



# EXTERNAL QUALITY ASSESSMENT

Bio Group Medical System



A POWERFUL TOOL  
FOR A TOTAL QUALITY  
IMPROVEMENT

## Who we are

Quality System since 1999 is a valuable tool for assessing the diagnostic quality of a laboratory.

Quality System is the EQA brand of **Bio Group Medical System**, involved in the diagnostic sector since 1985.

Quality System offers a wide range of scheme, in total 16 programs.

Different frequency options are available for most of the available schemes.

Bio Group Medical System has been **ISO 17043:2010** accredited as **Proficiency Testing Provider** by **ACCREDIA** (certificate n.17/P and related attachment that can be download from <https://www.accredia.it/banche-dati/>).

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.

## ISO/IEC 17043:2010 Accreditation

The Proficiency Testing Providers are responsible for the organization of the interlaboratory proficiency tests (VEQ), from the design to the choice and preparation of the objects, to the homogeneity and stability checks of the materials, to the distribution of the samples to the participants, to the statistical analysis of the data up to the evaluation of the results and issuing of the report with the participants' performances.

The activity carried out by the Proficiency Testing Providers, therefore, is fundamental to allow the participating laboratories to monitor their performance over time, through participation on an ongoing basis.

Accreditation as an organizer of interlaboratory proficiency tests in compliance with the UNI CEI EN ISO/IEC 17043:2010 standard demonstrates the technical competence of the organizer to design, organize and manage the tests indicated in the field of accreditation. The organizer of interlaboratory proficiency tests is in fact responsible for ensuring that the technical and management requirements, specified in the reference standard, are also satisfied by the collaborators and subcontractors involved in the test schemes subject to accreditation.

Bio Group Medical System is a PT Provider accredited ISO 17043:2010 by ACCREDIA (certificate n.17/P and related attachment downloadable from the website <https://www.accredia.it/banca-dati/>)

# Vision & Mission

“Ensure that each of our participants can provide their own patients a precise diagnosis and effective”

05



## **Aim of Quality System**

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

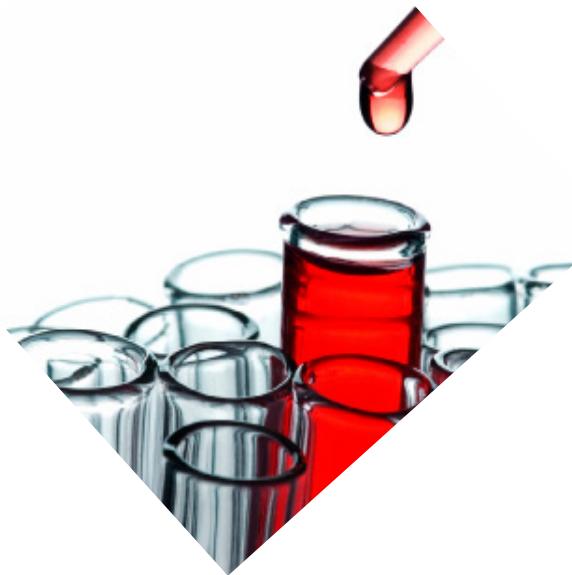
The external quality assessment statistically examines the final result of the entire work process, taking into consideration the pre-analytical phase, the entire phase involving the laboratory and also the final data transmission.

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.



# 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 Monthly

### 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 Monthly

Product Code:

MSEQSI1 - MSEQSI4 - MSEQSI12

### Level:

1 level per assay

## Scheme: HEMOSTASIS

### Sample material:

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

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

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

### Parameters:

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

### Statistical Elaboration:

Quantitative

### Frequency:

Yearly, Quarterly or Monthly

### 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 Monthly

Product Code:

