EQAS Explained
External Quality Assessment Programs

EQA programs are accepted around the world as invaluable tools used by laboratories to periodically assess the performance of their test systems. Results are objectively compared to other laboratories using the same methodologies, instruments and reagents.

When used in conjunction with daily quality controls, these external programs can give laboratories added confidence in reporting patient test results.

Objectives of EQA Programs

Understand the quality of your lab’s test results by evaluating each EQA report, investigating the root cause and implementing necessary corrective actions for poor performance.

- Assess the laboratory’s analytical quality and reliability in reported results
- Improve interlaboratory agreement
- Enhance worldwide standardization efforts in clinical testing
- Help detect equipment failure or reagent problems
- Aid in identifying potential corrective actions and evaluate their effectiveness
- Assist with verification of staff training effectiveness
- Demonstrate a commitment for continuous improvement and quality assurance to customers
Meeting the Essentials of a High Quality EQA Program

Bio-Rad meets the needs of over 18,000 participants worldwide with a large variety of EQA programs suited for clinical labs, blood banks and transfusion centers.

Statistics
- Large peer groups
- International participation
- Robust statistical analysis based on ISO 13528

Simple Reports
- Easy to read and interpret
- Comprehensive
- Fast turn-around time

Quality Samples
- High quality samples that mimic patient samples
- Clinically relevant ranges
- Multi analyte samples for consolidation and cost savings

Reliable Supplier
- Over 40 years experience in developing quality controls
- Accredited to ISO 17043:2010
- Team of expert advisors and technical support staff

Bio-Rad Laboratory’s EQAS Programs are developed and maintained under a compliant and comprehensive quality management system

The EQAS Programs are independently accredited, providing participants with confidence of high quality programs.

Accreditation to ISO/IEC 17043:2010
Bio-Rad EQAS Programs are accredited by the American Association for Laboratory Accreditation (A2LA) to ISO/IEC 17043:2010 “Conformity assessment General requirements for proficiency testing”. Accreditation recognizes the high quality of Bio-Rad EQAS programs and helps meet the regulatory needs of today’s clinical laboratory.

UK Oversight
- Recognized by the UK National Quality Assurance Advisory Panels (NQAAP)
- Recognized by the Joint Group on Quality Assurance (JWG QA)

Steering Committee
Bio-Rad EQAS Programs receive guidance from a panel of clinical and scientific experts who act on the behalf of participants to ensure the programs offer continued appropriateness and value.

“The laboratory should participate in interlaboratory comparison programmes that substantially fulfill the relevant requirements of ISO/IEC 17043.”

–ISO 15189:2012
Features and Benefits

- **17 fully accredited** comprehensive programs that serve the needs of clinical labs and blood banks worldwide
- Programs developed and maintained under a compliant and comprehensive quality management system to help labs meet regulatory requirements
- Professional and experienced technical **service and support** to assist with interpretation of results
- **Comprehensive analyte menus** covering a wide range of diagnostic tests to meet specific testing needs
- **Reference method values** for A1C, and select analytes in Clinical Chemistry and TDM programs, provided with every lot to deliver additional information and confidence in reported results (see program insert for more information)
- **Multiple levels** that cover most areas of clinical significance
- Convenient electronic reporting options: **EQAS Online and EQAS Mobile**, allowing for web-based reporting through PC, tablet and most smart phones
- Specialized electronic reports for **common interest groups** (Subgroups) which allows for easy monitoring of performance and long term data storage
- **Quality Specification Reports** to assess performance based on alternate scientific or national quality specifications such as Biological Variation (BV), CLIA, RiliBÄK, RCPA, IQMH, and GOST (Russia)

Visit [qcnet.com/eqas](http://qcnet.com/eqas) for valuable tools, tutorials and technical support.
Participating in EQAS is simple:

1. Contact your local Bio-Rad office to place an order and receive a unique laboratory number.
2. Register your test methods at eqasonline.qcnet.com.
3. A specimen package is shipped to you.
4. Test samples as a patient sample and under routine laboratory conditions.
5. Submit results online by the pre-determined date.
6. Review your reports and assess your performance within 3 days of statistical analysis.
7. Repeat the process until all samples have been tested in the cycle.
8. Helps assure reliability of your test configurations and make necessary changes at eqasonline.qcnet.com.
9. A Certificate of Achievement is issued if the minimum amount of acceptable data has been submitted.

