

## ORDIN DE PLATĂ

Nr.

894

DATA EMITERII

13 martie 2026

TIP.DOC.1

PLĂTIȚI:

200-00

LEI

Doua sute lei 00 bani

PLĂTITOR: (R) BIOSISTEM MLD SRL

CODUL IBAN

MD95ML00000002251429243

CODUL FISCAL

1010600028048

PRESTATORUL PLĂTITOR: BC'Moldindconbank'S.A.

BENEFICIAR: (R) IMSP Policlinica de Stat

CODUL IBAN

MD28TRPCCC518430E00027AA

CODUL FISCAL

1006601003924

PRESTATORUL BENEFICIAR: Ministerul Finantelor - Trezoreria de Stat

DESTINAȚIA PLĂȚII: /P/200,00/M//1010600028048/BIOSISTEM MLD SRL//Pentru garanția pentru oferta la procedura de achiziție publică nr. ocds-b3wdp1-MD-1772034714768 din 16.03.2026/

TIPUL TRANSFERULUI  
NORMAL/URGENT

N

L.Ș.

CODUL TRANZACȚIEI

101

DATA PRIMIRII

DATA EXECUTĂRII

SARIVAN GABRIEL

SARIVAN GABRIEL

Document transmis prin instrument de plată electronic cu acces la  
la distanță de tip internet-banking

SEMNĂTURA PRESTATORULUI

SEMNĂTURILE EMITENTULUI

L.Ș.

MOTIVUL REFUZULUI

Nota: Responsabilitatea privind veridicitatea și corectitudinea informației indicate în ordinul de plată îi revine emitentului\*

\*Regulamentul cu privire la transferul de credit, debitarea directă și atribuirea codurilor IBAN, aprobat prin HCE al BNM nr. 108 din 08.06.2023



GUVERNUL  
REPUBLICII  
MOLDOVA



SERVICIUL FISCAL DE STAT



# CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.  
№ 1430048

Din  
От 12.03.2026 14:30

## 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

56.68 MDL

În temeiul art. 129 pct. 13) lit. c) din Codul fiscal, suma neachitată a obligațiilor fiscale în cuantum de până la 500 de lei inclusiv nu se consideră restanță față de bugetul public național în scopul atestării lipsei restanțelor față de bugetul public național ale contribuabililor.

## VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

27.03.2026 14:30



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 integrat EVO / Справка выдана в соответствии со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Интегрированный правительственный портал EVO.

Generat și semnat de Portalul guvernamental integrat EVO la 12.03.2026 14:30

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 integrat EVO ([evo.gov.md](http://evo.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](http://msign.gov.md))

Сертификат скачен с Интегрированный правительственный портал EVO ([evo.gov.md](http://evo.gov.md)) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Интегрированный правительственный портал EVO ([msign.gov.md](http://msign.gov.md))

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. Московской, 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 în moneda națională 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**

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



**BIO GROUP – MEDICAL SYSTEM Srl**  
**Strumentazione e Diagnostici**  
 Loc. Campiano, 9/B – 47867 Talamello (RN)  
 e.mail: info@biogroupmedicalsistem.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 29<sup>th</sup>, 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





# Certificato Di Registrazione

Questo certificato è stato rilasciato a

**Microtrace Diagnostics srl**

Via Ca' di Vico 16, 47863 Novafeltria (RN) (Legal Site), Via IV Novembre 84,  
47863 Novafeltria (RN) (Operative site), Italy

come riconoscimento del Sistema Gestione Qualità aziendale in conformità alle Norme

**ISO 13485:2016**

Le attività coperte da questo certificato sono

**Progettazione e produzione di kit diagnostici in vitro per test di  
intolleranze alimentari e altri kit IVD**

Numero Del Certificato:

58429/C/0001/UK/It

Data d'emissione (originale):

13 Febbraio 2019

Data d'emissione:

13 Febbraio 2019

Emissione No:

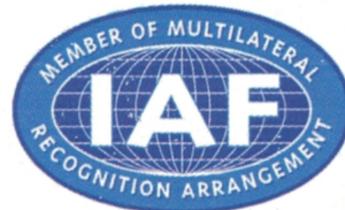
1

Data di Scadenza:

12 Febbraio 2022

Emesso da:

A nome del Scheme Manager



If there is any doubt as to the authenticity of this certificate, please do not hesitate to contact the Head Office of the Group on [info@urs-certification.com](mailto:info@urs-certification.com).  
URS is a member of United Registrar of Systems (Holdings) Ltd, United House, 4 Hinton Road, Bournemouth, BH1 2EE, UK. Company Registration no. 5298466



# EXTERNAL QUALITY ASSESSMENT



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/PA2254AR0.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.

