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

Digitally signed by Poiata Vitalie
Date: 2023.11.10 14:00:34 EET
Reason: MoldSign Signature
Location: Moldova

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

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

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

Acreditación

ENAC

Entidad Nacional de Acreditación

Otorga la presente / Grants this

ACREDITACIÓN
12/PPI020

a

BioSystems, S.A. (PREVECAL)

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

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

ENTIDAD NACIONAL DE ACREDITACIÓN ENAC

D. José Manuel Prieto Barrio
Presidente

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

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 This accreditation and its technical annex could be reduced, temporarily suspended and withdrawn.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

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

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

Código Validación Electrónica: L3Hf36Oo8A9IJ3Phr4
La vigencia de la acreditación y del presente certificado puede confirmarse en https://www.enac.es/web/enac/validacion-electronica o haciendo clic **aquí**

PREVECAL

BioSystems

BIOQUÍMICA HUMANO

COD 18045 - 12 x 5 mL

INTRODUCCIÓN

PREVECAL es un programa internacional de evaluación externa de la calidad organizado por BioSystems S.A., que ofrece a los laboratorios clínicos la posibilidad de completar su esquema de control interno con una estimación objetiva de la exactitud de sus procedimientos de medida.

CONTENIDO

Se proporcionan 3 niveles de concentración de cada componente, distribuidos entre los 12 meses de duración del programa y etiquetados con el mes en que deben analizarse. Cada nivel aparece, pues, en 4 meses distintos.

COMPOSICIÓN

PREVECAL Humano. Para 5 mL. Suero humano liofilizado que contiene diversos componentes a concentraciones adecuadas para una efectiva evaluación externa de la calidad de los procedimientos de medida. PREVECAL Humano no contiene conservantes que puedan interferir en las mediciones.

Todos los componentes de origen humano han resultado ser negativos para el antígeno HBs y para los anticuerpos anti-HCV y anti-HIV. Sin embargo, deben tratarse con precaución como potencialmente infecciosos.

PREPARACIÓN Y USO

1. Abrir con cuidado el vial etiquetado con el mes que corresponde, procurando evitar la pérdida de material liofilizado.
2. Pipetear 5 mL de agua destilada en el vial. Los valores obtenidos para los diferentes componentes dependerán de la exactitud con que se pipetee el agua destilada.
3. Tapar el vial con el tapón de caucho y dejarlo reposar durante unos 20 minutos a temperatura ambiente.
4. Agitar suavemente el vial, procurando evitar la formación de espuma, hasta disolver por completo todo el liofilizado.
5. Si el material ha de utilizarse para el análisis de elementos traza, evitar el contacto del material reconstituido con el tapón de caucho para impedir una posible contaminación.
6. Utilizar el Suero Control de Bioquímica reconstituido de forma idéntica a los sueros de los pacientes.

CONSERVACIÓN Y ESTABILIDAD

Conservar a 2-8ºC.

PREVECAL Humano es estable durante el transcurso del programa.

Los componentes del material reconstituido son estables al menos 7 días a 2-8ºC y 30 días a -20ºC (congelado solo una vez), exceptuando:

- La AST es estable 8 horas a 2-8ºC y 30 días a -20ºC.
- La fosfatasa alcalina es estable 5 horas a 2-8ºC y 30 días a -20ºC. Se recomienda dejar reposar el material reconstituido durante 1 hora a temperatura ambiente antes de realizar la medición.

La CK y la bilirrubina son sensibles a la luz. Conservar los viales protegidos de la luz.

Desechar el vial si hubiese indicios de contaminación microbiana o exceso de turbidez en el producto reconstituido.

ADVERTENCIAS Y PRECAUCIONES

Ejerza las precauciones habituales requeridas para manipular todos los reactivos de laboratorio. Las fichas de seguridad están disponibles para el usuario bajo petición. La eliminación de todos los residuos debe ser conforme a las normativas locales. Cualquier incidente grave que pueda ocurrir en relación al dispositivo debe ser comunicado a BioSystems S.A.

RESULTADOS E INFORMES

Una vez analizadas las muestras en las que el laboratorio participa, debe ingresar los resultados en la web PREVECAL, www.prevecal.net, accediendo con su código y contraseña.

La fecha límite de envío de resultados es el día 15 de cada mes, a excepción del mes de enero que se amplía el plazo hasta el día 31.

Los informes pueden ser descargados en la web PREVECAL accediendo con su código y contraseña.

Si desea más información consulte la Guía de Usuario disponible en la web PREVECAL.

Para cualquier consulta o reclamación contacte con la organización a través de la dirección dtprevecal@biosystems.es.

M18045c-04 08/2020

Las líneas laterales marcan las modificaciones en la versión actual.

BIOCHEMISTRY HUMAN

COD 18045 - 12 x 5 mL

INTRODUCTION

PREVECAL is an international external quality assessment program organized by BioSystems S.A. This program helps the clinical laboratories to complete their internal quality control scheme with an objective estimation of the accuracy of their measurement procedures.

CONTENTS

Each component has 3 levels of concentration distributed among the 12 months of the program and labelled with the month of the analysis. Thus, each level appears in 4 different months.

COMPOSITION

PREVECAL Human. For 5 mL. Freeze-dried human serum containing several components at concentrations suitable for an effective external quality assessment of the measurement procedures. PREVECAL Human does not contain preservatives which might interfere with the measurements.

Components from human origin have been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, they should be handled cautiously as potentially infectious.

PREPARATION AND USE

1. Carefully open the vial labelled with the corresponding month on it, avoiding any loss of the lyophilized material.
2. Pipette exactly 5 mL of distilled water into the vial. The component values depend on the accuracy of this reconstitution step.
3. Close the vial with the stopper and let it stand for 20 minutes at room temperature.
4. Swirl gently, avoiding the formation of foam, to ensure complete dissolution of contents.
5. If the material is to be used for analysis of trace elements, avoid contact of the reconstituted material with the stopper to prevent a possible contamination.
6. The reconstituted control serum is to be treated like the patient serum.

STORAGE AND STABILITY

Store at 2-8ºC.

PREVECAL Human is stable during the extent of the program.

The components of the reconstituted material are stable for at least 7 days at 2-8ºC and 30 days at -20ºC (when frozen once), excepting:

- AST is stable 8 hours at 2-8ºC and 30 days at -20ºC.
- Alkaline phosphatase is stable 5 hours at 2-8ºC and 30 days at -20ºC. It is recommended that the reconstituted material is allowed to stand for 1 hour at room temperature before measurement.

CK and bilirubin are sensitive to light. Store the vials protected from light.

Discard the vial if there are signs of microbial contamination or excessive turbidity in the reconstituted product.

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

RESULTS AND REPORTS

Once the sample is analyzed, you must enter the results in the PREVECAL website, www.prevecal.net, logging in with your user code and password.

The deadline for submission of results is the 15th of each month, except January which is extended until the 31st.

The reports can be downloaded from the PREVECAL website logging in with your user code and password.

For further information, see the User Guide available on the PREVECAL website.

For any questions or complaints contact the organization through the address dtprevecal@biosystems.es.

M18045i-04 08/2020

The lateral lines mark the modifications in the current version.

BioSystems S.A. Costa Brava, 30. 08030 Barcelona (Spain)
www.biosystems.global

PREVECAL

BioSystems

BIOCHIMIE HUMAIN

COD 18045 - 12 x 5 mL

INTRODUCTION

PREVECAL est un programme international d'évaluation externe de la qualité, organisé par BioSystems S.A., qui offre aux laboratoires médicales la possibilité de compléter leur schéma de Contrôle Interne grâce à une estimation objective de l'exactitude de leurs procédés de mesure.

CONTENU

Trois niveaux de concentration de chaque composant sont fournis, répartis sur les 12 mois de la durée du programme et étiquetés avec le mois où ils doivent être analysés. Chaque niveau apparaît alors sur 4 mois distincts.

COMPOSITION

PREVECAL Humain. Pour 5 mL. Sérum humain lyophilisée contenant divers composants à des concentrations suffisantes pour une évaluation efficace externe de la qualité des procédures de mesure. PREVECAL Humain ne contient pas de conservateurs pouvant interférer dans les mesures.

Les composants d'origine humaine ont été essayés et ont démontré être négatifs pour la présence d'anticorps anti-VIH et anti-VHC, ainsi que pour l'antigène HBs. Cependant, en tant que potentiellement infectieux, ils doivent se manipuler avec précaution.

PRÉPARATION ET UTILISATION

1. Ouvrir soigneusement le flacon étiqueté avec le mois correspondant, en tâchant d'éviter la perte de matériau lyophilisé.
2. Introduire à la pipette 5 mL d'eau distillée dans le flacon. Les valeurs obtenues pour les différents composants dépendront de l'exactitude avec laquelle l'eau distillée est introduite à la pipette.
3. Fermer le flacon avec le bouchon en caoutchouc et le laisser reposer pendant 20 minutes à température ambiante.
4. Agiter doucement le flacon, en tâchant d'éviter la formation de mousse, jusqu'à dissoudre complètement tout le lyophilisé.
5. Si le matériel doit être utilisé pour l'analyse d'éléments traces, éviter le contact du matériel reconstitué avec le bouchon en caoutchouc, afin d'éviter une éventuelle contamination.
6. Utiliser le Sérum Contrôle de Biochimie reconstitué identiquement aux sérums des patients.

CONSERVATION ET STABILITÉ

Conserver à 2-8ºC.

Le Sérum Contrôle de Biochimie lyophilisé est stable jusqu'à la date limite indiquée sur l'étiquette.

Les composants du matériel reconstitué sont stables au moins 7 jours à 2-8ºC et 30 jours à -20ºC (une seule congélation), sauf:

- L'AST, stable 8 heures à 2-8ºC et 30 jours à -20ºC.
- La phosphatase alcaline, stable 5 heures à 2-8ºC et 30 jours à -20ºC. Il est recommandé de laisser reposer le matériel reconstitué pendant 1 heure à la température ambiante avant de procéder à la mesure.

La CK et la bilirubine sont sensibles à la lumière. Conserver les ampoules à l'abri de la lumière.

Rejeter l'ampoule s'il y a des indices de contamination microbienne ou un excès de turbidité dans le produit reconstitué.

MISES EN GARDE ET AVERTISSEMENTS

Prenez les précautions habituelles nécessaires pour manipuler tous les réactifs de laboratoire. Les fiches de sécurité sont disponibles pour l'utilisateur sur demande. L'élimination de tous les résidus doit être conforme aux guides locales. Tout incident grave pouvant se produire en rapport avec le dispositif doit être communiqué à BioSystems S.A.

RÉSULTATS ET RAPPORTS

Une fois que les échantillons auxquels participe le laboratoire ont été analysés, vous devez introduire les résultats sur le site PREVECAL, www.prevecal.net, en y accédant avec votre code et mot de passe.

La date butoir pour envoyer les résultats est le 15 de chaque mois, sauf pour le mois de janvier où le délai est prolongé jusqu'au 31.

Les rapports peuvent être téléchargés sur le site PREVECAL en y accédant avec votre code et mot de passe.

Pour plus d'informations consultez le Mode d'emploi sur le site PREVECAL.

En cas de doute ou de réclamation, veuillez contacter l'organisation en écrivant à dtprevecal@biosystems.es.

M18045f-04 08/2020

Les lignes latérales marquent les modifications dans la version actuelle.

BIOQUÍMICA HUMANO

COD 18045 - 12 x 5 mL

INTRODUÇAO

PREVECAL é um programa internacional de avaliação externa da qualidade organizado pela BioSystems S.A., que oferece aos laboratórios clínicos a possibilidade de completar o seu esquema de Controle Interno com uma estimativa objetiva da exatidão de seus procedimentos de medida.

CONTEÚDO

São proporcionados 3 níveis de concentração de cada componente, distribuídos entre os 12 meses de duração do programa e etiquetados com o mês em que devem ser analisados. Cada nível surge, assim, em 4 meses diferentes.

COMPOSIÇÃO

PREVECAL Humano. Para 5 mL. Urina humana liofilizada que contém diversos componentes a concentrações adequadas para uma avaliação externa eficaz da qualidade dos procedimentos de medição. PREVECAL Humano não contém conservantes que possam interferir nas medições.

Os componentes de origem humana foram testados e demonstraram ser negativos para a presença de anticorpos anti-VIH e anti-VHC, bem como para o antígeno HBs. No entanto, devem ser manipulados com precaução como potencialmente infecciosos.

PREPARAÇÃO E UTILIZAÇÃO

1. Abrir cuidadosamente o frasco etiquetado com o mês que corresponde, procurando evitar a perda de material liofilizado.
2. Pipetar 5 mL de água destilada no frasco. Os valores obtidos para os diferentes componentes dependerão da exatidão com que se pipete a água destilada.
3. Tapar o frasco com a tampa de borracha e deixá-lo repousar durante cerca de 20 minutos à temperatura ambiente.
4. Agitar o frasco suavemente, procurando evitar a formação de espuma, até se dissolver por completo todo o liofilizado.
5. Se o material tiver de ser utilizado para a análise de elementos vestigiais, evitar o contacto do material reconstituído com a tampa de borracha para impedir uma possível contaminação.
6. Utilizar o Soro de Controlo de Bioquímica reconstituído de forma idêntica aos soros dos pacientes.

CONSERVAÇÃO E ESTABILIDADE

Conservar de 2 ºC a 8 ºC.

O Soro Controlo de Bioquímica liofilizado é estável até à data de validade indicada no rótulo.

Os componentes do material reconstituído são estáveis, pelo menos, sete dias de 2 ºC a 8 ºC e 30 dias a -20 ºC (congelado apenas uma vez), excetuando:

- A AST é estável 8 h a 2 ºC a 8 ºC e 30 dias a -20 ºC.
- A fosfatase alcalina é estável 5 horas a 2-8ºC y 30 días a -20ºC. É recomendável deixar repousar o material reconstituído durante 1 h à temperatura ambiente antes de realizar a medição.

A CK e a bilirrubina são sensíveis à luz. Conservar os frascos protegidos da luz.

Eliminar o frasco se houver indícios de contaminação microbiana ou excesso de turbidez no produto reconstituído.

ADVERTENCIAS E PRECAUÇÕES

Realize as precauções habituais necessárias para manipular todos os reagentes de laboratório. As fichas de segurança estão disponíveis para o utilizador mediante solicitação. A eliminação de todos os resíduos deve ser feita de acordo com as diretrizes locais. Qualquer incidente grave que possa ocorrer em relação ao dispositivo deve ser comunicado à BioSystems S.A.

RESULTADOS E RELATÓRIOS

Uma vez analisadas as amostras nas quais o laboratório participa, deve introduzir os resultados na página web PREVECAL, www.prevecal.net, acedendo com o seu código e palavra-passe.

A data limite de envio de resultados é o dia 15 de cada mês, com exceção do mês de janeiro no qual se amplia o prazo até dia 31.

Os relatórios podem ser descarregados na página web PREVECAL acedendo com o seu código e palavra-passe.

Se deseja obter mais informações, consulte o Manual do Utilizador disponível na página web PREVECAL.

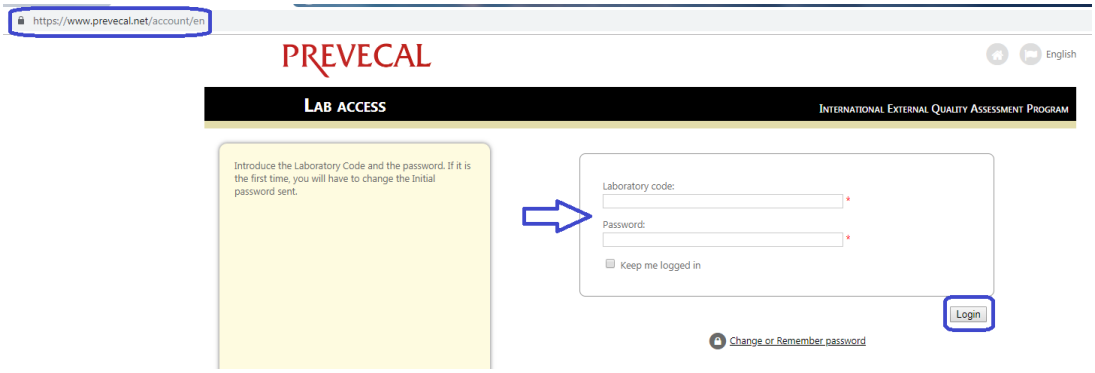
Para qualquer questão ou reclamação, entre em contacto com a organização através do e-mail dtprevecal@biosystems.es.

M18045p-04 08/2020

As linhas laterais mostram as modificações na versão atual.

