Troubleshooting Guide for EQA Results

Your External Quality Assurance (EQA) performance report will help you understand the quality of your lab's test results. EQA should be done in addition to internal quality controls (QC). EQA allows you to see how your lab is performing compared to a group of your peers.

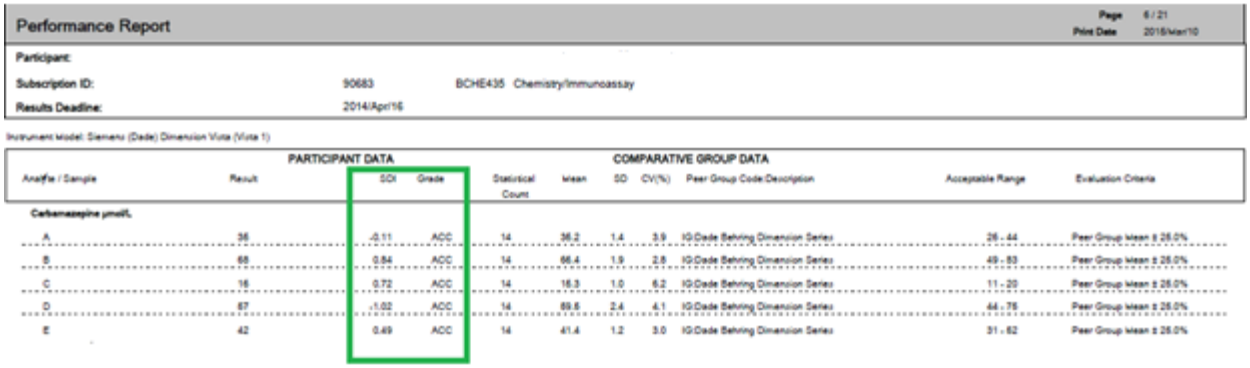
All results on your EQA performance report should be examined for unacceptable results, unusual trends, sudden shifts, or other problems.

Unacceptable EQA results can arise from both systematic and random sources of error. Systematic Errors are shown by all of your EQA results on one side of the target value and a bias is seen. For example all of your EQA results are above or below the peer group mean. Random Error is shown by results that are on average close to the target value but there are a few exceptions that show large deviations from the target value.

Were my EQA results within the acceptable range?

Participant data and Comparative Group data would list the information that would indicate if the EQA result is satisfactory or not and also how it compares to other labs.

Table 1. Participant Data



Performance Report

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Print Date 2015/Mar/10

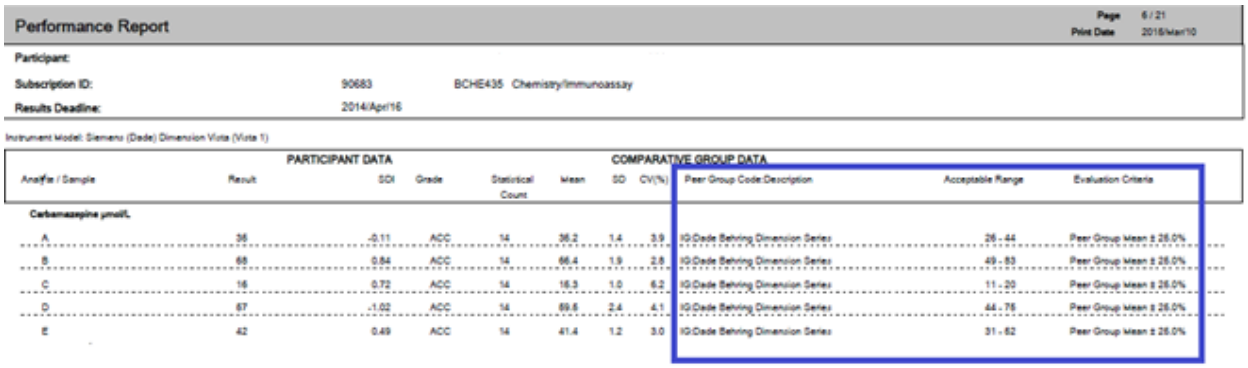
Participant:
Subscription ID: 90683 BCHE435 Chemistry/Immunoassay
Results Deadline: 2014/Apr/16

