REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

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

MD 0101250

Digitally signed by Poiata Vitalie
Date: 2024.11.28 16:00:17 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor 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 şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociaţii:
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 şi a întreprinzătorilor individuali şi 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

Date cu caracter personal

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

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

Data 14. IAN. 2016
Nr. 03/2 – 19/23

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

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

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

Lista fondatorilor Biosistem-mld SRL

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

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

Date generale despre ofertant

SRL Biosistem mld
Administrator: Poiata Vitalie
Adresa poştală: str. Albișoara 16/1 of.7, or. Chișinău
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519 **E-mail:** biosistem.mld@gmail.com; info@biosistem-mld.com
Cod IBAN: MD95ML0000000022514292 43
Banca: BC "Moldindconbank" S.A. fil. Invest
Codul băncii: MOLDMD2X329
Cod fiscal: 1010600028048
Cod TVA: 0607490

Cu respect,

Vitalie Poiata

Administrator

QUALITY
SYSTEM

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** accreditated 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, providng to partic-ipants 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

INFECTIVOLOGY
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:
Yearyly, 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

ALFA 1 GLOBULINE

ALFA 2 GLOBULINE

BETA GLOBULINE

GAMMA 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
PCR
RF
TRANSFERRINA
C3
C4
IGA
IGG
IGM

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

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
AMPHETAMINE/METAMPHETAMINE
BARBITURATES
BENZODIAZEPINE
BUPRENORPHINE
CANNABINOIDS
COCAINE
EXTASY
METAMPHETAMINE
METHADONE
MORPHINE
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
INFECTIVOLOGY	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
- Requirment: 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 Uncertainity
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 -3-2 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.

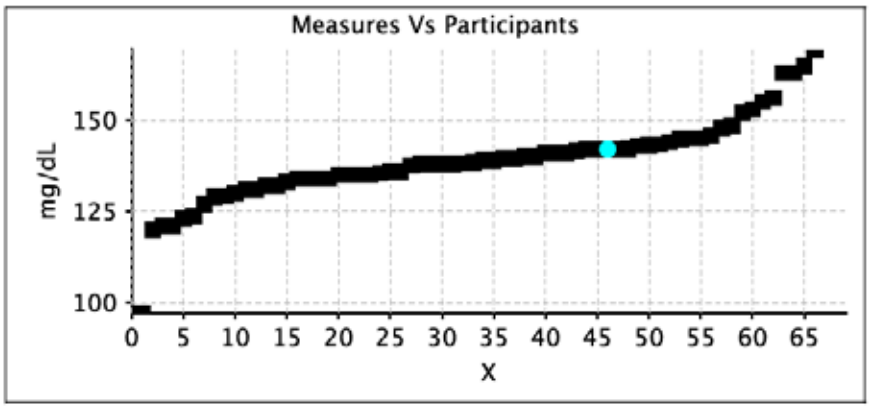
D%
Absolute error expressed as a percentage.