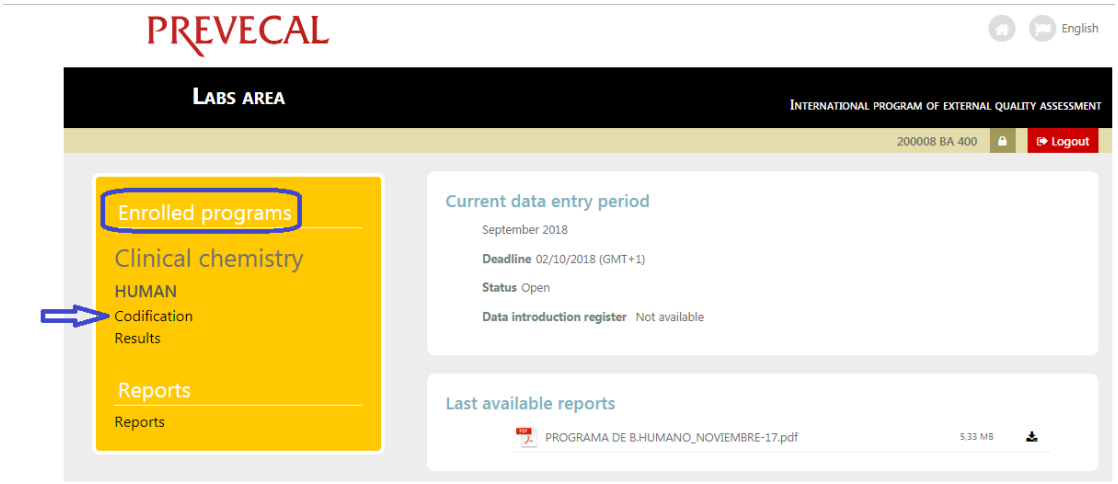
BioSystems S.A. Costa Brava, 30. 08030 Barcelona (Spain)
www.biosystems.global

1. Access to the website www.prevecal.net using the laboratory code and the password.

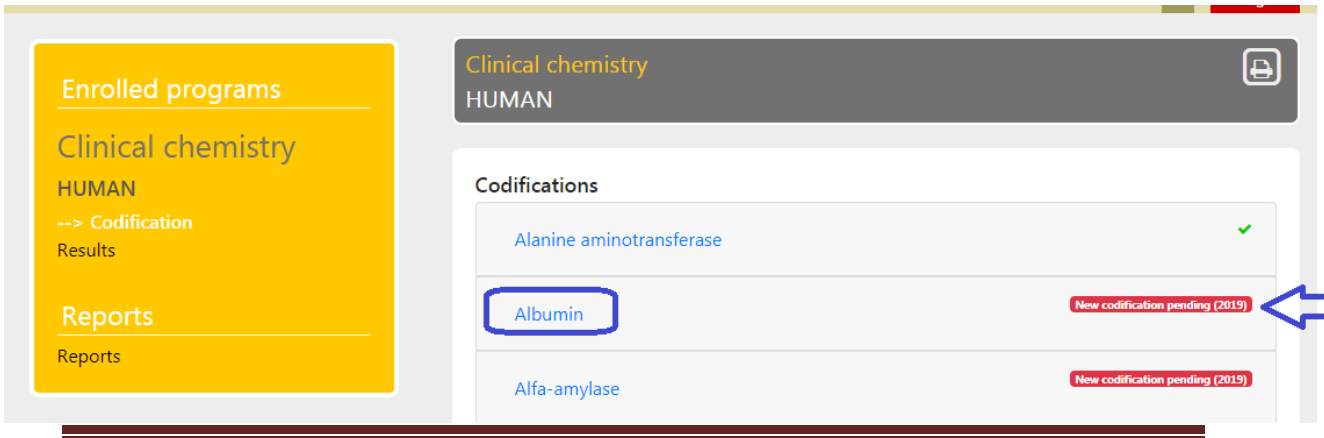


2. Access to Enrolled programs

3. Access the **Codification** option of the program you wish to codify.

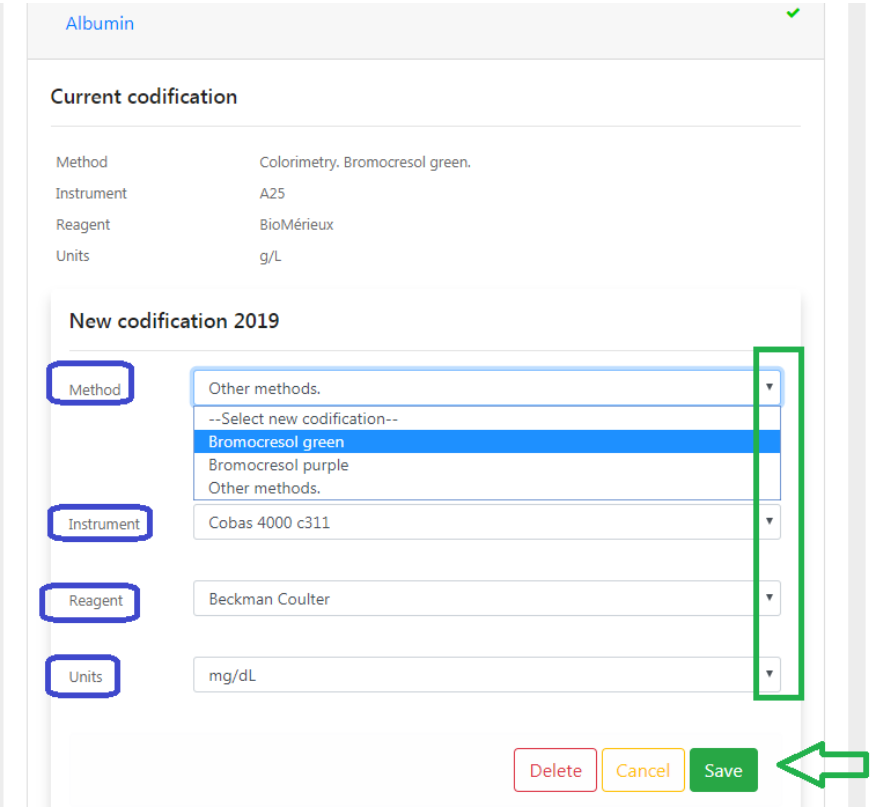


4. Select the magnitude you want to codify. The website allows codifying all the parameters included in each program. Is the laboratory who decides which parameters he wants to participate for the year 2019.



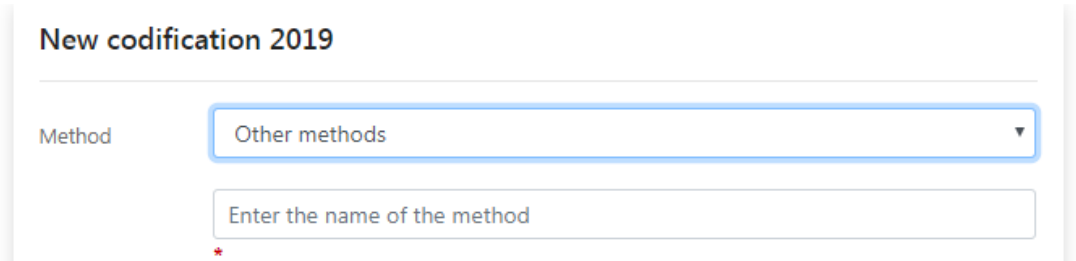
Attention: the alarm "New Codification pending (2019)" indicates that there is NO information for the method, instrument, reagent and units.

5. Access to the parameter. Choose the method, instrument, reagent and units by using the information contained in the drop-down. Once these fields are completed, click on **Save**.

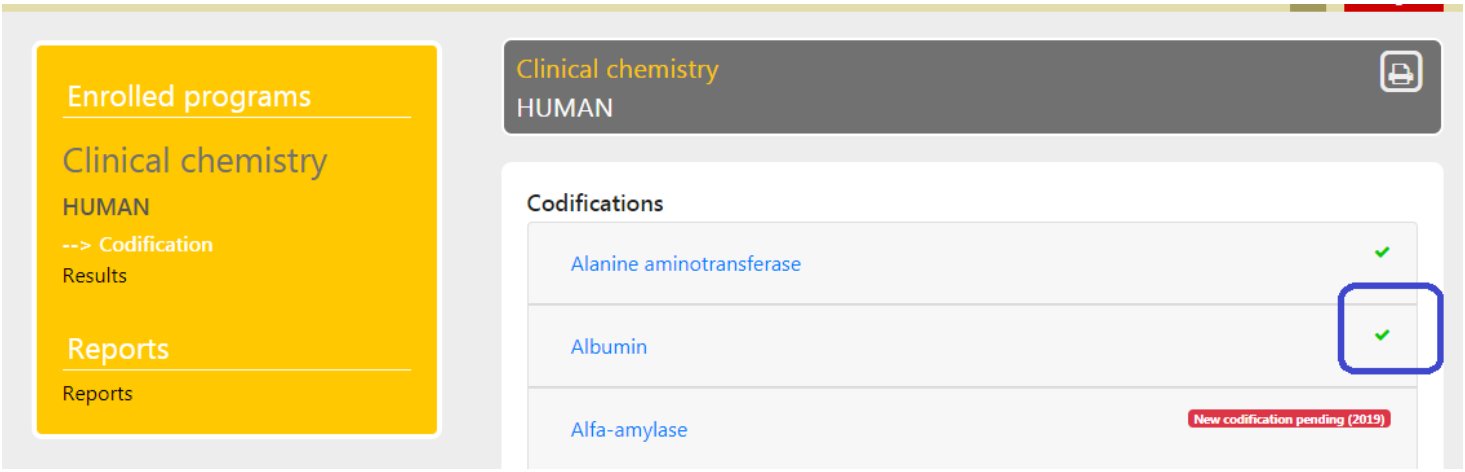


If it is the first time you participate in PREVECAL you will not find information in Current Codification. For further information go to the Codification Tables published on the website.

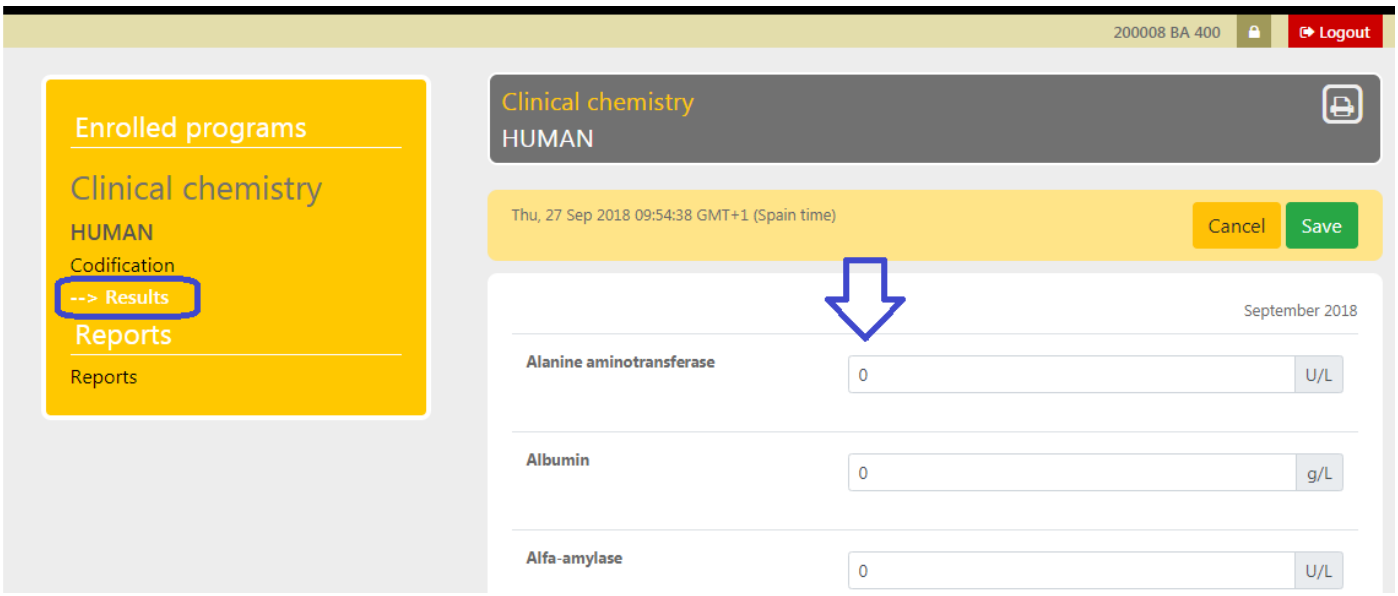
If you can not find the option you are using, please select **Others** and fill in the free field.



6. Exit the screen and verify the information has been correctly saved, **√** will appear. You have the 2019 codification done.

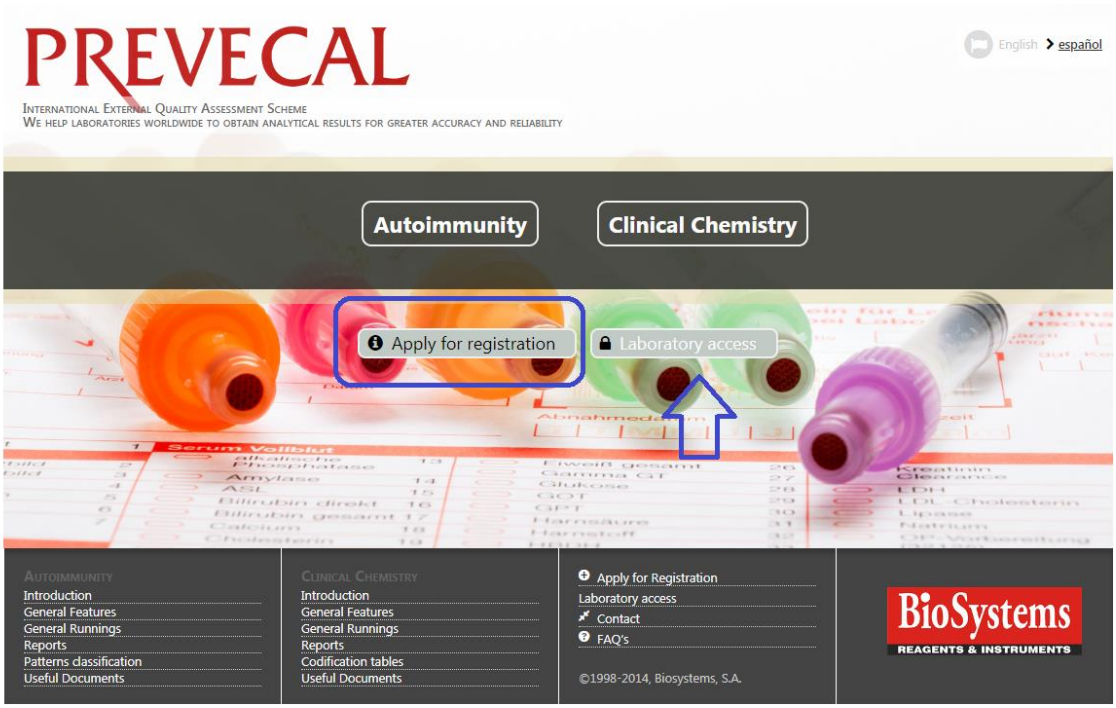


7. From 2nd of January send the results using the Results option.

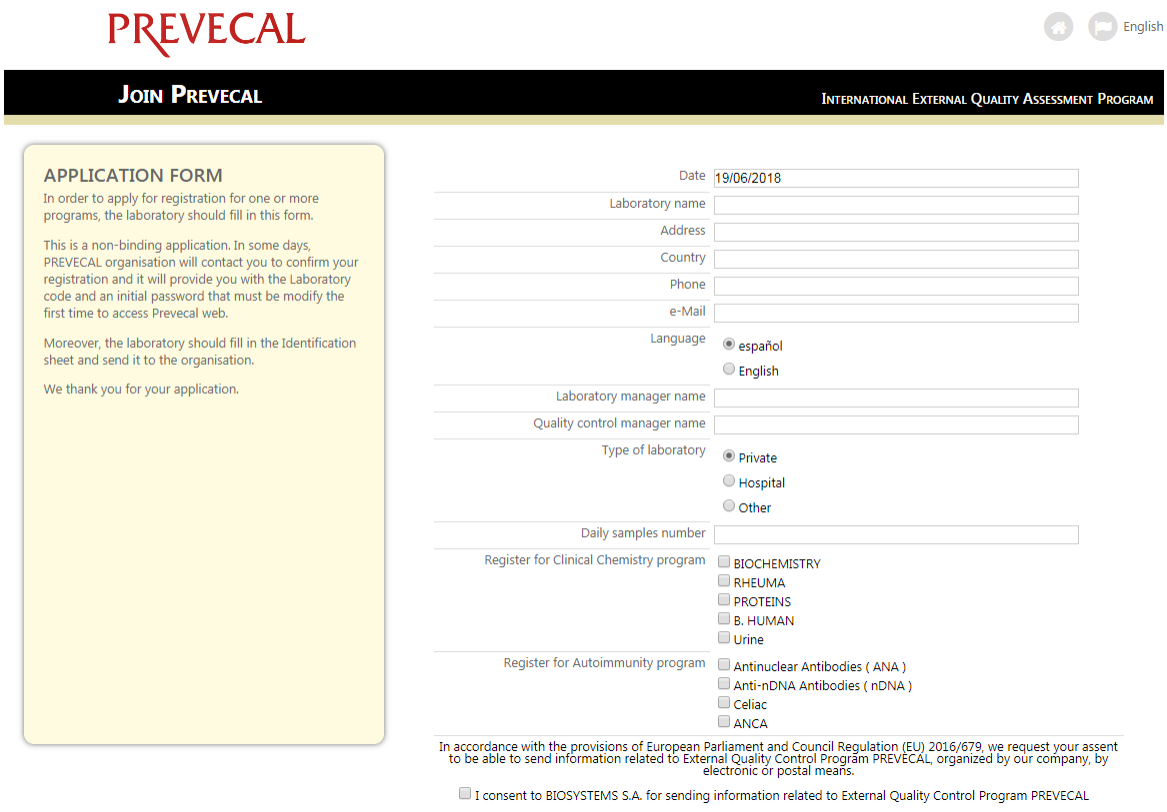


IMPORTANT: You must codify the parameter before sending results, since it is NOT POSSIBLE TO SEND RESULTS if the parameter has not been previously codified.

