri primite, *inclusiv pe tari:*	080					

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	090					

1	2	3	4	5	6	7
Alte datorii, *inclusiv pe tari:*	100					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100
Col.7 = col.3+col.4-col.5±col.6

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 2

Creante, investitii financiare si datorii pe termen lung aferente nerezidentilor, cu exceptia fondatorilor

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung – total	010					
Creante comerciale, *inclusiv pe tari:*	020					

1	2	3	4	5	6	7
Avansuri acordate, *inclusiv pe tari:*	030					

1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040					

1	2	3	4	5	6	7
Depozite, *inclusiv pe tari:*	050					

1	2	3	4	5	6	7
Alte creante si investitii financiare, *inclusiv pe tari:*	060					

1	2	3	4	5	6	7
Datorii pe termen lung – total	070					
Datorii comerciale, *inclusiv pe tari:*	080					

1	2	3	4	5	6	7
Avansuri primite, *inclusiv pe tari:*	090					

1	2	3	4	5	6	7

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	100					

1	2	3	4	5	6	7
Alte datorii, *inclusiv pe tari:*	110					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.60
Rd.070= rd.080 + rd.090 + rd.100 + +rd.110
Col.7 = col.3+col.4-col.5±col.6

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 3

Creante, investitii financiare si datorii curente aferente fondatorilor nerezidenti

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune				Sold la sfirsitul perioadei de gestiune	
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9	10
Creante si investitii financiare curente – total	010								
Creante comerciale, *inclusiv pe tari:*	020								

1	2	3	4	5	6	7	8	9	10
Avansuri acordate, *inclusiv pe tari:*	030								

1	2	3	4	5	6	7	8	9	10
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040								

1	2	3	4	5	6	7	8	9	10
Alte creante si investitii financiare, *inclusiv pe tari:*	050								

1	2	3	4	5	6	7	8	9	10
Datorii curente – total	060								
Datorii comerciale, *inclusiv pe tari:*	070								

1	2	3	4	5	6	7	8	9	10
Avansuri primite, *inclusiv pe tari:*	080								

1	2	3	4	5	6	7	8	9	10
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	090								

1	2	3	4	5	6	7	8	9	10
Datorii privind dividendele calculate, *inclusiv pe tari:*	100								

1	2	3	4	5	6	7	8	9	10
Alte datorii, *inclusiv pe tari:*	110								

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 – col.7 ± col.8

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 4

Creante, investitii financiare si datorii curente aferente nerezidentilor, cu exceptia fondatorilor

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune				Sold la sfirsitul perioadei de gestiune	
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9	10
Creante si investitii financiare curente – total	010								
Creante comerciale, *inclusiv pe tari:*	020								
Avansuri acordate, *inclusiv pe tari:*	030								
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040								
Depozite, *inclusiv pe tari:*	050								
Alte creante si investitii financiare, *inclusiv pe tari:*	060								
Datorii curente – total	070								
Datorii comerciale, *inclusiv pe tari:*	080								
Avansuri primite, *inclusiv pe tari:*	090								
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	100								
Alte datorii, *inclusiv pe tari:*	110								

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 – col.7 ± col.8

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 5

Investitii financiare in strainatate si participarea nerezidentilor in capitalul social

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Investitii financiare	010				
Cote de participatie si actiuni de pina la 10% inclusiv, in capitalul social al entitatilor nerezidente, *inclusiv pe tari:*	020				
Cote de participatie si actiuni de peste 10% in capitalul social al entitatilor nerezidente, *inclusiv pe tari:*	030				

1	2	3	4	5	6
Capital social	040				
Cote de participatie si actiuni de pina la 10% inclusiv, *inclusiv pe tari:*	050				

1	2	3	4	5	6
Cote de participatie si actiuni de peste 10%, *inclusiv pe tari:*	060				

Rd.010= rd.020 + rd.030
Rd.040= rd.050 + rd.060
Col.6 = col.3+col.4-col.5

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 6

Venituri si cheltuieli aferente tranzactiilor cu nerezidentii

Indicatori	Cod rd./ cod tara	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri – total	010		
Venituri aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, *inclusiv pe tari:*	020		

1	2	3	4
Venituri din dobinzi aferente activitatii operationale si altor activitati, *inclusiv pe tari:*	030		

1	2	3	4
Venituri din dividende si participatii in alte entitati,*inclusiv pe tari:*	040		

1	2	3	4
Venituri din decontarea datoriilor cu termenul de prescriptie expirat, *inclusiv pe tari:*	050		

1	2	3	4
Alte venituri, *inclusiv pe tari:*	060		

1	2	3	4
Cheltuieli – total	070		
Cheltuieli aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, *inclusiv pe tari:*	080		

1	2	3	4
Cheltuieli privind dobinzile, *inclusiv pe tari:*	090		

1	2	3	4
Cheltuieli si provizioane aferente creantelor comerciale si altor creante compromise, *inclusiv pe tari:*	100		

