

SMILE**GENERAL INVESTIGATION
CHECKLIST/FORM****SURVEY INFORMATION – EXTERNAL QUALITY ASSURANCE (EQA)****Note: Please complete the report and submit it to SMILE and your PNL within 30 days.****Site/Laboratory Name:** Alamo**EQA Provider and #:** CAP 9944668855

Survey Name:

CMMP-A 2012

Analyzer Name/Model: Not Applicable

Date Survey Received:

3 March 2012

Date Analysis Performed:

15 March 2012

Date Survey Results Submitted:

20 March 2012

Date Evaluations Available:

10 May 2012

Previous Survey Problems
(If yes, explain):

No

Investigation Performed By:

George Washington


Date:

15 May 2012

Unacceptable EQA Panel:**Date of Repeat testing:**

Specimen Number	Analyte	Reported Result	Repeated Result	Intended Result/Peer Group
XUP-08	KOH Prep	No result	Yeast present	Yeast present

ROOT CAUSE ANALYSIS**PRE-ANALYTICAL ERRORS:**

	YES	NO	N/A
1. Were proficiency testing materials received in the laboratory without delay? Please describe any delivery issues. Comments:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were specimens shipped and stored appropriately according to temperature requirements? Comments:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Did all EQA vials arrive intact (i.e. no missing, broken or leaking specimens) If not, did you contact the provider and SMILE? Comments:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Did you prepare/reconstitute/dilute-EQA specimens as indicated by the kit instructions? Comments:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If there were special instructions provided in the kit, were they followed? (Can be indicated by this symbol ) Comments: Special instruction on result form said to perform KOH regardless of source. Lab only does vaginal and sample was skin so thought it was not applicable	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Were the correct tests performed on the correct specimen(s)? Comments:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Was routine maintenance of instruments/equipment performed as scheduled (daily, weekly, monthly, etc.)? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8. Did you check lot numbers and storage conditions of kits, reagents, and materials used to perform testing on samples? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

SMILE – Investigation Form for Qualitative / Quantitative Testing

9. Were expiration dates verified before sample testing (Controls, reagents, etc.)? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
ANALYTICAL ERRORS:	YES	NO	N/A
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? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Did you evaluate the instrument/method for any problems prior to or after the EQA event? Describe any problems identified. Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Was the calibration at the time of the EQA event reviewed for acceptability? If not acceptable, comment:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. How do you establish your Quality Control (QC) mean and ranges? Comments: <input type="checkbox"/> Lab established <input type="checkbox"/> Use manufacturer's	<input checked="" type="checkbox"/> Not applicable		
5. Were all QC levels for this analyte within acceptable range(s) on day the survey was run? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6. Are Westgard QC rules used? If so, which ones? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Were QC/Levy Jennings charts reviewed for any trends, shifts and/or bias? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9. If manual calculation was performed for this analyte was it checked for accuracy? (dilutions, formula) Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10. Was instrument or reagent manufacturer contacted? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
11. Are questionable results reviewed by supervisor/pathologist before reporting? Comments:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
POST ANALYTICAL ERRORS:	YES	NO	N/A
1. Were the results correctly transcribed from the instrument print-out/ worksheets to the EQA Result Form? Comments:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were the correct instrument/method/reagent codes submitted to the EQA provider? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. Were the correct units reported? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Were results reported with correct decimal place? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6. Were your results graded in the appropriate peer group? Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Did you select the correct result code for photographic images and/or microscopic examinations? Comments:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INVESTIGATIVE ACTIONS AND ROOT CAUSE: Briefly discuss what actions were taken in this investigation and what you believe is the primary cause of this EQA problem. <i>Staff did not read all special directions on the result form. Laboratory performs KOH testing on vaginal only. The sample source was skin hence staff did not perform testing. Special instructions on the result form said to result regardless of sample source as long as this type of testing performed on any type specimen.</i> Was Personnel training/competency reviewed? Staff education or re-training conducted, <i>as appropriate?</i> Comments: <i>All testing personnel were trained to read all instructions including those one the result form.</i>			

Type of Error:		
<input type="checkbox"/> Methodological	<input type="checkbox"/> Survey evaluation problem	
<input type="checkbox"/> Technical	<input checked="" type="checkbox"/> Other (explain) Failure to read instructions	
<input type="checkbox"/> Clerical		
Study Impact: Were study participant results assessed for adverse effects? <i>If applicable, review participant results, amend results and notify the following---physicians, study staff and network representatives.</i> Comments: Did not impact patient results, lack of following special instructions.		
FUTURE PREVENTATIVE MEASURES/ ACTIONS: Briefly discuss how you will prevent this problem from occurring in the future. All staff attended a training session to go over all instructions including those that may be on result form only. Also have added a second check on EQA SOP. This check will ensure all results are correct from result form to electronic copy. Also will include reading of all instructions to make sure followed properly.		
PREPARED BY:		
Name/Title	Date	Signature
George Washington	15 May 2012	
FOR SMILE USE ONLY.		
SMILE Review:	<input checked="" type="checkbox"/> Acceptable and complete Investigation.	<input type="checkbox"/> Investigation is incomplete. See comments.
Comments:		
Name/Title:	Date: 20 May 2012	
Porky Pie		
FOR NETWORK USE ONLY.		
PNL Review:	<input checked="" type="checkbox"/> Acceptable and complete Investigation.	<input type="checkbox"/> Investigation is incomplete. See comments.
Comments:		
Name/Title:	Date: 21/May/2012	
Daffy Duck		

Table for supporting documents:

Attachment#	Description of attachments