

-----:
ORDIN DE PLATA NR.: 3361 TIP.DOC. 1 :
DATA EMITERII:joi, 12 decembrie :
=====:
PLATITI: 200-00 LEI: Doua Sute lei 00 bani :
:
:
=====:
PLATITOR: (R) 'BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" SRL MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R) Institutul d CONTUL DE PLATI/CODUL IBAN :
e Cardiologie IMSP MD98ML000000002251902161 :
CODUL FISCAL :1003600150613 / :
:
:
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
BC"Moldindconbank"S.A. :MOLDMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1733402408882 din : :
13.12.2024 : :
: :
: L.S. :
=====:
CODUL TRANZACTIEI:001: :
DATA PRIMIRII:12/12/2024 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTOR:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAAEDi65avx+fXSlAAAAAQOLMA0GCSq:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTI0MDEyNTEyMzE1N1oXDTI3MDEyNTEyNDM1NlowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQml :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAAEDijjVd7aJ5r0rAAAAAQOKMA0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTI0MDEyNTEyMzE1NVVoXDTI3MDEyNTEyNDMzNVowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
L.S. (semnatura electronica) :
CONDUCTOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:-----:
MOTIVUL REFUZULUI : L.S. :
-----:



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ 1433048

Din
От 02.12.2024 14:33

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1010600028048

Denumirea

Наименование

Societatea cu Răspundere Limitată BIOSISTEM MLD

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI

INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ
ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ
СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

17.12.2024 14:33



Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответствии со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la 02.12.2024 14:33

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

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SITUAȚIILE FINANCIARE

pentru perioada 01.01.2023 - 31.12.2023

Entitatea: BIOSISTEM MLD S.R.L.

Cod CUIÎO: 40717392

Cod IDNO: 1010600028048

Sediul:

MD:

Raionul(municipiul): 106, DDF RASCANI

Cod CUATM: 0150, SEC.RISCANI

Strada: 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: 10 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

la

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			
A.	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:			
	2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		

2.4. alte immobilizări necorporale	024		
3. Fond comercial	030		
4. Avansuri acordate pentru immobilizări necorporale	040		
Total immobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
II. Immobilizări corporale			
1. Immobilizări corporale în curs de execuție	060		
2. Terenuri	070		
3. Mijloace fixe, total	080	3384131	4438372
din care:			
3.1. clădiri	081		
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	3363063	4423127
3.4. mijloace de transport	084		
3.5. inventar și mobilier	085	21068	15245
3.6. alte mijloace fixe	086		
4. Resurse minerale	090		
5. Active biologice immobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru immobilizări corporale	120	5250844	2337159
Total immobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	8634975	6775531
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 immobilizate			
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	8634975	6775531
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	13899	24776
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	11123640	11490033
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	11137539	11514809
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	4552459	2646694
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	27696	45618
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	2268111	2251145
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6848266	4943457
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți nefiliate	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	10281443	27361722
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	28267248	43819988

	TOTAL ACTIVE (rd.230 + rd.420)	430	36902223	50595519
	P A S I V			
	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		
C.	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	35876971	29813141
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	18618853
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	35876971	48431994
	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	35882371	48437394
D.	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:			
	2.1. împrumuturi din emisiunea de obligațiuni	641		
	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		
	din care:			
	2.1. Împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	5266	59765
	4. Datorii față de părțile afiliate curente	740		
E.	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	143160	273711
	6. Datorii față de personal	760	866	
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	831429	1766706
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	39131	57943
	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	1019852	2158125
	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		
F.	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	36902223	50595519

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2023 până la 31.12.2023

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune
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		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	40621876	58891757
din care:			
venituri din vânzarea produselor și mărfurilor	011	39203671	57105542
venituri din prestarea serviciilor și executarea lucrărilor	012	1390733	1771148
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	27472	15067
Costul vânzărilor, total	020	22086174	32917436
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	21991682	32793096
costul serviciilor prestate și lucrărilor executate terților	022	92356	124340
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026	2136	
Profit brut (pierdere brută) (rd.010 - rd.020)	030	18535702	25974321
Alte venituri din activitatea operațională	040	128694	829270
Cheltuieli de distribuire	050	15271	4167
Cheltuieli administrative	060	3076978	3996115
Alte cheltuieli din activitatea operațională	070	1325483	879808
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	14246664	21923501
Venituri financiare, total	090	1530710	1070406
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	250190	337916
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	1280520	732490

Cheltuieli financiare, total	100	512939	1786338
din care:	101		
cheltuieli privind dobânzile			
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	512939	1786338
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	1017771	-715932
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	1017771	-715932
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	15264435	21207569
Cheltuieli privind impozitul pe venit	170	1872862	2588716
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	13391573	18618853

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
	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
I.	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)					
IV.	1. Corecții ale rezultatelor anilor precedenți	120	X			
	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 sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Recipisa

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 26.03.2024 17:05:42

Recipisa 2

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 09.04.2024 09:26:11

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.

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*

L. Svirepova
semnătura

MD 0101250





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

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 (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 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,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

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: **15.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461494



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: MOLDM2X329

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: MOLDM2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent
in moneda nationala al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu
IBAN MD95ML000000002251429243.

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

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

Cod Fiscal: 1010600028048; IBAN: MD95ML00000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

Scrisoare de informare

Prin prezenta, SRL „Biosistem mld”, va informeaza ca conform “*legii Nr. 160 din 22-07-2011 privind reglementarea prin autorizare a activității de întreprinzător*”, cu modificarile ulterior adoptate de parlamentul RM, *Importul, comercializarea, asistența tehnică si reparația dispozitivelor medicale* nu mai este activitate licentiata. Respectiv nu mai sunt eliberate licente pentru acest gen de activitate, iar licentele cu termenul de valabilitate expirat nu mai sunt prelungite.



Vitalie Poiata

L.Ș.

Acreditación



Otorga la presente / Grants this

ACREDITACIÓN

12/PPI020

a

BioSystems, S.A. (PREVECAL)

Según criterios recogidos en la norma UNE-EN ISO/IEC 17043, para las actividades como PROVEEDOR DE PROGRAMAS DE INTERCOMPARACIÓN definidas en el ANEXO TÉCNICO nº 12/PPI020. According to the criteria in the standard UNE-EN ISO/IEC 17043 for the Proficiency Testing Provider activities defined in the Technical Annex Nº 12/PPI020.

