

Microbiology Investigation Form Online Guidelines

This document is to be used as a guideline for completing the pSMILE Microbiology Investigation form online. Please do not limit your investigations to the suggestions provided in these guidelines.

I. Beginning the investigation

- A. When a new investigation is required by a pSMILE review, it will appear in the monthly EQA and Action Plan Update Email. The person assigned to work on the investigation will sign onto pSMILE.org and in the Quick Link area click on "IR for LABS".
- B. Click on "View IR" to begin completing the investigation form.
- C. For Bacteriology, Mycobacteriology, Mycology and Parasitology analytes use the 'pSMILE Microbiology Investigation' form.
- D. Separate forms are required if the causes for the sample failures are unrelated. For example, if one sample failed due to a clerical error and another analyte failed due to an instrument problem.
 - a) Click on "Enable – SPLIT IR".

Specimen ID	Analyte	Expected Result	Reported Result	Extended Result/Ref Group	ENABLE - SPLIT IR
CHB11	Bilirubin, total	0.8 mg/dL	<input type="text"/>	92-1.72	
CHB12	Bilirubin, total	0.7 mg/dL	<input type="text"/>	1.07-1.87	
CHB14	Bilirubin, total	0.7 mg/dL	<input type="text"/>	1.06-1.86	
CHB15	Bilirubin, total	1.7 mg/dL	<input type="text"/>	1.88-2.82	

- b) Check the row that should go into a different IR and then click on "Go SPLIT".

Specimen ID	Analyte	Expected Result	Reported Result	Extended Result/Ref Group	Check the row that should go into a different IR
CHB11	Bilirubin, total	0.8 mg/dL	<input type="text"/>	92-1.72	<input type="checkbox"/>
CHB12	Bilirubin, total	0.7 mg/dL	<input type="text"/>	1.07-1.87	<input type="checkbox"/>
CHB14	Bilirubin, total	0.7 mg/dL	<input type="text"/>	1.06-1.86	<input type="checkbox"/>
CHB15	Bilirubin, total	1.7 mg/dL	<input type="text"/>	1.88-2.82	<input type="checkbox"/>

Date of Repeat Testing: mm-dd-yyyy

NO repeat:

Explanation:

GO SPLIT

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

Complete all boxes requiring date and name of person performing investigation. Fill in repeated results and date of testing. If results are not repeated **must** click on "NO repeat" and explain why they were not repeated. The following will automatically be filled in on:

- 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 **Please answer all questions fully.**

II. Investigation Step

A. Pre-Analytical Errors

This portion of the investigation reviews the status of the EQA specimens before analysis and any problems that may have occurred with the samples, instrument/reagent or instructions.

Question 1: Were proficiency testing materials received in the laboratory without delay? Please describe any delivery issues.

If	Then
The survey was delayed in transit.	Mark "No"
	What caused the delay?
	Note how long it took to receive the survey at site on the Investigation form.
Survey was not delayed in transit.	Mark "Yes" Comment: no shipping problems.

Question 2: Were specimens shipped and stored appropriately according to temperature requirement? Comments:

If	Then
Survey was supposed to be refrigerated/cold in transit.	Note if the ice packs were cool/cold. Note if samples were cool.
Survey was sent with dry ice	Note if there was any dry ice in the container.
Survey was not at the correct temperature.	The samples may have been compromised.
	Note any discrepancies for temperature on the Investigation form.

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.

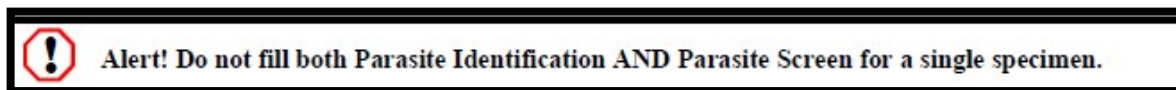
Question 3: Did all EQA vials arrive intact (i.e. no missing, broken or leaking specimens) If not, did you contact the provider and pSMILE? Comment:

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 specimen was requested from EQA provider?
Sample was missing.	Note if new specimen was requested from EQA provider?

Question 4: Did you prepare/reconstitute/dilute EQA specimens as indicated by the kit instructions? Comment:

Question personnel responsible for reconstitution of samples.	
If	Then
Survey specimens were not reconstituted as 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? (Can be indicated by this symbol ) Comment: See example below



Check all instructions provided with the survey including any special instructions on the result form. Question personnel responsible for analyzing the survey how they processed the samples.	
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 specimen?

Check survey specimens – do they look like they have been run? Question personnel assigned the analysis of the survey which samples were used.	
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 the wrong survey was used.

Question 7: Was routine maintenance of instruments/equipment performed? Comment:

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

Question 8: Were media examined for acceptability (quality, storage, expiration and QC)? Comment:

Check	Note
Media logs.	If all media lot numbers used for EQA testing were in acceptable condition, stored properly, and used before expiration date.

Question 9: Did you check lot numbers and storage conditions of kits, reagents, and materials used to perform testing on samples? Comment:

Check	Note
Maintenance logs.	If all routine checks had been performed before EQA testing.

Question 10: Were all expiration dates verified before sample testing? (Control, reagents, etc.) Comment:

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 the status of the EQA specimens during analysis and any problems that may have occurred.

Question 1: Were organisms handled by the laboratory staff using routine procedures?

