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**From:** Langly Gee [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=LANGLY GEE5CB]  
**Sent:** 3/2/2014 1:14:35 AM  
**To:** Sunny Balwani [/o=theranos organization/ou=first administrative group/cn=recipients/cn=sbalwani]; Mark Pandori [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=mark pandori16d]  
**CC:** Erika Cheung [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=erika cheung80b]; Aurelie Soupe [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=aurelie soupped8a]; Romina Riener [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=romina rienerdb2]; Daniel Young [/o=theranos organization/ou=first administrative group/cn=recipients/cn=dyoung]; Sharada Sivaraman [/o=theranos organization/ou=first administrative group/cn=recipients/cn=ssivaraman]; Suraj Saksena [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=suraj saksena]; Tina Lin [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=tina lin942]; Adam Rosendorff [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=adam rosendorfd92]  
**Subject:** RE: New QC measure for Edisons

Sunny/All:

Attached is the study to compare predicate versus Edison's results for TSH, Vitamin D and FT4. Mark and Daniel has signed off on the study. Adam and Hoda has reviewed the draft and provided their comments.

Sharada and Suraj, please comment.

The study is to start March 10 and continue for four weeks. Data analysis will follow and determine next steps.

Any questions, let me know.

Langly

**From:** Sunny Balwani  
**Sent:** Tuesday, February 25, 2014 1:23 PM  
**To:** Mark Pandori  
**Cc:** Langly Gee; Erika Cheung; Aurelie Soupe; Romina Riener; Daniel Young; Sharada Sivaraman; Suraj Saksena; Tina Lin; Adam Rosendorff  
**Subject:** RE: New QC measure for Edisons  
**Importance:** High

Langley/All.

Please make sure that EDTA-Plasma (or appropriate matrix) is used for EDISONS and the appropriate ones for predicate methods. This may require collection of multiple vacutainer for this QC study. So #2 below should be Edison specific Vacutainer. Once we have done this for couple of times, we should remove the assays from the list for which we are doing this QC check. We have TREMENDOUS amount of data on Edisons and our ELISAs over last 6+ years to know they perform extremely well and for many assays, better than predicate methods. So this needs to be perfectly planned and perfectly executed. If CLIA team needs help pulling the right data then please include the appropriate team members. Also, I would like to see a project execution plan that CLIA should generate (Langley to own) and then Sharada, Suraj and Daniel will review and sign off before we begin this.

However, most important to me is the point that this needs to be communicated as to WHY are we doing this. This is to generate additional QC data across our entire CAPSYS and Normandy process. There should not be ANY doubts created about our assays and methods in the minds of CLIA or anyone outside CLIA. I am already extremely irritated by unplanned runs of PT samples around Vitamin D and others and how it was handled and communicated when no one from Edison team was included, provide opportunity to prepare, provide feedback before running these samples on Serum on Edisons. I don't want a repeat of this chaos again.

Please keep me in the loop and updated in real time.

Let me know if there are any questions or confusion.

Thanks.

**From:** Mark Pandori  
**Sent:** Monday, February 24, 2014 3:27 PM  
**To:** Langly Gee; Erika Cheung; Jamie Liu; Aurelie Souppe; Romina Riener  
**Cc:** Adam Rosendorff  
**Subject:** New QC measure for Edisons

All,

As per our earlier discussion:

We will be applying a new Quality measure to our Edison tests.

Going forward, *once per week*, (Wednesday the first week, Monday thereafter) we will be collecting and comparing 5 samples as follows:

1. Venipuncture on predicate (SST for Vit D, EDTA for others)
2. Venipuncture on Edison
3. Fingerstick on Edison

Such comparisons will be performed initially using these four tests: Vit D, TPSA, FT4, TSH. We will add more tests to this process over time.

I have submitted the Inhouse Study request forms, and I've indicated for the collection people to notify Langly, Erika and Jamie by email once the specimens are ready.

The data generated will be sent to Langly, who will tabulate and compare the results.

Thank you for your work and cooperation with this.