Fecha de entrada en vigor / Coming into effect: 26/04/2019



D. José Manuel Prieto Barrio
Presidente

La acreditación mantiene su vigencia hasta notificación en contra. Este documento no tiene validez sin su correspondiente anexo técnico. La presente acreditación y su anexo técnico están sujetos a modificaciones, suspensiones temporales y retirada. Su vigencia puede confirmarse en www.enac.es.

The accreditation maintains its validity unless otherwise stated. The present accreditation is not valid without its corresponding technical annex. This accreditation and its technical annex could be reduced, temporarily suspended and withdrawn. The state of validity of it can be confirmed at www.enac.es.

ENAC es firmante de los Acuerdos de Reconocimiento Mutuo establecidos en el seno de la European co-operation for Accreditation (EA) y de las organizaciones internacionales de organismos de acreditación, ILAC e IAF (www.enac.es)

ENAC is signatory of the Multilateral Recognition Agreements established by the European co-operation for Accreditation (EA) and the International organizations of accreditation bodies, ILAC and IAF (www.enac.es)

Ref.: CPPI/11294 Fecha de emisión 30/07/2021
El presente documento anula y sustituye al de ref. CPPI/10429

6M91021910

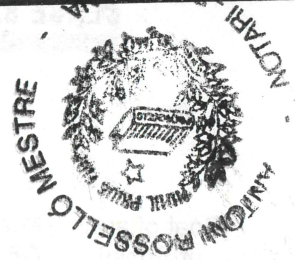
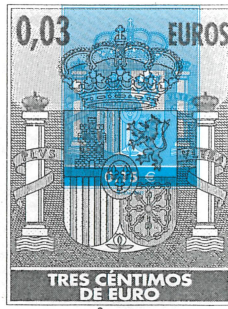
06/2019



JOSEP PEÑARROJA FA
ADVOCATE AND SOLICITOR
COMMISSIONER FOR OATHS
OFFICIAL TRANSLATOR
GRAN VIA 594 SA 2ª
08007 BARCELONA SPAIN



CLASE 8ª



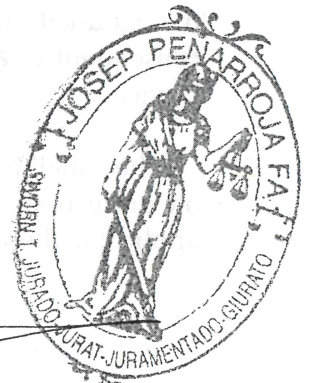
Traducción Jurada *Official translation*

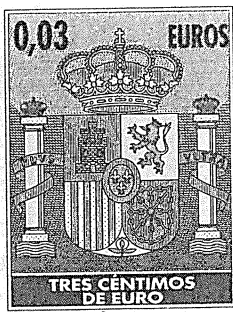
Josep Peñarroja Fa
Intérprete Jurado de Inglés
Official Translator of English

Certifica que la que antecede es traducción
fiel y completa al inglés de un documento
redactado en español.

Do hereby certify that the attached translation
is a true and accurate rendering into English
of a document in Spanish.

Barcelona, - 3 MAR 2020





CLASE 8.^a

Traducción Jurada

[Coat of arms of Spain]

MINISTRY OF HEALTH

[Logo] Spanish Medicines and Medical Devices Agency

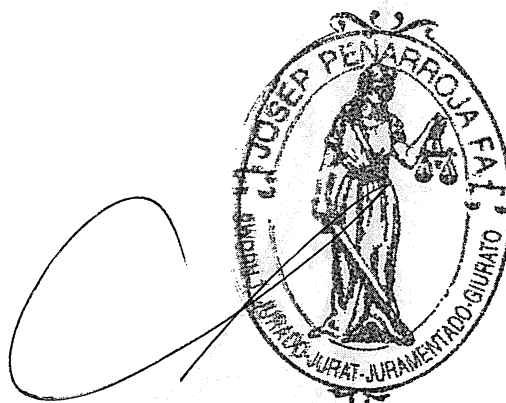
NOTIFICATION

OUR REF.: PS/DP/MFD
DATE: 19 February 2020
RE: Information to the recipient

RECIPIENT: **BIOSYSTEMS, S.A.**
C/ COSTA BRAVA, N.º 30
08030 BARCELONA (SPAIN)

With regard to the products listed below, produced by your company, considering that they are subject to external quality assessment procedures:

- PREVECAL BIOCHEMISTRY
- PREVECAL PROTEINS
- PREVECAL URINE
- PREVECAL RHEUMA
- PREVECAL BIOCHEMISTRY HUMAN
- PREVECAL ANA
- PREVECAL nDNA
- PREVECAL CELIAC
- PREVECAL ANCA
- PREVECAL COAGULATION
- PREVECAL VETERINARY



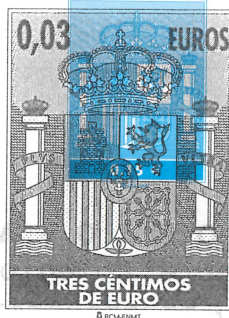
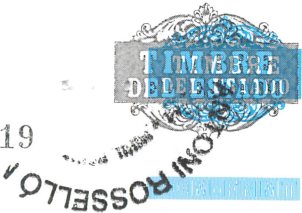
You are hereby advised that:

These products **do not** fall within the scope of Royal Decree 1662/2000, of 29 September, which transposes Directive 98/79/EC of the European Parliament and of the Council, of 27 October 1998, on in vitro diagnosis medical devices, and, consequently, are outside the sphere of competence of this Department of Medical Devices.

They shall be marketed as provided for under the general commercial laws, the laws on protection of users and consumers, and any other specific regulations which are applicable thereto.

0N98961929

06/2019



CLASE 8.^a

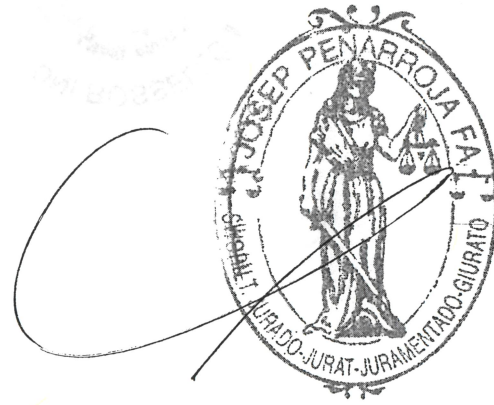
Traducción Jurada

THE HEAD OF THE DEPARTMENT
OF MEDICAL DEVICES
[Signature and seal of the Spanish Medicines
and Medical Devices Agency]
Carmen Ruiz-Villar Fernández-Bravo

E-MAIL:
mpizarro@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 50 09
FAX: 91 822 52 77

[There is a seal which states that the document has been recorded by the Spanish Ministry of Health, dated 20 February 2020]



TESTIMONIO.- ANTONIO ROSSELLÓ MESTRE, Notario del Ilustre Colegio de Cataluña, con residencia en Barcelona, -----

DOY FE: Que el presente testimonio es fiel reproducción, por fotocopia, del documento original, que me exhibe. Y para que conste libro el presente, extendido en dos folios de papel del Timbre del Estado, exclusivo para Documentos Notariales, serie FA, número el presente y el anterior correlativo en orden ascendente. -----

Barcelona a once de marzo de dos mil veinte. -----

Figura en el libro indicador con el N° 453/2020 de la Sección Segunda.-----



Antonio Roselló Mestre

CERTIFICATO DI ACCREDITAMENTO

Accreditation Certificate

ACCREDITAMENTO N. **0017P REV. 00**
ACCREDITATION N.