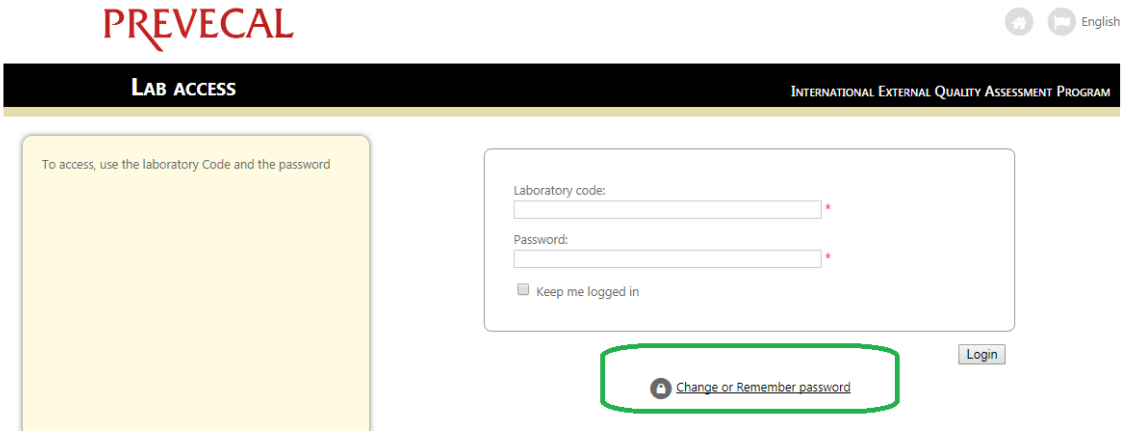
1. MAIN MENU



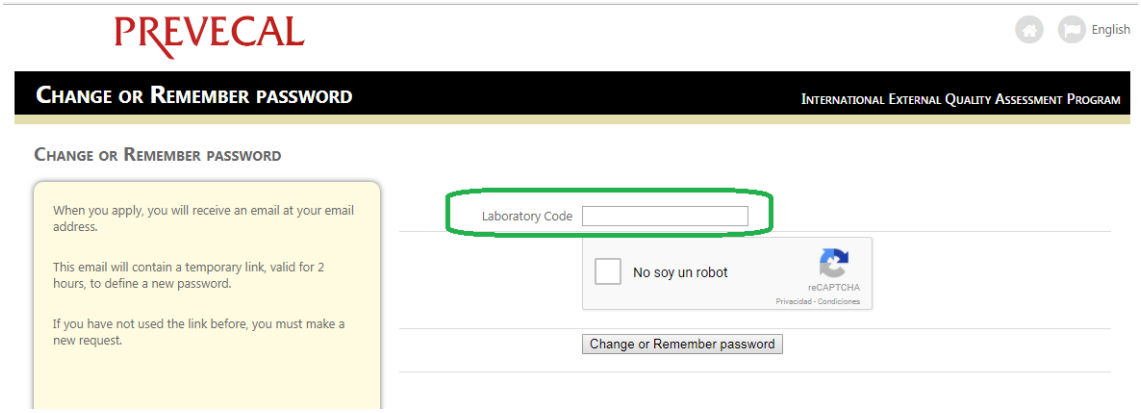
Apply for registration: allows new laboratories to apply for registration



Laboratory access: allows the access of registered participants, using the Laboratory Code and the personal password

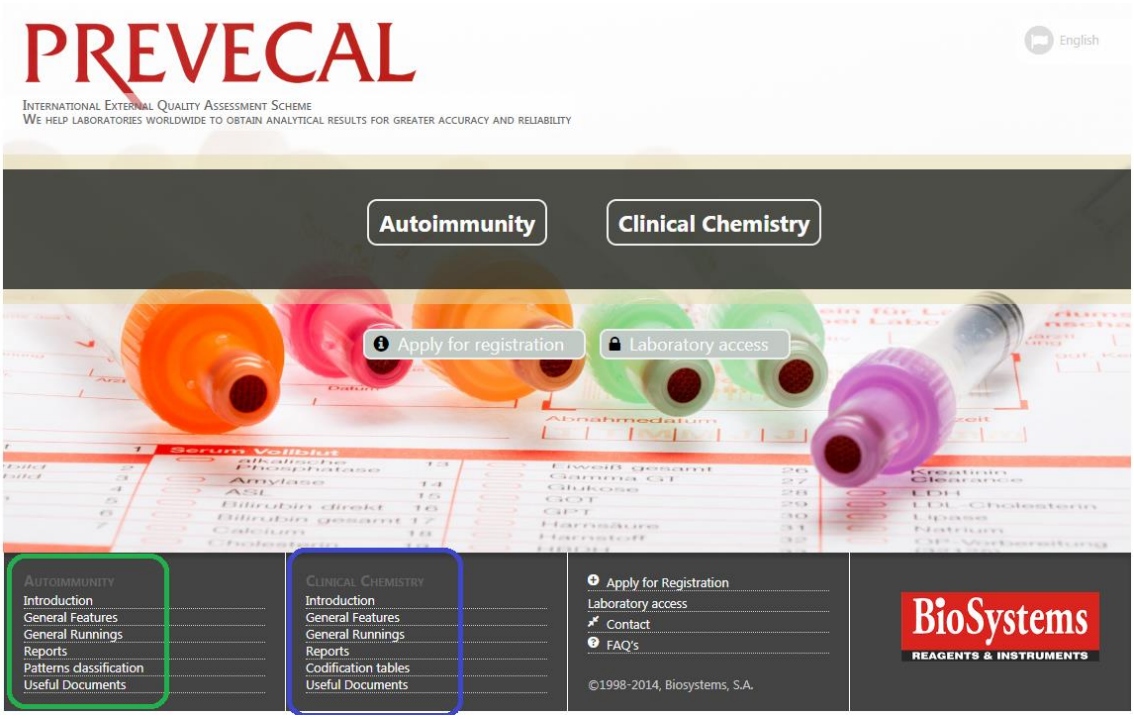


Change or Remember password: allows laboratory to change its password or re-establish the password in case of forgetfulness or loss

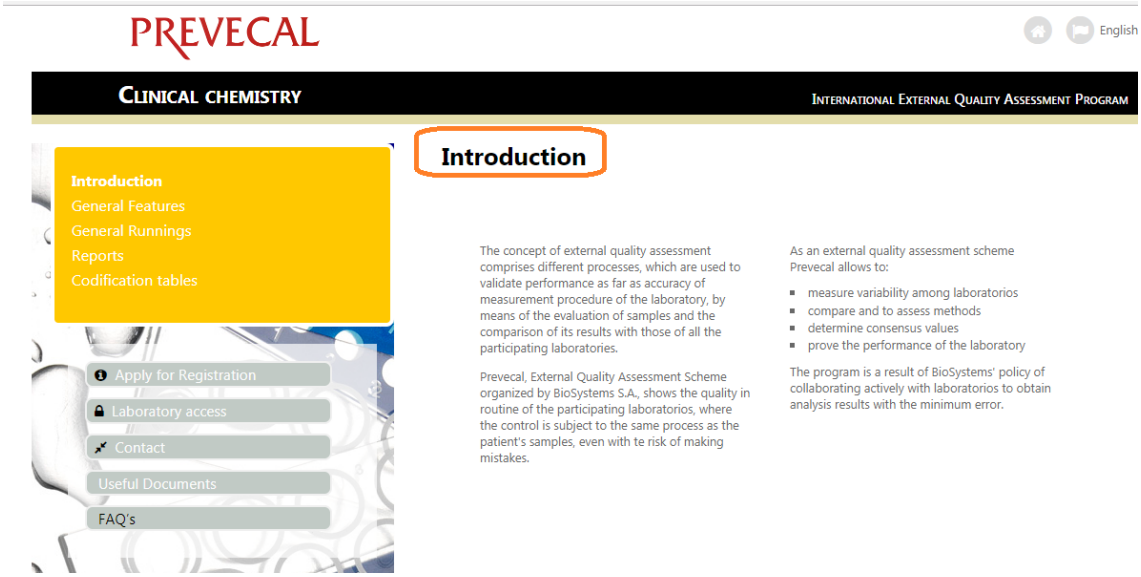


The laboratory must enter its code and mark the option No soy un robot and send. Then he will receive a link in the contact email to re-establish the password. The link is valid only 2h.

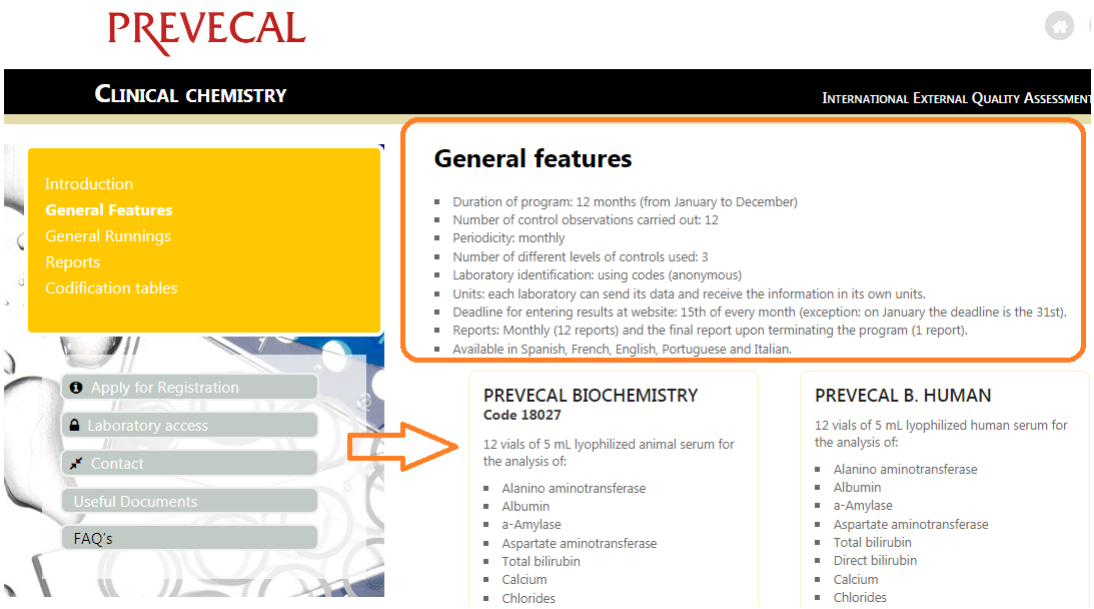
2. AUTOIMMUNITY / CLINICAL CHEMISTRY



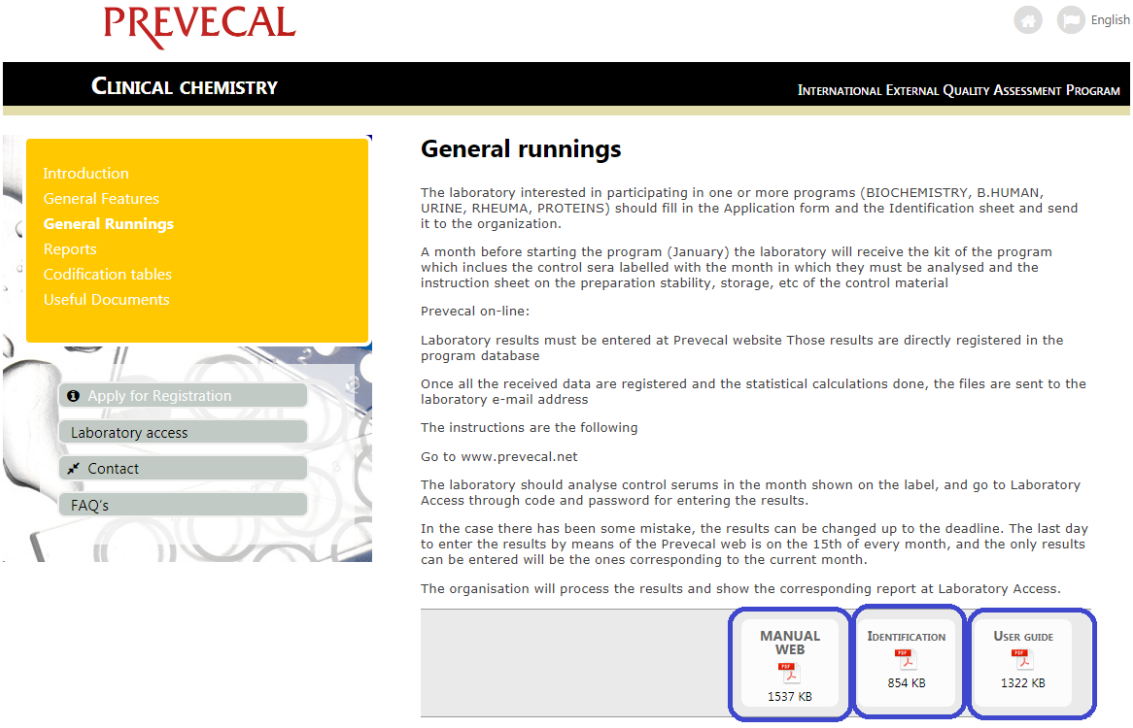
Introduction: description of the aim of an external quality program and the profits of performing PREVECAL



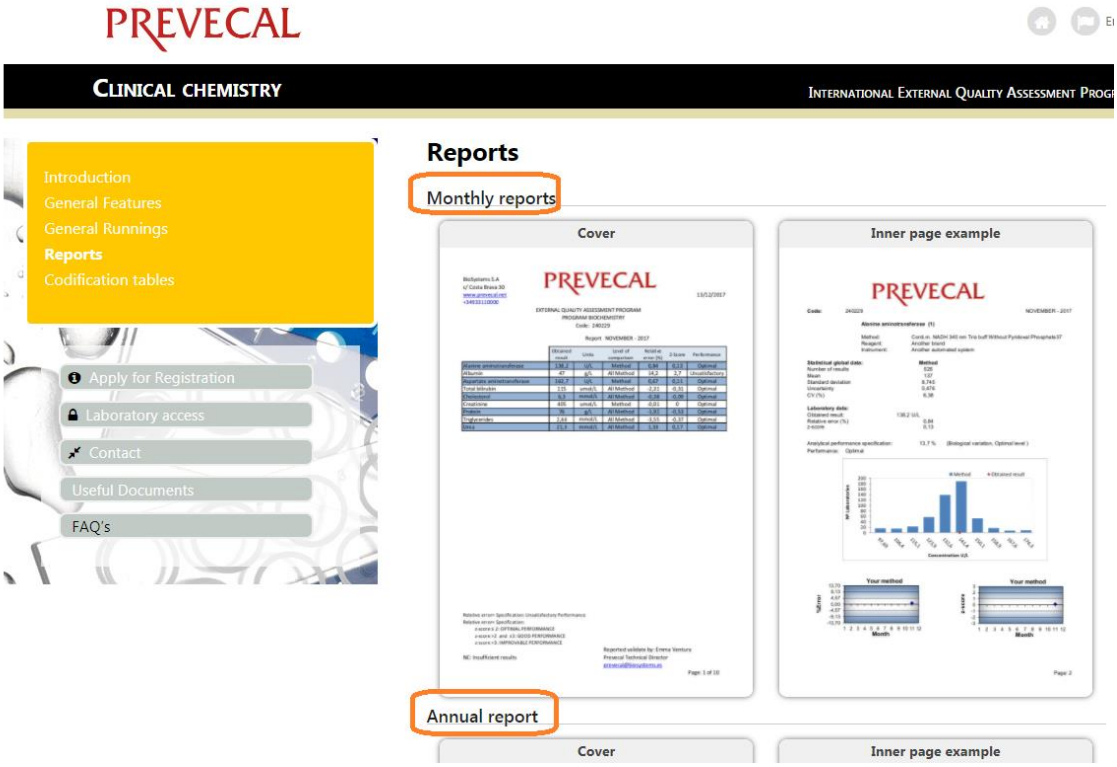
General features: description of the general characteristics of each area



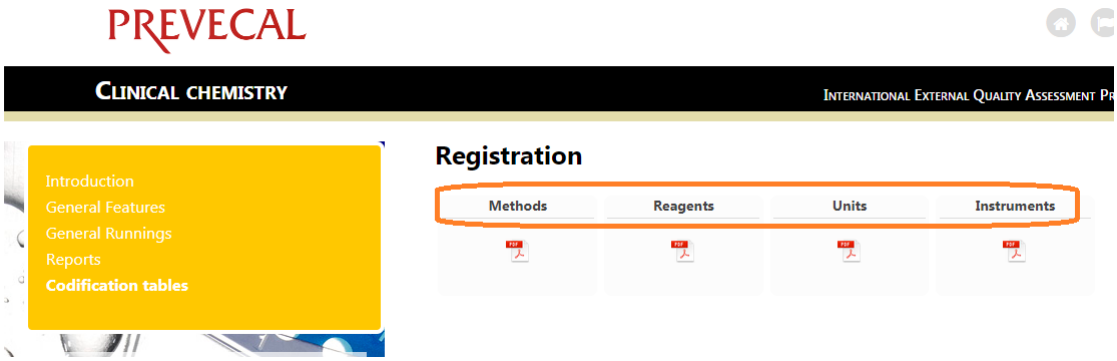
General Runnings: description of the running's of the program. Includes the User's Guide and the Identification Sheet needed to complete the registration process



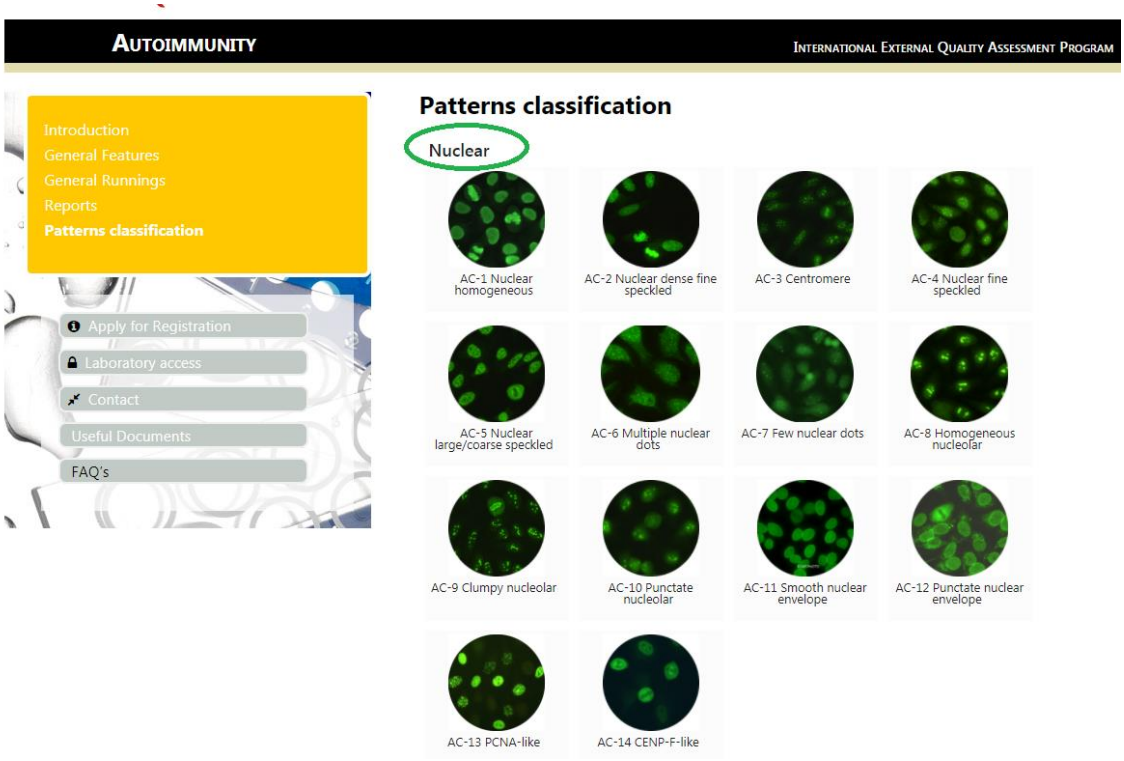
Reports: includes graphic examples of the different monthly, quarterly or annual reports of each area.