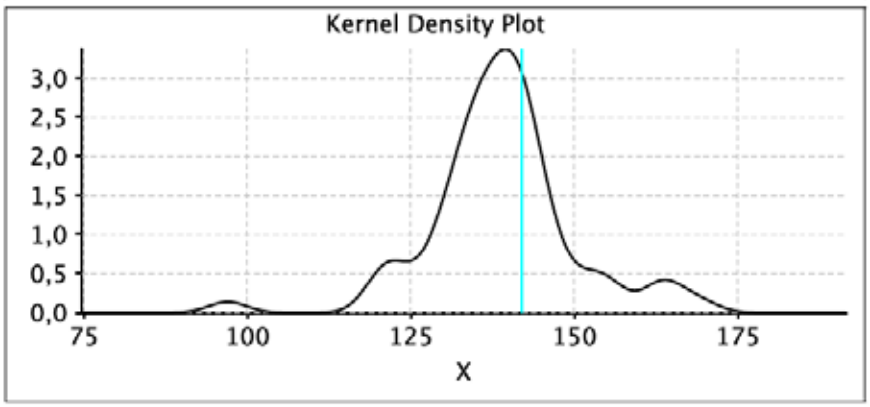
QUANTITATIVE REPORT - GRAPHIC

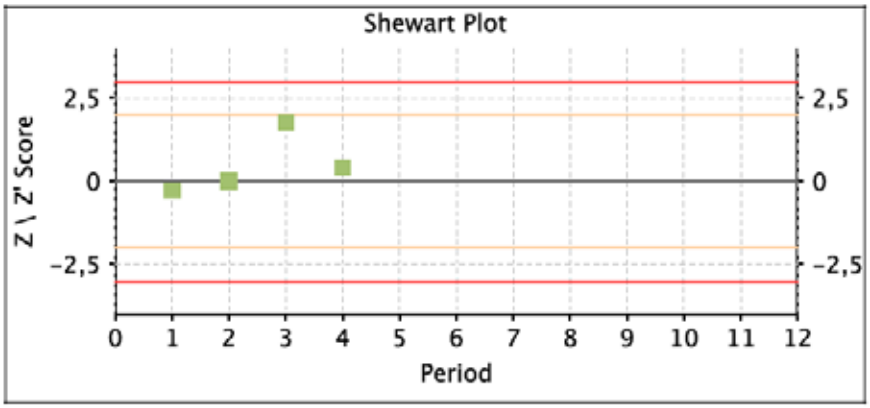
QUALITY SYSTEM	**CLINICAL CHEMISTRY MONTHLY CYCLE 2019** Scheme: : MSQSCH12/MSEQSCH12/MSEQSCH1	RdP: Final Revision **ZKN170_16_2019_4.pdf**	ACCREDIA
	Participant : ZKN170 **Sample Lot : CH-1904**	Issued on 03/05/2019 Authorized by RQS Paolo Cocci	

Analit	**TRIGLYCERIDES**	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

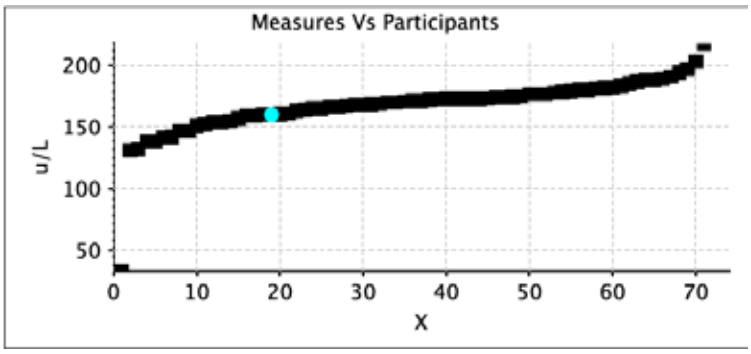






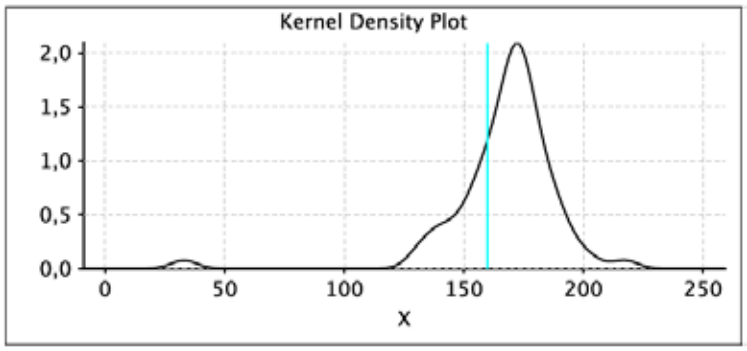
Measures Vs Participants

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.