MSEQUALITYE12 - MSEQUALITYE8 - MSEQSE8

**Level:** 1 level per assay

During the cycle we send different levels to analyze



## Scheme: ELECTROPHORESIS

### Sample material:

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

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

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

### Parameters:

ALBUMINE

BETA GLOBULINE

ALFA 1 GLOBULINE

GAMMA GLOBULINE

ALFA 2 GLOBULINE

### Statistical Elaboration:

Quantitative

### Frequency:

Yearly, Quarterly or Monthly

### Product Code:

**MSEQALITYEF - MSEQSEF12 - MSEQSEF1**

### Level:

1 level per assay

During the cycle we send different levels to analyze

## Scheme: SPECIFIC PROTEINS

### Sample material:

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

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

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

### Parameters:

|              |     |
|--------------|-----|
| ASO          | C4  |
| PCR          | IGA |
| RF           | IGG |
| TRANSFERRINA | IGM |
| C3           |     |

### Statistical Elaboration:

Quantitative

### Frequency:

Yearly, Quarterly or Monthly

### 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, Quarterly or Monthly

Product Code: MSEQSCM1 - MSEQSCM4 - MSEQSCM12

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

## Scheme: HbA1C

### Sample material:

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

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

### Parameters:

**HbA1C**

**Statistical Elaboration:** Quantitative

**Frequency:** Yearly, Quarterly or Monthly

## Scheme: INFECTIVOLOGY

### Sample material:

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

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

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

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

contained in the reference standard ISO 13528:2015.

### Parameters:

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

### Statistical Elaboration:

Qualitative

### Frequency:

Yearly, Quaterly

Product Code:

MSEQSSE1 - MSEQUALITYS

### Level:

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



## Scheme: MICROBIOLOGY

### Sample material:

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

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

### Statistical Elaboration:

Qualitative

### Frequency:

Yearly, Quarterly

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, Quarterly

**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, Quarterly

**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, Quarterly

**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, Quarterly

## 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, Quarterly

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

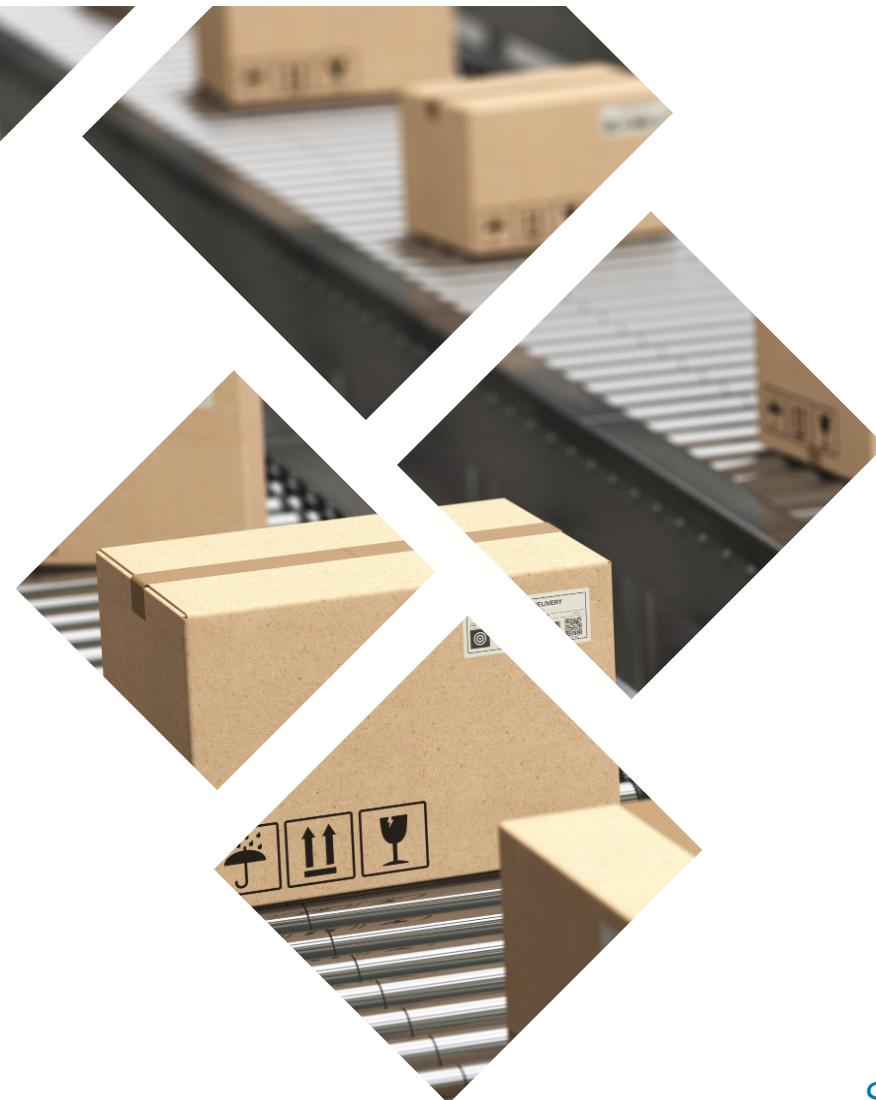
**Frequency:** Yearly, Quarterly

MSEQSSM1 - MSEQUALITYSM

**Level:** 1 file per assay

# 03.

## Schedule



### SHIPMENT SCHEDULE

|                     | JAN   | FEB | MAR   | APR   | MAY | JUN   | JUL   | AUG | SE    | CT    | NOV | DEC   |
|---------------------|-------|-----|-------|-------|-----|-------|-------|-----|-------|-------|-----|-------|
| CLINICAL CHEMISTRY  | QS    | QS  | QS/QS |
| HEMOSTASIS          | QS    | QS  | QS/QS |
| IMMUNOASSAY         | QS    | QS  | QS/QS |
| SPECIFIC PROTEINS   | QS    | QS  | QS/QS |
| ELECTROPHORESIS     | QS    | QS  | QS/QS |
| HEMATOLOGY          | QS/QS | QS  | QS    |
| 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    |
| CARDIAC MARKERS     | QS/QS | QS  | QS    |
| ESR                 | QS    |     |       | QS    |     |       | QS    |     |       | QS    |     |       |
| URINE SEDIMENTATION | QS    |     |       | QS    |     |       | QS    |     |       | QS    |     |       |
| SMEAR               | QS    |     |       | QS    |     |       | QS    |     |       | QS    |     |       |