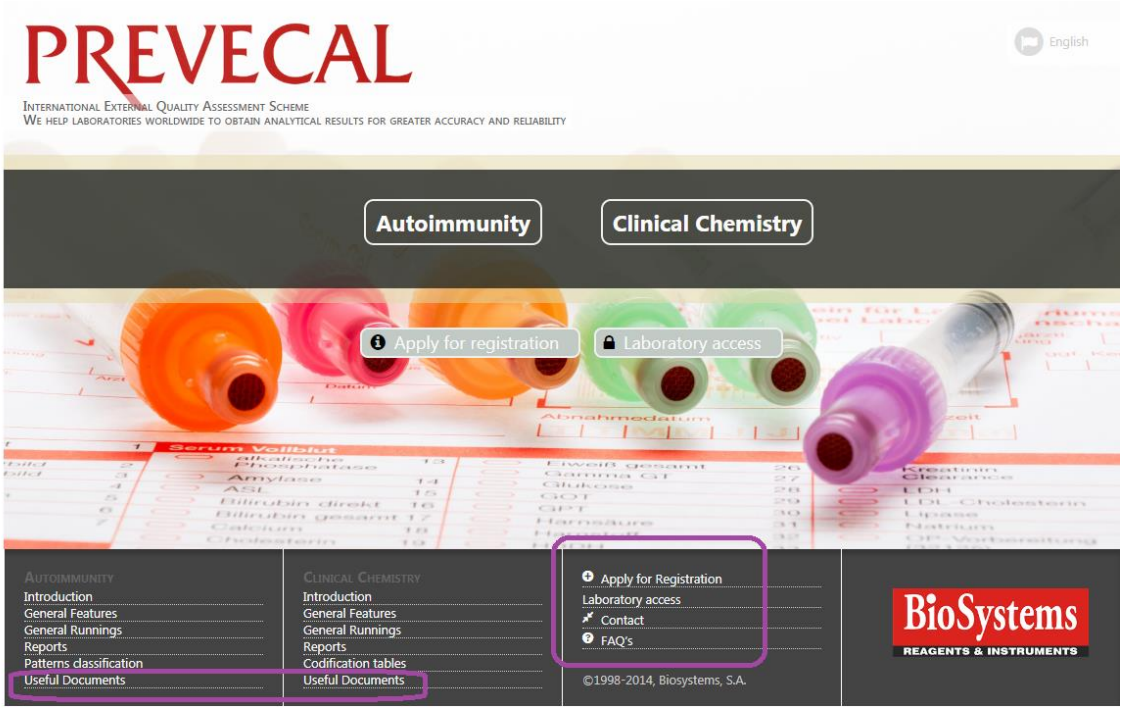
Codification tables: information about the methods, instruments, reagents and units that can be use in PREVECAL.



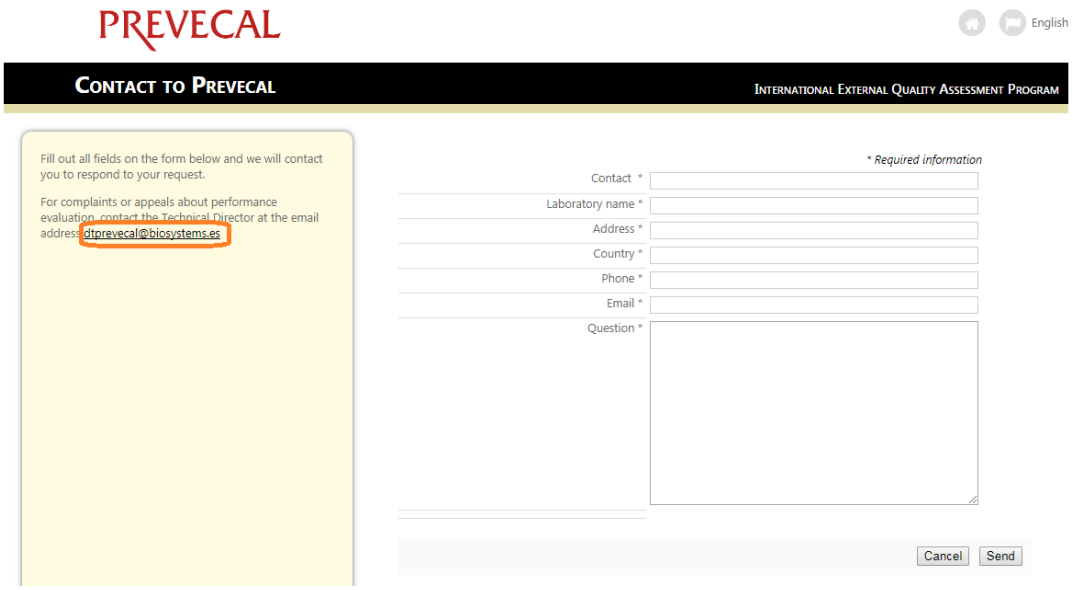
Patterns Classification: includes photos of each type of pattern that the program offers.



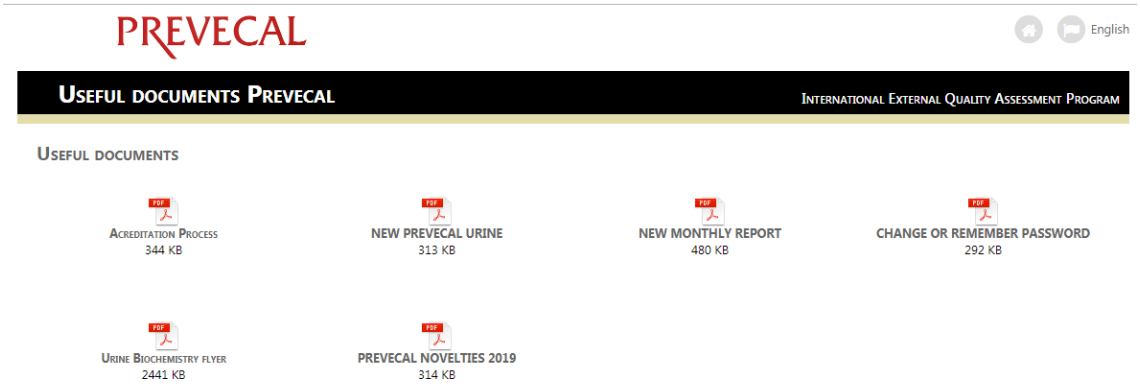
3. OTHERS MENUS



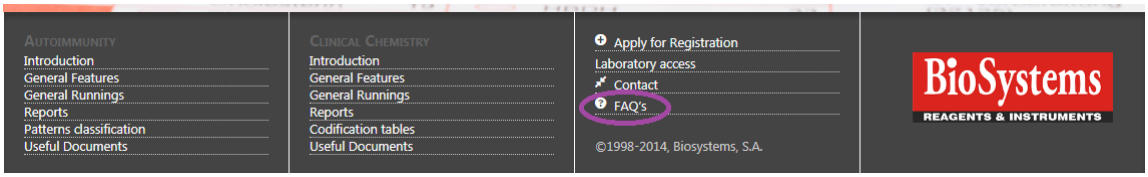
Contact: allows the laboratory to contact with the organization. Remember to use the published email to make technical inquiries



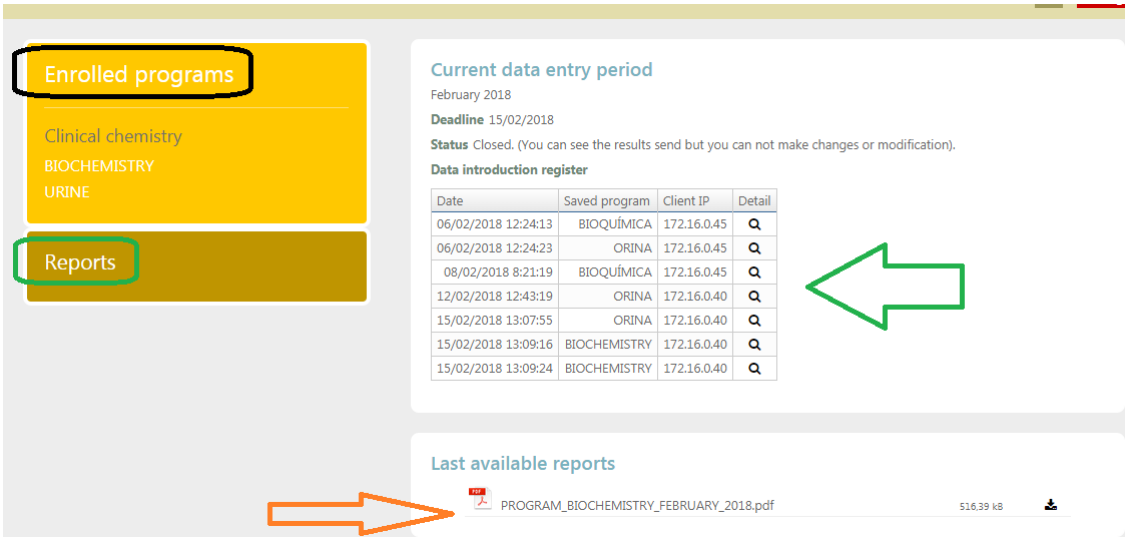
Useful Documents: Important information on issues related to the development of the Program.



FAQ'S: most common and frequent queries and doubts among the participants



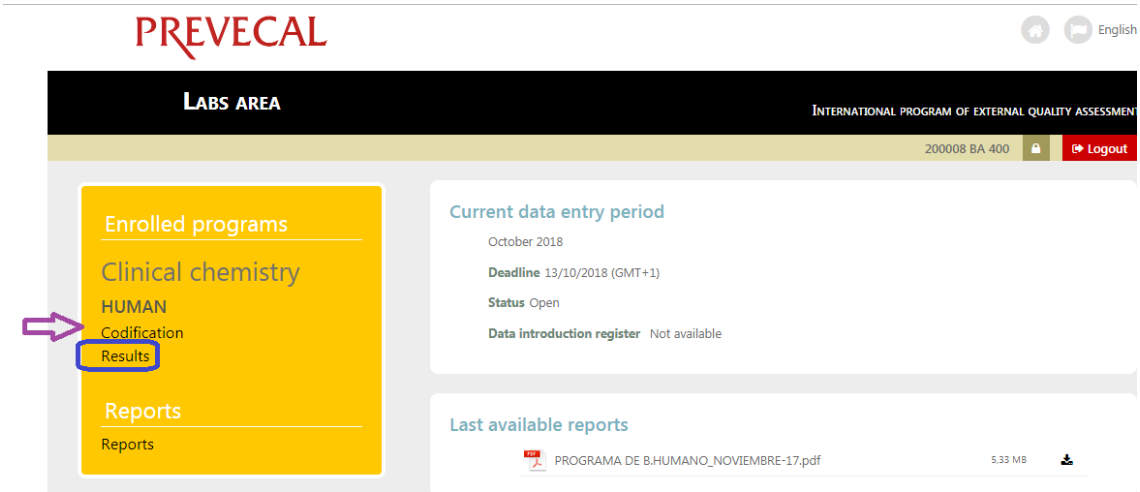
4. LABS AREA



The table registers the date where results were sent.

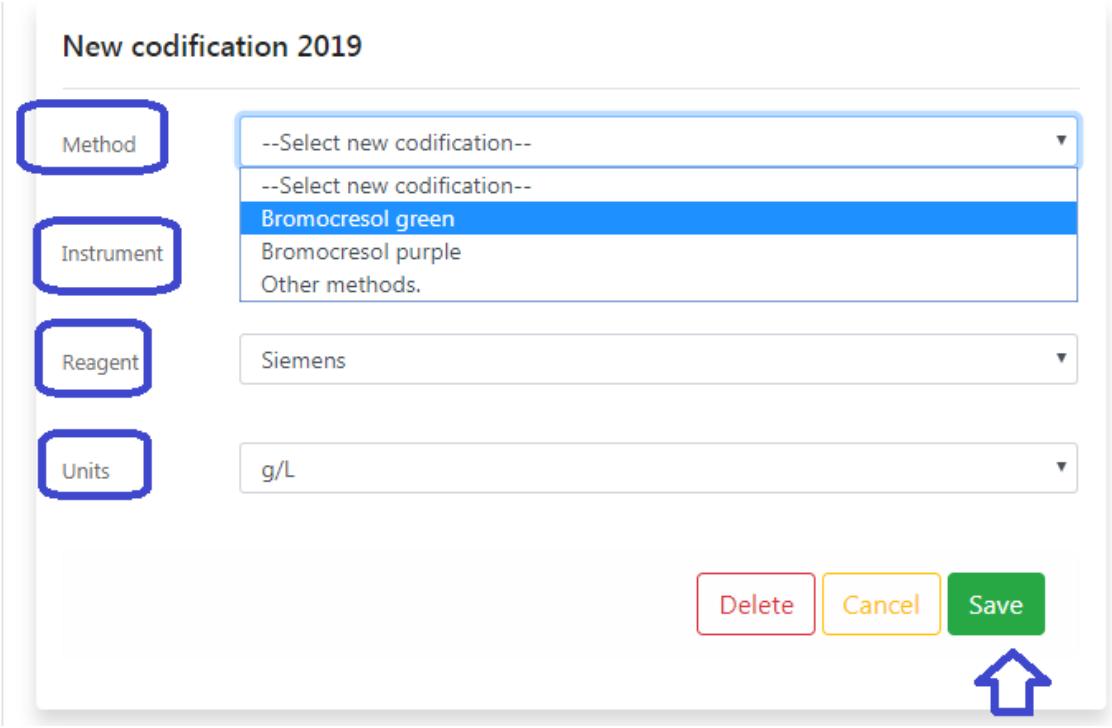
The screen also allows consulting the last published report.

Enrolled programs: access to the programs registered by the laboratory and chooses the option: Codification or Results



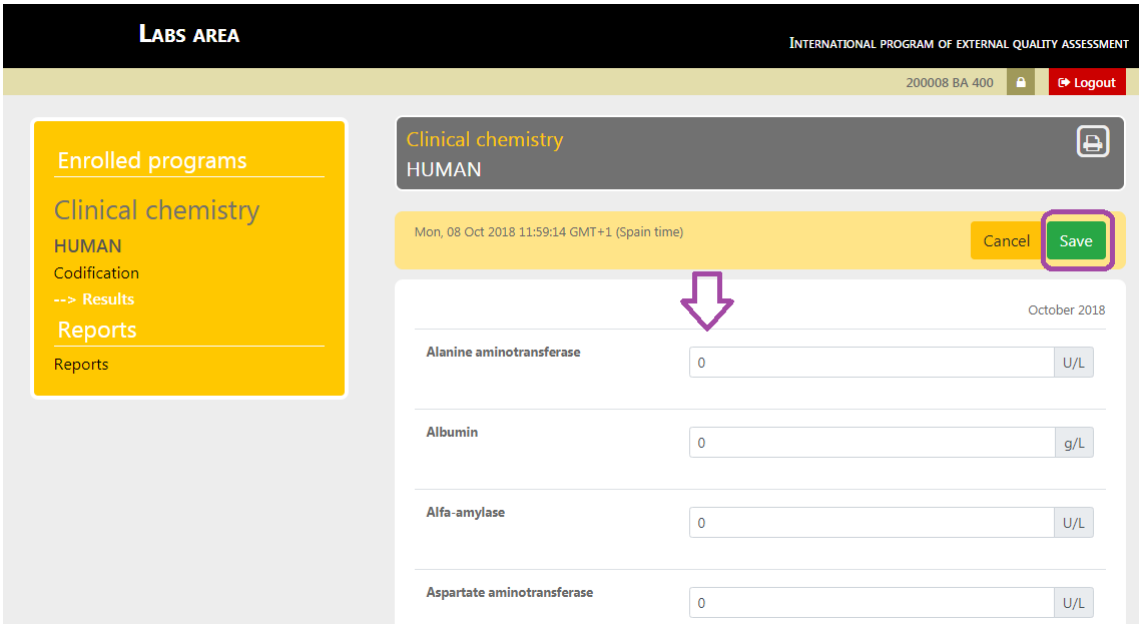
Codification: important to complete this option before sending results. Encode the method, instrument, reagent, unit from each parameter you whish to participate.