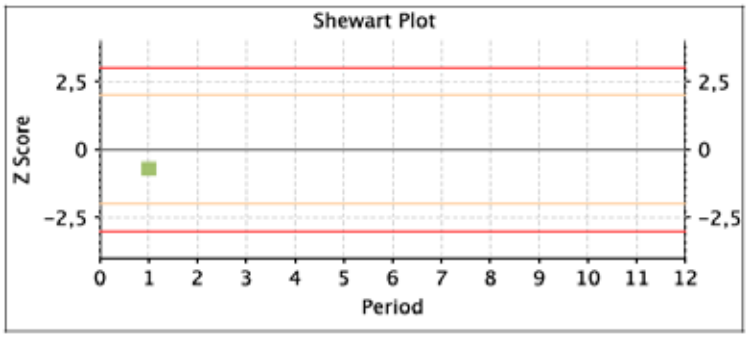
Kernel Density Plot

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

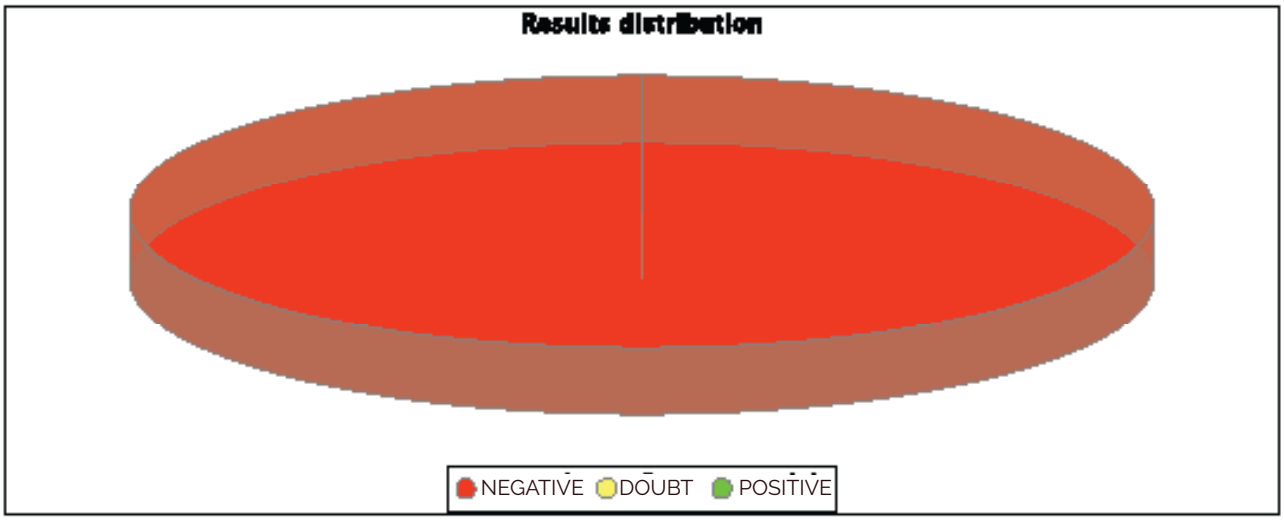
Graph showing in time order the Z scores obtained on the single analyte. Very useful to verify the performance over time of the services and especially useful for the verification of the effectiveness of any corrective actions carried out following a questionable or acceptable performance. It is the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



QUALITATIVE REPORT - GRAPHIC

QUALITY SYSTEM	**SEROLOGY JANUARY 2019**	RdP: Reissue ZKH032_9_2019_1.pdf
	Participant:XC032 Sample Lot : SI-1901	Issued on 04/03/2019 Authorized by RQS Paolo Cocci

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.

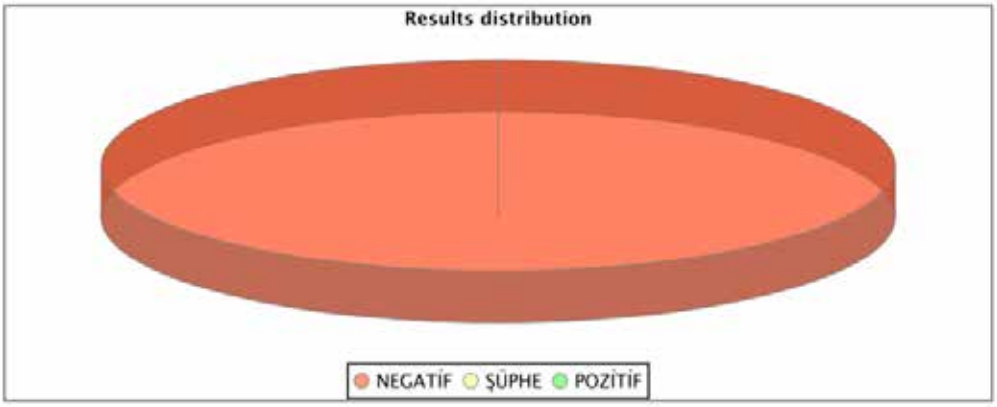
Positive results percentage
This index is the number of positive results found by the participants.