Mark Pandori

**Author(s):**

Signature:	Date:
Name: Langly Gee	Title: QA/QC Manager

**Reviewer(s):**

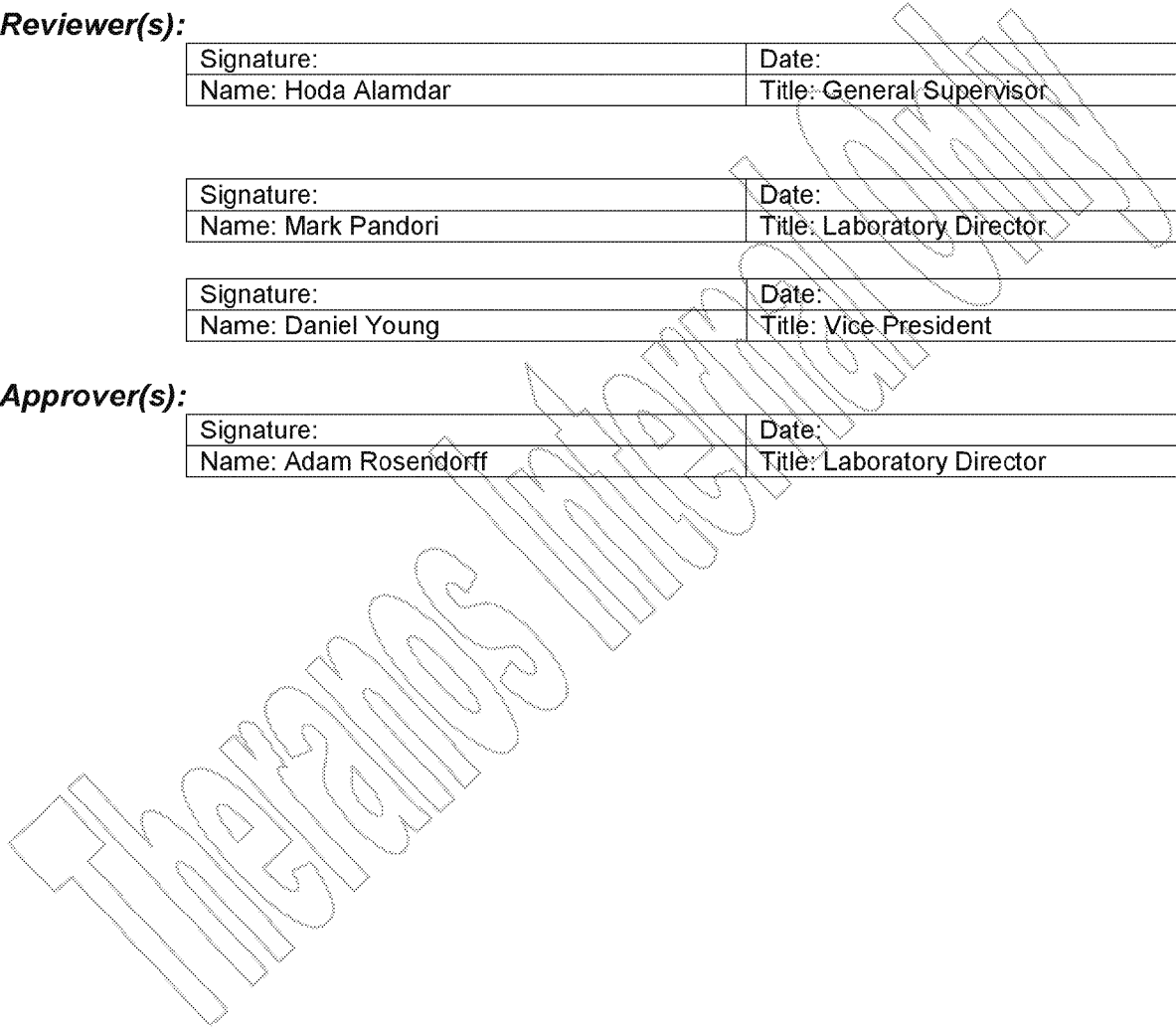
Signature:	Date:
Name: Hoda Alamdar	Title: General Supervisor