Select the information provide in each dropdown to complete the codification.

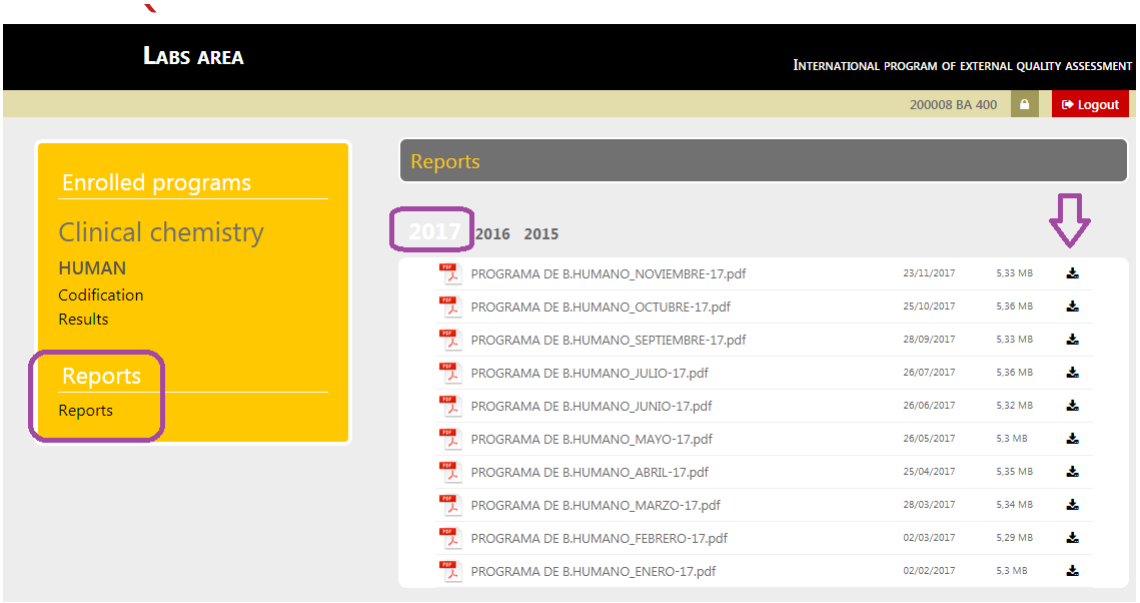


Save the information.

Results: send the results of the selected program after you finish the codification. Important saving results to complete the shipment.



Reports: allows consulting the published reports of the current year, as well as consulting the reports of the previous years



Apply for Registration
Laboratory access
Contact
FAQ's

General features

- Duration: 12 months (from January to December)
- Evaluation carried out: 12
- Periodicity: monthly
- Control levels used: 3
- Laboratory identification: laboratory code (anonymous)
- Units: each laboratory can send its data and receive the information in its own units.
- Deadline: day 15th of every month (exception: January deadline is day 31rst).
- Reports: Monthly (12 reports) and final report.
- Available Languages: Spanish, French, English, Portuguese and Italian.

PREVECAL BIOCHEMISTRY
Code 18027

12 vials of 5 mL lyophilized animal serum for the analysis of:

- Alanino aminotransferase
- Albumin
- α-Amylase
- Aspartate aminotransferase
- Total bilirubin
- Calcium
- Chlorides
- Cholesterol
- HDL-cholesterol
- Creatine kinase
- Creatinine
- Alkaline phosphatase
- Inorganic phosphate
- Glucose
- γ-Glutamyltransferase
- Iron
- Lactate*
- Lactate dehydrogenase
- Lipase
- Magnesium
- Potassium
- Sodium
- Total protein
- Triglycerides
- Uric acid
- Urea
- Zinc*

*Mensurand not included in the accreditation scope.

PREVECAL VETERINARY*
Code 18081

12 vials of 5 mL lyophilized animal serum for the analysis of:

- Alanino aminotransferase
- Albumin
- α-Amylase
- Aspartate aminotransferase
- β-Hydroxybutyrate
- Biliar Acid
- Total bilirubin
- Calcium
- Chlorides
- Cholesterol
- HDL cholesterol
- Cholinesterase
- Creatine kinase
- Creatinine
- Alkaline phosphatase
- Inorganic phosphate
- Glucose
- γ-Glutamyltransferase
- Iron
- Lactate
- Lactate dehydrogenase
- Lipase
- Magnesium
- Potassium
- Sodium
- Total protein
- Triglycerides
- Uric acid
- Urea
- Zinc

*Program not included in the accreditation scope.

PREVECAL COAGULATION*
Code 18082

12 vials of 1 mL lyophilized human serum for the analysis of:

- Prothrombine Time
- Activated Partial Thromboplastin Time
- Clauss Fibrinogen
- Thrombin Time

*Program not included in the accreditation scope.

PREVECAL B. HUMAN
Code 18045

12 vials of 5 mL lyophilized human serum for the analysis of:

- Alanino aminotransferase
- Albumin
- α-Amylase
- α-Amylase pancreatic*
- Aspartate aminotransferase
- β-Hydroxybutyrate*
- Total bilirubin
- Direct bilirubin
- Calcium
- Chlorides
- Cholesterol
- HDL-cholesterol
- LDL-cholesterol
- Cholinesterase
- Creatine kinase
- Creatinine
- Alkaline phosphatase
- Inorganic phosphate
- Glucose
- γ-Glutamyltransferase
- Iron
- Lactate*
- Lactate dehydrogenase
- Lipase
- Magnesium
- Potassium
- Sodium
- Total protein
- Triglycerides
- Uric acid
- Urea
- Zinc*

*Mensurands not included in the accreditation scope.

PREVECAL URINE*
Code 18067

12 vials of 5 mL lyophilized urine for the analysis of:

- Albumin
- α-Amylase
- α-Amylase Pancreatic
- Calcium
- Chloride
- Citrate
- Creatinine
- Glucose
- Magnesium
- Inorganic phosphate
- Potassium
- Proteins
- Sodium
- Uric acid
- Urea

*Program not included in the accreditation scope.

PREVECAL PROTEINS
Code 31010

12 vials of 1 mL lyophilized human serum for the analysis of:

- Immunoglobulin A
- Immunoglobulin G
- Immunoglobulin M
- Complement C3
- Complement C4
- Transferrin
- Ferritin
- α1-Acid glycoprotein*
- Prealbumin*
- hsCRP*

*Measurands not included in the scope of accreditation.

PREVECAL RHEUMA
Code 31009

12 vials of 1 mL lyophilized human serum for the analysis of:

- Anti-streptolysin O
- C-reactive protein
- Rheumatoid factors

TIMBRE DEL ESTADO

0M7122959

06/2019

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

CLASE 8.ª

0,03 EUROS
TRES CÉNTIMOS DE EURO

ANTONI ROSSELLO MESTRE NOTARI

Traducción Jurada — Official translation

Josep Peñarroja Fa
Intérprete Jurado de Inglés
Official Translator of English

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

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

Barcelona, - 3 MAR 2020

TRADUCTOR JURADO - JURAT
Josep Peñarroja Fa
OFFICIAL TRANSLATOR

JOSEP PEÑARROJA FA
TRADUCTOR JURADO-JURAT-JURAMENTADO-GIURATO

TIMBRE DEL ESTADO

0,03 EUROS
TRES CÉNTIMOS DE EURO

0N9696073

NOTARI - BARCELONA - MESTRE

CLASE 8.ª

Traducción Jurada

[Coat of arms of Spain] **MINISTRY OF HEALTH**

[Logo] Spanish Medicines and Medical Devices Agency

NOTIFICATION

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

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

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

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

J. JOSEP PENARROJA FAI
TRADUCTOR JURAT - JURAMENTADO - GIURATO

You are hereby advised that:

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

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

Traducción Jurada

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

E-MAIL:
mpizarro@aemps.es

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

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

JOSEP PENARROJA FA
TRADUCTOR-JURADO-JURAT-JURAMENTADO-GIURATO

T E S T I M O N I O.- ANTONIO ROSSELLÓ MESTRE, Notario del Ilustre Colegio de Cataluña, con residencia en Barcelona, ----------

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

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

Figura en el libro indicador con el Nº 453/2020 de la Sección Segunda.----------

SELLO DE LEGITIMACIONES Y LEGALIZACIONES

COLEGIO NOTARIAL DE CATALUÑA

FE PÚBLICA NOTARIAL

CONSEJO GENERAL DEL NOTARIADO ESPAÑOL

NOTARIADO EUROPA

NIHIL PRIUS FIDE

ANTONI ROSSELLÓ MESTRE

47584805

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

Declaration of conformity certificate

We: Bio Group Medical System Srl Loc. Campiano 9/B, Talamello (RN) 47863 Italy

Ensure and declare with sole responsibility that the products:

Internal code: MSEQSCH12 EDMA Code: 38220000	Commercial name: QS Clinical Chemistry 12 First lot introduced in market: 101-AA
Internal code: MSEQSHE12 EDMA Code: 38220000	Commercial name: QS Hematology 12 First lot introduced in market: 202-AA
Internal code: MSEQSCO12 EDMA Code: 38220000	Commercial name: QS Coagulation 12 First lot introduced in market: 303-CC
Internal code: MSEQSIM12 EDMA Code: 38220000	Commercial name: QS Immunology 12 First lot introduced in market: 102-CC
Internal Code: MSEQSHB12 EDMA Code: 38220000	Commercial name: QS HBA1C 12 First lot introduced in market: 161-CA

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, 25/08/2021

The Executive Manager
Paolo Buonvicino

BIO-GROUP
MEDICAL SYSTEM Srl
Con socio unico
Loc. Campiano 9/B - 47867 Talamello (RN)
P.IVA / C.Fisc. 00964170419

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

Declaration of conformity certificate

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

Internal code: MSEQUALITYCH 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 EDMA Code: 30021095	Commercial name: QS Hematology First lot introduced in market: 2020-EN
Internal code: MSEQUALITYC EDMA Code: 38220000	Commercial name: QS Coagulation First lot introduced in market: 084
Internal code: MSEQUALITYI 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 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:

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- 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.

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

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, 25/08/2021

The Executive
Manager
Paolo Buonvicino

QUALITY SYSTEM INFORMATION

QUALITY SYSTEM **qs@biogroupmedicalsystem.com**

CLINICAL CHEMISTRY AND IMMUNOLOGY LEVEL 1 PROFICIENCY TESTING

General information on the organisation and management

Organizer **Registered office and headquarters**	Bio-Group Medical System S.r.l. – Divisione Quality System Loc. Campiano 9/B 47867 Talamello (RN)-Italy PHONE:+39 0541 920686 FAX: +39 0541 922130 MAIL: qs@biogroupmedicalsystem.com
Subcontracted activities	• Preparation of the proficiency test items The QS Division uses highly qualified, certified suppliers in compliance with the provisions specified in the standard 17043:2010 • Homogeneity and stability tests The data issued by accredited supplier/according to UNI EN ISO/IEC 17025:2018 and UNI EN ISO/IEC 15189:2013 is checked by the coordinator who evaluates its compliance. Homogeneity and stability data are available for consultation at the company for a minimum period of four years.
Main reference documents	UNI CEI EN ISO/IEC 17043:2010 Conformity assessment – General requirements for collaborative proficiency testing UNI EN ISO 9000:2005 Quality management systems - Basic principles and terminology ISO 13528:2015 Statistical methods for use in proficiency testing by interlaboratorycomparisons JCGM 100 :2008 Evaluation of measurement data – Guide to the expression of measurement uncertainty UNI ISO 5725 – 1-6:2004 Accuracy (trueness and precision) of results and measurement methods, Part 1, 2, 3, 4, 5, 6. ILAC G13:08/2007 Guidelines for the Requirements for the Competence of Providers ofProficiencyTestingSchemes UNI CEI 70099:2008 International Metrology Glossary -Basic and general concepts and related terms (VIM)

Date	Rev.	Reason	Drafting of document	Approval	Archiviazione
29/03/2019	00	First Issue	COP	RQS	RGQ
06/11/2019	01	Variation Point 6.1 Exclusion from processing			
31/03/2020	02	Introduction of Hematology test			
					

Contents

1. 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. The 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.

The repeatability of the same analysis under the same working conditions (verified by means of internal checks) is a first approach in assessing the errors. The comparison with a multiparty agreed mean value ensures and validates the data assessed by internal checks.

The Quality System represents an external Quality Assurance (EQA), i.e. it consolidates or provides guidance for strengthening the approach to quality control of the laboratory.

2. Condition for participation and registration for PT

The QS is open to: clinical analysis laboratories, multispecialist diagnostic centres, nursing homes and similar entities**.**

Expected number of participants;Given the many years of experience of QS Division in this field, we expect a number of 150 participants.

The registration can be done directly by the laboratory concerned or by Distributors. In the case of direct entitlement by the laboratory or from Distributors throughout Italy, the person in charge at the centre sending the request must complete the registration form in all its parts, and send it (MOD.18), as well as the contract and the customer Privacy Policy.

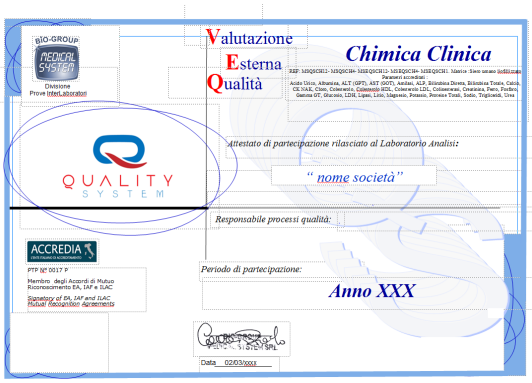
In the case of registration via a foreign Distributor, the latter must compile the form 27, specifying the data of the testing labs and the selection of the relative proficiency testing.

The participant must ensure the following:

- Internet access
- PDF Reader
- Internet Browser (Firefox - Chrome)

After verifying the conditions listed above, the QS division will proceed with the registration of the centre by sending the website access credentials (User and Password) and detailed instructions for participation in the proficiency test, by email and also by enclosing the relative documents in a parcel upon the first delivery.

The **participation certificate** for the current year will be issued the first time the OPV is submitted.



The packaging of OPV sent contains the method of use form IFU.
This document INFO is also available on the website of the Bio-Group MEDICAL SYSTEM Quality System Division.
In case of changes to the programming or if a Supplement to the reviewed Test Report is issued, participants are timely informed via e-mail.

Upon each delivery, the system participants will receive:

- *The test samples*
- *A letter of introduction* describing the material sent and how to use it.

The participant can contact at any time the Quality Control Division of Bio-Group Medical System, which is available for any clarifications or issues concerning the processed data, either by calling 0541920686, room 3 or sending an email to qs@biogroupmedicalsystem.com

3. Test Materials

The proficiency testing items are Human Lyophile Serums or Control blood simulating the biological findings usually measured by the participants. These Control samples will present a range of values completely comparable with those found in the working routine of the participants. To this end, the coordinator will choose Control samples which give measurements that can be referred to both physiological and pathological intervals.
The operating instructions are shown in a document identified by the acronym ISTRU.
The test methods are freely chosen by each participating laboratory.
In compliance with the provisions of UNI CEI EN ISO/IEC 17043:2010 (p.to 4.6.1.2), 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.

Test list:

- Clinical Chemistry 12 monthly samples level 1 MSQSCH12-MSEQSCH12
- Clinical Chemistry 4 quarterly samples level 1 MSQSCH4 - MSEQSCH4
- Clinical Chemistry 1 sample, level 1 MSEQSCH1
- Immunology 12 monthly samples level 1 MSQSI12-MSEQSI12
- Immunology 4 quarterly samples level 1 MSQSI4 - MSEQSI4
- Immunology 1 sample, level 1 MSEQSI1
- Hematology 8 parameters monthly 12 samples MSQSE812-MSEQUALITYE12
- Hematology 8 parameters quarterly 4 samples MSQUALITYE8-MSEQUALITYE8
- Hematology 8 parameters 1 sample Year MSEQSE8

The tested parameters are as follows:

Clinical Chemistry level 1: Bile Acids*, Uric Acid, Albumin, ALT (GPT), AST (GOT), Amylase, ALP, Bicarbonates*, Direct Bilirubin, Total Bilirubin, Calcium, CK NAK, Chlorine, Cholesterol, HDL Cholesterol, LDL Cholesterol, Cholinesterase, Creatinine, Iron, Phosphorus, GT Range, Glucose, LDH, Lipase, Lithium, Magnesium, Potassium, Total Protein, Copper*, Sodium, Triglycerides, UIBC*, Urea, Zinc*.
Test Coordinator: Dr. Montini Matteo – QS Division of Biogroup Medical System S.r.l.
* Parameters not covered by ACCREDIA accreditation

Immunology level 1: 25 OH Vitamin D*, ACTH*, Alpha-Fetoprotein, C Peptide*, CA 125, CA 15-3, CA 19-9, Carbamazepine*, CEA, Cortisol, DHEA Sulphate*, Digoxin*, Estradiol, Ferritin, Folates, FSH, FT3, FT4, β-HCG, HGH*, IgE, Insulin*, PTH*, LH, Phenobarbital*, Phenytoin*, Progesterone, Prolactin, PSA-FREE, PSA, T3, T4, Testosterone, TGAB*, Theophylline*, Thyroglobulin*, TMAB*, TPO AB*, TSH, Valproic Acid*, Vitamin B12*

Hematology: Erytrocites (RBC), Leucoiyes (WBC), Hemoglobin (HB), Hematocrite (HCT), Mean cells volume (MCV)*,Mean cell haemoglobin concentration (MCHC), Red Distribution Width (RDW), Mean haemoglobin contain (MCH), Platellets (PLT), Mean platellets volume (MPV).
Test Cordinator Dr. Matteo Montini- Divisione QS di Biogroup Medical System Srl

*Parameters not covered by ACCREDIA accreditation
The proficiency test involves 4 determinations per year on 4 samples or twelve determinations on twelve samples.
Before distribution to the participants, each test material is tested by the QS Division based on the COP, ensuring the requirements of uniformity and stability according to the goals required for the test. The tests will be carried out on a number of statistically significant rates according to the instructions contained in the reference standard ISO 13528:2015.
In the case of a failure of these testings, the material shall not be distributed and the test will be scheduled again, giving timely notice about the test to the members.
The test material is preserved until the publication of the last test report of the relative PT.

