Quantitative Online Investigation Form Guideline

This document is intended as a guideline for completing the pSMILE online Investigation Report (IR) form. Please do not limit your investigation steps to the suggestions provided in these guidelines.

The pSMILE General Quantitative EQA Investigation form should be used for all quantitative analytes.

I. Beginning the investigation

A. When a new investigation is indicated by a pSMILE review, it will be noted in the monthly EQA and Action Plan Update Email. The person assigned to work on the investigation will sign onto pSMILE.org and navigate to the Quick Links area and select “IR for LABS”.

B. Click on “View IR” to begin completing the investigation form.

C. Complete all boxes requiring date and name of person performing the investigation. Fill in repeated test results and date of repeat testing. If testing was not repeated, please click on “NO repeat” and explain why testing was not repeated.

D. The following fields will be automatically populated:

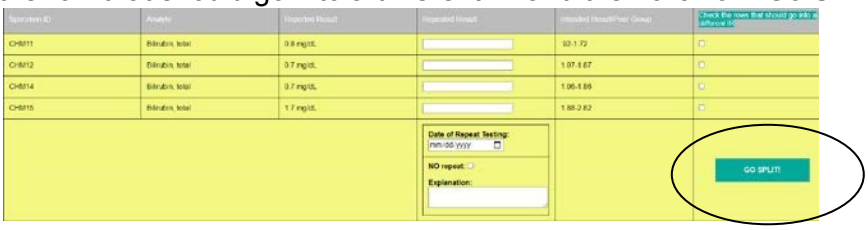
- Site/Laboratory Name
- EQA Provider and #
- Survey Name
- Previous Survey Problems
- Specimen Number
- Analyte
- Reported result
- Intended Result/Peer Group
- Analyzer Name/Model if applicable
- Date Evaluation Available

E. Separate investigation forms are required if more than one analyte is unsuccessful and the causes for each of the EQA failures are unrelated.

For example, if one analyte failed due to a clerical error and another analyte failed due to an instrument problem, two separate investigation forms must be completed. See instructions below:

1. Click on “Enable – SPLIT IR”.

2. Check the row that should go into a different IR and then click on “Go SPLIT”.



One IR form can be used for multiple analytes if the problem was due to a single cause. For example, if there was a sampling error that affected all Hematology analytes, then all of the analytes can be listed on one form because the cause and corrective action would be the same for all analytes.

II. Investigation Steps: Please answer all questions as completely as possible.

A. Pre-Analytical Errors

This portion of the investigation reviews any problems that may have occurred with the samples, instrument/reagent or instructions prior to sample analysis.

Question 1:

Were EQA samples received in the laboratory without delay? Please describe any shipping or delivery issues.

If	Then
The survey was delayed in transit.	Mark “Yes”
	Document the cause of delay and note how long it took to receive the survey at site.
Survey was not delayed in transit.	Mark “No” Comment: No shipping problems.

Question 2:

Were EQA specimens shipped and stored appropriately according to EQA Provider’s temperature requirements?

If	Then
Survey was not shipped according to temperature requirements.	Note the condition/temperature of samples upon receipt.
Survey was sent with dry ice	Note if there was any dry ice in the container.
Survey was received at the proper temperature.	Note that the package was received at the proper temperature on the Investigation form.
Survey was stored at the lab before testing.	Note how long and under what conditions the survey was stored at the lab before testing.

Survey was not stored properly once received at the lab.	Note the storage condition of the survey on the Investigation form.

Question 3:

Did all EQA vials arrive intact (i.e. no missing, broken or leaking specimens) If not, did you contact the EQA provider and pSMILE?

If	Then
The specimen(s) were broken, leaking or damaged upon receipt.	Note the conditions of the specimens upon receipt at the lab on the Investigation form.
	Note if new specimens were requested from EQA provider.
	Note if pSMILE was contacted about the problem.
Sample was missing.	Note if new specimen was requested from EQA provider?
	Note if pSMILE was contacted about the problem.

Question 4:

Were the EQA specimens prepared/ reconstituted/ diluted as indicated by the kit instructions?