Start next cycle
Web-based Reporting with EQAS Online or EQAS Mobile

Manage your EQAS Program using any device with an Internet connection

Accessing EQAS is simple. Registering on QCNet.com allows users to utilize EQAS Online where contact details, test configurations, and reports can be viewed. Participants can also report test results, download reports, set reminders and gain access to important program notifications.

The most intuitive way to manage your EQAS programs

- Configure test, instrument and reagent setups for accurate statistical comparisons
- Access with any internet connected smartphone
- Configuration updates and results transmitted automatically
- Receive email reminders of upcoming sample due dates or available reports
- Establish multiple user levels
- Maintain up-to-date contact information

Available anywhere at anytime

- No more handwritten result forms
- Eliminate late data caused by postal delays
- No more method questionnaires
- Eliminate errors due to poor fax quality
- Reduce the use of paper
- No need for local software installations
- Intuitive color coding to quickly identify submitted, late or missing results
- Updated reports available within 24 hours
- View, save or print PDF reports at your convenience

Seamlessly and securely manage your account electronically through EQAS Online or EQAS Mobile. Login to QCNet.com/eqasonline today!
EQAS Reports

EQAS participants receive regular sample reports once enrolled in a program. These detailed reports are presented in an easy-to-read graphical format.

Types of EQAS Reports

A number of comprehensive and informative reports are available to EQAS participants.

- Sample Report .................................. Monthly
- Quality Specification Report ...................... Monthly
- End-of-Cycle Report ............................... Annual
- Method Summary Report .......................... Annual
- Subgroup Report .................................. Monthly

For more in-depth program and report information, please refer to the EQAS Program User Guide on www.qcnet.com
Sample Reports

Quantitative Reports

Comprehensive performance data is provided in an easy-to-read graphical format for each reported analyte.

A. Statistical Analysis .......................... Comparative statistics for your peer, method and all results
B. Histograms ................................. Distribution of results by peer, method and all results
C. Z-score Trend Charts ....................... Glimpse of your performance over time
D. Most Reported Instruments ........ Assessment of other instrument performances
Quantitative Reports continued (detail)

A. Statistical Analysis

1. Your reported result and unit

2. The three levels of comparison. Ideally you will be compared to other laboratories using the same analyte, method, instrument, reagent combination as yours (Your Peer); requires a minimum of 9 results.

3. Number of results used in the comparative statistics

4. Mean of all returned results

5. Standard Deviation. Spread of data points around the mean value of a normal distribution

6. Coefficient of Variation = \[ \frac{\text{Standard Deviation} \times 100}{\text{Mean}} \]

7. Expanded uncertainty (U) of the consensus mean expressed at 95% confidence interval using a coverage factor of \( k=2 \).

\[ \frac{1.25 \times \text{Robust Standard Deviation}}{\sqrt{N}} \times k \]

Lower values, close to zero, indicate low uncertainty. Higher values indicate greater uncertainty (or reduced confidence) in the comparator results.

8. Number of comparator SD that your result differs from the comparator mean. Z scores are a measure of your laboratory’s bias relative to your comparator group. Acceptable performance is identified as falling within \( \pm 2 \) Z score.

\[ Z\text{-score} = \frac{\text{Your Result} - \text{Comparator Mean}}{\text{Comparator SD}} \]

9. The average Z score for the last six samples, independent of cycles.

\[ \% = \frac{\text{Your Result} - \text{Comparator Mean} \times 100}{\text{Comparator SD}} \]

10. Mean bias of a laboratory’s result relative to the comparator mean, expressed as a %.
Quantitative Reports continued (detail)

**B. Histograms**
Three Histograms show the distribution of the results received on time for each sample by Peer, Method and All Results (or Mode).

1. Number of participants in the tallest bar
2. Your result (arrow)
3. The lowest and highest reported value with a maximum of 5SD

**C. Trend Charts**
Trend Charts provide a visual representation of how well a test is working.

4. Levey-Jennings Chart
5. Twelve rolling sample dates
6. Comparator means for each sample
7. Your laboratory’s comparator Z-score
8. Yundt-Plot indicates if there is test bias
9. Concentration of the reported samples
10. Your laboratory’s comparator Z-score

**D. Most Reported Peer Groups**
Statistics for 9 peer groups with the highest participation to quickly assess performance of other instrument/Method/Reagent combinations.