4. Test aim

The purpose of the QS is to allow a comparison between independent laboratories. The external quality evaluation statistically examines the end result of all the work process taking into account: the pre-analytical phase, the analytical phase, and finally the post analytical phase that involves reporting and last transmission of the data.
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.
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.

5. Test execution timelines

5.1 Distribution date and frequency for immunology and clinical chemistry PT

According to the "Quality System", the samples to be analysed must be sent every three months, monthly or once a year.

This frequency is not too burdensome for the operator and, at the same time, it allows the laboratory to control the functioning of the instruments, the attention of the personnel and the application of the operating procedures constantly.
This delivery frequency is adapted to the needs of the analyst and allows creating data archives for a historical analysis of the laboratory quality and for checking the effectiveness of any corrective actions; the annual schedule of sample deliveries is distributed as follows:

	Jan.	Feb.	**Mar.**	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Clinical Chemistry 1monthly level MSQSCH12/MSEQSCH12	•	•	•	•	•	•	•	•	•	•	•	•
Clinical Chemistry 1quarterly level MSQSCH4/MSEQSCH4			•			•			•			•
Immunology 1 monthly level MSQSI12/MSEQSI12	•	•	•	•	•	•	•	•	•	•	•	•
Immunology 1 quartrly level MSQSI14/MSEQSI14			•			•			•			•

By January 10 are shipped all OPV for the year of monthly shipment; by March 10 are shipped the OPV quarterly packages. Subscriptions are accepted at any time of the year, and OPV will be shipped from current period to the end of the year. In case the above shipping dates cannot be observed, participants will be informed by email.

The proficiency testing with MSEQSCH1 code and MSEQSI1 code involve sending only one sample throughout the year. Membership can be obtained at any time of the year and it will be shipped for the test in progress or the next.

The results are determined and sent via web interface by the last day of the reference month.

5.1.1 Dates and frequency of distribution of Hematology tests

In order to ensure the performance of the tests within the declared stability of the control blood sent as an OPV for the hematology tests and to guarantee an acceptable interval between issue of the test report and execution of the subsequent test to allow the participant to implement of corrective actions in a reasonable time, the hematology test follows the following deadline calendar

TEST MONTH	SAMPLE SENDING	RESULTS SUBMITTING DEAD LINE	REPORTS PUBBLICATION
APRIL	WITHIN APRIL SECOND WEEK	30-apr	04-mag
MAY		20-mag	24-mag
JUNE		06-giu	10-giu
JULY	WITHIN JULY SECOND WEEK	31-lug	04-ago
AUGUST		20-ago	24-ago
SEPTEMBER		06-set	10-set
OCTOBER	WITHIN OCTOBER SECOND WEEK	31-ott	04-nov
NOVEMBER		20-nov	24-nov
DECEMBER		06-dic	10-dic

5.2 Method of distribution

The OPV are shipped by courier within the deadline set in the shipping schedule. The material is shipped at the headquarters of each laboratory in writing directly or through distributors that guarantee the shipment to laboratories within the time limits and conditions specified in the contract. Any problems in receiving the material (delays beyond 7 days, faults of packaging or appearance, material leaking from the bottle, etc.) should be promptly reported to the Laboratory Test QS Division. OPV availability is guaranteed in addition

to those distributed, limited to cases of failed delivery by the carrier agreed or due to accidental damage, but no later than the time set for the execution of the determinations.

5.3 Transmission of results

The results are transmitted within the deadline established by the programming of the test (see p. to 5), via the secured area of the website qs-veq.it , by selecting the test in question; to access please enter the User and the Password referred to herein on p. to 7.
To facilitate data entry, upon the first access to the website's home page, you will have to set up the Data entry tables where the participant will insert the tools and the methods used for the tests. Depending on the provisions under section 5.5.3 of ISO 13528:2015 standard, the results must always be expressed in numerical form. Results of the type "<…", " below or above the detection limit" are not allowed.

Each program has a different electronic report sheet containing specific mandatory fields that must be compiled in order to proceed to the processing phase.

For each parameter will be required:

1) METHOD: the main analytical methods used by the laboratories are available for selection
2) UNIT OF MEASUREMENT
3) INSTRUMENT
4) VALUE obtained after the examination of the samples.

All four data MUST be reported under penalty of exclusion from the statistical processing, as it is difficult to include them in a class of approval.

5.4 Issuance of the Test Reports

The test reports will be published in the restricted area of the qs-veq.it website within 10 days from the last date set for the execution of the test, unless there are exemptions previously communicated.
Participants who do not submit their results within the set time limit will not obtain an accredited test report.
The test reports will be available for four years from the date of publication.

6 Evaluating the performance of laboratory and statistical treatment of data

In order to provide an instrument that allows the participant to make an immediate and unambiguous assessment of the quality of the examination, the QS Division shall carry out the statistical analysis in accordance with ISO 13528:2015, as follows:

- The value assigned to each measurement is represented by the consensus mean calculated according to algorithm "A" ISO 13528:2015, which allows the exclusion of aberrant values from the mean, making this consensus mean scarcely influenced by incorrect values

- The measurement uncertainty of the assigned value is calculated based on standard deviation by the formula: $U(X_{pt}) = 1{,}25\left(\frac{s}{\sqrt{p}}\right)$ where:
  - s: robust standard deviation
  - p: number of participants

- Rejected type σ: calculated using the formula σ_{pt}= RSD% * x_{pt} where RDS% is the relative standard deviation calculated on the historic value of the parameter and x_{pt} is the approval mean of the parameter
- Laboratory performance evaluation is expressed by Z-index calculated as follows: $Z = \frac{(x-X)}{\sigma}$ where x is the average of approval, X is the value of the participant and σ is the standard deviation, and the Z-index is calculated as follows:

$$Z' = \frac{(x_i - x_{pt})}{\sqrt{\sigma_{pt}^2 + u^2(x_{pt})}}$$

  Where $u^2(x_{pt})$represents the uncertainty of measurement

- Since it concerns an assessment of the performance of the approval mean , the Z-score and Z'-score indices are used interchangeably:
  Z-score: this is calculated when the measurement uncertainty is negligible or$u(x_{pt})$< 0.3 σ_{pt}.
  Z'-score: this is calculated when the measurement uncertainty is not negligible or $u(x_{pt})$>0.3 σ_{pt}.

Typically the absolute Z value obtained by the participant provides the indications summarised in the following table:

$|Z|$≤2 indicates "satisfactory" performances and does not generate any signal

2.0<$|Z|$<3.0 indicates "questionable" performances and generates a Warning signal

$|Z|$≥3.0 indicates "unsatisfactory" performances and generates an Action signal

Each measurement is also provided with a Shewart chart that allows assessing, for the purpose of self-improvement, the performance monitoring over time.

6.1 The following were excluded from processing

The measurements entered and affected by coarse error (i.e.: typographical error 2.1 instead of 21) will be excluded from processing; the participant will receive from the test Coordinator by email the measurement excluded and detailed reason for exclusion.

For statistical populations of less than 20 participants but above 15, the outlier measures are excluded by using the Grubbs Test. The participant will receive notification of the exclusion.

Statistical populations with less than 15 participants but more than 5 will be processed outside accreditation and will receive an indicative performance index.

All subsets statistics whose number of participants is less than 5 are excluded from processing. Also in this case, the test Coordinator will notify participants by email.

6.2 Issuance of the test reports

The Coordinator can communicate the cancellation of a test report in the event of serious incidents.

He shall reissue the test report indicating the review status.

7. Confidentiality

QS in the test report will use the registration code assigned to the same test as the only identifying element of the data source. The code is known only to the QS and the laboratory Division. If the OPVs are shipped to the distributor, the code is also known by the latter.

The participant must ensure that both the USER and the password assigned during registration will not be disclosed to third parties; at the same time, QS Division assumes the obligation of confidentiality in this respect.
The participant may agree to waive anonymity in order to:

- discuss his/her own results;
- establish a process of mutual assistance to improve their skills and performance;
- use the results for the purposes of external recognition (accreditation, etc.);
- communicate results to the competent authorities, which in turn may request that the same results are delivered in an official form by COP.

The test report that is available only on the reserved area of the website qs.biogroupmedicalsystem.com, is accessible to every participant and the Quality System division.

The participant agrees not to share information with others about the results of the determinations made in the course of the Test.
In the presence of objective evidence of collusion between attendees or falsifying results, QS reserves the right to exclude from the test any subjects who have been guilty of such conduct.

8.Complaints and appeals

Participants in the tests who intend to submit Appeals/Complaints relating to aspects

connected to the execution of the Tests, must submit a written request, enclosing the necessary

documentation. Such request shall be sent to the mail address qs@biogroupmedicalsystem.com, addressed to the Coordinator of the test.

INSTRUCTIONS FOR THE PARTICIPANTS

QUALITY SYSTEM

qs@biogroupmedicalsystem.com

Date	Rev.	Reason	Drafting of document	Approval	Archiviazione
29/03/2019	00	First Issue	COP	RQS	RGQ
06/11/2019	01	Variation Point 6.1 Exclusion from processing			
31/03/2020	02	Introdution Hematology tests			
					

Contents

1. Introduction

This document, in accordance with the requirements of UNI EN ISO/IEC 17043:2010, contains instructions for handling and preparation of samples, carrying out the tests, submission of results and receipt of the test report. These instructions apply to the following tests:

Code	Proficiency test
MSQSCH4/MSEQSCH4	Clinical Chemistry qtly.
MSQSCH12/MSEQSCH12	Clinical Chemistry mthly.
MSEQSCH1	Clinical chemistry 1spl annually
MSQSI4/MSEQSI4	Immunology quarterly
MSQSI12/MSEQSI12	Monthly Immunology
MSEQSI1	Immunology 1spl annually
MSQSE812-MSEQUALITYE12	Hematology 8 P mothly
MSQUALITYE8-MSEQUALITYE8	Hematology 8 P quarterly
MSEQSE8	Hematology 8 P annually 1spl

2. Test Materials

The test materials, for all tests listed above, consist of lyophilized serums of human origin. The serum used was carefully selected and tested, with negative results for HIV - HCV and HBsAg. Serum samples were tested for homogeneity and stability and the test results are filed at the company. However, it is advisable to treat the product with the precautions used for potentially infected materials, according to good laboratory practice:
Use laboratory gloves to avoid skin contact.
Protect eyes with appropriate eye masks
Do not eat, drink or smoke in the workplace.

3. Receipt of test materials

The laboratories will receive the following testing samples:

CLINICAL CHEMISTRY 1 Lvl. Code MSQSCH4/MSEQSCH4 Quarterly Test 4 bottles by March 10
CLINICAL CHEMISTRY 1 Lvl. Code MSQSCH12/MSEQSCH12 Monthly Test 12 bottles by January 10
CLINICAL CHEMISTRY 1 Lvl. Code MSEQSCH1 Annual Test 1 bottle relative to the test in progress or the next
IMMUNOLOGY 1 Lvl. Code MSQSI4/MSEQSI4 Quarterly Test 4 bottles by March 10
IMMUNOLOGY 1 Lvl. Code MSQSI12/MSEQSI12 Monthly Test 12 bottles by January 10
IMMUNOLOGY 1 Lvl. Code MSEQSI1 Annual Test 1 bottle relative to test in progress or the next
HEMATOLOGY 8 parameters Code MSQSE812-MSEQUALITYE12Monthly Test 12 samples
HEMATOLOGY 8 parameters Code MSQUALITYE8-MSEQUALITYE8Quarterly Test 4 samples
HEMATOLOGY 8 parameters Code MSEQSE8 Annually 1 sample

Should the package containing the proficiency testing items be delivered to the laboratory after more than 7 days from the shipment date, the participant must immediately notify QS by phone or e-mail at the numbers below; the same applies for any non-delivery or receipt of damaged packages.
The Customer Care office will initiate the verification procedure and ensure the shipment of new test materials. In order to fulfil such need, the proficiency testing organiser shall prepare a surplus stock of material for each individual test lot, in the amount of 10% of the necessary quantity.

Upon proficiency testing item receipt, the laboratory must check that the content of the package corresponds to the subscription programs.

4. Storage of test materials

Testing sample bottles should be stored at a temperature of 2-8°C

5. Use of test materials and running of tests Clinical Chemestry and Immunology

1. Remove the test bottle from the refrigerator and wait until it reaches approximately room temperature.
2. Open the vacuum sealed bottle carefully and add the required amount of distilled water.
3. Close with the rubber cap and leave the solution to rest for 20-30 minutes at room temperature, away from light. Then shake gently until completely dissolved.
4. Do not use the reconstituted serum earlier than 1 hour and after 18 hours.

5. Make sure that the distilled water used is of good quality: the values of certain analytes (Ca, Cl, Na, K) may vary significantly.
6. Run the tests required using the test material like a normal sample of a patient.

6. Use of test materials and running of tests Hematology

1. Remove the bottle to be tested from the refrigerator and wait for it to reach approximately room temperature by placing it on a blood cell shaker or in any case shaking it gently.
2. Perform the cytometric blood count analysis as if it were a normal sample of human origin

7. Entering and sending of test results

7.1 The following were excluded from processing

The measurements entered and affected by coarse error (i.e.: typographical error 2.1 instead of 21) will be excluded from processing; the participant will receive from the test Coordinator by email the measurement excluded and detailed reason for exclusion.

For statistical populations of less than 20 participants but above 15, the outlier measures are excluded by using the Grubbs Test. The participant will receive notification of the exclusion.

Statistical populations with less than 15 participants but more than 5 will be processed outside accreditation and will receive an indicative performance index.

All subsets statistics whose number of participants is less than 5 are excluded from processing. Also in this case, the test Coordinator will notify participants by email.

7.2 Issuance of the test reports

The Coordinator can communicate the cancellation of a test report in the event of serious incidents.

He shall reissue the test report indicating the review status.

8. Confidentiality

QS in the test report will use the registration code assigned to the same test as the only identifying element of the data source. The code is known only to the QS and the laboratory Division. If the OPVs are shipped to the distributor, the code is also known by the latter.

The participant must ensure that both the USER and the password assigned during registration will not be disclosed to third parties; at the same time, QS Division assumes the obligation of confidentiality in this respect.
The participant may agree to waive anonymity in order to:

- discuss his/her own results;
- establish a process of mutual assistance to improve their skills and performance;
- use the results for the purposes of external recognition (accreditation, etc.);
- communicate results to the competent authorities, which in turn may request that the same results are delivered in an official form by COP.

The test report that is available only on the reserved area of the website qs.biogroupmedicalsystem.com, is accessible to every participant and the Quality System division.
The participant agrees not to share information with others about the results of the determinations made in the course of the Test.
In the presence of objective evidence of collusion between attendees or falsifying results, QS reserves the right to exclude from the test any subjects who have been guilty of such conduct.

All the steps of the process are managed via the dedicated website qs.biogroupmedicalsystem.com

The laboratory must have :

- Internet access
- PDF Reader
- Internet Browser (Firefox - Chrome)

Following the subscription, each lab will receive an identification code that corresponds to the username and the password for the first login to the reserved are on the website. The password will have to be changed immediately and will expire within 180 days, to ensure maximum privacy

All test results must be entered and sent by the end of the month indicated in the table below:

	Jan.	Feb.	**Mar.**	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Clinical Chemistry 1monthly level MSQSCH12/MSEQSCH12	•	•	•	•	•	•	•	•	•	•	•	•
Clinical Chemistry 1quarterly level MSQSCH4/MSEQSCH4			•			•			•			•
Immunology 1 monthly level MSQSI12/MSEQSI12	•	•	•	•	•	•	•	•	•	•	•	•
Immunology1 quarterly level MSQSI4/MSEQSI4			•			•			•			•

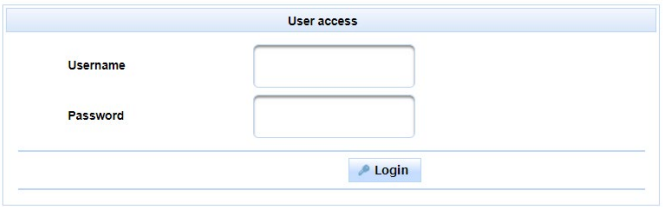
Hematology

TEST MONTH	SAMPLE SENDING	RESULTS SUBMITTING DEAD LINE	REPORTS PUBLICATION
APRIL	WITHIN APRIL SECOND WEEK	30-apr	04-mag
MAY		20-mag	24-mag
JUNE		06-giu	10-giu
JULY	WITHIN JULY SECOND WEEK	31-lug	04-ago
AUGUST		20-ago	24-ago
SEPTEMBER		06-set	10-set
OCTOBER	WITHIN OCTOBER SECOND WEEK	31-ott	04-nov
NOVEMBER		20-nov	24-nov
DECEMBER		06-dic	10-dic

After this date, you will not be able to send replacement samples.