EMESSO DA **DIPARTIMENTO LABORATORI DI PROVA**
ISSUED BY

SI DICHIARA CHE **BIO-GROUP MEDICAL SYSTEM S.r.l.**
WE DECLARE THAT

Sede/Headquarters:
- Loc. Campiano 9/b - 47867 Talamello RN

È CONFORME AI REQUISITI **UNI CEI EN ISO/IEC 17043:2010**
DELLA NORMA

MEETS THE REQUIREMENTS **ISO/IEC 17043:2010**
OF THE STANDARD

QUALE **Organizzatori di prove valutative interlaboratorio**
AS **Proficiency Testing Provider**

Data di 1^a emissione
1st issue date
14-11-2018

Data di modifica
Modification date
14-11-2018

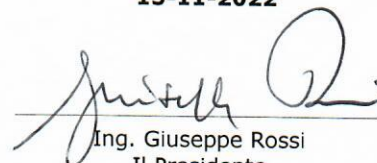
Data di scadenza
Expiring date
13-11-2022



Dott.ssa Silvia Tramontin
Il Direttore di Dipartimento
The Department Director



Dott. Filippo Trifiletti
Il Direttore Generale
The General Director



Ing. Giuseppe Rossi
Il Presidente
The President

L'accreditamento attesta la competenza tecnica dell'Organizzazione relativamente al campo di accreditamento riportato nell'Elenco Schemi allegato al presente certificato di accreditamento.

Il presente certificato non è da ritenersi valido se non accompagnato dagli Elenchi Schemi, che possono variare nel tempo.

La vigenza dell'accreditamento può essere verificata sul sito web (www.accredia.it) o richiesta al Dipartimento di competenza.

The accreditation certifies the technical competence of the organisation limited to the scope detailed in the attached Enclosure. The present certificate is valid only if associated to the annexed schedule, that may vary in the time.

Confirmation of the validity of accreditation can be verified on website www.accredia.it or by contacting the relevant Department.



BIO GROUP – MEDICAL SYSTEM Srl
Strumentazione e Diagnostici
 Loc. Campiano, 9/B – 47867 Talamello (RN)
 e.mail: info@biogroupmedicalsystem.com
 Tel. +39 0541 920686
 Fax +39 0541 922130

Declaration of conformity certificate

We: Bio Group Medical System Srl Loc. Campiano 9/B, Talamello (RN) 47867 Italy
 Ensure and declare with sole responsibility that the products:

Internal code: MSEQUALITYCH-MSEQSCH12-MSEQSCH4 EDMA Code: 38220000	Commercial name: QS Clinical Chemistry First lot introduced in market: 112-NB
Internal code: MSEQUALITYPS EDMA Code: 38220000	Commercial name: QS Specific Protein First lot introduced in market: 220-NB
Internal code: MSEQUALITYEF EDMA Code: 38220000	Commercial name: QS Electrophoresis First lot introduced in market: 220-NB
Internal code: MSEQUALITYE8-MSEQSE12 EDMA Code: 30021095	Commercial name: QS Hematology First lot introduced in market: 2020-EN
Internal code: MSEQUALITYC-MSEQSC12-MSEQSC4 EDMA Code: 38220000	Commercial name: QS Coagulation First lot introduced in market: 084
Internal code: MSEQUALITYI-MSEQSI12-MSEQSI4 EDMA Code: 38220000	Commercial name: QS Immunology First lot introduced in market: 360
Internal code: MSEQUALITYB EDMA Code: 38220000	Commercial name: QS Bacteriology First lot introduced in market: 326
Internal code: MSEQUALITYS EDMA Code: 38220000	Commercial name: QS Serology First lot introduced in market: 1020-SI
Internal code: MSEQUALITYU EDMA Code: 38220000	Commercial name: QS Urine First lot introduced in market: 002-U
Internal Code: MSEQUALITYH-MSEQSHB12 EDMA Code: 38220000	Commercial name: QS HBAIC First lot introduced in market: 001-H
Internal Code: MSEQUALITYD EDMA Code: 38220000	Commercial name: QS Drug of Abuse First lot introduced in market: 330-D
Internal Code: MSEQUALITYSO EDMA Code: 38220000	Commercial name: QS FOB First lot introduced in market: 110-F
Internal Code: MSEQUALITYESR EDMA Code: 30021095	Commercial name: QS ESR First lot introduced in market: 001-V
Internal Code: MSEQUALITYCM EDMA Code: 38220000	Commercial Name: QS Cardiac Marker First lot introduced in market: 201-C

meet the provisions of Council Directive 98/79/CE, annex I, as expected according to Council Directive 98/79/CE, annex III, concerning In Vitro Medical-Diagnostic Devices, which apply to us.

To this purpose, we guarantee and declare, on our own responsibility, what follows:

- ◆ Subsequent lots will be consistent with technical specification of the first lot. This conformity will be attested on the quality control certificate.
- ◆ The specified item satisfy the all dispositions applicable of Directive 98/79/CE
- ◆ We undertake in storing and placing to the competent Authority disposal the technical dossier of the product, as required by Council Directive 98/79/CE, annex III, as well as the production and control registrations for a period of at least 5 years after the last production date of the last lot.
- ◆ The specified device is designed, manufactured, and commercialized with date of first release not preceding the present one.

The present conformity declaration has validity of a maximum of 5 years.

Moreover, the manufacturer declare to have established and to maintain an appropriate procedure to guarantee the post-sale surveillance, as requested by Council Directive 98/79/CE.