If	Then
Survey specimens were not reconstituted per kit instructions.	Note the reconstitution problems on the Investigation form.

Question 5:

If there were special instructions provided in the kit, were they followed? (Special instructions can be indicated by this symbol) See example below:

XE-2100/XE-2100L, XE-5000 and XT-2000i/XT-1800i

Note: For the Sysmex XE-2100, XE-5000 and XT series instruments, specimens **must** be analyzed in the **QC program** to obtain WBC differential data. Read and follow the sample handling instructions before analyzing the samples. Perform analysis of all samples using the aspiration mode that the majority of your patient samples are processed in: either closed vial (primary) or open vial (secondary) mode.

- Flags are likely to accompany the differential results when Survey specimens are tested in the patient mode. Although these flags may trigger manual differential review on a patient specimen, please ignore the differential results and report the automated instrument differential.

If	Then
Special instructions were not followed.	Note on investigation form why they were not followed.

Question 6:

Were the correct tests performed on the correct specimens(s)?

If	Then
Incorrect testing was performed on vials.	Note on investigation form what was incorrectly performed and why.
Incorrect survey was used.	Note on investigation form if wrong survey was used.

Question 7:

Was routine maintenance of instruments/equipment performed as scheduled (daily, weekly, monthly, etc.)?

Check	Note
Maintenance logs for preventative maintenance schedule.	Note if there was maintenance that was not performed or if any instrument problems may have occurred. Example – Background were checks out the first time.

Question 8:

Did you check lot numbers and storage conditions of kits, reagents, and materials used to perform testing on samples?

Check	Note
Were kits/reagents/material checks performed before testing? (Temperature, reconstitution, cuvette check, etc.)	Note on investigation form any discrepancies in testing.

Question 9:

Were all expiration dates verified before sample testing? (Control, reagents, etc.)

Check	Note
Reagent logs during the time of the survey.	The open dates, expiration dates and any problems on specific lot numbers as noted by manufacturers.

B. Analytical Errors

This portion of the investigation reviews any problems that may have occurred during analysis of the samples.

Question 1:

Did you review the current and past EQA event for bias, shifts and trends? If present, were investigations performed and what were the outcomes? This question is looking at EQA results of the analyte using the SDI value:

$$\text{SDI} = \frac{\text{Lab result} - \text{Mean}}{\text{SD}}$$

The indications of these occurrences are as follows:

Bias is indicated when two or more specimens within a single EQA event have an SDI > ± 2.0.

Trend is indicated when bias increases progressively in one direction for three consecutive survey events.

Shift is indicated if an abrupt change in bias occurs for all samples from the previous survey event; the change in bias must be at least 2 SDI and greater than ±1 SDI from the mean.

If	Then
Bias occurs	Can indicate the instrument may need adjustment to either its calibration, laser, etc.
Shift occurs	Can indicate a major change on your instrument. It could have been calibrations, parts, new reagent.
Trend occurs	Can indicate a possible deterioration of a part such as a lamp.
Check	**Note**
Previous EQA events or EQA reviews	Any internal investigations performed for past bias, shift or trend.
	Describe all action taken to resolve problem.

Question 2:

Did you evaluate the instrument/method for any problems prior to or after the EQA event? Describe any problems identified.

Check	Note
Instrument/test log	Any problems that may have occurred before or after EQA event.
	Describe all action taken to resolve problem.

Question 3: Was the calibration at the time of the EQA event reviewed for acceptability? If not acceptable, comments:

Your laboratory should have established acceptable ranges for your OD/values readings as compared to previous calibration. Your instrument can indicate that a calibration run has passed but individual points in the calibration data may be outside of the usual range seen in the past.

Check	Note
The calibration history of the instrument.	The date of the last calibration (especially if it was just before or after the survey). For those instruments that require daily calibration ensure all QC is within range and no bias, trend or shift is noted. NOTE: It is best if calibration is required for the instrument to perform it at least several days to a week before running the survey specimens to allow the instrument to stabilize.
	The date the calibration was reviewed by a supervisor.

