

To: Elizabeth Holmes[eholmes@theranos.com]
From: Sunny Balwani
Sent: Thur 8/22/2013 10:05:00 PM
Importance: Normal
Subject: FW: *Important Demo this Thursday, 8/22** - PLEASE REPLY
Received: Thur 8/22/2013 10:04:00 PM

From: Surekha Gangakhedkar
Sent: Thursday, August 22, 2013 2:57 PM
To: Sunny Balwani; Daniel Edlin; Daniel Young
Subject: RE: *Important Demo this Thursday, 8/22** - PLEASE REPLY

Hi Sunny,

This cartridge was a recent build, given the issues that we have seen with evaporation of reagents in the previous builds, the date of expiration was also lowered. The last time this lot was used was for the demo on 8/13 where all the runs went well with no failures. The same lot was used for re-calibration of TT3 yesterday. So all efforts have been made to QA or troubleshoot this cartridge.

With the present run, here is the break-up of the results:

1. TPO – OORL result is Normal
2. Tg Ab – OORL due to Substrate evaporation. This has been a known problem for many years and there is no way to QC a sealed cartridge.
3. TT4 – Result reported
4. TT3 – OORL – This assay was recalibrated yesterday. The issue with this run is that the range of the calibration RLU is between 49,000 to 1500 RLU. The RLU for this tip was 293326. This points to carry over/contamination during the run and not related to assay issues.
5. TSH – Result reported, in range
6. FT4 – Result reported, High. Since we do not have sample to test on the reference method, not possible to make a conclusion on the high results.

Surekha

From: Sunny Balwani
Sent: Thursday, August 22, 2013 1:58 PM
To: Daniel Edlin; Surekha Gangakhedkar; Daniel Young
Subject: RE: *Important Demo this Thursday, 8/22** - PLEASE REPLY

To say this is deeply disappointing will be a gross understatement. We have been asking to get this cartridge built and QAed and tested for months now and every single run we have had on thyroid panel has been a disaster.

I am not even going to ask why this keep happening at this point.

From: Daniel Edlin
Sent: Thursday, August 22, 2013 1:56 PM
To: Sunny Balwani
Subject: FW: *Important Demo this Thursday, 8/22** - PLEASE REPLY

Sunny,

Unfortunately by the looks of the Thyroid panel results below it appears to have had major issues again. This is after calibration was re-done yesterday, after a clinical correction was put in place for TT3, and after Daniel reviewed recent data and said he was confident that at least 5 of these results would work.

Dan

From: Surekha Gangakhedkar
Sent: Thursday, August 22, 2013 1:46 PM
To: Daniel Edlin; Daniel Young
Subject: RE: *Important Demo this Thursday, 8/22** - PLEASE REPLY

Date 8/22/213UD

Sample ID	Sample Matrix	Test	HCT Factor	Whole Blood Result	Serum Equivalent Result	Unit
	Whole Blood EDTA	TPO	1.60			IU/mL
		Tg Ab	1.00			IU/mL
		TT4	1.00			ug/dL
		TT3	1.00			ng/dL
		TSH	1.60			uIU/mL
		ft4	1.60		ng/dL

From: Daniel Edlin
Sent: Thursday, August 22, 2013 12:23 PM
To: Daniel Young; Paul Patel; Kwesi Mercurius; Prasad Gawande; Surekha Gangakhedkar; Tina Noyes; Sharada Sivaraman; Chinmay Pangarkar; Nishit Doshi; Marilyn Nourse; Elaine Than; Xinwei Sam Gong
Cc: Samartha Anekal; Christian Holmes
Subject: RE: *Important Demo this Thursday, 8/22** - PLEASE REPLY

All,

Once completed, please send your results to Daniel and me for review and compilation.