Talamello, January the 29th, 2019

BIO GROUP
MEDICAL SYSTEM SRL
 Loc. Campiano 9/B – 47867 Talamello (RN)
 P.IVA C.Fisc. 0096170419

Cap. Soc. € 75.300,00 i.v. – Reg. Trib. Pesaro 7163 C.C.I.A.A. 98204 – P.IVA C.Fisc. 0096170419





EXTERNAL QUALITY ASSESSMENT

Bio Group Medical System



A POWERFUL TOOL
FOR A TOTAL QUALITY
IMPROVEMENT

01.

Who we are

Quality System since 1999 is a valuable tool for assessing the diagnostic quality of a laboratory. Quality System is the EQA brand of **Bio Group Medical System**, involved in the diagnostic sector since 1985.

Quality System offers a wide range of scheme, in total 16 programs. Different frequency options are available for most of the available schemes.

Bio Group Medical System has been **ISO 17043:2010** accredited as **Proficiency Testing Provider** by **ACCREDIA** (certificate n.17/P and related attachment that can be download from <http://pa.sinal.it/PA2254AR1.PDF>).



Bio Group Medical System is member of The European Organisation For External Quality Assurance Providers in Laboratory Medicine (**EQALM**).

Statistical Elaboration procedures have been validated in cooperation with **Urbino University**.



Introduction

The clinical analysis laboratory has as its ultimate goal the generation of data about the health of the patient, data that will be used later in the diagnostic process. For this purpose, it plays a leading role in defining the behaviour that a clinician should follow to deal with a diagnosis or a follow-up treatment or a condition.

Therefore, the work carried out in a clinical analysis laboratory must follow a series of quality procedures in order to obtain a final data that meets the required precision and accuracy criteria.

Each laboratory must be able to work in compliance with the quality rules to ensure that the generated reports are as accurate as possible. In fact, that data output by clinical analysis is subjected to systematic and random errors. If the operator knows the magnitude of these errors, this will compensate system errors and provide experimental data as close as possible to reality.

Aim of Quality System

The purpose of the QS is to allow a comparison between independent laboratories.

The external quality assessment statistically examines the final result of the entire work process, taking into consideration the pre-analytical phase, the entire phase involving the laboratory and also the final data transmission.

The control results allow making deductions on the good functioning of both the process itself as an organised structure and the various phases of which it is composed; in some cases, they also allow obtaining suggestions on the type of problem that prevents it from obtaining a good result.

In other words, the participation in QS programs is a valuable tool for assessing the diagnostic quality of a laboratory.

The periodic control obtained via QS allows the operator to assess his analytical system by comparing the results obtained with those of the daily IQC, thus validating the latter and the entire organisation.

The QS offers precise indications on any possible anomaly and is, therefore, a powerful tool for the constant improvement of the "Total Quality" and data quality assurance.



Vision & Mission

An experienced team working on the diagnostic field since 1985, providing to participants high standard quality samples.

“We trust it is important to give to all patients the right diagnosis.”



02.

Our Schemes

CLINICAL CHEMISTRY

34 Parameters - Lyophilized Sera
1 Level - Yearly / Quaterly / Monthly

HEMOSTASIS

7 Parameters - Lyophilized Plasma
1 Level - Yearly / Quaterly / Monthly

ELECTROPHORESIS

5 Parameters - Lyophilized Sera
1 Level - Yearly / Quaterly / Monthly

CARDIAC MARKERS

10 Parameters - Lyophilized Sera
1 Level - Yearly / Quaterly / Monthly

INFECTIOLOGY

29 Parameters - Lyophilized Sera
1 Level - Yearly / Quaterly

URINE CHEMISTRY

13 Parameters - Liquid Sample
1 Level - Yearly / Quaterly

DRUGS OF ABUSE

12 Parameters - Liquid Sample
1 Level - Yearly / Quaterly

ERYTHROCYTE SED. RATE

Liquid Sample
1 Level - Yearly / Quaterly

IMMUNOASSAY

35 Parameters - Lyophilized Sera
1 Level - Yearly / Quaterly / Monthly

HEMATOLOGY

8 Parameters - Liquid Sample
1 Level - Yearly / Quaterly / Monthly

SPECIFIC PROTEINS

9 Parameters - Lyophilized Sera
1 Level - Yearly / Quaterly / Monthly

HBA1C

Lyophilized Sera
1 Level - Yearly / Quaterly / Monthly

MICROBIOLOGY

1 Lyophilized Sera
1 Level - Yearly / Quaterly

URINE SEDIMENTATION

Liquid Sample
1 Level - Yearly / Quaterly

FECAL OCCULT BLOOD

Liquid Sample
1 Level - Yearly / Quaterly

BLOOD SMEAR

Electronic File
Yearly - Quaterly

Scheme: CLINICAL CHEMISTRY

Sample material:

The proficiency testing item is **Human Lyophilized Serum** simulating the biological findings usually measured by the participants. These Serums will present a range of values completely comparable with those found in the working routine of the participants. The coordinator will choose Serums which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

ALBUMINE	CHOLINESTERASE	LDH	TOTAL CHOLESTEROL
ALP	CK NAK	LDL CHOLESTEROL	TOTAL PROTEINS
ALT	COPPER	LIPASE	TRIGLYCERIDES
AMYLASE	CREATININE	LITHIUM	UIBC
AST	DIRECT BILIRUBIN	MAGNESIUM	UREA
BICARBONATE	GAMMA GT	PHOSPHORUS	URIC ACID
BILE ACIDS	GLUCOSE	POTASSIUM	ZINC
CALCIUM	HDL CHOLESTEROL	SODIUM	

Statistical Elaboration:

Quantitative

Frequency:

Yearly, Quaterly or Montlhy

Product Code:

MSEQSCH1 - MSEQSCH4 - MSEQSCH12

Level:

1 level per assay

Scheme: IMMUNOASSAY

Sample material:

The proficiency testing item is **Human Lyophilized Serum** simulating the biological findings usually measured by the participants. These Serums will present a range of values completely comparable with those found in the working routine of the participants. The coordinator will choose Serums which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

25 OH VITAMIN D	CORTISOL	IgE	T4
ALPHAPROTEIN	DHEA Sulfate	INSULIN	TESTOSTERONE
B-HCG	DIGOXIN	INTACT PTH	TG AB
C PEPTID	ESTRADIOL	LH	THYROGLOBULIN
CA 125	FERRITIN	PROGESTERONE	TMAB
CA 15-3	FOLATE	PROLACTIN	TPO AB
CA 19-9	FSH	PSA FREE	TSH
CARBAMAZEPINE	FT3	PSA TOTAL	VITAMIN B12
CEA	FT4	T3	