Comment:

Question personnel responsible for processing the sample and ask how they handled the organism.	
If	Then
Survey organisms were not handled using routine procedure.	Note on the Investigation form. Comment why not handled using routine testing procedure.

Question 2: Were method histories reviewed for correct procedure (*approved algorithm, correct testing followed / interpretation*)? Comment:

Check	Note
Procedure to see if approved algorithm, correct testing followed or interpreted.	Any discrepancies in testing.

Question 3: Were procedures reviewed to ensure laboratory practices are in line with recommended practices? (Example: CLSI, ASM) Comment:

Check	Note
Documentation for recommended practice	Any discrepancies in testing.

Question 4: Were the organisms reported to the correct level of identification following routine practices? Comment:

Check	Note
Results	If organisms were reported to the same level as patient testing.
If	Then
Organism not reported to same level as patient	Comment on why routine practice was not followed.

Question 5: Has EQA performance been reviewed to determine if there were any problems with particular pathogens and/or sample types in previous events?

Check	Note
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Previous EQA events for similar problems.	Any similar problems from past EQA events. Could indicate problem in laboratory practice or procedures.
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Question 6: Was instrument or reagent manufacturer contacted? Comment

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.

Question 7: Are questionable results reviewed by supervisor/pathologist before reporting? Comment

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

C. Post Analytical Errors

This portion of the investigation is looking at the results of the analyte and any problems that may have occurred.

Question 1: Was the PSR (Participant Summary Report) reviewed for other participant failures and related comments? Comments:

Check to see if other participants had similar failures.	
If	Then
Similar failures noted.	Comment on findings.

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?) Comment:

Compare all instrument printout or worksheet to the EQA results	
If	Then
Results do not match	Indicate if it was a transcription /clerical error.
Results match	Answer "Yes"

Question 3: Did the completed EQA Result Form match the electronic results submitted? If no, how do you assure the accuracy of transcribed results? After entering results into the EQA website online you should save your approved copy to compare later as needed. Without this step there is no way for you to access what was entered at that time. This copy can also be used as a double check against your answer to check for transcription/clerical errors.

Note if you fax your results instead of entering them through the website it may be a transcription error by EQA provider. Check your Result Form used for faxing against those of the report.

Compare all electronic copy EQA results	
If	Then
Results do not match	Check electronic copy against Result Form copy.
	Decide where transcription/clerical error occurred.
Results match	Answer "Yes"
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 4: Were the correct instrument /method /procedure/ reagent reported on the provider result Form? Comment:

It can be difficult to decide on the correct code. You can either contact your manufacturer or pSMILE representative for help.

Check all instrument, method and reagent code entered for this analyte.	
If	Then
Codes were incorrect used.	Choose correct codes
	Grade results using the correct peer group
Codes were used.	Answer "Yes"

Question 5: Were your results graded in the appropriate peer group? Comment:

Check to see if correct peer group was used for your results.	
If	Then
Incorrect peer group used.	Manually grade using correct group.
	Comment on final grade of analyte with correct peer group.

IV. Type of Error

From your Investigative Actions and Root Cause section to decide the type of error.

- Methodological
 - If the error was caused by incorrect coding such as incorrect instrumentation or reagent code, provide correct coding. Results can then be evaluated again to ensure result(s) are within the intended range.
 - If specimen was run in the incorrect mode, rerun specimen in the correct mode and compare the results to intended response. (This is often seen on certain Hematology instruments where the survey should be run in the QC mode and not the patient mode.)
- Technical
 - Technologist misidentified organism.
 - Correct the technical problem and rerun the specimen(s) and enter in the table at the beginning of the form. Check to ensure rerun answer is within the intended result.
- Clerical
 - The following areas could involve clerical error:
 - Transcription error by the tech to the worksheet.
 - Transcription error from the worksheet to the EQA provider result form.
 - If results are faxed, transcription error from the EQA provider results form to the website.
 - If results were entered online, transcription error on entry of the results.
 - Mix-up of samples.
 - Incorrect decimal points or codes used.
- Survey evaluation problems
 - The following could qualify as survey evaluation problems:
 - EQA provider evaluated specimen incorrectly, put it in the wrong peer group.
 - Did not result in the correct units.

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:

Check	Note
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Study participant laboratory results to determine if any results were adversely affected by the problem.	If incorrect results were reported in the DAIDS toxicity table range or if it is suspected that results should have been reported in the toxicity table range but were incorrectly under/over reported. Note: Do not provide confidential patient information in your investigation report. Inform study personnel of all findings in accordance with protocol requirements.
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 is checked by two people.
 - Ensure expired media/reagent is not used.
 - Ensure that all QC was within range.
 - Provide retraining to personnel as needed.
 - Provide up-to-date resource materials for bench staff.
- Example for Future Preventative Measures/Actions for example in section IV
 - Investigation: Incorrect identification of organism on blood smear.

Future Preventative Measure

- Provide retraining to personnel that misidentified specimen.
- When quality of slide is in question request new slide from provider.

VII. Laboratory Personnel Sign Here:

The person preparing the Investigation form should add any comments in the “Comment” box and email address. Add any supporting documents in this section. It can be 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.

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 initial and date will be saved in the History box.

If any section is not filled an alert will pop-up with missing section in red. All sections must be completed.

VIII. pSMILE, Network and POC Review Section

This section is used by pSMILE and designated Laboratory Center (LC) 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 main contact person and person that filled out the investigation (if different from the main contact).
- The investigation will be reopened for the laboratory to update 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.