Thanks very much

From: Daniel Edlin
Sent: Thursday, August 22, 2013 11:31 AM
To: Daniel Young; Paul Patel; Kwesi Mercurius; Prasad Gawande; Surekha Gangakhedkar; Tina Noyes; Sharada Sivaraman; Chinmay Pangarkar; Nishit Doshi; Marilyn Nourse; Elaine Than; Xinwei Sam Gong
Cc: Samartha Anekal; Christian Holmes
Subject: RE: *Important Demo this Thursday, 8/22** - PLEASE REPLY

Hello all,

I'm heading in to collect the finger stick sample, please be ready to meet in the lab in the next few minutes.

Thanks,

Dan

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From: Daniel Young

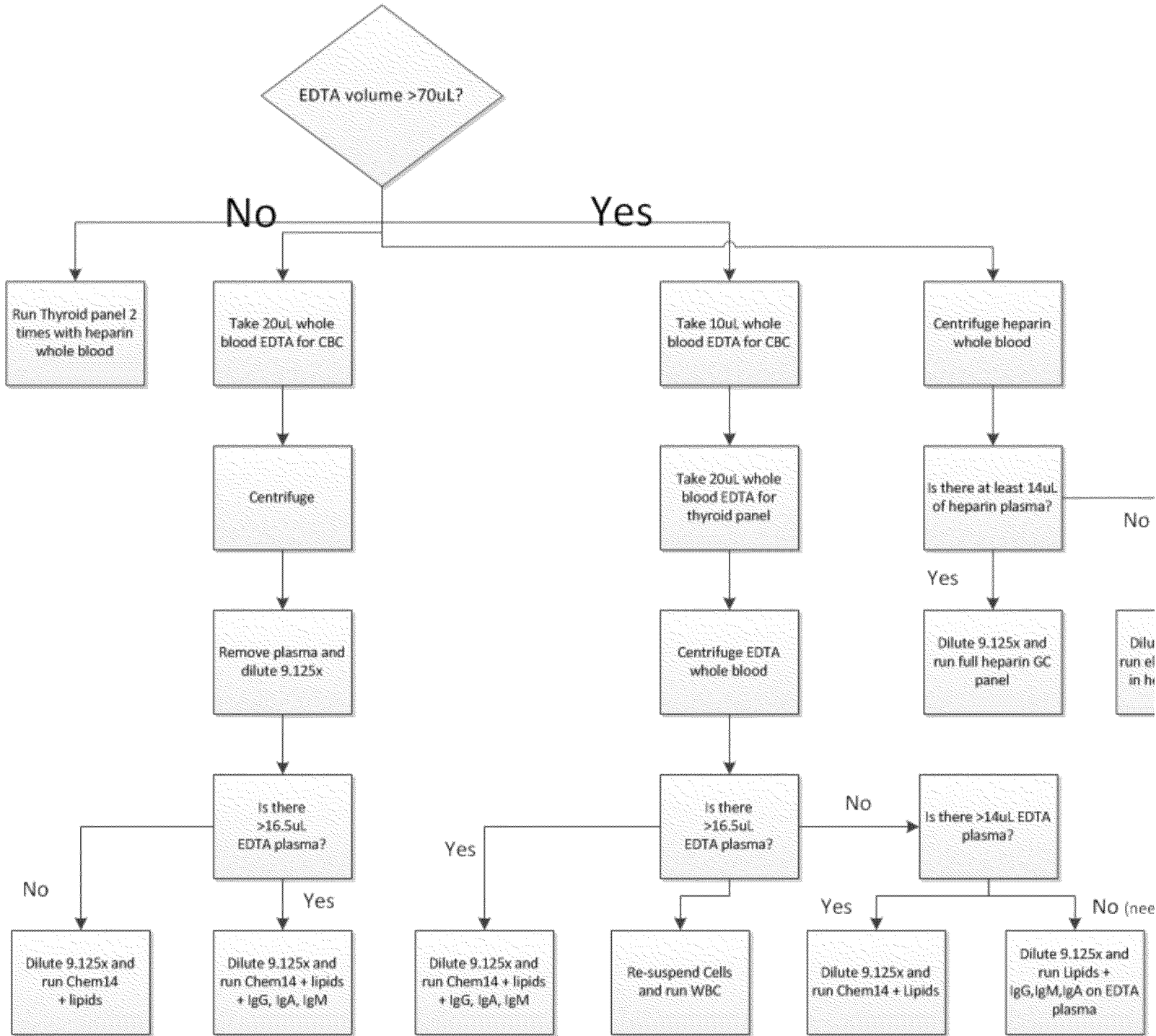
Sent: Wednesday, August 21, 2013 8:40 PM