The open and expiration dates of all calibrators used during the calibration.	If calibrators were used within the expiration date, stored properly, etc.
When calibration is required.	When it is done, such as with each lot change, each change of reagents or a specified time interval.
All of the calibration factors.	If the correct calibration factors were used for all points.
OD/Values on calibration	If values are outside of usual range, calibration may
	have been unacceptable.

Question 4:

How do you establish your Quality Control (QC) mean and ranges? Comments: Common practice is to enter the manufacturer's QC means and ranges for new lot numbers. After at least 20 points the laboratory should then establish their own QC mean and ranges. If the laboratory continues to use the manufacturer's numbers they could be inappropriate for your instrument. Your instrument may have tighter SD allowing a possible out of range point to be acceptable. It is highly recommended to always to establish your own mean and ranges.

How	Note
Are means for QC established?	If manufacturer means are used or if the lab establishes their own mean with parallel testing.
Are QC ranges established?	If manufacturer ranges (SD's) are used or if the lab establishes their own ranges (SD's).

Question 5:

Were all QC levels for this analyte within acceptable range(s) on the day the EQA survey was run?

Standard deviation is a statistical measure of the scattering of a set of data. A range of 2SD will give a 95% confidence limit of this data. It is recommended that a 2SD limit be used for acceptable range on your QC charts.

Check	Note
All QC run on the day of the survey.	Any QC problems, if not within acceptable limit.

Question 6:

Are Westgard QC rules used? If so which ones?

Westgard QC ruled are a multi-rule QC using a combination of decision criteria or control rules to decide whether an analytical run is in-control or out-of-control. To understand these rules please go to psmile.org under Resources/Process Control/Quality Control/ Guidelines to Westgard Rules.

If	Then

Westgard rules used.	List rules used in comments section.
	Note any failures of Westgard rules around the time of the EQA event.

Question 7:

Were QC/Levey Jennings charts reviewed for any trends, shifts and/or biases?

What are Levey-Jennings charts?

It is a graph that quality control data is plotted on to give a visual indication whether a laboratory test is working well. The distance from the mean is measured in SD.

What is a bias?

It is the consistent deviation of measured values from true values caused by systematic errors in a procedure. In simple terms is it when QC data points are consistently on one side of the mean.

What is a shift?

It is when the QC data move suddenly upward or downward from the mean and continue the same way changing the mean.

What is a trend?

It is when the QC data slowly move up or down from the mean and continue moving the same direction over time. The difference between shift and trend is that a trend is a slow process where a shift is an abrupt process.

Check	**Note**
Quality Control records during the time of the survey.	Any problems that occurred such as biases, trends, or out of range values before or after the EQA event.
	If records had been reviewed during the time of the survey.
If	**Then**
Bias	Can indicate mean is not correct for instrument might need to establish own mean.
	Check calibration history to see if could have caused the bias.
Shift	Check to see if new QC used – could indicate problem with new vial
	Check service log to see if there were any parts replaced that could cause the change.
Trend	To see if instrument has any parts such as lamps that may need replacement after specific use.
	Check reagents that may have been improperly stored that could affect their performance. (Example some types of hematology diluent if frozen will then thaw in layers. Recommended to always mix boxes upon receipt.)

Question 8:

Does your laboratory track precision by monitoring Coefficient of Variation (CV) for this analyte? If yes, was your CV acceptable at the time of the survey?

What is CV?

It is defined as the ratio of the standard deviation to the mean. When measured over time it basically indicates how precise your instrument measurement is. For additional information on the use of CVs contact your pSMILE coordinator or visit the pSMILE.org website for additional resources.

If	Note
Coefficient of Variation (CV) used for this analyte.	The Coefficient of Variation for this analyte during the testing period (month prior, during and after the EQA event.)
	Any CV out of acceptable criteria.