Statistical Elaboration:

Quantitative

Frequency:

Yearly, Quaterly or Montlhy

Product Code:

MSEQSI1 - MSEQSI4 - MSEQSI12

Level:

1 level per assay

Scheme: HEMOSTASIS

Sample material:

The proficiency testing item is **Human Lyophilized Plasma** simulating the biological findings usually measured by the participants. These Plasma will present a range of values completely comparable with those found in the working routine of the participants. The coordinator will choose plasma which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

- | | | |
|-----------------|------------------|---------------------------|
| PT PROTROMBINIC | ANTITHROMBIN III | APTT TIME |
| PT INR | FIBRINOGEN | ANTITHROMBIN III ACTIVITY |
| PROTEIN C | APTT | |
| PROTEIN S | D DIMER | |

Statistical Elaboration:

Quantitative

Frequency:

Yearly, Quaterly or Montlhy

Product Code:

MSEQSC1 - MSEQSC4 - MSEQSC12

Level:

1 level per assay

During the cycle we send different levels to analyze

Scheme: HEMATOLOGY

Sample material:

The proficiency testing item is **Human Blood** simulating the biological findings usually measured by the participants. These samples will present a range of values completely comparable with those found in the working routine of the participants. The coordinator will choose samples which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

RDW/IDR-SD	RBC/GR	RDW/IDR
MCHC	HGB	PLT/PLQ
MPV	MCV/VMG	HCT
WBC/GB	MCH/TCMH	

Statistical Elaboration:

Quantitative

Frequency:

Yearly, Quaterly or Montlhy

Product Code:

MSEQUALITYE12 - MSEQUALITYE8 - MSEQSE8

Level: 1 level per assay

During the cycle we send different levels to analyze



Scheme: ELECTROPHORESIS

Sample material:

The proficiency testing item is **Human Lyophilized Serum** simulating the biological findings usually measured by the participants. These Serums will present a range of values completely comparable with those found in the working routine of the participants. The coordinator will choose Serums which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

ALBUMINE

BETA GLOBULINE

ALFA 1 GLOBULINE

GAMMA GLOBULINE

ALFA 2 GLOBULINE

Statistical Elaboration:

Quantitative

Frequency:

Yearly, Quaterly or Montlhy

Product Code:

MSEQALITYEF - MSEQSEF12 - MSEQSEF1

Level:

1 level per assay

During the cycle we send different levels to analyze

Scheme: SPECIFIC PROTEINS

Sample material:

The proficiency testing item is **Human Lyophilized Serum** simulating the biological findings usually measured by the participants. These Serums will present a range of values completely comparable with those found in the working routine of the participants. The coordinator will choose Serums which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

ASO	C4
PCR	IGA
RF	IGG
TRANSFERRINA	IGM
C3	

Statistical Elaboration:

Quantitative

Frequency:

Yearly, Quaterly or Montlhy

Product Code:

MSQEQUALITYPS - MSEQSPS12 - MSEQSPS4

Level:

1 level per assay

During the cycle we send different levels to analyze

Scheme: CARDIAC MARKERS

Sample material:

The proficiency testing item is **Human Lyophilized Serum** simulating the biological findings usually measured by the participants. These Serums will present a range of values completely comparable with those found in the working routine of the participants. The coordinator will choose Serums which give measurements that can be referred to both physiological and pathological intervals. Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test. Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

BNP	CKMB	HS CRP	NT PRO BNP	TROPONIN T
CARDIAC D DIMER	HOMOCYSTEINE	MYOGLOBIN	PROCALCITONIN	TROPONIN I

Statistical Elaboration: Quantitative

Frequency: Yearly, Quaterly or Monthly

Product Code: MSEQSCM1 - MSEQSCM4 - MSEQSCM12

Level: 1 level per assay. During the cycle we send different levels to analyze,

Scheme: HbA1C

Sample material:

The proficiency testing item is **Human Lyophilized Blood** simulating the biological findings usually measured by the participants. These samples will present a range of values completely comparable with those found in the working routine of the participants. The coordinator will choose samples which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test. Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

HBA1C

Statistical Elaboration: Quantitative

Frequency: Yearly, Quaterly or Monthly

Scheme: INFECTIOLOGY

Sample material:

The proficiency testing item is **Human Lyophilized Serum** simulating the biological findings usually measured by the participants. These Serums will present a range of values completely comparable with those found in the working routine of the participants.

The coordinator will choose Serums which give measurements that can be referred to both physiological and pathological intervals

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions

contained in the reference standard ISO 13528:2015.

Parameters:

CHLAMYDIA IGG	HBCAB	HCV	ROSOLIA IGM
CHLAMYDIA IGM	HBCAB IGM	H. PYLORI IGG	SYPHILIS IGG
CYTOMEGALOVIRUS IGG	HBCAG	HERPES VIRUS I IGG	SYPHILIS IGM
CYTOMEGALOVIRUS IGM	HBEAB	HERPES VIRUS II IGG	TOXOPLASMA IGG
EPSTEIN BARR VCA IGG	HBEAG	HIV	TOXOPLASMA IGM
EPSTEIN BARR VCA IGM	HBSAB	HIV 1-2	TREPONEMA IGG
HAV IgG	HBSAG	ROSOLIA IGG	TREPONEMA IGM
HAV IGM			

Statistical Elaboration:

Qualitative

Frequency:

Yearly, Quaterly

Product Code:

MSEQSSE1 - MSEQUALITYS

Level:

1 level per assay. During the cycle we send different levels to analyze



Scheme: MICROBIOLOGY

Sample material:

The proficiency testing item is **Lyophilized Bacterial Strain** simulating the biological findings usually measured by the participants. These samples will present a range of bacterial strains completely comparable with those found in the working routine of the participants.

Test samples must be treated in the same manner as that applied for the samples tested in the routine procedure. For each test parameter is required a single determination.

Statistical Elaboration:

Qualitative

Frequency:

Yearly, Quaterly

Product Code:

MSEQSB1 - MSEQUALITYB

Level:

1 bacterial strain per assay



Scheme: URINE CHEMISTRY

Sample material:

The proficiency testing item is **Synthetic Urine** simulating the biological findings usually measured by the participants. These samples will present a range of values completely comparable with those found in the working routine of the participants.