Signature:	Date:
Name: Mark Pandori	Title: Laboratory Director

Signature:	Date:
Name: Daniel Young	Title: Vice President

**Approver(s):**

Signature:	Date:
Name: Adam Rosendorff	Title: Laboratory Director



## theranos

- Purpose:** To test AAP protocols for Theranos methods for ft4, TSH and Vitamin D
- References:** CL SOP-00020 Current Rev. Proficiency Testing for Theranos Lab-Developed Tests: Edison 3.5
- CL SOP-09201 Rev. A. Siemens IMMULITE 2000 Third Generation TSH in Serum or Plasma
- CL SOP-09205 Rev. A Siemens IMMULITE 2000 Free T4 Assay in Serum or Plasma
- CL SOP-09400 Rev. A Vitamin D 25-OH Total Assay on DiaSorin LIAISON Analyzer
- CL SOP-19001 Rev. A Thyroid Stimulating Hormone on Edison 3.5 Theranos System
- CL SOP-19002 Rev. A Total 25-OH Vitamin D on Edison 3.5 Theranos System
- CL SOP-19003 Rev. A Free Thyroxine on Edison 3.5 Theranos System
- CL SOP-19007 Rev. X SOP, <Edison 3.5 Periodic QC>
- CL SOP-00023 Rev. B Westgard and Levey-Jennings Quality Control

**Materials:** EDTA CTN (double sided EDTA)  
Purple top venous  
SST venous

**Procedure:**

- 1.0 Every Monday, preferably, between 9AM and 11AM, for the next four weeks, five Theranos employees, males and females with various ages, weight and ethnicity will be drawn for both venous and Fingerstick at 1601. Each employee will be drawn one purple top venous, one SST venous and two EDTA CTN (double sided EDTA) Fingerstick. Phlebotomist will follow their internal procedure concerning safety, proper handling of samples and will de-identify any Protected Health Information from the CLIA testing personnel. Phlebotomist will also randomly vary employees from week to week to limit the number of times an employee is drawn for this study.
- 1.1 After samples from the five employees are collected, the phlebotomist will place samples in the 2-8°C CLIA refrigerator and alert CLIA personnel by email.
- 1.2 Predicate Method:
  - TSH – Siemens Immulite 2000
  - ft4 – Siemens Immulite 2000
  - Vitamin D – DiaSorin LIAISON

## 1.3 Theranos Method:

TSH – Edison 3.5 (6-tip Capsys)  
FT4 - Edison 3.5 (6-tip Capsys)  
Vitamin D – Edison 3.5 (6-tip Capsys)

- 1.4 Ensure extra inventory of controls, reagents and cartridges are available to perform this study in addition to regular patient testing. As a suggestion, 60 extra tests per month on Immulite and LIAISON and 30 extra tests for Edison per month (plus additional controls for 4 additional runs per month).
- 1.5 Ensure staff are trained and have documented their training for the SOPs being performed.
- 1.6 Perform appropriate daily, weekly and or monthly maintenance on the instruments prior to running quality controls. If maintenance does not pass, inform a CLS.
- 1.7 Run appropriate quality controls and verify it has passed and no Westgard rules are violated prior to running samples. Inform a CLS, if quality controls failed.
- 1.8 Remove samples from refrigerator and label samples appropriately with the Date and sample number (i.e. 3/3/14 S1, 3/3/14 S2, etc.).
- 1.9 Run venous samples in replicates of three (n=3) on the predicate methods following the SOPs listed in the reference section. Run venous and Fingerstick samples in singlet (n=1) on the Theranos methods following the SOPs listed in the reference section.
- 1.10 Submit electronic results from each assay to QA/QC, Daniel Young, Adam Rosendorff, Mark Pandori, Hoda Alamdar, Suraj Saxena and Sharada Sivaraman.
- 1.11 QA/QC to tabulate results for each sample and determine mean, standard deviation and CV, as appropriate.
- 1.12 Compare venous and Fingerstick results versus predicate results for each sample as a percent recovery.

Acceptance Criteria: Quality Controls must all pass

Post Study: After the analyzes of the four weeks of data, a meeting will be held to determine next steps and to design further acceptance criteria.

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	Pred, S	Edison, S	Edison, EDTA-plasma
TSH			
ft4			
25-OH VitD			

Theranos Internal Only