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 Qualitative EQA Investigation form should be used for all qualitative and semi-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:

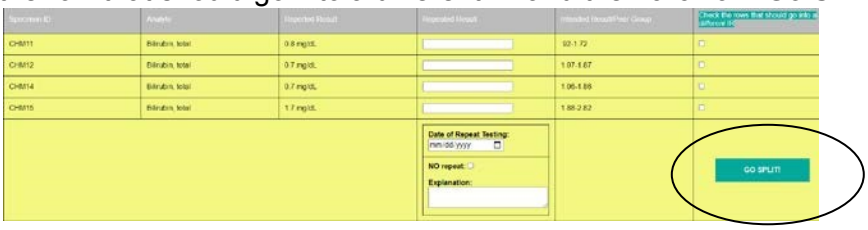
- Site/Laboratory Name
- EQA Provider and #
- Survey Name
- Previous Survey Problems
- Specimen Number
- Analyte
- Reported result
- Intended Result/Peer Group
- Analyzer Name/Model if applicable
- Date Evaluation Available

**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”<br>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 contactacted 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)**

| 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.<br>Example – Background were checks out the first time. |

**Question 8:**

**If timers are used, are the calibrations current?**

| If | Then |
|---|---|
| Calibration had not been performed semiannually | Comment on investigation form that timer's calibration had not been performed. |
| Calibration had been performed semiannually | Comment on investigation that calibration was up to date. |

**Question 9:**

**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 10:**

**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. |

**Question 11:**

**Were all specimen cassettes pre-labeled before testing?**

| If | Then |
|---|---|
| Cassettes were not pre-labeled | Ask technologist performing the testing how they ensured correct sampling occurred. |
| Cassettes were prelabeled. | Mark “Yes” no other comment required. |

**Question 12:**

**Were all specimens/reagents allowed to warm to ambient temperature?**

| If | Then |
|---|---|
| Specimen/reagents were allowed to warm to ambient temperature. | Mark “Yes” no other comment required. |
| Specimen/reagents were not allowed to warm to ambient temperature. | Mark “No” and comment why specimens/ reagents were not allowed to warm. |

**Question 13:**

**Are reagents and samples added in the appropriate order and at the appropriate times?**

| If | Then |
|---|---|
| Specimen and reagents were added at appropriate time. | Mark “Yes” no other comment required. |
| Specimen and reagents were not added at appropriate time | Mark “No” and comment why not added correctly |

## B. Analytical Errors

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

**Question 1:**

**Were all QC results for this analyte acceptable on the day the survey was run?**

| If | Then |
|---|---|
| Yes | Comment that all QC was run and acceptable |
| No | Comment what corrective action performed for unacceptable results. |

**Question 2:**

**Were timing steps performed as per written SOP?**

| If | Then |
|---|---|
| Correct timing was used. | Comment correct timing used. |
| Correct timing was not used. | Comment incorrect timing used and if technologist was re-trained. |

**Question 3:**

**Has the SOP been updated to reflect the current test kit instructions?**

| If | Then |
|---|---|
| SOP instructions are up to date. | Mark “Yes” |
| SOP instructions are not up to date. | Mark “No” and update SOP to reflex current test kit instructions. |

**Question 4:**

**Are samples analyzed as defined in the SOP**

| If | Then |
|---|---|
| Yes | Mark “Yes” |
| No | Mark “NO” and comment why there were not analyzed as defined in the SOP. |

**Question 5:**

**Was the correct amount of specimen and reagent used**

| If | Then |
|---|---|
| Yes | Mark “Yes” |
| No | Mark “NO” and comment why correct amount of specimen and reagent were not used. |

**Question 6:**

**If titers were required were correct dilutions made:**

| If | Then |
|---|---|
| Yes | Mark “Yes” |
| No | Mark “No” and comment why incorrect dilutions were used. Also, comment if retraining was performed. |

**Question 7:**

**Were EQA samples properly mixed before testing?**

| If | Then |
|---|---|
| Yes | Mark “Yes” |
| No | Mark “No” and comment why correct mixing was not done. |

**Question 8:**

**Was the internal control result acceptable?**

| If | Note |
|---|---|
| Yes | Mark “Yes” |
| No | Mark “No”. Explain why results were accepted with unacceptable internal control. |

**Question 9:**

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

| If | Then |
|---|---|
| Yes | Mark “Yes” Explain when results are reviewed. |
| No | Mark “No” |

**Question 10:**

**Was the instrument or reagent manufacturer contacted?**

| If | Note |
|---|---|
| The manufacturer was consulted | Mark “Yes” and comment: |
| | Any response from the manufacturer such as bad lots, parts, incorrect calibration points, etc. |
| | Any service performed for survey problem. |
| | Service recommended for the survey problem. |
| If manufacturer was not consulted | Mark “No” |

## 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 all special resulting instructions followed?**

Sometimes there are survey-specific instructions for the analyte. (Example: Only whole numbers for pH for Roche Specific Gravity.)

| **If** | **Then** |
|---|---|
| Specific resulting instructions were not used. | Mark “No” and explain why instructions were not followed. Comment if retraining of personnel was performed. |
| Specific resulting instructions were used. | Mark “Yes” |

**Question 5:**

**Were correct units reported?**

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

**Question 6:**

**Was the correct manufacturer code chosen?**

| If | Then |
|---|---|
| No | Mark “No” Comment on what code should have been used. |
| Correct peer group used. | Answer “Yes” |

**Question 7:**

**Did you select the correct result code for photographic images/or microscopic examinations?**

| If | Then |
|---|---|
| No | Mark “No” Comment on what code should have been used. |
| Yes | 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.

**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
  - 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.

- 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
  - 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 were affected. | Review the test history for each affected participant to confirm that they had follow-up testing since the error 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.