The coordinator will choose samples which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

ALBUMINE	BLOOD	LEUKOCYTES	UROBILINOGEN
ASCORBIC ACID	GLUCOSE	MICROALBUMIN	PROTEIN / PH
BILIRUBIN	KETONES	NITRITE	SPECIFIC GRAVITY

Statistical Elaboration: Quantitative/Qualitative

Frequency: Yearly, Quaterly

Product Code: MSEQSU1 - MSEQUALITYU

Level: 1 level per assay. During the cycle we send different levels to analyze

Scheme: URINE SEDIMENTATION

Sample material:

The proficiency testing item is **Synthetic Urine** simulating the biological findings usually measured by the participants. These samples will present a range of values completely comparable with those found in the working routine of the participants.

The coordinator will choose samples which give measurements that can be referred to both physiological and pathological intervals.

Parameters:

RED BLOOD CELLS	WHITE BLOOD CELLS	CASTS	CRYSTAL
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Statistical Elaboration: Qualitative

Frequency: Yearly, Quaterly

Product Code: MSEQSUS1 - MSEQUALITYUS

Level: 1 level per assay. During the cycle we send different levels to analyze

Scheme: DRUGS OF ABUSE

Sample material:

The proficiency testing item is **Synthetic Urine** simulating the biological findings usually measured by the participants. These samples will present a range of values completely comparable with those found in the working routine of the participants.

The coordinator will choose samples which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions

contained in the reference standard ISO 13528:2015.

Parameters:

AMPHETAMINE	BUPRENORPHINE	METAMPHETAMINE
AMPHETAMINE/METAMPHETAMINE	CANNABINOIDS	METHADONE
BARBITURATES	COCAINE	MORPHINE
BENZODIAZEPINE	EXTASY	OPIATES

Statistical Elaboration: Qualitative

Frequency: Yearly, Quaterly

Product Code: MSEQSD1 - MSEQUALITYD

Level: 1 level per assay. During the cycle we send different levels to analyze,

Scheme: FECAL OCCULT BLOOD

Sample material:

The proficiency testing item is **Synthetic Stool** simulating the biological findings usually measured by the participants. These samples will present a range of values completely comparable with those found in the working routine of the participants.

The coordinator will choose samples which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the COP before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions

contained in the reference standard ISO 13528:2015.

Parameters:

FECAL OCCULT BLOOD

Statistical Elaboration: Quantitative

Frequency: Yearly, Quaterly

Scheme: ERYTHROCYTE SEDIMENTATION RATE

Sample material:

The proficiency testing item is **Human Blood** simulating the biological findings usually measured by the participants. These samples will present a range of values completely comparable with those found in the working routine of the participants.

The coordinator will choose samples which give measurements that can be referred to both physiological and pathological intervals.

Each test material is tested by the QS Division based on the Coordinator before distribution to the participants, ensuring the requirements of uniformity and stability according to the goals required for the test.

Tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.

Parameters:

ESR 1 HOUR

ESR 2 HOURS

K. INDEX

Statistical Elaboration: Quantitative/Qualitative

Frequency: Yearly, Quaterly

Product Code: MSEQSEES1 - MSEQUALITYES

Level: 1 level per assay. During the cycle we send different levels to analyze,

Scheme: BLOOD SMEAR

Sample material:

The proficiency testing item is **an Electronic File** simulating the biological findings usually measured by the participants. These files will present a range of values completely comparable with those found in the working routine of the participants.

The coordinator will choose files which give measurements that can be referred to both physiological and pathological intervals.

Statistical Elaboration: Qualitative

Frequency: Yearly, Quaterly

MSEQSSM1 - MSEQUALITYSM

Level: 1 file per assay

03. Schedule



SHIPMENT SCHEDULE

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SE	CT	NOV	DEC
CLINICAL CHEMISTRY	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS
HEMOSTASIS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS
IMMUNOASSAY	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS
SPECIFIC PROTEINS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS
ELECTROPHORESIS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS
HEMATOLOGY	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS
INFECTIOLOGY	QS			QS			QS			QS		
MICROBIOLOGY	QS			QS			QS			QS		
URINE	QS			QS			QS			QS		
DRUG OF ABUSE	QS			QS			QS			QS		
FECAL OCCULT BLOOD	QS			QS			QS			QS		
HBA1C	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS
CARDIAC MARKERS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS	QS/QS	QS	QS
ESR	QS			QS			QS			QS		
URINE SEDIMENTATION	QS			QS			QS			QS		
SMEAR	QS			QS			QS			QS		

QS = Quaterly shipment QS = Monthly shipment

04.

Web Site





- Website available in multiple language
- Hypertext Transfer Protocol Secure
- Requirement: web access, Adobe Reader
- No additional software required
- Password data protection regulation



- User friendly dashboard
- Easy data entry
- Report Download Area
- Reports available for 4 years
- View, print or store reports

05.

Statistical Elaboration

The test report represents the final result of the external quality control and is the reference document for the participating laboratory.

Quality System elaborates **two types of Reports**:

Quantitative Report, where the data is a numerical result

Qualitative Report, where the data is a positive, negative or doubtful result

In each test report model, both the statistical and performance indexes and graphical representations are shown to make the participant immediately understand the possible presence of errors and their possible origins.

QUANTITATIVE REPORT - INDEX

Consensus Value:

CV is the target value of the test or expected value. It is calculated according to algorithm A of ISO 13528: 2015: all the measurements sent by the participants converge. The algorithm excludes aberrant measurements in order to calculate a robust average of the measurements sent. This average, poorly influenced by aberrant values is the target value of the test.

Standard Deviation:

SD is the dispersion of data sampled in the test. It is calculated according to the requirements of algorithm A of ISO 13528: 2015 and is also a robust marker that is not influenced by too aberrant data.

Assigned DS:

It is the standard deviation assigned to the test, calculated by the provider on the basis of the parameter's historical data.

The provider calculates the average of the analyte standard deviations in recent years and expresses the relative standard deviation or RDS.

The standard deviation is the consensus average multiplied by RDS. The standard deviation will be used to calculate the Z and Z' performance indices. This allows a fairer evaluation of the performance without the low number of participants or excessive mistakes among the participants could give rise to too severe performance indexes.

Standard Uncertainty

S.U. is the estimate linked to a test result that characterizes the excursion of the values within which the true value is assumed to fall. In calculating the performance index it represents a fundamental discriminant:

if it is less than 30% of the assigned standard deviation then it is considered negligible and only the standard deviation participates in the calculation of the Z Score performance index; if it is more than 30% of the assigned standard deviation then it is no longer negligible and must be considered in the calculation of the performance index which will become Z' Score.

Z Score

Performance index calculated as the ratio between the absolute error (difference between measured value and consensus average) and the assigned standard deviation.