To: Daniel Edlin; Paul Patel; Kwesi Mercurius; Prasad Gawande; Surekha Gangakhedkar; Tina Noyes; Sharada Sivaraman; Chinmay Pangarkar; Nishit Doshi; Marilyn Nourse; Elaine Than; Xinwei Sam Gong

Cc: Samartha Anekal; Christian Holmes

Subject: RE: *Important Demo this Thursday, 8/22** - PLEASE REPLY

Please review the proposed workflow for tomorrow's demo (very similar to last week):



From: Daniel Edlin

Sent: Wednesday, August 21, 2013 4:52 PM

To: Paul Patel; Kwesi Mercurius; Prasad Gawande; Surekha Gangakhedkar; Tina Noyes; Sharada Sivaraman; Chinmay Pangarkar; Nishit Doshi; Marilyn Nourse; Elaine Than; Michael Chen; Gayle Lee; Pey-Jiun Ko; Clarissa Lui; Derek Xing

Cc: Daniel Young; Samartha Anekal; Christian Holmes

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THPFM0002698495

Subject: RE: *Important Demo this Thursday, 8/22** - PLEASE REPLY

Importance: High

Hello all,

I wanted to check in with everyone here to make sure we are ready for tomorrow's demo which will start at 10:30AM. We will need to make sure that this goes flawlessly.

Please reply with the status of being able to run the assays below on your respective platforms.

Similar to the demo workflow from 8/13, we will plan to run CBC, Chem 14, Lipids, and Thyroid Panel on the sample.

Do let me know if there are any questions, issues or concerns that need to be addressed beforehand.

Thank you,

Dan

From:Daniel Edlin

Sent: Tuesday, August 20, 2013 3:51 PM

To: Paul Patel; Kwesi Mercurius; Prasad Gawande; Surekha Gangakhedkar; Tina Noyes; Sharada Sivaraman; Chinmay Pangarkar; Nishit Doshi; Marilyn Nourse; Elaine Than; Michael Chen; Gayle Lee; Pey-Jiun Ko; Clarissa Lui; Derek Xing

Cc: Daniel Young; Samartha Anekal; Christian Holmes

Subject: **Important Demo this Thursday, 8/22**

Importance: High

Hello all,

This Thursday 8/22 we will be hosting a demo at our offices. There will be one male patient, one finger stick draw, and timing is TBD (sometime between 10:30AM – 4PM).

I will follow with an updated workflow, but planned tests will consist of some combination of the following: CBC, Chem 14, Lipids, Thyroid panel or Male Health.

For this demo we will need to turn around results faster than ever before- ideally in 1 hour and no longer than 2 hours.

Product Egr Team - please prepare:

- 5 BCDs
- 2 Urine Vessels
- Conditioned shipping box (I have this and will return it)
- 5 Finger warmers

Sam and Michael – similar to last week, please set up two minilabs, one 4s, and one 3.5 in Interview Room #1. The minilabs, 4s, and 3.5 should have the Demo App that can run null protocols.

Can everyone here please bring up any questions, concerns, or issues with being able to do the above ASAP so we can work on addressing them before Thursday.

For example, are there any developments on:

- BCD issues for GC assays

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THPFM0002698496

- TT3 – verify whole blood vs. plasma correlations

I will update everyone with additional details as I receive them.

Thanks,
Dan

