

**To:** Jamie Liu[jliu@theranos.com]  
**From:** Erika Cheung  
**Sent:** Wed 2/26/2014 7:07:37 PM  
**Importance:** Normal  
**Subject:** FW: New QC measure for Edisons  
**Received:** Wed 2/26/2014 7:07:37 PM

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**From:** Sunny Balwani  
**Sent:** Tuesday, February 25, 2014 2:19 PM  
**To:** Adam Rosendorff; Mark Pandori  
**Cc:** Langly Gee; Erika Cheung; Aurelie Souppe; Romina Riener; Daniel Young; Sharada Sivaraman; Suraj Saksena; Tina Lin  
**Subject:** RE: New QC measure for Edisons

This is what we did for all of our validation work we did for each of these assays when we brought them for CLIA. I am not sure what new information we will get but if you want to rerun this once to generate QC data, I have no issues with the following as communicated yesterday. this one time will be useful to clarify any confusion caused by the PT samples.

We can then decide how often we need to do this. this is something you and Mark can decide and then Langley can implement.

Thanks.

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**From:** Adam Rosendorff  
**Sent:** Tuesday, February 25, 2014 1:29 PM  
**To:** Sunny Balwani; Mark Pandori  
**Cc:** Langly Gee; Erika Cheung; Aurelie Souppe; Romina Riener; Daniel Young; Sharada Sivaraman; Suraj Saksena; Tina Lin  
**Subject:** RE: New QC measure for Edisons

Sunny

Just to clarify, EDISONS are EDTA-plasma and the majority of immunoassays on the predicate instruments are serum.

With this study, we will collect EDTA-plasma CTNs (for EDISON assays), and the right vacutainer (mostly red-top serum vacutainers) for the predicate assays.

I will work with Langly before we submit the plan to Daniel and yourself.

Adam

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**From:** Sunny Balwani  
**Sent:** Tuesday, February 25, 2014 1:23 PM  
**To:** Mark Pandori  
**Cc:** Langly Gee; Erika Cheung; Aurelie Souppe; 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.

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**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