Instrument Model: Siemens (Dade) Dimension Vista (Vista 1)

	PARTICIPANT DATA			COMPARATIVE GROUP DATA						
Analyte / Sample	Result	SDI	Grade	Statistical Count	Mean	SD	CV(%)	Peer Group Code:Description	Acceptable Range	Evaluation Criteria
Carbamazepine µmol/L										
A	36	-0.11	ACC	14	36.2	1.4	3.9	IG:Dade Behring Dimension Series	26 - 44	Peer Group Mean ± 25.0%
B	68	0.84	ACC	14	66.4	1.9	2.8	IG:Dade Behring Dimension Series	49 - 83	Peer Group Mean ± 25.0%
C	16	0.72	ACC	14	16.3	1.0	6.2	IG:Dade Behring Dimension Series	11 - 20	Peer Group Mean ± 25.0%
D	87	-1.02	ACC	14	89.6	2.4	4.1	IG:Dade Behring Dimension Series	44 - 75	Peer Group Mean ± 25.0%
E	42	0.49	ACC	14	41.4	1.2	3.0	IG:Dade Behring Dimension Series	31 - 62	Peer Group Mean ± 25.0%

Results that were outside the acceptable range are signified with UNACC. SDI (Standard deviation index) is a measure of distance, or bias, of one result compared to the mean of results from its peer group. The greater the SDI, the farther is one result from the mean of its peer group, which indicates deviation from normal performance.

Table 2. Comparative Group Data



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E	42	0.49	ACC	14	41.4	1.2	3.0	IG:Dade Behring Dimension Series	31 - 52	Peer Group Mean ± 20.0%

To review how one performed in reference to others, the data under Comparative Group Data would be helpful.

The acceptable range is determined by the evaluation criteria for that analyte. For example if the evaluation criteria is Peer Group Mean +/- 2SD then the target value (peer group mean) is determined from the results submitted in that peer group, after outliers have been removed. We would then add and subtract 2 Standard Deviations from the mean to get the upper and lower limits of the acceptable range.

The peer group is ideally a group of labs that are all using the same instrument and reagent for that particular analyte. The peer group you were evaluated in is shown in small print under the Comparative Group Data heading. For example, the example above shows that the peer group consists of labs that use the Dade Behring Dimension Series instruments. Note that depending on the number of participants in a peer group, your peer group might change from one test event to another and you might be graded with another peer group in the next test event.

The evaluation criteria is used to determine the acceptable range for each analyte and is always shown in the last column of your performance report. Depending on the test program, a result could be evaluated against the peer group mean or a pre-determined reference value.

What are possible sources of error to cause unacceptable results?

Always ensure that your registration is correct in OASYS. If you have selected the incorrect reagent, instrument or submethod it could cause your results to be evaluated in the incorrect peer group.

Sporadic test results identified as unacceptable can be classified as random errors while series of test results identified as unacceptable may be due to a systematic error. See the following chart for examples of common causes to these two types of errors classified by the testing phase:

Table 3. Common causes of random errors and systemic errors.

Pre-analytical	Analytical	Post-analytical
Causes of Random Errors		
Insufficient mixing of sample, especially following freezing and for samples requiring good homogeneity (for example, hematology samples)	Poor pipetting	Transcription errors
	Sample mix-up	Incorrect result unit submitted
	testing not performed immediately after sample vials are opened (for example, blood gases vials)	Incorrect submethod selected
	Dilution-related problem (wrong dilution factor used, result not corrected for dilution factor, incorrect calculation)	Online result entry errors ('typo')
	Suspected/known imprecision problem with test	Calculation (manual and automatic) errors
	Cross-contamination or carryover	Result unit conversion not done or done incorrectly
	Mis-labelled sample in sampling rack	Mis-graded/Mis-interpreted result
Causes of Systematic Errors		
Inaccurate reconstitution (wrong diluent, inaccurate diluent amount, inadequate equilibration of reconstituted material)	Reagents contaminated, expired	Incorrect sequence of results entered during online result entry
Insufficient mixing/centrifuging before testing	Instrument error or malfunction	
Incorrect storage of test kits and/or reagents and/or EQA samples	instrument parameters changed	
Compromised samples during shipping	Ineffective or inconsistent washing	
Temperature of samples not proper for testing (room temperature is required for some samples)	Contamination of equipment	
	Calibration-related issues with instrument (not calibrated, expired calibration, suboptimal calibration results, calibration drift)	
	Wrong assay used for testing sample	