Question 9:

If any manual calculation was performed for this analyte was it checked for accuracy? (Dilutions, formula)

If	Then
Result was outside the analytical measurement range.	Was the sample diluted?
The specimen was diluted.	Verify that the measured result was within the AMR before calculating the result using the dilution factor.
	Verify that the correct dilution factor was used to calculate the results.
Analyte requires a calculated formula for result	Verify calculation. Example of calculated analytes: Cholesterol LDL, Micro-albumin/Creatinine Ratio.
	Check analytes used in calculation for unacceptable results that can affect this analyte.

Question 10:

Are questionable results reviewed by supervisor/pathologist before reporting results?

If	Then
Abnormal results are reviewed	What criteria are used for review by supervisor/pathologist?
	What were the comments/decisions of the supervisor/pathologist?

Question 11:

Was the instrument or reagent manufacturer contacted?

If	Note

The manufacturer was consulted	Any response from the manufacturer such as bad lots, parts, incorrect calibration points, etc.
Service recommended for the survey problem.	Any service performed for survey problem.

C. Post Analytical Errors

This portion of the investigation reviews the results of the analyte reported to the EQA provider and any problems that may have occurred after analysis of the samples.

Question 1:

Were the results correctly transcribed from the instrument printout or worksheets to the EQA Result Form?

Compare all instrument printout or worksheet to the EQA results	
If	**Then**
Results do not match	Answer “No”. Indicate it was a transcription /clerical error.
Results match	Answer “Yes”

Question 2:

Did you verify that the electronic results submitted matched the EQA result form (i.e. was the provider website checked for accuracy of results submitted?)

Comments:

After entering results on the EQA provider’s website, you should save your approved/printed copy to compare later as needed. This copy can also be used as a double check against your answers to check for transcription/clerical errors.

Note: if you fax your results, there is a possibility that there may be a transcription error by the EQA provider. Check the Result Form used for faxing against the EQA provider’s report.

Compare all electronic copies of EQA results	
If	**Then**
Electronic results were verified	Answer “Yes”
Results do not match	Check electronic copy against Result Form copy.
	Decide where transcription/clerical error occurred.
If results faxed	**Note**
Check your copy against survey results.	Any discrepancy due to misinterpretation of entry.
Do not match survey results.	Contact EQA provider of error and request revised survey.

Question 3:

Were the correct instrument/method/reagent codes submitted to the EQA provider?

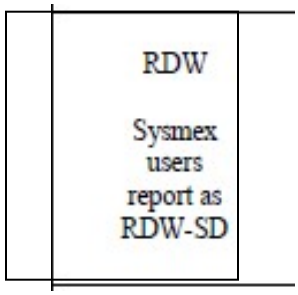
It can be difficult to decide on the correct reagent/instrument code. You can contact your manufacturer or pSMILE representative for help if you have any questions.

If	Then
Codes used were incorrect.	Choose correct codes
	Grade results using the correct peer group
Correct codes were used.	Answer “Yes”

Question 4:

Were correct units reported?

Sometimes the EQA provider specifies the units for the analyte. Below is an example where the RDW can only be resulted in SD.



If	Then
No	Mark “No” and comment why correct units were not reported. Comment if retraining of personnel was performed.
Yes	Mark “Yes”

Question 5:

Were results reported with correct decimal place? Comments:

If	Then
Decimal place was incorrect.	Correct the decimal place.
	Grade results using the correct results.
Decimal place was correct.	Answer “Yes”

Question 6:

Were your results graded in the appropriate peer group?

If	Then
Incorrect peer group	Manually grade using correct peer group.

used.	Comment on final grade of analyte with correct peer group.
Correct peer group used.	Answer “Yes”

III. Investigative Actions and Root Cause: Briefly discuss the actions taken in the investigation and what you believe is the primary cause of this EQA problem.

- Determine which of the above errors caused the incorrect result. It may be a combination of problems such as clerical and technical.
- Once the root cause of error has been identified, discuss what actions were taken in the investigations such as recalibration, service by manufacturer, re-analysis of samples or retraining of staff.