11. Number of results received (N)
12. Mean
13. Coefficient of Variation (CV)
14. Expanded Uncertainty (U) of the Consensus Mean (see page 7)
A. Sample Summary Report Page
Provides a summary of performance for all results reported and registered for a particular sample.

1. Summary of Data
Data is sorted alphabetically by instrument and provides a quick snapshot of any warnings or rejections.

2. Problem Classification
An area for the reviewer to add comments, sign and date. Maintaining this type of information can be helpful in responding to external audits by providing objective evidence of the review and any actions taken.

B. Data on File Report Page
The last section of the Sample Report provides a summary of all results received within a cycle, and is sorted alphabetically by instrument.

1. Sample numbers

2. All received results, grouped by instrument. Exceptions are color coded for easy review

3. Legend of exception flags
Qualitative Reports

A. Peer Qualitative (Sample) Report
Color coding helps to quickly analyze your responses

1. Peer histogram displays the number of results for all possible responses, expressed as a % of total, together with your color coded response arrow
2. Trend charts show the last 12 samples and can span across cycles. Both provide visual representations of test performance vs. the consensus

B. Peer-Method-All Results Report (Blood Typing)
1. Identify systematic errors with these trend charts over the past 12 samples. A grey bar indicates span of consensus responses
2. Up to 9 largest peer group histograms are displayed for comparison
3. Method and All Results histograms for an overall glimpse of your performance

Note: Consensus for the EQAS Blood Typing Program is only reached when ≥5 labs report ≥80% of the same response.
Quality Specification Report

Quantitative Programs

A supplemental evaluation of your results may be generated against locally mandated or scientific performance specifications.

1. Report is available for every sample through EQAS Online
2. Select from a choice of available specifications (ex. Rilíbæk, CLIA, BV)
3. Your comparator group
4. Percentage deviation is calculated for each analyte
   \[
   \% = \frac{\text{Your Result} - \text{Comparator Mean} \times 100}{\text{Comparator SD}}
   \]
5. Acceptable performance for your selected specification is indicated per analyte
6. See if your absolute % deviation is lower (✔) or higher (✘) than your selected criteria
End of Cycle Report

Analyte Summary Report

An overall assessment report of your lab’s performance is provided at the end of each cycle. Statistics are recalculated to include all data points submitted throughout the cycle.

A. Analyte Summary
   Summary of statistics for all samples by comparator group

B. Cycle Comparative Statistics by Batch
   All comparator group statistics grouped by batch or level

C. Batch Z-score Frequency Histograms
   Distribution of Z-scores by batch or level

D. Regression Line Analysis
   Graphical representation of your measurement linearity
Analyte Summary Report continued (detail)

A. Analyte Summary
1. Batch (level) number
2. Sample numbers associated by batch
3. Your results with flags or exceptions noted
4. Robust mean of the comparator to which you were compared
5. Your Lab Z-score
   \[ Z\text{-score} = \frac{\text{Your Result} - \text{Comparator Mean}}{\text{Comparator SD}} \]
6. Your Batch Z-score
   \[ \frac{\text{Your Mean Batch Result} - \text{Comparator Mean Batch}}{\text{Comparator Batch SD}} \]
7. Reference Values provided on select programs and analytes for information only.

B. Cycle Comparative Statistics by Batch
1. Cycle statistics by batch for each of the comparator groups (Peer, Method, All Results or Mode)
2. Number of data points in the batch
3. Robust calculation of the mean
4. Robust calculation of the standard deviation
5. Coefficient of Variation = \[ \frac{\text{Standard Deviation} \times 100}{\text{Mean}} \]
6. Expanded uncertainty (U) of the mean = \[ 1.25 \times \frac{\text{Robust Standard Deviation}}{\sqrt{N}} \]
7. Your % deviation from the comparator mean = \[ \frac{\text{Your Batch Mean} - \text{Comparator Batch Mean}}{\text{Comparator Batch Mean}} \times 100 \]
C. Batch Z-score Frequency Histograms

Analyze all lab Z-score distributions by batch to help detect any concentration dependent biases.