1	2	3	4
Alte cheltuieli, *inclusiv pe tari:*	110		

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 7

Bunuri ale nerezidentilor inregistrate in conturi extrabilantiere

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Bunuri primite in baza contractelor de comision, *inclusiv pe tari:*	010				

1	2	3	4	5	6

1	2	3	4	5	6
Bunuri primite spre prelucrare,*inclusiv pe tari:*	020				

1	2	3	4	5	6
Bunuri obtinute din materialele prelucrate, *inclusiv pe tari:*	030				

Col.6 = col.3+col.4-col.5

Informaţiile privind activele imobilizate

Anexa 7

Indicatori	Nr. rind	Existenţa la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieşirea în cursul perioadei (la costul de intrare)	Existenţa la sfîrşitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrşitul perioadei	Deprecierea acumulată la sfîrşitul perioadei
A	1	2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuţie	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200								
2.1 brevete şi mărci	210								
2.2. licenţe de activitate	220								
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuţie	300								
4. Terenuri	400		x					x	
5. Mijloace fixe, total din care:	500								
5.1. clădiri	510								
5.2. construcţii speciale	520								
5.3. maşini, utilaje, instalaţii de transmisie	530								
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente şi inventar	550								
5.6. costuri ulterioare aferente obiectelor neînregistrate în bilanţ	560								
5.7. mijloace fixe primite în leasing financiar	570								
5.8. mijloace fixe primite în gestiune economică	580								
5.9. alte mijloace fixe	590								
6. Resurse minerale	600								
7. Investiţii imobiliare, total	700								

Persoanele responsabile de semnarea rapoartelor financiare ale entităţii*
* conform art.36 din Legea contabilităţii

Documente atașate - Notă explicativă (fișierul pdf)

Biosistem 2019.pdf

Versiune de imprimare

Salvare

Recipisa

Respondent
Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.
A prezentat raportul: RSF1
Pentru perioada fiscala: A/2019
Data prezentarii: 31.03.2020
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 31.03.2020 17:42:37

Versiune de imprimare

Salvare

Recipisa 2

Respondent
Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.
A prezentat raportul: RSF1
Pentru perioada fiscala: A/2019
Data prezentarii: 31.03.2020
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 21.05.2020 10:13:29

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

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. / № A2100779 **din** / от 20.01.2021

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/lei.

4. Valabil pînă la / Действителен до 04.02.2021

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"// 20.01.2021 ora 15:30:49
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,16)

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 nr. ocds-b3wdp1-MD-1610694912358

din 29.01.2021

din cadrul CAPCS

Declarație

Prin prezenta, SRL „Biosistem-mld”, declara ca pentru produsele noi sau necunoscute, vor fi prezentate mostre în termen de 5 zile de la solicitare

_____Vitalie Poiata

L.Ş.

To: Whoever it may concern

22.01.2021

MANUFACTURER'S DECLARATION

We, Turklab Tibbi Malzemeler San ve Tic. A.s. located at ITOB OSB 10017 sk. No: MENDERES, IZMIR, TURKEY manufacturer of “RTHIV02 Anti-HIV 1/2 TEST, WB/S/P” and “RTTP02 Anti-Syphilis Test”, do hereby declare that:
The rapid tests from the offer for the tender Nr. ocds-b3wdp1-MD-1610694912358 from 29.01.2021 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.

Chairman

Dr. Şahin Yağlıdere

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

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 affored 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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Anna Małgorzata Wyroba
Member of the Board

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 08:47:33 +02'00'

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

Member of Multilateral Recognition Arrangement IAF

Anna Małgorzata Wyroba
Member of the Board

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 08:48:40 +02'00'

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

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 cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored 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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Anna Małgorzata Wyroba
Member of the Board

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

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:02:27 +02'00'
Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

SOĞUK DAMGA VARDIR

TERCÜME

T.C.
TORBALI 6. NOTERLİĞİ
Tel: 0232 854 70 07 Fax: 0232 854 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 herebycertifythatthisdocument has beentranslatedfromits English intoTurkishtrulyandcorrectlyby me.03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C.
TORBALI 6. NOTERİ
Selma ZİYREK

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

№09971

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 cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored 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

T.C.
TORBALI 6. NOTERİ
Selma ZİYREK

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

Anna Małgorzata Wyroba
Member of the Board

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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

TERCÜME

№09971

SERTİFİKA EKİ

SADECE SERTİFİKA İLE BAĞLANTILI OLARAK GEÇERLİDİR

No. M – 56/4/2020

İşbu sertifika, aşağıda yer alan faaliyetler kapsamındaLokasyonun tasdiki için hazırlanmıştır:

Fabrika 2:ITOB 10031 Sokak No: 15,
Tekeli-Menderesİzmir, 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 Üyesi

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

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İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.
I herebycertifythatthisdocument has beentranslatedfromits English intoTurkishtrulyandcorrectlyby me.03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C.
TORBALI 6. NOTERİ
ZİYREK

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

№0971

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

T.C.
TORBALI 6. NOTER
Selma ZİYREK

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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