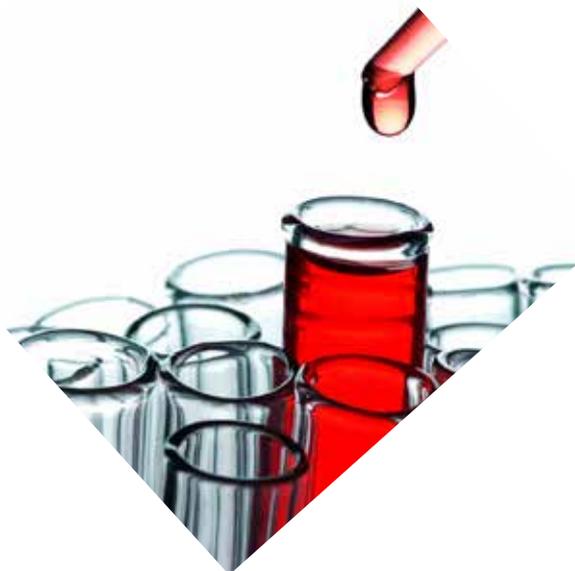


## Vision & Mission

---

*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

### ELECTROPHORESIS

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

### HEMOSTASIS

7 Parameters - Lyophilized Plasma  
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

### SPECIFIC PROTEINS

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

### HEMATOLOGY

8 Parameters - Liquid Sample  
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

# 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: 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: 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:

MSEQSE1 - MSEQSE4 - MSEQSE12

**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

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									
HEMOSTASIS	QS	QS	QS/QS									
IMMUNOASSAY	QS	QS	QS/QS									
SPECIFIC PROTEINS	QS	QS	QS/QS									
ELECTROPHORESIS	QS	QS	QS/QS									
HEMATOLOGY	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									
CARDIAC MARKERS	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%**

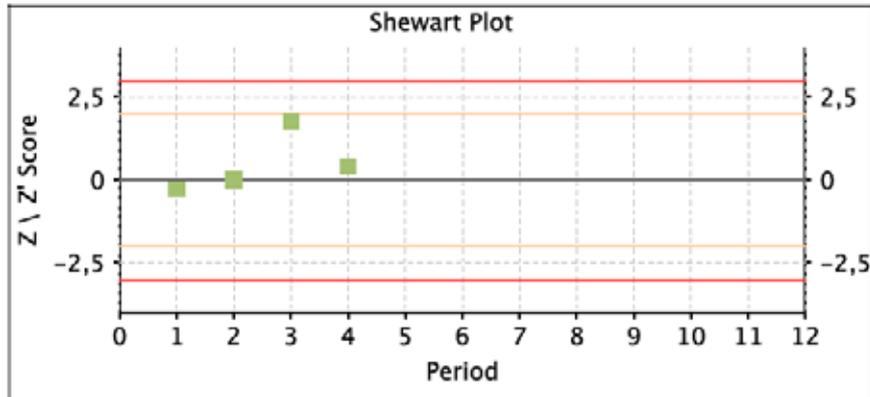
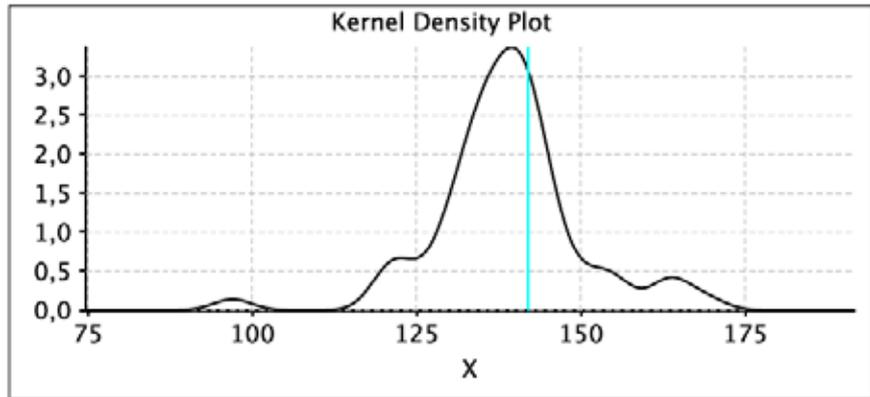
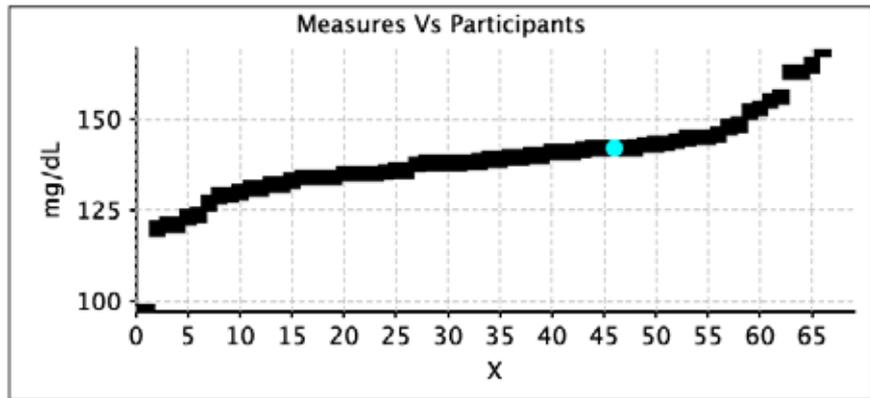
Absolute error expressed as a percentage.

