

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. Chișinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

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

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

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

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

CERTIFICATO DI ACCREDITAMENTO Accreditation Certificate

ACCREDITAMENTO N.
ACCREDITATION N.

0017P REV. 00

EMESSO DA
ISSUED BY

DIPARTIMENTO LABORATORI DI PROVA

SI DICHIARA CHE
WE DECLARE THAT

BIO-GROUP MEDICAL SYSTEM S.r.l.

Sede/Headquarters:

- Loc. Campiano 9/b - 47867 Talamello RN

È CONFORME AI REQUISITI
DELLA NORMA

UNI CEI EN ISO/IEC 17043:2010

MEETS THE REQUIREMENTS
OF THE STANDARD

ISO/IEC 17043:2010

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

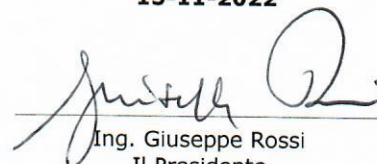
Data di scadenza
Expiring date
13-11-2022



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 validità 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)
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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 HBA1C 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

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

BIO GROUP
MEDICAL SYSTEM SRL
Loc. Campiano 9/B – 47867 Talamello (RN)
P.I.A.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

HBA_{1C}

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 Montlthy

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 Montlhy

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 Montlhy

Scheme: INFECTIVOLOGY

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%

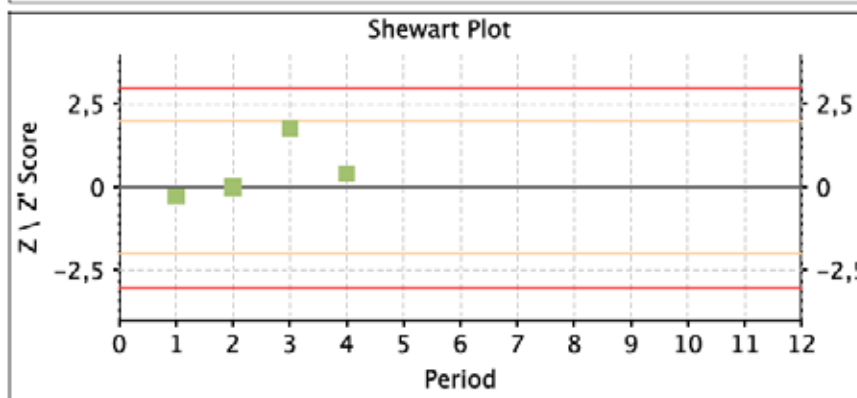
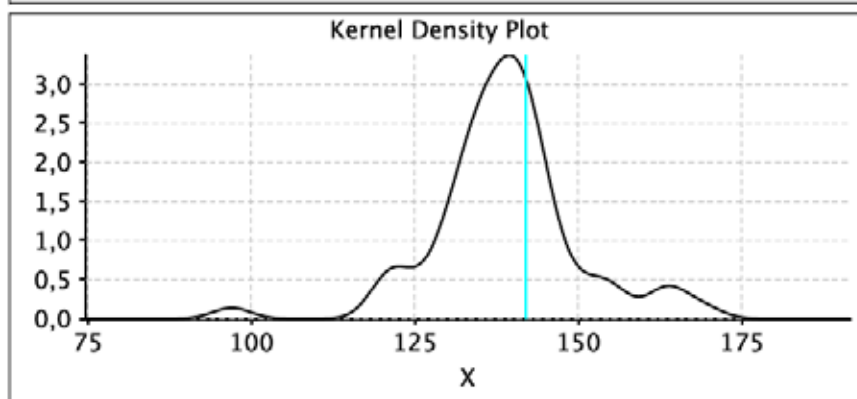
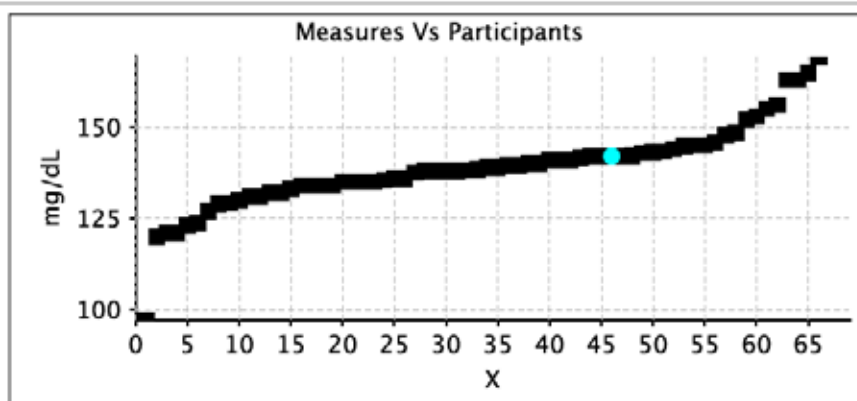
Absolute error expressed as a percentage.