IAF

Anna Małgorzata Wyroba

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

Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

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

CE 1434

Michał Pachowski, PhD
President

Application No: 57/2019
Module: H6

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

CE 1434

Michał Pachowski, PhD
President

Application No: 57/2019
Module: H7

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

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. 879 009 6203

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:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - 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: 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. 879 009 6209

CE

Rapidan® Tester

INSTRUCTION FOR USE
Anti-HIV 1/2 TEST, WB/S/P

Anti-HIV (HIVab) Detection in
Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: RTHIV02

Human Immunodeficiency Virus Antibody Cassette Test

BACKGROUND INFORMATION

HIV (human immunodeficiency virus) is the virus that causes AIDS (Acquired Immunodeficiency Syndrome), destroys certain blood cells that are crucial to the normal function of the immune system, which defends the body against illness. It occurs when the immune system is weakened by HIV to the point where a person develops any number of diseases or cancers.

HIV cannot be transmitted through casual, everyday contact. Mosquitoes and other insects do not transmit HIV. HIV can be spread by sexual contact with an infected person, by sharing needles and/or syringes and/or other injecting equipment or, less commonly (and now very rarely in countries where blood is screened for HIV antibodies), through transfusions of infected blood or blood clotting factors.

Early laboratory diagnosis of primary human immunodeficiency virus (HIV) infection is based on the detection of viral RNA or p24 antigen in plasma or serum prior to antibody seroconversion. The diagnostic window of HIV infection may be reduced on average by 4-5 days by screening for p24 antigen. HIV infection is most commonly detected through the test of a sample of blood or oral fluid. If the blood or oral fluid sample contains HIV antibodies -proteins the body produces to fight off the infection- the person is HIV-positive. Rapid immunochromatographic test devices offer significant advantages which include being of cost-effective testing, early diagnosis, easy to operate and rapid initiation of treatment.

INTENDED USE

Anti-HIV 1/2 Test is a rapid qualitative immunoassay for the detection of 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) in human whole blood / serum / plasma.

REAGENTS

Recombinant HIV antigen, anti-HIV monoclonal antibody and recombinant HIV antigen conjugated with colored particles.

METHOD

Anti-HIV 1/2 Test uses immunochromatographic technology for the qualitative detection of anti-HIV in human whole blood / serum / plasma. Sample is introduced from sampling pad. If there is anti-HIV in the sample at detectable level, anti-HIV binds to the mobile recombinant HIV 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-HIV in the sample at detectable level then sample moves to the test area "T" together with unbound recombinant HIV 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-HIV 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 HIV 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 HIV; 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 HIV 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 and 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, 1 drop of diluent is added into the sample well and allowed to soak in.

For Whole Blood Samples: Draw whole blood 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.

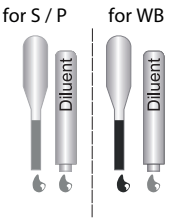
When using Capillary Blood Samples: Collect 25 µl of fingerstick whole blood using the capillary tube (not provided) and transfer it into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.

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 HIV 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 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

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).

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 and Specificity

Using results of positive samples (505/505) and negative samples (1911/1911); sensitivity, specificity values with the 95% confidence interval are calculated as;

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

Seroconversion panels: 30 seroconversion panels were studied with Türklab Anti-HIV 1/2 Test and compared to results from CE Marked EIAs as reference assays. Türklab Anti-HIV 1/2 Test was capable of detecting antibodies to HIV 1/2 in a similar manner of the CE Marked EIA tests.

Interferences: Following potentially interfering substances were tested with Anti-HIV 1/2 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 Anti-HIV 1/2 Test.

- Anti-HBs whole blood / serum / plasma samples,
- HBsAg whole blood / serum / plasma samples,
- Anti-HCV 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-HIV 1/2 Test. The results showed that there was a good correlation of testing results between venous whole blood and capillary blood.

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4. Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis, *World Health Organization*, 2nd edition, 2017.
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6. Badwan A., Mohammed M.A., (2008). "Rapid Immunochromatographic Detection By Amplification Of The Colloidal Gold Signal", *International Publication Number*. WO 2008/071342 A1.
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10. "UNAIDS urges a scaling up of HIV vaccine research to stop new infections", *Press Statement*, GENEVA, 17 May 2018.
11. Global AIDS Update; 2018.

TÜRKLAB
let us diagnose
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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

ULTRA SENSITIVE **Anti-Syphilis Test**

For Syphilis Antibody (Anti-*Treponema pallidum*) Detection in Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: RTTP02

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.

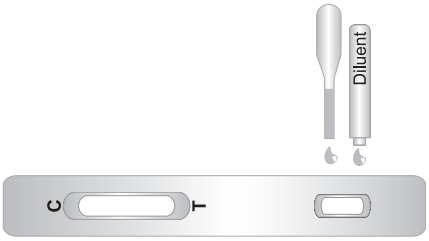
TEST PROCEDURE

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.

NEGATIVE POSITIVE INVALID INVALID



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- *T. Pallidum* 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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CE

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