*Note that some of these causes can result in both a systemic error and a random error. For example, insufficient mixing of EQA samples could affect all result levels, resulting in a systematic error, if wrong pre-analytical instructions are followed.

Do I need to do anything further if I do not have any unacceptable results?

Yes!

Even if your results are acceptable you can determine if trends are developing that could result in a future failure. The best way to detect problems is to examine the Standard Deviation Index (SDI) results. Although looking at the SDI will give a quick interpretation of your results, you may have unacceptable results with small SDIs. This can occur if the evaluation criteria do not use the SD to generate the acceptable range.

If EQA data has a Gaussian distribution, then 68% of results should fall within 1 SD, 95% within 2 SD, and 99.7% within 3 SD. Therefore you should want your EQA data to have a small SDI (close to the target) and have both positive and negative SDI for any given analyte to eliminate the possibility of bias.

The performance reports will give your SDI. The Standard Deviation Index (SDI) is calculated by:

SDI = (your result – peer group mean)/ peer group SD.

Question 1:

Do half or more of my SDI results exceed +/- 1?

If yes, review your procedures and instrumentation for possible systematic errors that could result in a future failure.

Question 2:

Are all of my SDIs positive or all negative?

If so, significant bias (systematic error) is present and calibration data should be reviewed to determine if a shift has occurred. Bias can usually be eliminated by recalibration.

Question 3:

Does the range of SDI between the largest and smallest EQA result exceed 4 SDI?

If so, random error is a possibility and the procedure should be evaluated for potential sources of imprecision.

If you are able to answer "No" to all of the above questions then..... "Congratulations on successfully completing your EQA test event!"

I have unacceptable results..... Now what?

Determine what caused your unacceptable results and take corrective action.

All EQA errors must be thoroughly investigated and documented. Investigation should include the following steps.

Question 1:

Is one result more than +/- 3 SDI?

If so, there is a high probability of random error such as transcription error. Review the report carefully and determine if it is a clerical error or another problem mentioned in Table 3 with the focus on post-analytical errors.

Question 2:

Is there more than one result that has a large SDI (> +/- 3) and the SDI difference is also large between these results?

If so there is a high probability of results entered in the wrong unit or possibly the samples were mixed up.

Step 1:

Review your copy of the original EQA data submission form and compare it to the performance report. You should look for transcription errors, transposition of answers, coding errors, miscalculations, or grading mistakes.

Step 2:

Review all test result printouts from your instrument. You should look for incorrect units on your performance report from your instrument print out and also look for transcription errors.

Question 3:

Do you have unacceptable results and all above situations have been ruled out or do not apply?

Step 3:

If clerical and transcription errors have been ruled out, then a systematic error could have happened and the sources of systematic errors that are listed above should be investigated with the focus on the analytical errors.

Review quality control results from the same day - was the EQA result accepted when QC was out of control? Were there any QC shifts or trends? Review calibration data from the testing period – had the instrument just been calibrated? How was the calibration compared to previous calibrations?

Review your registration in OASYS to ensure that the reagent catalog numbers in OASYS match the catalog numbers of your reagent and the submethod selected is correct.

Step 4:

Retest the original EQA sample if possible and with QC material at the same time if desired. If repeat testing produces an acceptable result, then the original result was affected by analytical error. Note that if the repeat results are optimal it could mean that instrument maintenance might have been done before repeat testing which would have corrected any instrument problems.