	CLINICAL CHEMISTRY MONTHLY CYCLE 2019 Scheme: : MSQSCH12/MSEQSCH12/MSEQSCH1	RdP: Final Revision ZKN170_16_2019_4.p df	 <small>UNIONE ITALIANA DI ACCREDITAMENTO DIP. N° 00179 Membro degli Accordi di Mutuo Riconoscimento EA, DAF e ILAC Signatory of EA, DAF and ILAC Mutual Recognition Agreements</small>
	Participant : ZKN170 Sample Lot : CH-1904	Issued on 03/05/2019 Authorized by RQS Paolo Cocci	

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

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

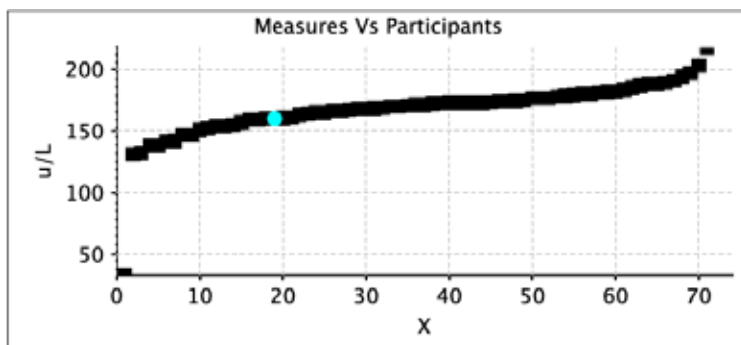
Measure	142,0
Z Score	0,41
Standard Deviation	7,43
Assigned Value (robustus mean)	138,62
Assigned DS	8,32
Standard Uncertainty	1,14
CV%	5,36
Difference	3,38
D%	2,44



Measures Vs Participants

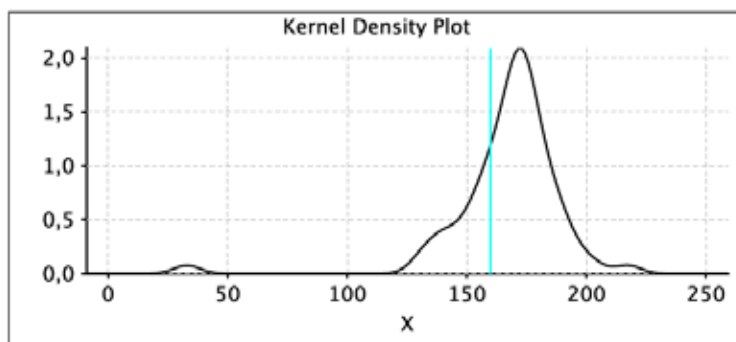
The graph represents the distribution of the measurements of the individual participants ordered by size.

