To: Sunny Balwani[sbalwani@theranos.com]
Cc: Adam Rosendorff[arosendorff@theranos.com]; Kerry Elenitoba-Johnson[kjohnson@theranos.com]; Hoda Alamdar[halamdar@theranos.com]
From: Silvia Chang
Sent: Sat 7/27/2013 12:30:56 AM
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Subject: Proficiency Testing Details
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Sunny,

Per your request, here are the details for handling, scheduling and submitting proficiency samples. I have attached the SOP for reference.

- Currently we are signed up with 3 different proficiency institutes: API, NYSP, and CAP. That way we cover a wider spectrum of assays we offer in house.
- Depending on the institute, there may be several test events per year following a shipping calendar with the category of tests listed (e.g. API's 1st test event was Chemistry, Immunology and Immunohematology).
- I created a calendar in Outlook listing the scheduled shipments of all 3 institutes with their respective due dates. This will allow us enough time to order reagents two weeks prior to the scheduled arrival of the proficiency samples.
- Once the proficiency samples arrive, we accessioned them into LABDAQ and treat them as they were patients.
- Multiple analytes can be tested on a single sample, and thus multiple analyzers need to be used. To reduce the opened stability of the sample, we create a plan assigning personnel and analyzers to each sample set. An example document is attached.
- Before testing, we follow the instructions listed on the proficiency documents to ensure proper pre-analytical techniques are followed.
- Depending on the institute, results can be entered into LABDAQ and transmitted electronically. API has a unique feature of allowing us to export a csv file and upload it into their system. Hoda can comment more on this. Other institutes like CAP and NYSP have a paperless option where we enter the results manually (no exporting).
- After submission, we get our scores back in about a month or two. If there are any discrepancies in values, we start an investigation and if needed, we order troubleshooting samples. Findings are recorded and documented. Any issues should be resolved at this point.

Adam/Kerry/Hoda – Please add to the list if I have missed anything.

Let me know if you have any question.

Thanks,

Silvia Chang

Lab Scientist

Theranos, Inc.

1601 S. California Av.

Palo Alto, CA 94304

(650) 492-9616

schang@theranos.com

Proficiency Testing and Alternative Assessment Procedure

Author(s):

Signature:	Date:
Name: Arnold B Gelb	Title: Laboratory Director

Reviewer(s):

Signature:	Date:
Name: Hoai P Nguyen	Title: Clinical Laboratory Scientist

Signature:	Date:
Name: Arnold B Gelb	Title: Laboratory Director

Approver(s):

Signature:	Date:
Name: Arnold B Gelb	Title: Laboratory Director

The medical/laboratory director or the director's designee should review all copies of this procedure at least once a year. The director should keep a log of the copies being maintained.

Reviewed By:	*Date:*	*Comments:*

Proficiency Testing and Alternative Assessment Procedure

CONTENTS

1 PURPOSE

1.1 This procedure describes those programs established and implemented to provide a mechanism to assess the accuracy of all test systems (assays) by means of Proficiency Testing performed in this laboratory.

2 SCOPE

2.1 This procedure applies to all assays performed in this laboratory.

3 DEFINITIONS AND ABBREVIATIONS

AAB	American Association of Bioanalysts
AAP	Alternative Assessment Procedure
API	American Proficiency Institute
CAP	College of American Pathologists
CMS	Centers for Medicare and Medicaid Services
PT	Proficiency Testing
SOP	Standard Operating Procedure
TP	Testing Personnel
TS	Technical Supervisor
QC	Quality Control

4 RESPONSIBILITIES

4.1 Laboratory Testing Personnel are responsible for the following:

4.1.1 Receiving and processing the proficiency testing samples

4.1.2 Reporting the results to the TS or designee for evaluation

4.1.3 Completing applicable fields on CL FRM-00006-F1 *Proficiency Testing Evaluation*

4.2 The Laboratory Technical Supervisor is responsible for the following:

4.2.1 Making sure that proficiency testing samples are identified and prepared for the Laboratory

4.2.2 Ensuring that over a 12 month PT cycle, samples representing the entire range of each assay are selected and submitted for testing

4.2.3 Evaluating proficiency testing sample results

4.2.4 Completing applicable fields on CL FRM-00006-F1 *Proficiency Testing Evaluation*

4.3 The Laboratory Director is responsible for the following:

4.3.1 Reviewing and approving each PT testing event documentation.

5 PROCEDURE

5.1 General Requirements

5.1.1 PT testing will be performed at the frequency required by approved commercial PT programs or a minimum of every 6 months for all tests not enrolled in an approved PT program.