See below for **example investigation**:

EQA Failure: Two Hematocrit results were out on the high side. It was also observed that the RBC was running a positive bias. ○ Actions Taken:

- Checked for any problems with specimens such as delays, broken vial, or incorrect storage.
- Checked all samples to ensure correct vial run and all kit instructions followed.
- Checked instrument and reagents to ensure all routine checks had been done.
- Checked previous EQA events and saw positive bias on both the RBC and Hematocrit.
- Instrument had been calibrated 2 months prior to EQA event and was acceptable.
- All QC material was within acceptable criteria but it was noted that the RBC and Hematocrit were running a positive bias. The QC material was run on the manual mode to determine if there was a similar bias. It was noted that the manual mode ran consistently higher than the primary mode.
- CV for the primary mode was within acceptable criteria.
- Re-ran survey specimen on the primary and manual mode. Results showed that the manual mode answers ran higher than the primary mode causing them to be in the unacceptable range. ○ Primary cause of error:
- It appears that the manual mode of the instrument produce higher results than the primary mode.

Was Personnel training/competency reviewed? Staff education or re-training conducted, as appropriate?

- As part of your investigation include if any personnel had to be re-trained due to the EQA failure. This could be limited to the personnel performing the EQA event or extended to the entire staff due to the addition of new procedural steps.

IV. Type of Error

Review your Investigative Actions and Root Cause section to determine the type of error that caused the EQA failure.

- Methodological

  o The following are examples technical errors: SOP steps not followed reconstitution or sample preparation steps performed incorrectly, sample mix-up.

- Technical
  - The following are examples of technical errors: instrument failure, procedural steps not followed, staff not properly trained. o Correct the technical problem, rerun the specimen, and enter in the table at the beginning of the form. Check to ensure rerun answer is within the intended range.

- Clerical
  - The following are examples of clerical error: transcription errors by the tech to the worksheet, incorrect results entered on EQA provider website, incorrect reagent/method codes used.
  - Once the clerical error is identified, take steps to ensure the error will not reoccur.

- Survey evaluation problems

  o The following are examples of survey evaluation problems: EQA provider evaluated specimen against the incorrect peer group, incorrect units of measure reported.

V. Study Impact

Were study participant results assessed for adverse effects?

If applicable, review participant results, amend results and notify the following -- physicians, study staff and network representatives. Comments:

If	**Then**
Study participant results	Review the test history for each affected participant to confirm that they had follow-up testing since the error
were affected.	occurred. Retest stored specimens if possible to confirm and/or correct the error.
	Amend results as needed.
	Notify the physicians, study staff and network representatives of the amended results. Recommend recollection and repeat testing to verify suspected errors.

VI. Future Preventative Measures: Briefly discuss how you will prevent this problem from reoccurring in the future.

• The following are possible preventative measures:

- Ensure that all transcription of data is checked by two staff members. ○ Ensure instruments are within their calibration period and all calibration points are correct.
- Ensure that all QC was within range.
- Provide retraining to personnel as needed.

VII. Laboratory Personnel Signature

The person preparing the Investigation form should add any comments in the "Comment" box. Add any supporting documents in this section including instrument printouts, QC charts, service documentation, etc.

To upload document click on Choose Files.

- Navigate to file and click on it and click open.
- Once file is attached click on "Upload" to attach.
- The investigation can be saved for later entry by clicking on the "Save Progress" button.
- Once investigation is complete click on "Sign & Submit" button.

The personnel initials and date will be saved in the History box. If any section is not filled in, an alert will pop-up with the missing section. All sections must be completed.

VIII. pSMILE, Network and POC Review Section

This section is used by pSMILE and the designated Primary Network Laboratory (PNL) to review your investigation. They will either accept it or mark it incomplete and request more information. If either pSMILE or Network rejects the investigation:

- An email will be sent to the laboratory main contact person and the person who filled out the investigation (if different from the main contact).
- The investigation will be reopened for the laboratory to revise the investigation as needed.
- An email will be sent out for DAIDS POC to acknowledge the investigation.
- Once acknowledge then pSMILE will closed the investigation and all investigations and documents will be combined in one PDF and sent back to the laboratory for their records.