	<b>CLINICAL CHEMISTRY MONTHLY CYCLE 2019</b> Scheme : M5QSCH12/MSEQSCH12/MSEQSCH1	RdP: Final Revision <b>ZKN170_16_2019_4.p df</b>	 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
	<b>Participant : ZKN170 Sample Lot : CH-1904</b>	Issued on 03/05/2019 Authorized by RQS Paolo Cocci	

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

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

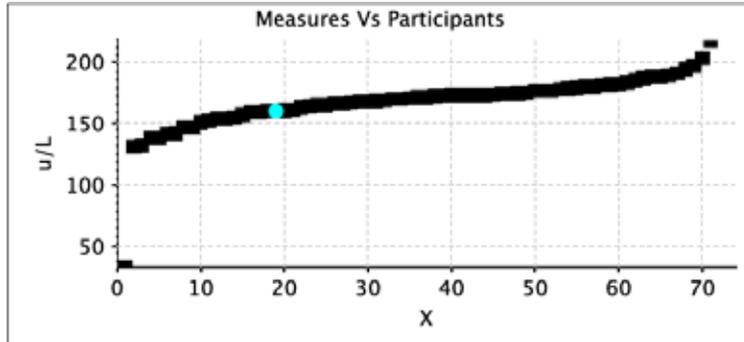
Measure	<b>142,0</b>
Z Score	<b>0,41</b>
Standard Deviation	7,43
Assigned Value (robustus mean)	138,62
Assigned DS	8,32
Standard Uncertainty	1,14
CV%	5,36
Difference	3,38
D%	2,44



### Measures Vs Participants

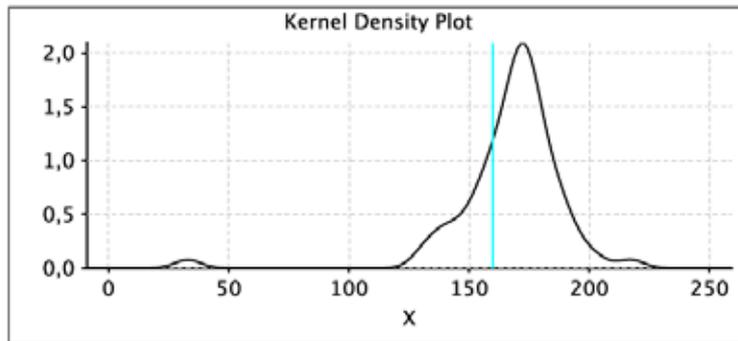
The graph represents the distribution of the measurements of the individual participants ordered by size.