Question 4:

Is the EQA result still unacceptable?

If the repeat result is still unacceptable, attention should be focused on specimen identification and labeling errors, if testing is performed from an aliquot instead of from the original vial/container. If possible, retest by sampling from the original vial/container and not from an aliquot. Specimen preparation should also be reviewed for reconstitution or dilution error, pipetting problems, and aliquot evaporation due to delay between reconstitution and analysis. EQA material should be examined for instability, contamination, chemical interference, an incompatible matrix effect, or shipping delays.

Review quality management tools such as instrument logs, maintenance logs, and troubleshooting logs to see if, before the testing of samples, major maintenance (i.e. sampling probes replaced, instrument parameters changed, etc.) was performed or occurrence of incidents which might potentially affect results.

It would also be helpful to ask the laboratory personnel who performed the original testing to see how the testing was handled, especially for tests requiring more manual procedures.

Step 5:

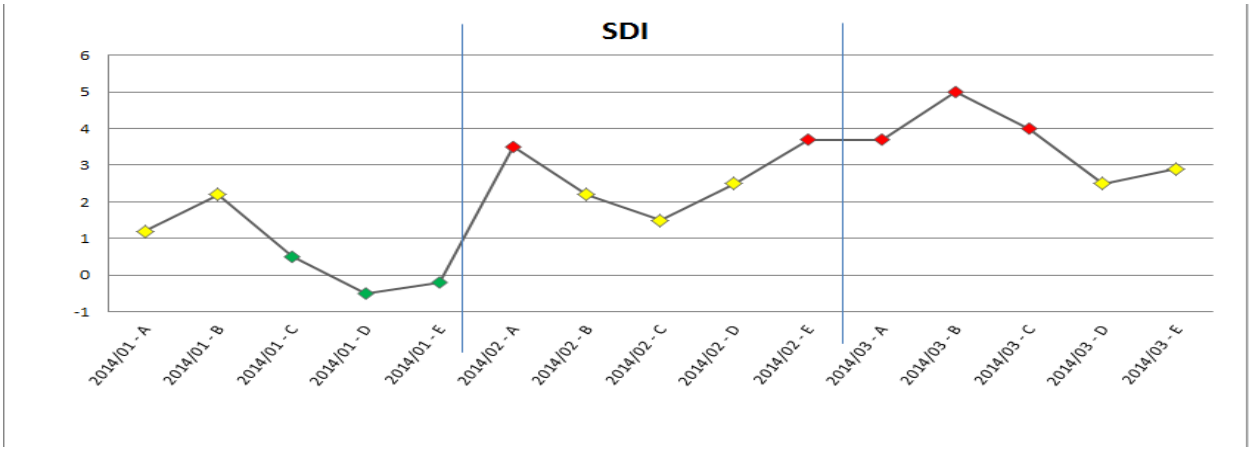
Determine your corrective action. Do you need to recalibrate? Was it a random error that better attention will correct? Did your error affect the testing done on patient samples? Should better instructions be given to staff on reconstituting, handling, and storing EQA samples?

Ensure that you can explain all of your unacceptable results and your instrument is producing accurate results. Continue to monitor your QC results after the test event. Document your investigations and corrective action and prepare for the next test event.

My current EQA evaluation has unacceptable results again.