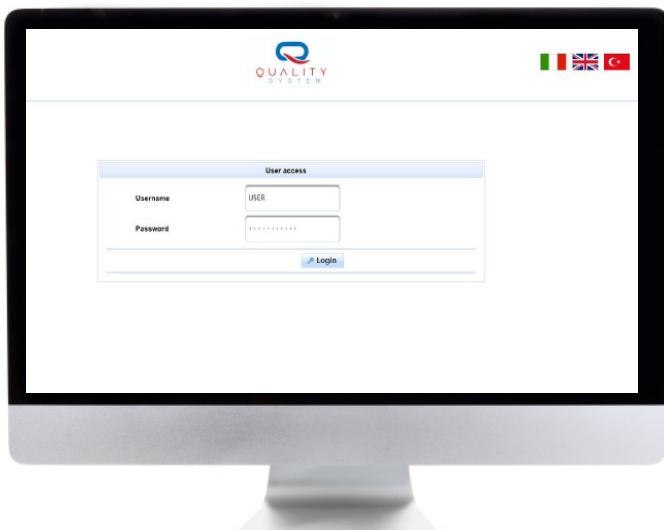
QS = Quaterly shipment

QS = Monthly shipment

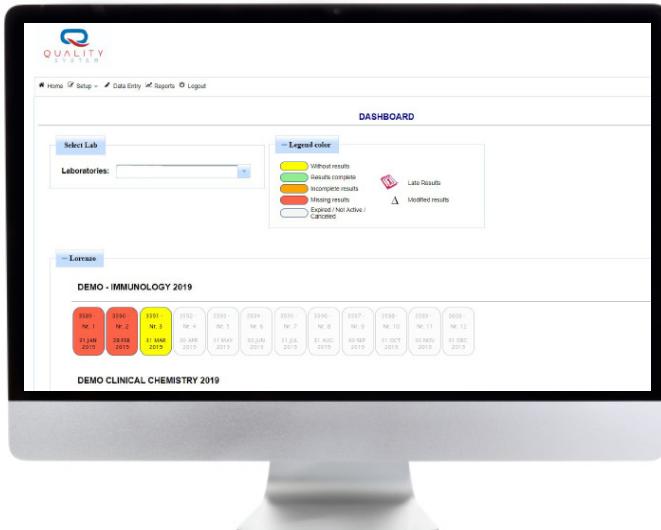
# 04.

## **Web Site**





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



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

# 05.

## Statistical Elaboration

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

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

Quantitative Report, where the data is a numerical result

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

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

## QUANTITATIVE REPORT - INDEX

### Consensus Value:

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

### Standard Deviation:

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

### Assigned DS:

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

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

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

### Standard Uncertainty

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

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

### Z Score

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

If the value of Z is between -2 and 2, the performance will be acceptable; if the value is between -3-2 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

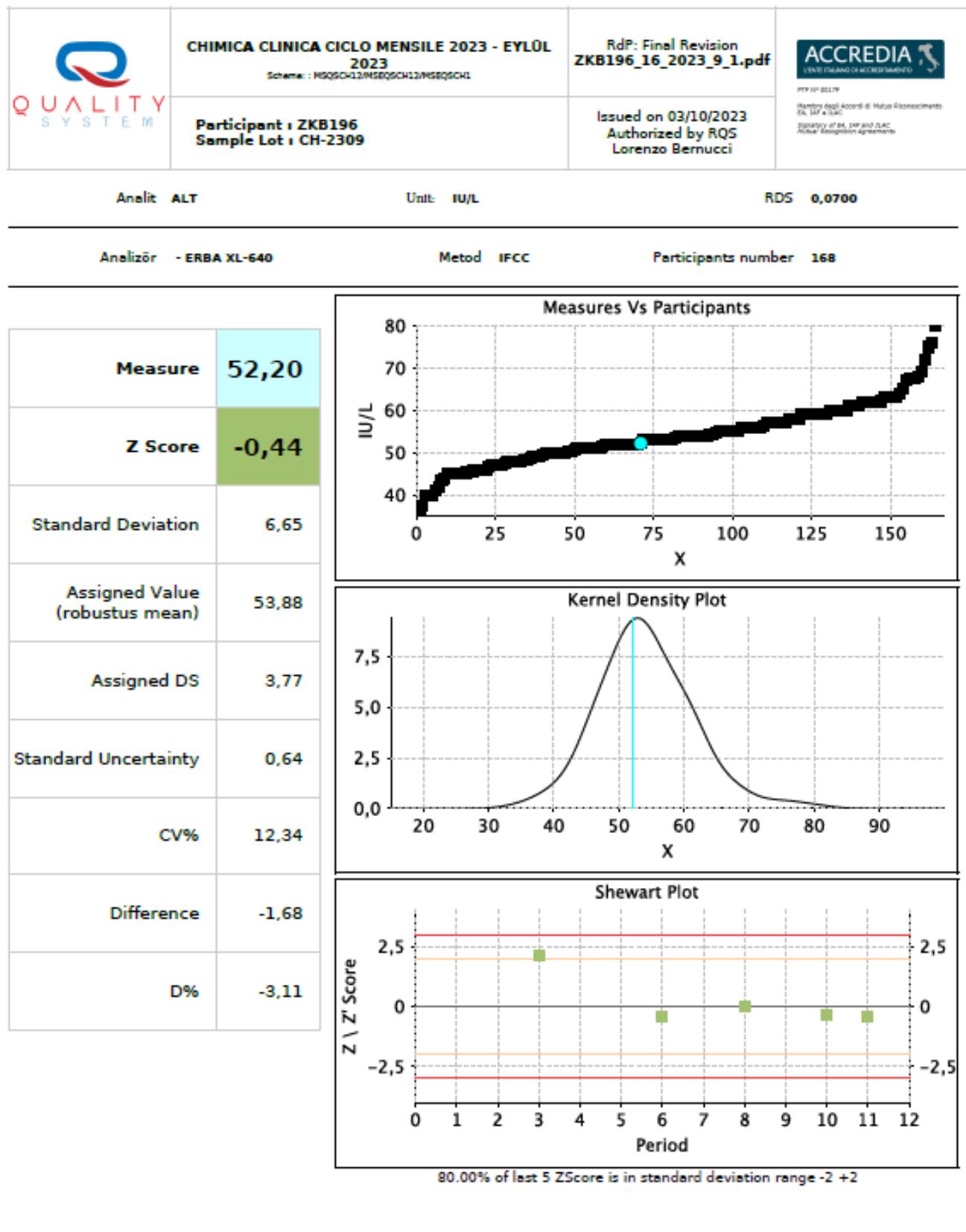
Expresses variance of data distribution in percent.