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

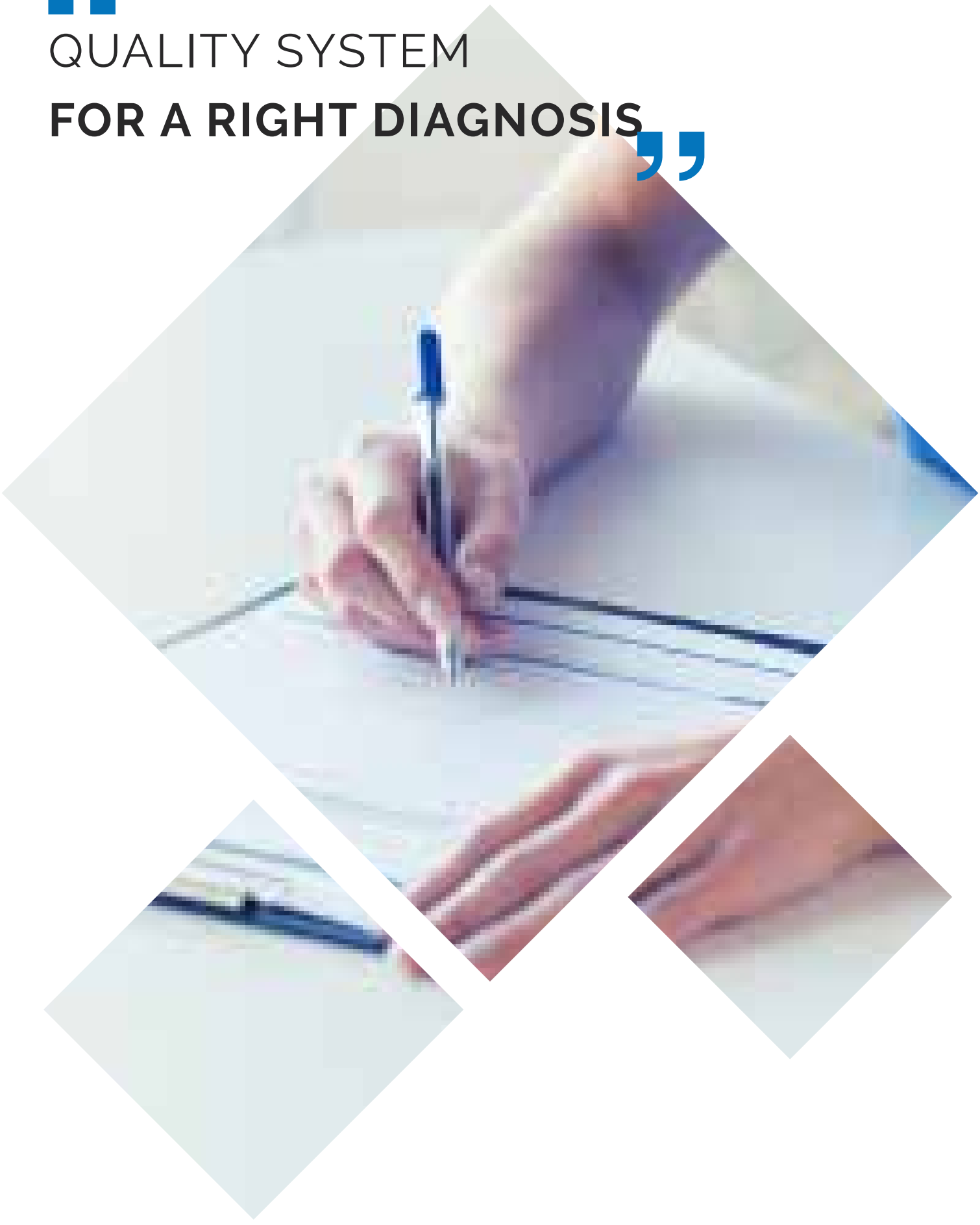
Assigned value
It is the expected result of the test: it is defined as the most frequent of the results provided.

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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ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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 / *AS*: **Organizzatori di prove valutative interlaboratorio** / ***Proficiency Testing Provider***

MD-CA-01 rev. 03

Data di 1ª 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.

ACCREDIA

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info@accredia.it | www.accredia.it | Partita IVA - Codice Fiscale 10566361001

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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

BIO GROUP
MEDICAL SYSTEM SRL
The Executive Manager
Loc. Campiano 9/B - 47867 Talamello (RN)
P.IVA C.Fisc. 00504170419