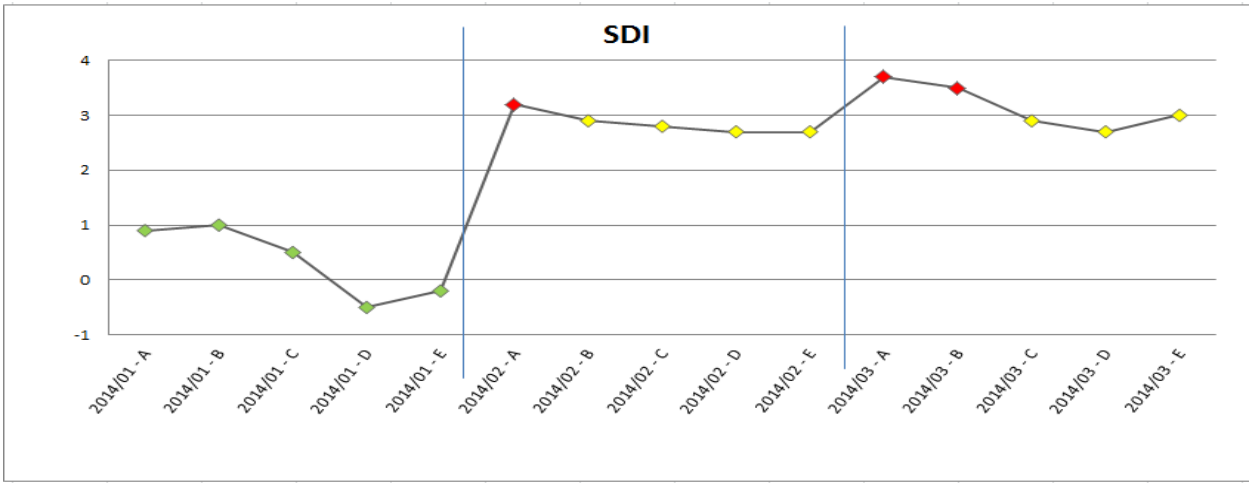
Historical performance reports could be of help in this case as it helps to monitor trends and shifts of data, which could result in systematic errors over time. Two examples have been included below for demonstration of trends and shifts. Historical performance reports could be generated on the OASYS website. (Lab Reports > Historical Performance)

Graph 1: Gradual Shift of data over 3 test events



The gradual upward SDI trend seen over the 3 test events of 2014 could indicate a gradual degradation of the test system such as reagent instability and 'aging' of measurement/detection components, such as the light source in a photometric measuring unit.

Graph 2: Abrupt shift of data between first and second test event



Between the first test event and second test event of 2014, a sudden shift of SDI was seen which indicates systemic errors at play here. Were the instrument parameters changed? Was any major instrument maintenance performed? Was the reagent changed in the lab, thus a new submethod was in use, but registration information was not updated when submitting results?

As a test event usually consists of 2 or more samples which span the analytical range, it helps to investigate which levels of samples suffer from higher unacceptable rates. If it's a quantitative test, if the levels that fail are near the upper or lower analytical range, then the analytical range of the assay might have to be re-validated. If it's a qualitative or semi-quantitative test, if the levels that fail have values near the cut-off level of the test (i.e. failing to detect a weak positive sample), then the test's sensitivity is of suspicion.

As the above problems are all systemic errors, root cause analysis must be performed right away and corrective action implemented to prevent future failures.

Why are my results not evaluated (NE shown as grade)?

The most common reason in which results are not evaluated could be:

A.) the peer group for your laboratory's particular instrument/reagent/method could be small (<10 participants) and thus not statistically sound to be evaluated as a separate group and/or

B.) having your result evaluated with a larger peer group would mean an unjust evaluation with divergent data

It has been documented in studies and articles that bias is often times seen between assays. In order words, because of the inherent differences between instruments/reagents/methodologies and depending on the size of the bias between groups, often times it is best to evaluate with more specific (i.e. similar) peer groups than broad peer groups. A larger peer group means this bias effect would be incorporated as well which might falsely increase the acceptable result range if SD is used in calculating the range.

…But are those results satisfactory?

Participation Statistics reports (Lab Reports > Participation Statistics) could be generated in OASYS for a specific test event and program. These reports would list the different evaluated peer groups, the acceptable result ranges of those peer groups, and other relevant statistics within the peer groups. Even though your own peer group is not available, it is still beneficial for quality assurance purposes to examine the report and see if your result is similar to other results generated through different instruments and methods.

Is further help needed?

Please make use of the help resources in the OASYS Support Center (Help > Support Center > Support Resources) for common issues such as changing registration, shipping/handling problems, and submitting results. Submit a help request to if necessary and a support staff member will respond as soon as possible.