5.1.2 All PT testing will be performed in the same manner as and part of the normal patient testing following the approved SOP for each test.

5.1.3 PT samples are not sent to any other laboratory for analysis.

5.1.4 Laboratory personnel are prohibited from communicating PT results with other clinical laboratories or their personnel.

5.1.5 Laboratory personnel will immediately report to the General Supervisor any PT samples received from outside laboratories.

5.1.6 The Technical or General Supervisor will report these cases to the Regional Office of CMS.

5.1.7 Specimen Testing

5.1.8 The PT specimens will be tested following the approved SOP for each test.

5.1.9 Proficiency testing samples are tested in the same manner as patient specimens and when possible, testing will be rotated through all testing personnel annually.

5.1.10 Proficiency testing samples are tested by personnel who routinely perform patient testing in the laboratory.

5.1.11 Proficiency testing samples are tested the same number of times routine patient samples are tested (i.e. re-testing of proficiency testing samples occurs only if similar re-testing routinely occurs for patient specimens.)

5.2 Commercial PT testing

5.2.1 As available, CMS-regulated and FDA-approved tests are enrolled in approved commercial PT programs.

5.2.2 The tests currently enrolled in a commercial PT program are listed in the current rev of CL ATT-00006-A1.

5.2.3 Laboratory personnel will follow all instructions provided by the commercial PT program for specimen handling, storage, testing, and results reporting and complete and submit all required documentation, as applicable. See CL ATT-00006-A3 for API electronic result reporting.

5.2.4 Upon receipt the PT scores will be reviewed by the TS or delegate.

5.2.5 Any unacceptable and/or unsatisfactory results will be thoroughly investigated to determine problems and root cause.

5.2.6 The TS or delegate will develop and implement corrective action(s) to minimize recurrence of the problem(s) identified.

5.2.6.1 The TS or delegate will document these activities on CL FRM-00006-F1 *Proficiency Testing Evaluation.*

5.2.7 Any testing events not scored by the PT organization will be evaluated by the TS to determine if results successfully demonstrated test accuracy using laboratory QC data and results distribution data supplied by the PT organization.

5.2.7.1 If the TS determines that test results failed to adequately demonstrate required accuracy he/she will launch a full investigation to determine possible problems and root cause.

5.2.7.2 As applicable the TS will develop and implement corrective action(s) to minimize recurrence of the problem(s) identified.

5.2.7.3 The TS will document these activities on CL FRM-00006-F1 *Proficiency Testing Evaluation.*

5.3 Alternative Assessment Procedure (AAP)

5.3.1 For non-CMS-regulated tests or those which lack FDA clearance, commercial or external PT programs may not be available for certain analytes. In such instances, an AAP may help validate the quality of ongoing test system performance.

5.3.2 In most cases, blind retesting of 3 – 5 patient samples by a different operator every 6 months is acceptable when a test is in active use (i.e., on the test menu; for any exceptions, see attachment A2).

5.3.3 Over time and when it is practical to obtain suitable samples, employ samples across the clinically relevant range of analysis.

5.3.4 Acceptability Criterion: For quantitative tests, limits of acceptability will be derived from recent QC data (i.e., mean ± 2 standard deviations) unless otherwise specified in Attachment A2. For qualitative tests, if at least 20 samples are available, construct a 2x2 contingency table and calculate a Kappa statistic by standard methods. Kappa values exceeding 0.6 are considered acceptable.

6 RECORDS

6.1 All PT records will be retained for a minimum of 3 years

7 ATTACHMENTS

7.1 CL ATT-00006-A1 Proficiency Testing by Analyte

7.2 CL ATT-00006-A2 Alternative Assessment Procedure by Analyte.

7.3 CL FRM-00006-F1 Proficiency Testing Evaluation

7.4 CL ATT-000006-A3 LabDAQ LIS API PT Export Instructions

8 REFERENCES

8.1 42 CFR Part 493 Subpart H, Participation in Proficiency Testing for Laboratories Performing Tests of

Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

8.2 42 CFR Part 493.1236, Standard: Evaluation of proficiency testing performance

8.3 42 CFR Part 493.1445, Standard: Laboratory Director Responsibilities

8.4 CLSI Guideline GP27

8.5 CLSI Guideline GP 29

9 REVISION HISTORY

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO Number**
A	06/09/2011	A. Gelb	CL ECO-00001
B	01/08/2012	A. Gelb	CL ECO-00041
C	11/27/2012	A. Gelb	CL ECO-00092
Section Number	**Description and Justification of Changes**		
All	Initial Release		
5.3, 7, 8	Title. Expanded AAP, attachments and references		
5.2.3, 7.4	Add attachment for electronic result reporting		

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