### Difference

It expresses the absolute error of the performance, i.e. the difference between the measurement and the consensus mean.

### D%

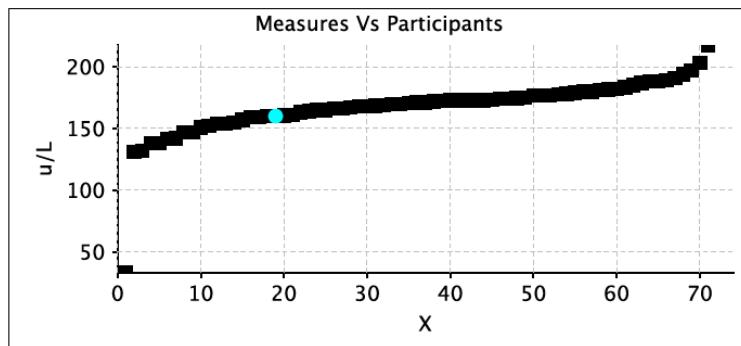
Absolute error expressed as a percentage.



## Measures Vs Participants

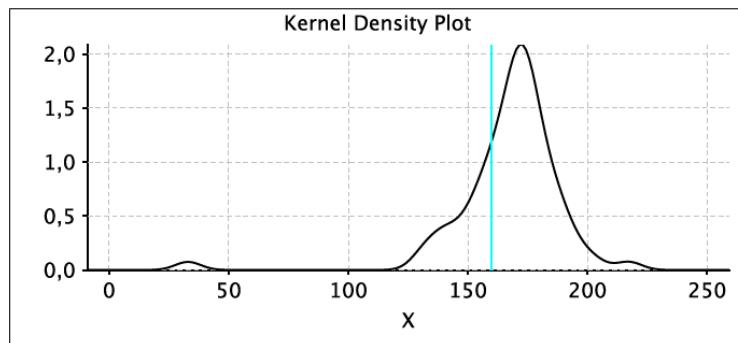
The graph represents the distribution of the measurements of the individual participants ordered by size.

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



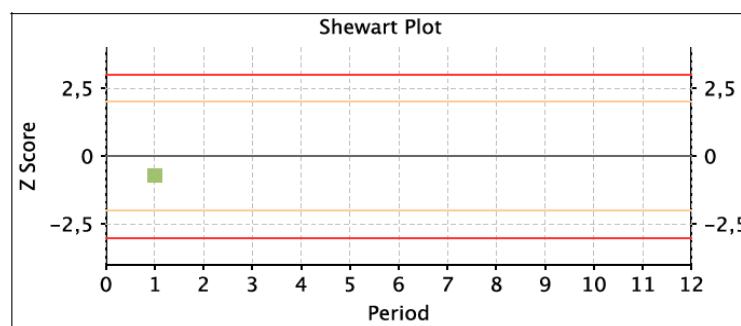
## Kernel Density Plot

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.