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



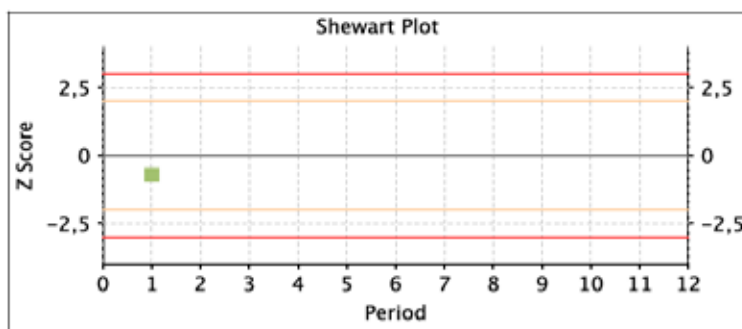
Kernel Density Plot

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

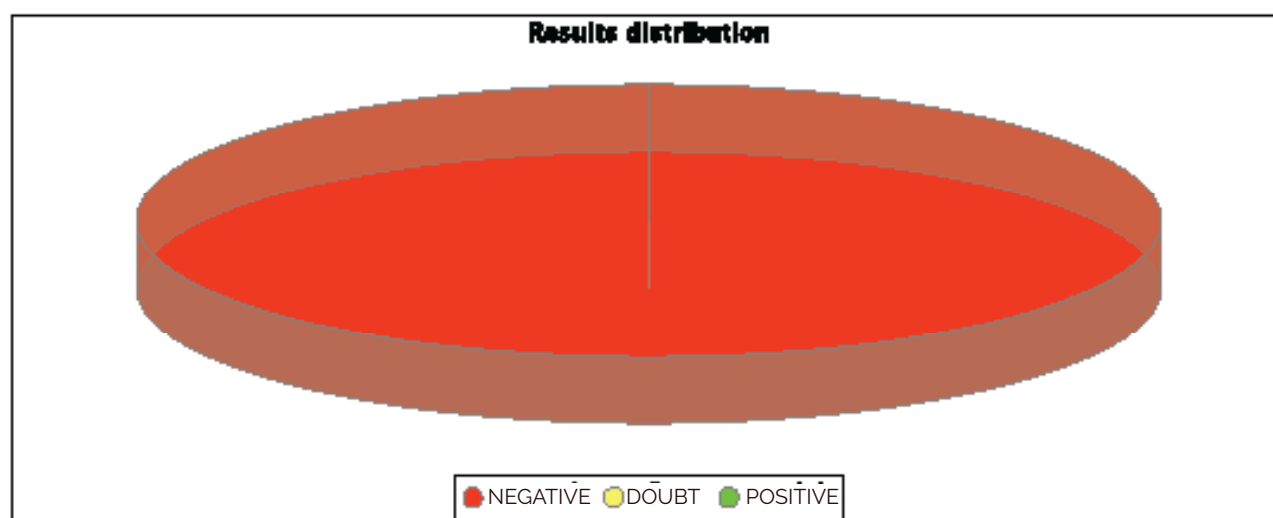
Graph showing in time order the Z scores obtained on the single analyte. Very useful to verify the performance over time of the services and especially useful for the verification of the effectiveness of any corrective actions carried out following a questionable or acceptable performance. It is the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

Analyte	HCV	Analyzer	- Abbott ARCHITECT i1000SR	Method	Chemiflex
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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

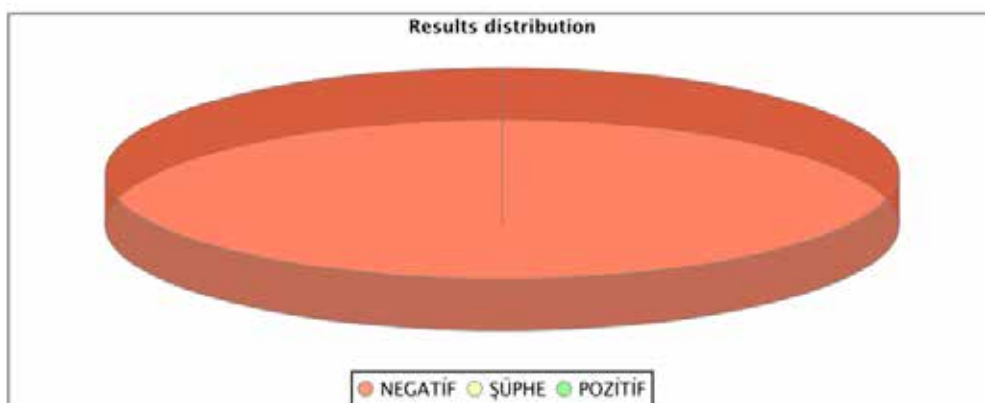
It is the expected result of the test: it is defined as the most frequent of the results provided.

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



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QUALITY SYSTEM

FOR A RIGHT DIAGNOSIS

”





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