Enter and send the obtained results via the website **www.qs-veq.it**

Enter the username received; upon first login, the password is associated with a username



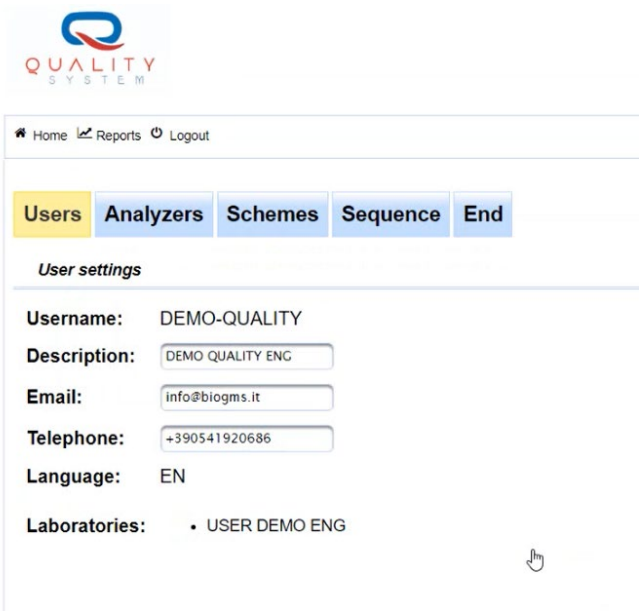
Once you logged in for the first time, you will be prompted to change the temporary password

Pursuant to the provisions on privacy, the password will expire every 180 days. Upon expiration, the above message will be prompted.

Save the new password and the system will ask you to login again.

A wizard will guide you to set up your reserved area.

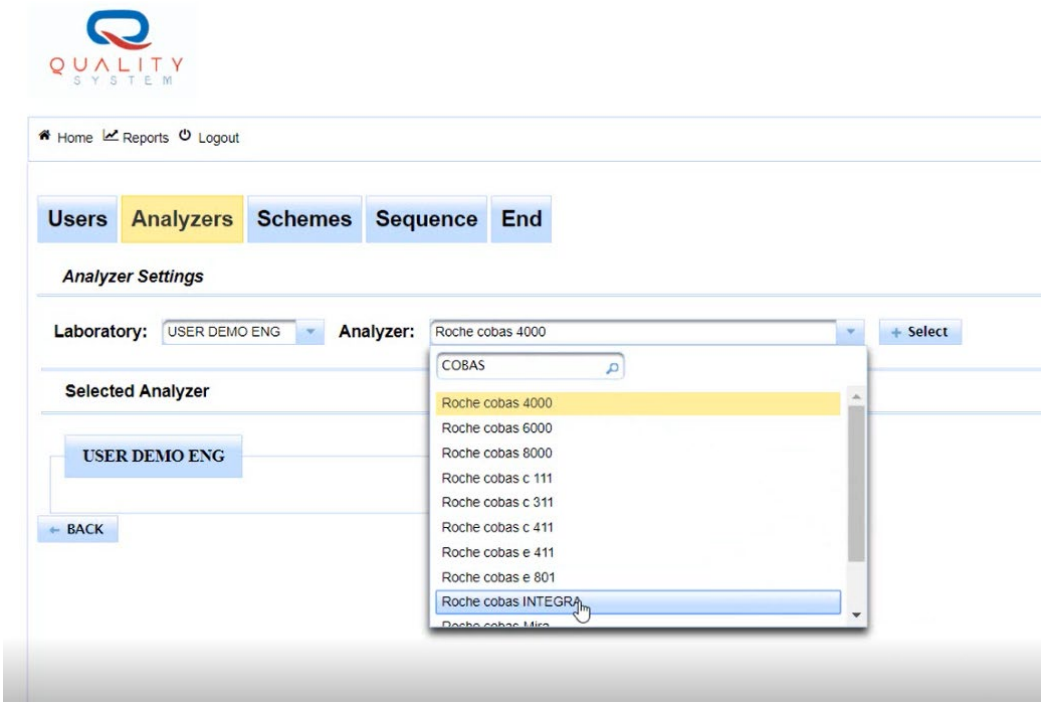
Click on the green banner to proceed with the setup of the result entry sheets. This preliminary operation allows you to enter the results obtained fast and easy, during the test, avoiding any coarse errors.



Check if your data are correct. If not, please inform us by email to qs@biogoupmedicalsystem.com

Now, the setup wizard will show you the setup steps to follow:

Analzyers



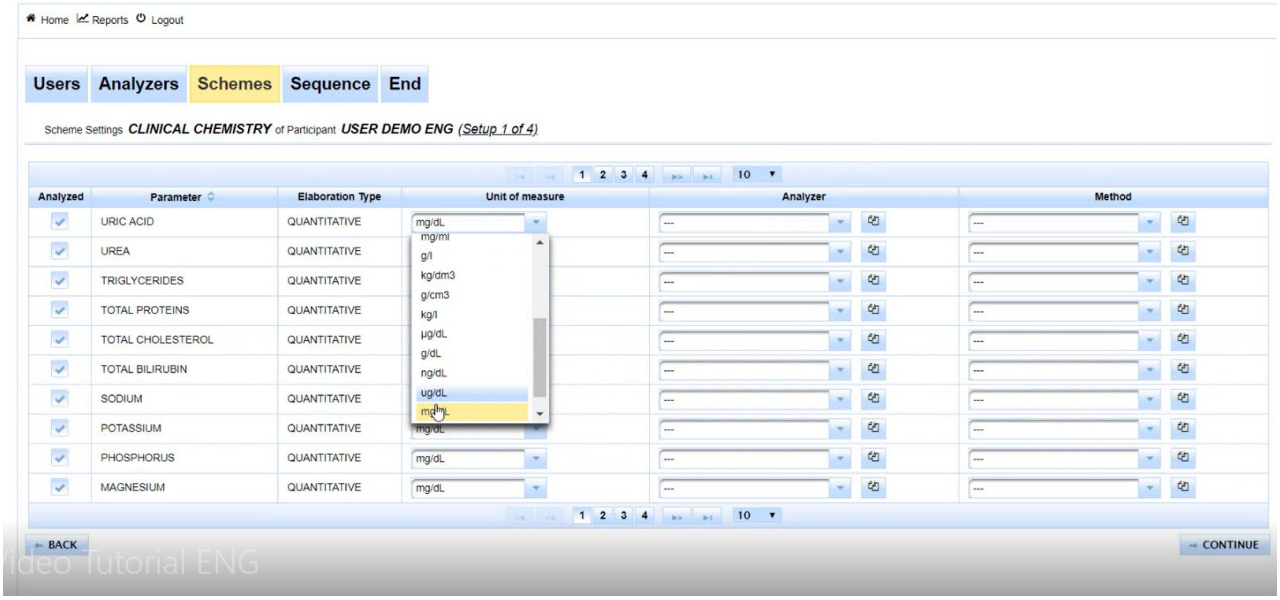
In this window you have to enter the instruments used to carry out the tests of all examinations, by clicking on the instrument selected in the drop-down menu. To add other instruments, click on SELECT and proceed as described above.

Once you have entered the instruments, click on next.

If the instrument used is not available in the list, contact the Customer Service immediately at + qs@biogroupmedicalsystem.com, specifying the name, brand and model of the instrument.

How to set up the Data entry sheets

If you click on next, the Wizard prompts a sheet setup window for each test.



In this sheet, select:

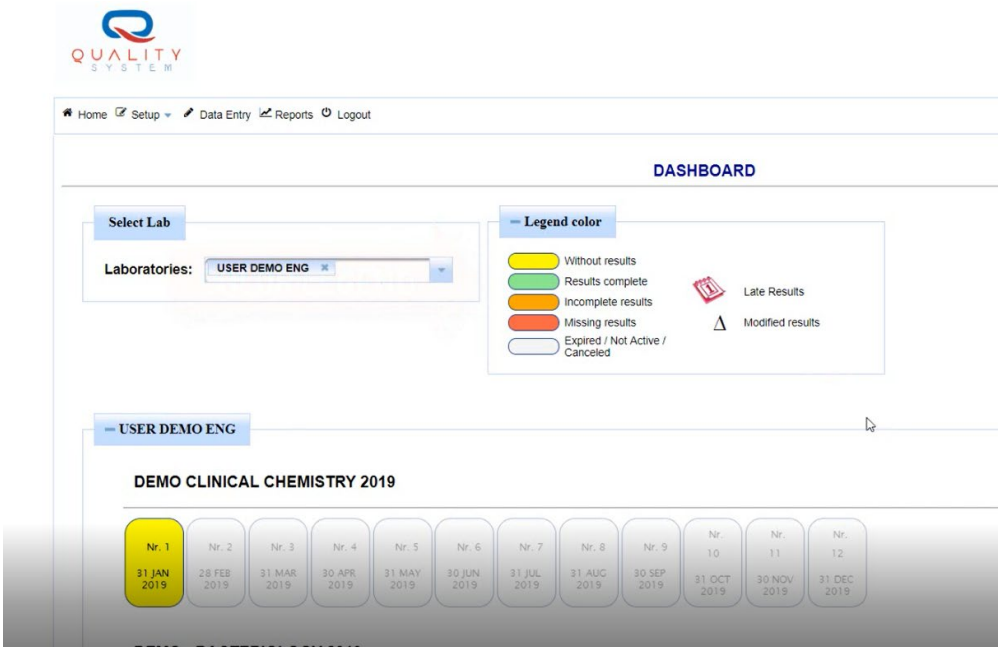
- the analytes under testing
- the unit of measurement
- the instrument (in the drop-down you will find only the previously used instruments). The pushbutton  allows you to select the same instrument for all analytes
- the method

If you cannot find the method used in the drop-down menu, contact the Customer Service immediately at qs@biogroupmedicalsystem.com, specifying the method used.

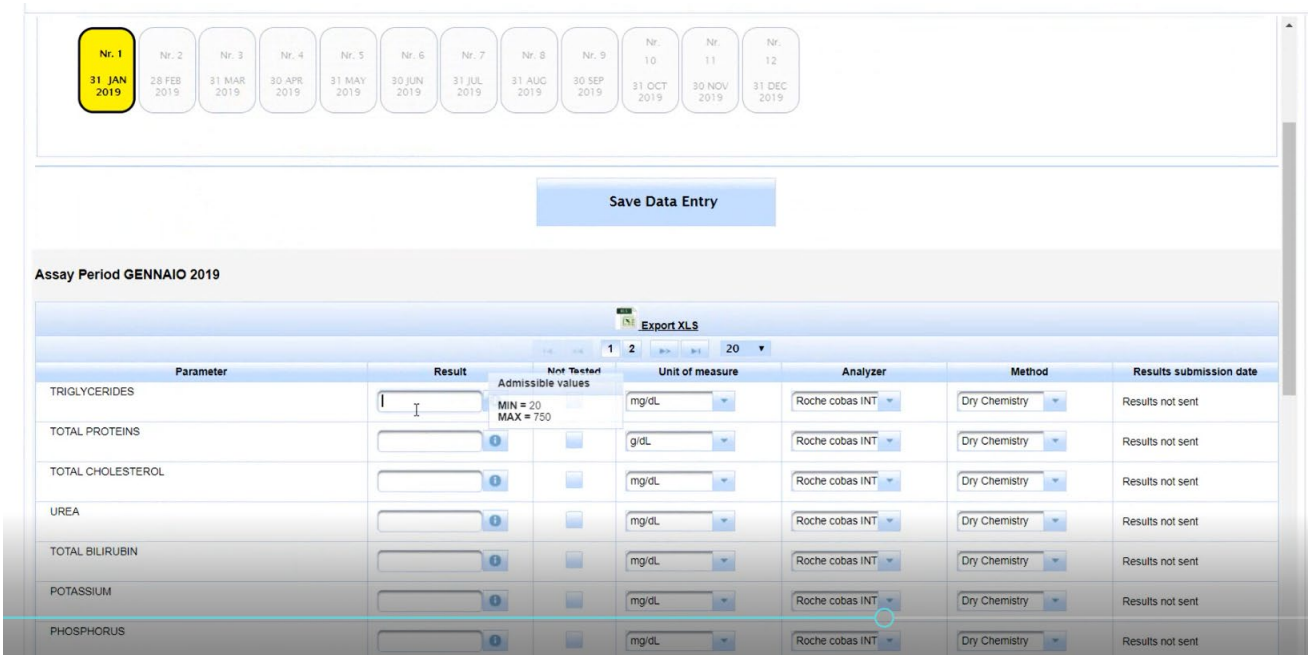
The setup can be changed later from time to time, by opening the Setup menu from the home page.

If you click on next, the Wizard will prompt the next step.

Once you have finished the initial setup, your Home page will prompt the list of tests in your subscription and the box of the relative specimens



By clicking on the active box, yellow, you can enter the relative results; once you have entered the results, click on the bottom left pushbutton “Save Data Entry”.



A waring will be prompted on top page to confirm that data has been entered successfully and that you can edit the results before the expiration date

A message will appear after data entry confirmation.

The data can be changed within the dead line stated into the related box.

Clicking on the menu icon “Reports” you can download your reports.

For each test parameter is also defined the number of digits to be entered before and after the decimal point as shown in the following table.

Parameter list and number of digits to insert for **Clinical Chemistry:**

Parameter	**Number of digits to enter**
BILE ACIDS	From 1 to 3 before the comma; up to 2 after
URIC ACID	From 1 to 3 before the comma; up to 2 after
ALBUMIN	From 1 to 3 before the comma; up to 2 after
ALP	From 2 to 3 before the comma; up to 2 after
HALT	From 1 to 3 before the comma; up to 2 after
AMYLASE	From 2 to 3 before the comma; up to 2 after
AST	From 1 to 3 before the comma; up to 2 after
BICARBONATES	From 1 to 3 before the comma; up to 2 after
DIRECT BILIRUBIN	1 before the comma; up to 2 after
TOTAL BILIRUBIN	From 1 to 3 before the comma; up to 2 after
CALCIUM	From 1 to 3 before the comma; up to 2 after
CK NAK	From 2 to 3 before the comma; up to 2 after
CHLORINE	From 1 to 3 before the comma; up to 2 after
CHOLESTEROL	From 2 to 3 before the comma; up to 2 after
HDL CHOLESTEROL	From 1 to 3 before the comma; up to 2 after
LDL CHOLESTEROL	From 2 to 3 before the comma; up to 2 after
CHOLINESTERASE	From 4 to 3 before the comma; up to 5 after
CREATININE	From 1 to 3 before the comma; up to 2 after
IRON	From 2 to 3 before the comma; up to 2 after
PHOSPHOR	From 1 to 3 before the comma; up to 2 after
GAMMA GT	From 1 to 3 before the comma; up to 2 after
GLUCOSE	From 2 to 3 before the comma; up to 2 after
LDH	From 2 to 3 before the comma; up to 2 after
LIPASE	From 2 to 3 before the comma; up to 2 after
LITHIUM	From 1 to 3 before the comma; up to 2 after
MAGNESIUM	From 1 to 3 before the comma; up to 2 after

POTASSIUM	From 1 to 3 before the comma; up to 2 after
TOTAL PROTEINS	From 1 to 3 before the comma; up to 2 after
COPPER	From 2 to 3 before the comma; up to 2 after
SODIUM	From 2 to 3 before the comma; up to 2 after
TRIGLYCERIDES	From 2 to 3 before the comma; up to 2 after
UREA	From 1 to 3 before the comma; up to 2 after

Parameter list and number of digits to insert for **Immunology**

Parameter	**Number of digits to enter**
ALPHA FETO-PROTEIN	From 1 to 3 before the comma; up to 2 after
CA 125	From 1 to 3 before the comma; up to 2 after
CA 15-3	From 1 to 3 before the comma; up to 2 after
CA 19-9	From 1 to 3 before the comma; up to 2 after
CARBAMAZEPINE	From 1 to 3 before the comma; up to 2 after
CEA	From 1 to 3 before the comma; up to 2 after
CORTISOL	From 1 to 3 before the comma; up to 2 after
DIGOXIN	From 1 to 3 before the comma; up to 2 after
ESTRADIOL	From 1 to 4 before the comma; up to 2 after
FERRITIN	From 1 to 4 before the comma; up to 2 after
FOLATE	From 1 to 3 before the comma; up to 2 after
FSH	From 1 to 4 before the comma; up to 2 after
FT3	From 1 to 3 before the comma; up to 2 after
FT4	From 1 to 3 before the comma; up to 2 after
HCG	From 1 to 5 before the comma; up to 2 after
IgE	From 1 to 4 before the comma; up to 2 after
LH	From 1 to 4 before the comma; up to 2 after
PROGESTERONE	From 1 to 3 before the comma; up to 2 after
PROLACTIN	From 1 to 3 before the comma; up to 2 after
PSA FREE	From 1 to 3 before the comma; up to 2 after
PSA TOTAL	From 1 to 3 before the comma; up to 2 after
T3	From 1 to 3 before the comma; up to 2 after
T4	From 1 to 3 before the comma; up to 2 after
TESTOSTERONE	From 1 to 4 before the comma; up to 2 after
TG AB	From 1 to 5 before the comma; up to 2 after
THYROGLOBULIN	From 1 to 3 before the comma; up to 2 after
TMAB	From 1 to 3 before the comma; up to 2 after
TPO AB	From 1 to 3 before the comma; up to 2 after
TSH	From 1 to 3 before the comma; up to 2 after

Parameter	Number of digit to enter
RDW/IDR-SD	From 1 to 3 before the comma; up to 2 after
MCH	From 1 to 3 before the comma; up to 2 after
MPV	From 1 to 3 before the comma; up to 2 after
WBC	From 1 to 3 before the comma; up to 2 after
RBC	From 1 to 3 before the comma; up to 2 after
HGB	From 1 to 3 before the comma; up to 2 after
MCV	From 1 to 3 before the comma; up to 2 after
MCHC	From 1 to 3 before the comma; up to 2 after
RDW/IDR	From 1 to 3 before the comma; up to 2 after
PLT	From 1 to 3 before the comma; up to 2 after
HCT	From 1 to 3 before the comma; up to 2 after

8.Viewing the Test Reports

Each participant can view and download only his own test reports from the tenth working day of the month following the month in which the test was carried out.