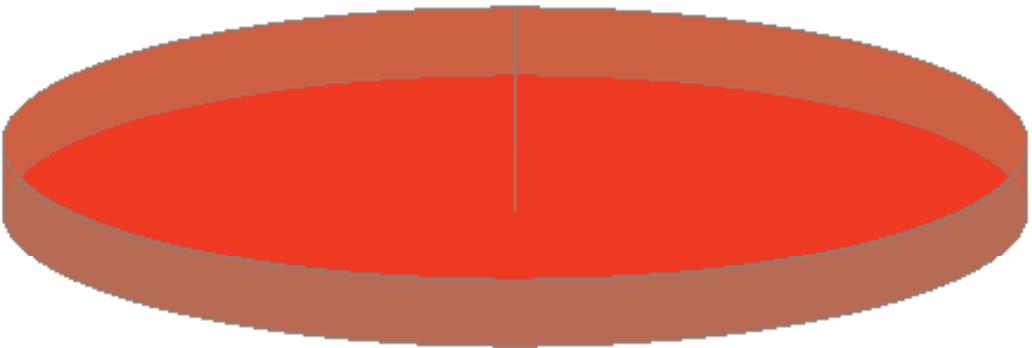


# QUALITATIVE REPORT - GRAPHIC

|  |   |  |
|--|---|--|
| <br><b>QUALITY SYSTEM</b> | <b>SEROLOGY JANUARY 2019</b>                              | RdP: Reissue<br><b>ZKH032_9_2019_1.pdf</b>             |
| <b>Participant: XC032</b><br><b>Sample Lot : SI-1901</b>   |   | Issued on 04/03/2019<br>Authorized by RQS Paolo Coccia |
| <b>Analyte</b> <b>HCV</b>  | <b>Analyzer</b> <b>- Abbott<br/>ARCHITECT<br/>i1000SR</b> | <b>Method</b> <b>Chemiflex</b>                         |

**Results distribution**



NEGATIVE   DOUBT   POSITIVE

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

January 2019

Acceptable

Mod 51

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## 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**

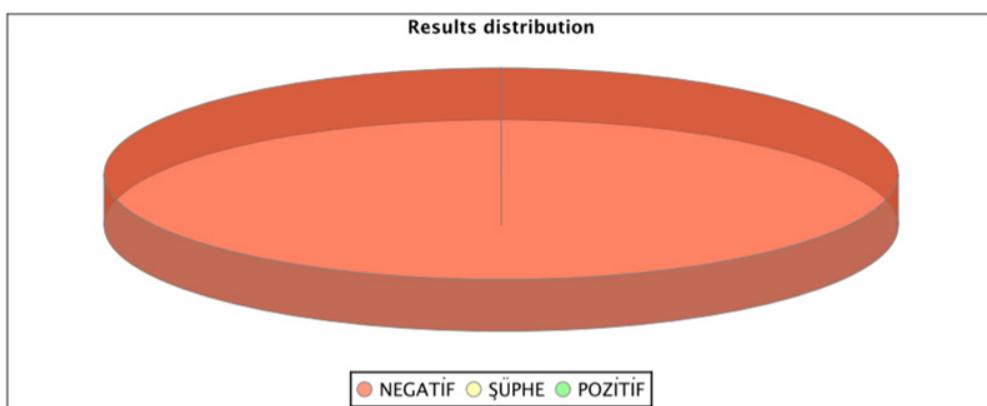
It is the expected result of the test: it is defined as the most frequent of the results provided.

### **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

”





## **Bio Group Medical System**

Loc. Campiano 9/B  
47867 - Talamello (RN) - Italy  
Phone: +39 0541 920686 (Ext. 5)  
Fax: +39 0541 922130  
[qs@biogroupmedicalsystem.com](mailto:qs@biogroupmedicalsystem.com)  
[www.biogms.it](http://www.biogms.it)