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



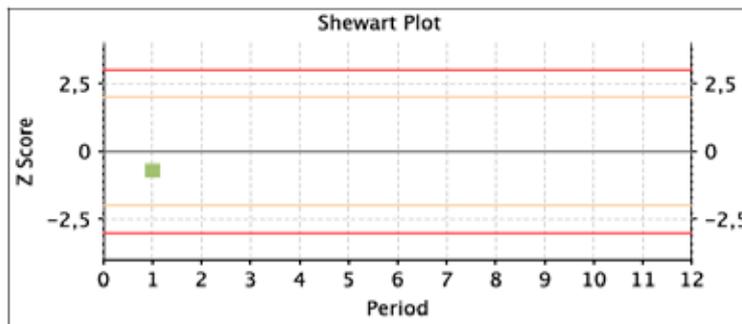
### Kernel Density Plot

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

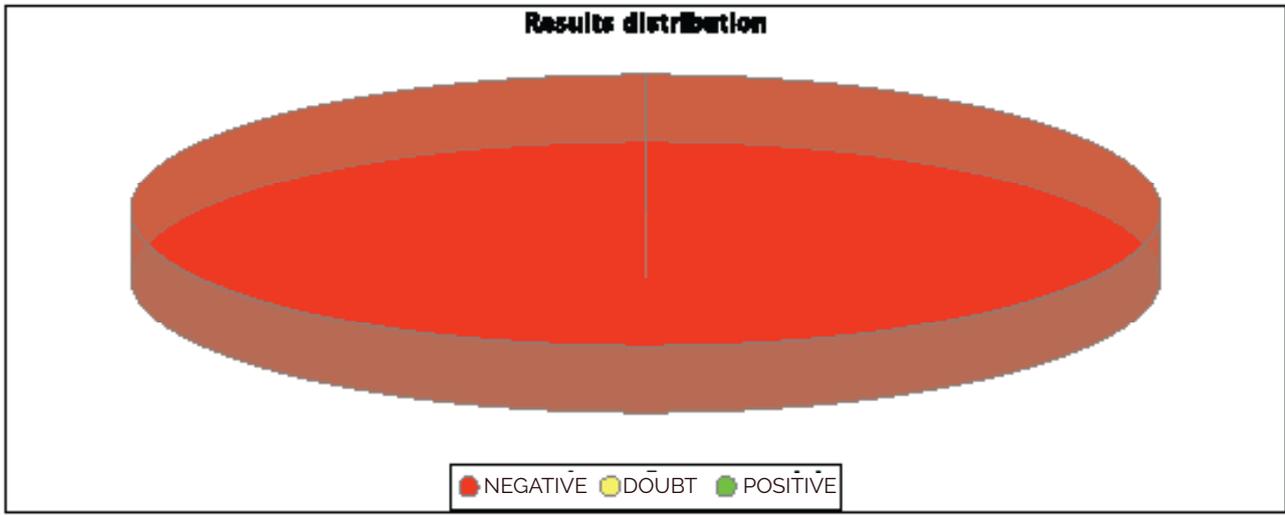
Graph showing in time order the Z scores obtained on the single analyte. Very useful to verify the performance over time of the services and especially useful for the verification of the effectiveness of any corrective actions carried out following a questionable or acceptable performance. It is the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



# QUALITATIVE REPORT - GRAPHIC

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

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



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

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**

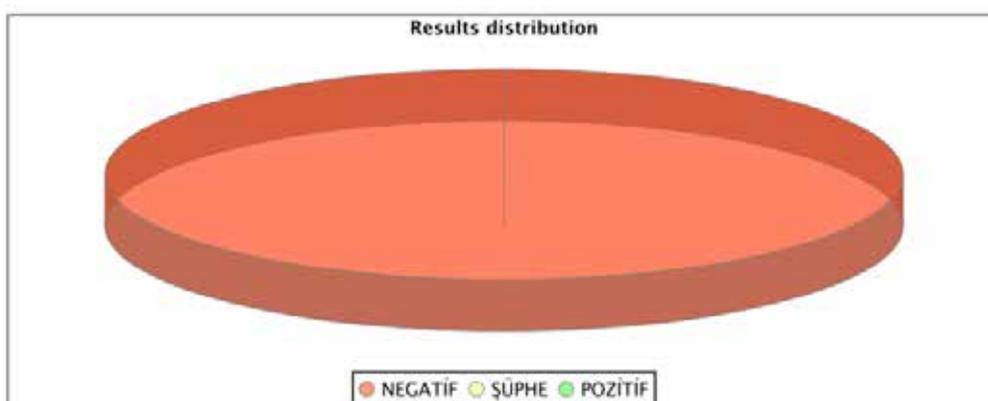
It is the expected result of the test: it is defined as the most frequent of the results provided.

### **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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