If the value of Z is between -2 and 2, the performance will be acceptable; if the value is between -3 and -2 and between 2 and 3 the performance will be questionable, if the value is less than -3 or greater than 3 the performance will be unacceptable.

Z' Score

If the measurement uncertainty is not negligible, it is responsible for calculating this performance index. For the interpretation the considerations expressed for the Z Score are valid.

CV

Expresses variance of data distribution in percent.

Difference

Esprime l'errore assoluto della prestazione cioè la differenza tra misura e media di consenso.

D%

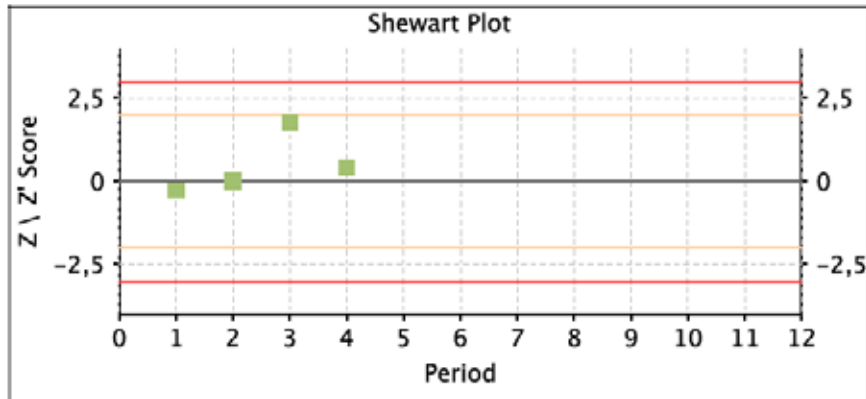
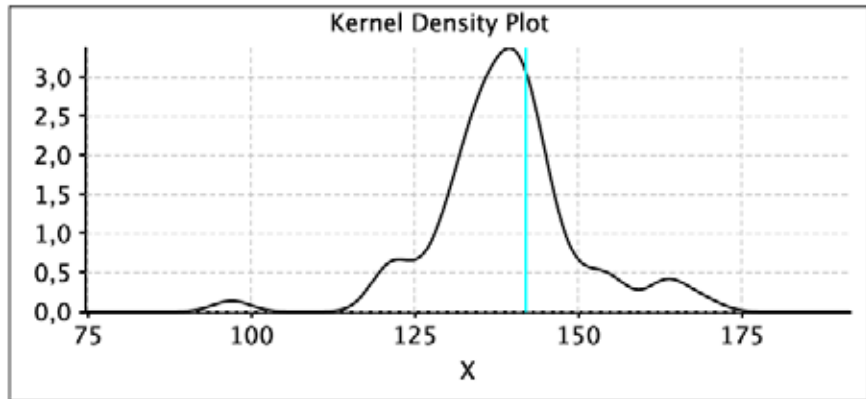
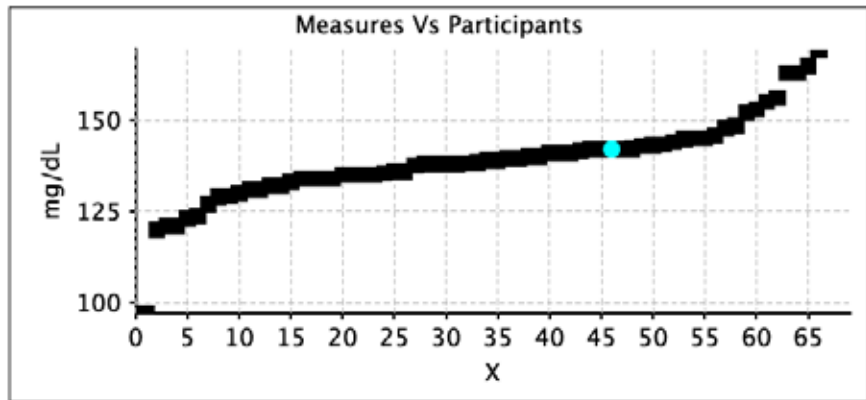
Absolute error expressed as a percentage.

	CLINICAL CHEMISTRY MONTHLY CYCLE 2019 Scheme : MSQSCH12/MSEQSCH12/MSEQSCH1	RdP: Final Revision ZKN170_16_2019_4.p df	 Istituto Nazionale di Accreditamento IRIF N° 00177 Member degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC Signatory of EA, IAF and ILAC Mutual Recognition Agreements
	Participant : ZKN170 Sample Lot : CH-1904	Issued on 03/05/2019 Authorized by RQS Paolo Cocci	

Analit **TRIGLYCERID** Unit of measurement **mg/dL** RDS **0,0600**
 ES

Analizör **- ERBA XL-640** Method **Lipase/GPO-PAP** Participants number **66**

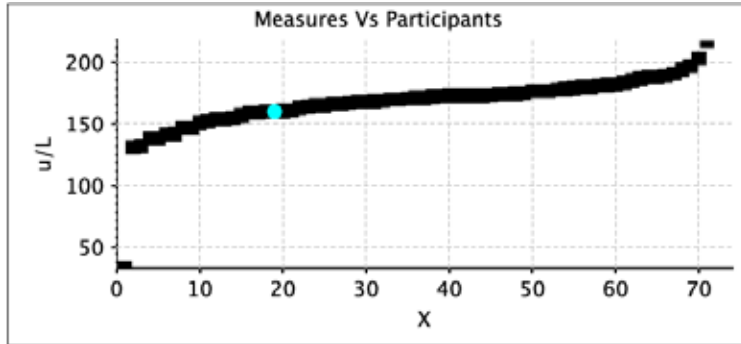
Measure	142,0
Z Score	0,41
Standard Deviation	7,43
Assigned Value (robustus mean)	138,62
Assigned DS	8,32
Standard Uncertainty	1,14
CV%	5,36
Difference	3,38
D%	2,44



Measures Vs Participants

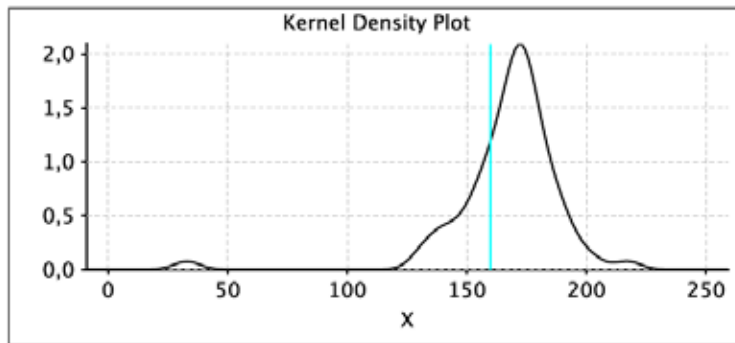
The graph represents the distribution of the measurements of the individual participants ordered by size.