1. Number of participants in the tallest bar
2. Your result (arrow)
3. Your comparator level (Peer, Method, All Results or Mode)
4. Batch Z-score distribution depicted within 3SD limits

D. Regression Line Analysis

The Regression Line is a graphical representation of your laboratory’s measurement linearity for the selected analyte.

1. Your comparator level
2. Legend indicating regression line slope, intercept and correlation coefficient against your comparator level
3. Results are plotted on the Y axis against the comparator mean values plotted on the X axis
4. Ideal fit (dashed) line with a slope of 1. Solid lines represent +/- 10% deviation from this. Provides a visual evaluation of your correlation to your comparator level and any biases that may exist
Mean Z-score Report

Mean Z-score Report
Clinical Chemistry (Monthly) Program

Lab 555555
DEMO LAB
555 5th STREET
DEMO, DM
55555

Mean Z-score Report
Cycle 14
Lot No: 211300

Instrument: Siemens Dimension Series

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Your Mean $Z$-score</th>
<th>Your Percentile</th>
<th>Mean $Z$-score Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phosphorus</td>
<td>0.14</td>
<td>6%</td>
<td>0.14</td>
</tr>
<tr>
<td>Potassium</td>
<td>0.43</td>
<td>41%</td>
<td>0.26</td>
</tr>
<tr>
<td>TIBC</td>
<td>0.46</td>
<td>12%</td>
<td>0.44</td>
</tr>
<tr>
<td>Urea</td>
<td>0.62</td>
<td>25%</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Instrument: Siemens Dimension Xpand/EXL Series

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Your Mean $Z$-score</th>
<th>Your Percentile</th>
<th>Mean $Z$-score Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloride</td>
<td>0.74</td>
<td>44%</td>
<td>0.45</td>
</tr>
<tr>
<td>Sodium</td>
<td>0.60</td>
<td>22%</td>
<td>0.48</td>
</tr>
</tbody>
</table>

A. Mean Z-score

1. Mean of absolute Z-scores for each individual sample analyte
2. Your mean absolute Z-score expressed as a % of the comparator distribution
   [50% Percentile = your result is in the center of the distribution]
3. Visual presentation of the mean absolute Z-score distribution and where your result falls. A lower % (value to the left of the center) indicates better than average performance with less bias, whereas a higher % indicates worse than average performance with more bias against your comparator group.

B. Performance Score Histograms

4. Distribution of overall performance scores (mean Z-scores) for labs in your country displayed as five quintiles (20% groups).
   - Lowest/best performance . . . left hand column
   - Highest/worst performance . . . right hand column

5. Worldwide distribution of performance scores. Your performance is compared on a worldwide basis
Method Summary Report

Quantitative Programs Only


Subgroup Report

The Subgroup Report is provided in Microsoft® Excel® format to the designated subgroup leader with each sample close. All individual laboratories in the subgroup are included along with their performance for each registered analyte in the sample.

EQAS Tip

Method Summary Reports are a great performance evaluation tool when you’re looking for a new instrument for your laboratory.

EQAS Tip

Subgroup Reports allow the head of a subgroup, or satellite labs, to monitor and compare performance of each site within the group in one simple, and customizable, spreadsheet. Individual sites will continue to receive their monthly Sample Reports.
Sample Report Review Poster

This tool offers easy to follow steps that will help with analysis and interpretation of EQAS Sample Reports and flagged results.

Troubleshooting Checklist

This checklist can be used with the EQAS Sample Review Chart to help troubleshoot flagged results.
Bio-Rad EQAS Programs

Blood Gas
Blood Typing
Cardiac Markers
Clinical Chemistry (Monthly)
Coagulation
Ethanol/Ammonia
Hematology
Hemoglobin
HIV/Hepatitis
Immunoaosay (Monthly)
Lipids
Serum Proteins
Syphilis
Therapeutic Drug Monitoring
ToRCH/EBV/MuMZ
Urinalysis
Urine Chemistry

EQAS
An independent, external assessment of performance in comparison to your peers.

Independent QC
Ongoing, proactive, unbiased daily QC that helps identify errors as they occur or begin to trend.

Unity
QC Data Management tools that help you create a strategy to reduce risk and streamline QC workflow.