Message

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Sent: 4/14/2014 4:42:56 PM
To: Mark Pandori [mpandori@theranos.com]
CC: Sunny Balwani [sbalwani@theranos.com]
Subject: Emailing: CL SOP-00020_Profiency testing EDISON 3_5.docx

Mark and Sunny

Attached in the updated EDISON AAP protocol.

Regards,

Adam

Your message is ready to be sent with the following file or link attachments:

CL SOP-00020_Profiency testing EDISON 3_5.docx

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1 Purpose

1.1 The purpose of this proposal is to devise an alternative assessment protocol (AAP) for laboratory-developed tests on the EDISON 3.5 immunoassay instrument.

1.2 Guideline: 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.

2 Scope

2.1 The alternative assessment protocol (AAP) applies to all laboratory developed tests on the EDISON 3.5 instrument, and will be conducted immediately following the receipt of proficiency testing results from the American Proficiency Institute (API). The API conducts proficiency testing of all 4 Immunoassays offered at time of SOP drafting (tPSA, 25-OH Vit D, TSH, fT4) three times a year. The AAP should be conducted minimally every 6 months.

3 Responsibilities

3.1 It is the responsibility of the technical supervisor (TS), to ensure that the alternative assessment procedure (AAP) is conducted at least twice times a year for all 4 analytes.

3.2 Laboratory Testing Personnel are responsible for the following:

3.2.1 Receiving and processing the proficiency testing samples from in-house patient collections.

3.2.2 Reporting the results to the TS or designee for evaluation

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

3.3 The Laboratory Technical Supervisor is responsible for the following:

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

3.3.2 Ensuring that over a 12 month PT cycle, samples representing the entire range of each

assay are selected and submitted for testing

3.3.3 Evaluating proficiency testing sample results

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

3.4 The Laboratory Director is responsible for the following:

3.4.1 Reviewing and approving each PT testing event documentation.

4 Procedure

4.1 Obtain 5 venous clinical samples from an in-house collection.

4.2 Obtain also, 5 matching fingerstick (capillary specimens)

4.3 At least 10mL of K2-EDTA anticoagulated blood should be collected for the venous clinical specimens.

4.4 Run the predicate Siemens Immulite 2000 and Theranos LDT methods in parallel

4.5 Run 6 replicates of the Siemens Immulite test for each venous clinical sample- the mean of these runs is the "assigned value."

4.6 Run 1 replicate (singleton) for the Theranos method on the venous clinical sample

4.7 Run 1 replicate (singleton) for the Theranos method on the fingerstick clinical sample

4.8 Calculate the average bias of the Theranos method as follows: Average bias = mean (Theranos)-mean (Immulite)/mean (Immulite)

4.9 In the event that analyte samples, as determined by the predicate method, do not span the a clinically relevant medical decision level (CL-DOC-95010 (Appendix I), clinical samples should be supplemented ("spiked") with exogenous analyte to bring it into range.

5 Proficiency testing schedule

5.1 For the first year of testing with Theranos methods, the AAP will be conducted every week, for a total of 52 AAP PT events.

5.2 After the first year of testing with Theranos methods, the AAP frequency will be reduced to monthly events.

6 Acceptance criteria

6.1 The bias for the Theranos method run on venous blood (see 4.8) should not exceed the total allowable bias as stated in the assay validation report *(Allowable bias (%)=Total Allowable Error (%)-CV(%))*

6.2 The bias for the Theranos method run on fingerstick (capillary) blood (see 4.8) should not exceed the total allowable bias as stated in the assay validation report *(Allowable bias (%)=Total Allowable Error (%)-CV(%))*

6.3 If an analyte fails >20% (>1 out of 5) of the 5 patient clinical samples, then the proficiency will be deemed to have failed the proficiency event.

6.4 Proficiency for running Theranos methods on venous and fingerstick samples will be assessed independently.

6.5 If an analyte fails a proficiency event, corrective actions will be implemented, according to QOP-00006

6.6 If an analyte fails two consecutive proficiency events, testing will be discontinued for that analyte, until such time as the assay is corrected.

6.7 Proof of a correction of AAP PT is demonstrated by passing two consecutive AAP PT re-testing events.

6.7.1 Resumption of testing will only occur upon documentation and approval by the laboratory director.

6.7.2 All proficiency failures (including failure of 1 out of 5 challenges for an AAP PT event) will be documented and corrective action described, by the QA/QC director.

6.7.3 All documentation related to AAP PT will be reviewed and signed off by the laboratory director, or his/her designee.

7 RECORDS

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

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	11/26/2013	A. Rosendorff	ECO-000126
Section Number	**Description and Justification of Changes**		