This graph allows to identify at a glance the normality of the distribution and the possible magnitude of the measurement error committed.



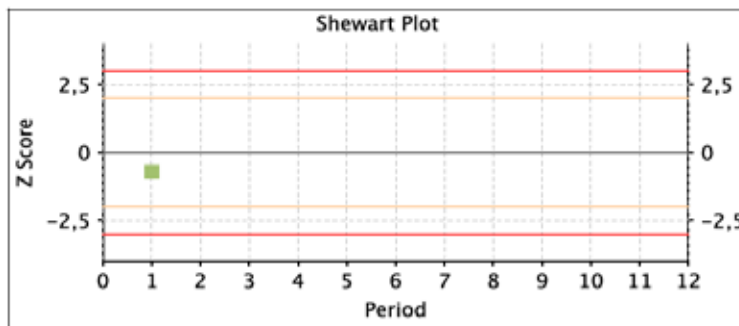
Kernel Density Plot

It represents the distribution of results in probability density: it is useful to understand how any mistake made is not due to imprecision of method / instrument or to uneven statistical data.



Shewart Plot

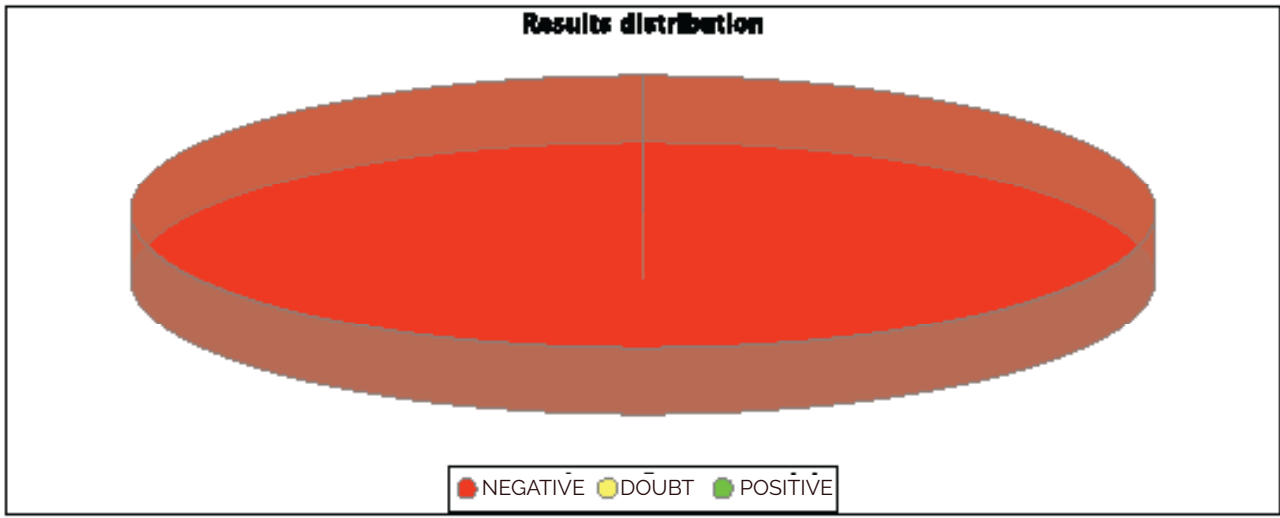
Graph showing in time order the Z scores obtained on the single analyte. Very useful to verify the performance over time of the services and especially useful for the verification of the effectiveness of any corrective actions carried out following a questionable or acceptable performance. It is the most important graph for the management of laboratory control charts.



QUALITATIVE REPORT - GRAPHIC

	SEROLOGY JANUARY 2019	RdP: Reissue ZKN032_9_2019_1.pdf
	Participant:XC032 Sample Lot : SI-1901	Issued on 04/03/2019 Authorized by RQS Paolo Cacci

Analyte HCV **Analyzer** - Abbott ARCHITECT i1000SR **Method** Chemiflex



Participants	112		
Negative results percentage	100,00 %	Measure	NEGATIVE
Positive results percentage	0,00 %	Assigned value	NEGATIVE
Doubt results percentage	0,00 %	Performance index	Acceptable

January 2019
 Acceptable

QUANTITATIVE REPORT - INDEX

The qualitative report expresses particularly synthetic data and performance indices.

Negative results percentage

This index is the number of negative results found by the participants.

Positive results percentage

This index is the number of positive results found by the participants.

Doubt results percentage

This index is the number of doubt results found by the participants.

Assigned value

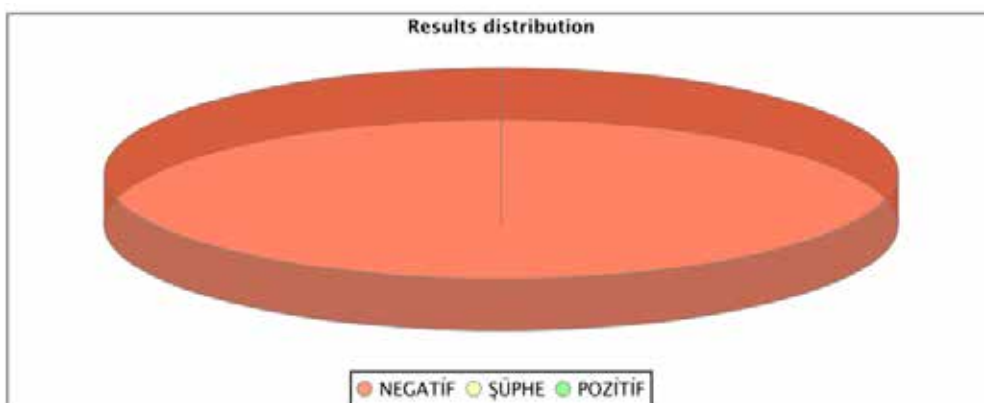
It is the expected result of the test: it is defined as the most frequent of the results provided.

Performance index

If the value provided by the participant corresponds to the assigned value, the performance index will be defined as acceptable; if it does not correspond it will be defined as unacceptable.

Results distribution

Partitioning graph that identifies the percentages of responses received



“

QUALITY SYSTEM
FOR A RIGHT DIAGNOSIS

”





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