For those subscribed to annual testing, the final test reports will be available by 31 December of the reference year.

Previous test reports can also be viewed, if available.

If you have any problems, please contact

HELP in line at 0541920686 off. 3 Sonia off. 14 Matteo

Or send an email to ***qs@biogroupmedicalsystem.com*** , ***support@biogms.zendesk.com***

CERTIFICATO DI ACCREDITAMENTO
Accreditation Certificate

ACCREDITAMENTO N. / *ACCREDITATION N.* **0017P** REV. **02**

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

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

Data di 1ª emissione *1st issue date* **14-11-2018**	Data di revisione *Review date* **18-10-2022**	Data di scadenza *Expiring date* **12-11-2026**

L'accreditamento attesta la competenza, l'imparzialità e il costante e coerente funzionamento 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 e può essere sospeso o revocato o ridotto in qualsiasi momento nel caso di inadempienza accertata da parte di ACCREDIA.
La vigenza dell'accreditamento può essere verificata sul sito web (www.accredia.it) o richiesta al Dipartimento di competenza.
The accreditation attests competence, impartiality and consistent operation in performing laboratory activities, limited to the scope detailed in the attached Enclosure.
The present certificate is valid only if associated to the annexed Lists and can be suspended, withdrawn or reduced at any time in the event of non fulfilment as ascertained by ACCREDIA.
Confirmation of the validity of accreditation can be verified on the website (www.accredia.it) or by contacting the relevant Department.

Il QRcode consente di accedere direttamente al sito www.accredia.it per verificare la validità del certificato di accreditamento rilasciato al CAB.
La data di revisione riportata sul certificato corrisponde alla data di aggiornamento / di delibera del pertinente Comitato Settoriale di Accreditamento. L'atto di delibera, firmato dal Presidente di ACCREDIA, è scaricabile dal sito www.accredia.it, sezione 'Documenti'
The QRcode links directly to the website www.accredia.it to check the validity of the accreditation certificate issued to the CAB.
The revision date shown on the certificate refers to the update / resolution date of the Sector Accreditation Committee. The Resolution, signed by the President of ACCREDIA, can be downloaded from the website www.accredia.it, 'Documents' section.

ACCREDIA è l'Ente Unico nazionale di accreditamento designato dal governo italiano, in applicazione del Regolamento Europeo 765/2008.
ACCREDIA is the sole national Accreditation Body, appointed by the Italian government in compliance with the application of REGULATION (EC) No 765/2008.

ACCREDIA - Dipartimento Laboratori di prova

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

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.

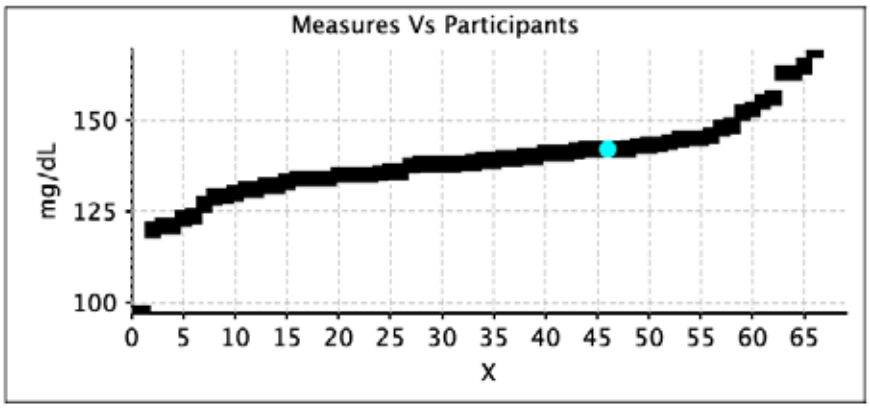
D%
Absolute error expressed as a percentage.

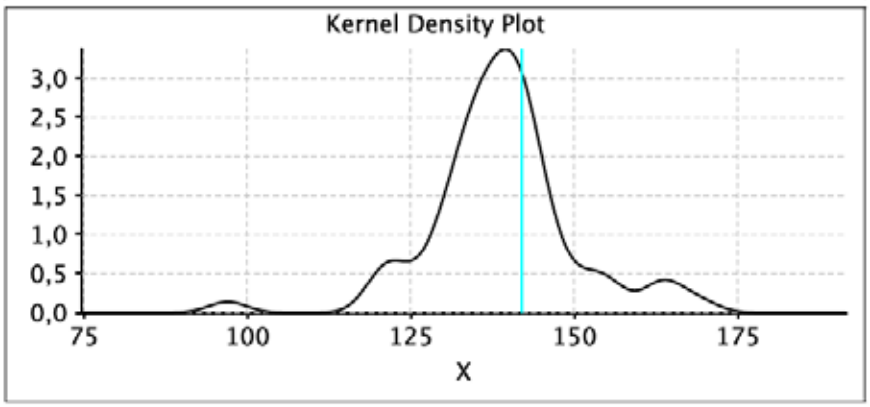
QUANTITATIVE REPORT - GRAPHIC

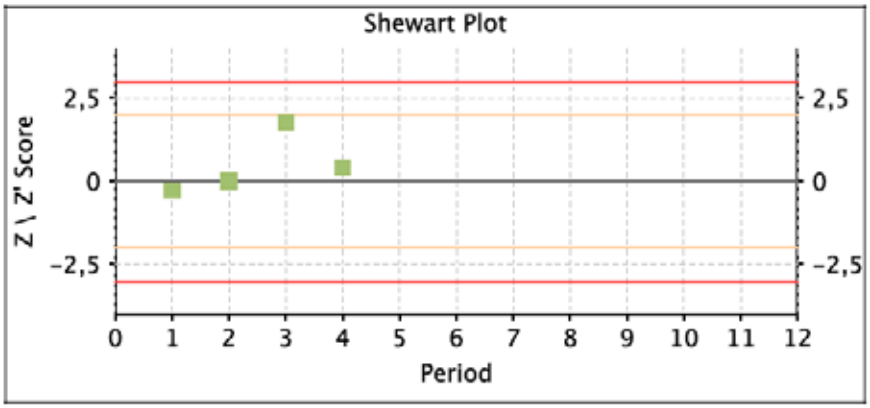
QUALITY SYSTEM	**CLINICAL CHEMISTRY MONTHLY CYCLE 2019** Scheme: : MSQSCH12/MSEQSCH12/MSEQSCH1	RdP: Final Revision **ZKN170_16_2019_4.pdf**	ACCREDIA
	Participant : ZKN170 **Sample Lot : CH-1904**	Issued on 03/05/2019 Authorized by RQS Paolo Cocci	

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

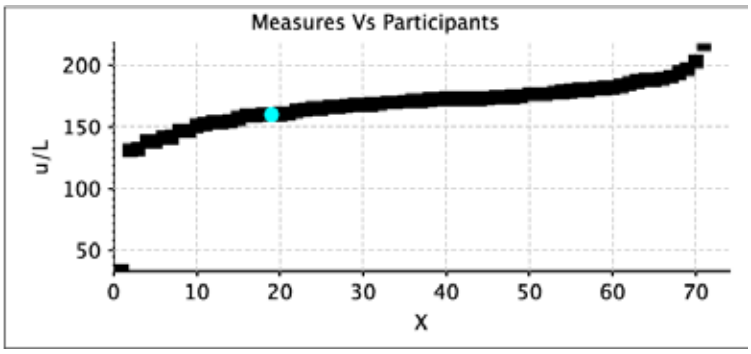






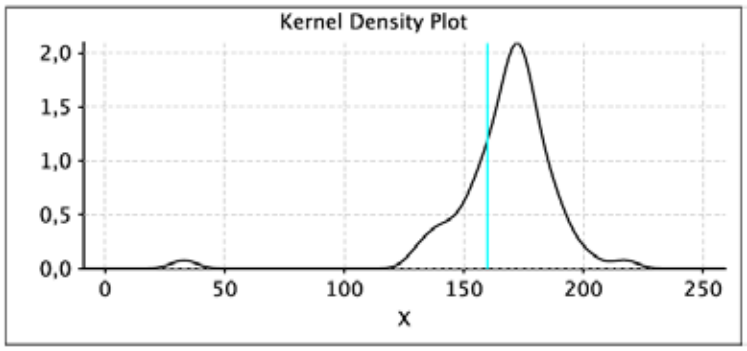
Measures Vs Participants

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.



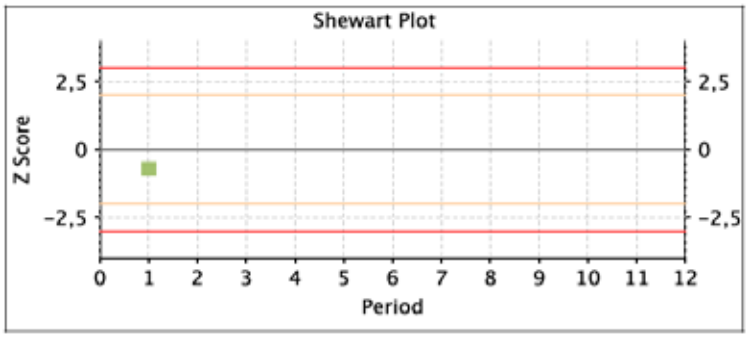
Kernel Density Plot

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

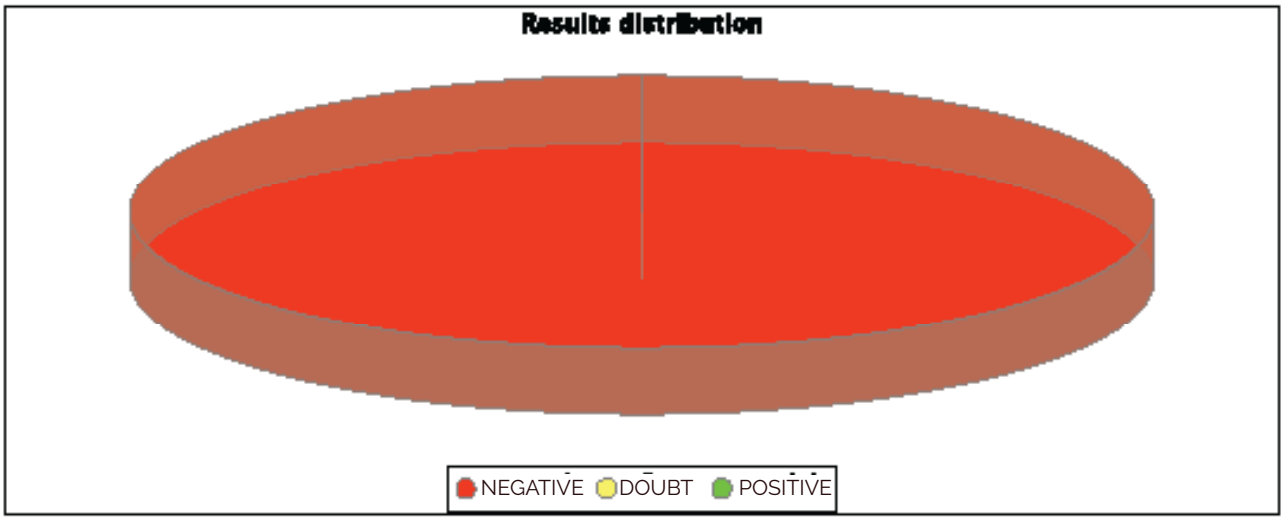
Graph showing in time order the Z scores obtained on the single analyte. Very useful to verify the performance over time of the services and especially useful for the verification of the effectiveness of any corrective actions carried out following a questionable or acceptable performance. It is the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

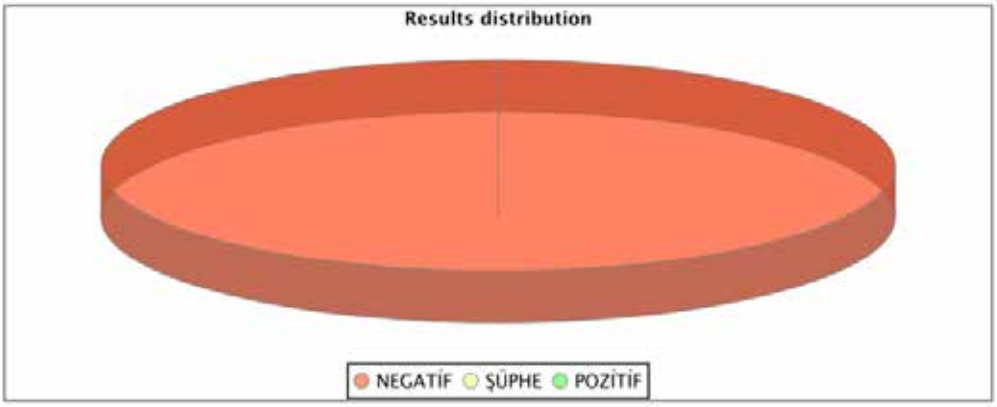
Positive results percentage
This index is the number of positive results found by the participants.

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

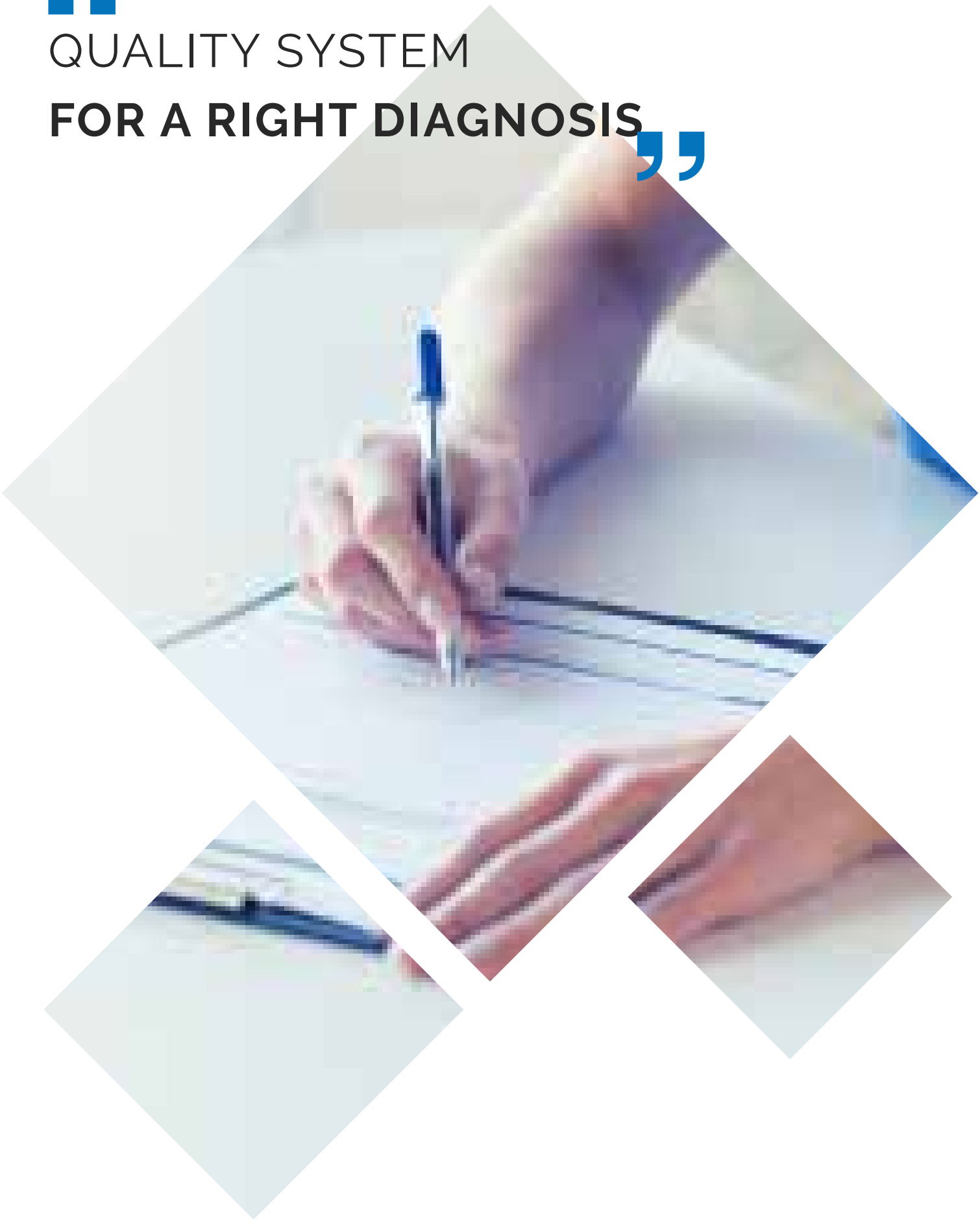
Assigned value
It is the expected result of the test: it is defined as the most frequent of the results provided.

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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