

To: Elizabeth Holmes[eholmes@theranos.com]; Sunny Balwani[sbalwani@theranos.com]
Cc: Daniel Young[dyoung@theranos.com]; Christian Holmes[cholmes@theranos.com]
From: Daniel Edlin
Sent: Sat 6/1/2013 11:57:35 PM
Importance: Normal
Subject: RE: Demo report coordination
Received: Sat 6/1/2013 11:57:36 PM
Theranos Lab Report, .pdf

Great. The changes have been made to the attached report. I will send it shortly.

From: Elizabeth Holmes
Sent: Saturday, June 01, 2013 4:56 PM
To: Sunny Balwani
Cc: Daniel Young; Daniel Edlin; Christian Holmes
Subject: Re: Demo report coordination

Agree b

On Jun 1, 2013, at 7:48 PM, "Sunny Balwani" <sbalwani@theranos.com> wrote:

We should do that because that's what all computerized LIS systems will do. No fuzzy logic...

From: Elizabeth Holmes
Sent: Saturday, June 01, 2013 4:47 PM
To: Daniel Young
Cc: Daniel Edlin; Sunny Balwani; Christian Holmes
Subject: Re: Demo report coordination

Ok let's send it out after these changes. I assume it is best practice to leave the H and L respectively for the ones that are just one point out of range - I have seen some reports that don't flag it.

On Jun 1, 2013, at 7:44 PM, "Daniel Young" <dyoung@theranos.com> wrote:

Total Hb should have a "L" next to it.

I think "Basic Cell Blood Count" makes sense since we do not have platelets this time.

Otherwise I think it is good to go.

From: Elizabeth Holmes
Sent: Saturday, June 01, 2013 4:42 PM
To: Daniel Edlin
Cc: Daniel Young; Sunny Balwani; Christian Holmes
Subject: Re: Demo report coordination

Pending my last email,

Daniel - assuming you agree with the three out of ranges (at least two are clearly right on the edge) - we'll send it out now.

On Jun 1, 2013, at 6:31 PM, "Daniel Edlin" <dedlin@theranos.com> wrote:

The final report is attached.

Thanks,

Dan

From: Elizabeth Holmes
Sent: Saturday, June 01, 2013 3:29 PM
To: Daniel Edlin
Cc: Daniel Young; Sunny Balwani; Christian Holmes
Subject: Re: Demo report coordination

Go ahead and prepare final report I'll review in parallel

On Jun 1, 2013, at 5:57 PM, "Daniel Edlin" <dedlin@theranos.com> wrote:

Sorry about that, that's correct.

From: Daniel Young
Sent: Saturday, June 01, 2013 2:54 PM
To: Daniel Edlin; Elizabeth Holmes
Cc: Sunny Balwani; Christian Holmes
Subject: RE: Demo report coordination

You mean Mumps IgG has been added to CMP section, and total Hb is with CBC panel, correct?

From: Daniel Edlin
Sent: Saturday, June 01, 2013 2:51 PM
To: Elizabeth Holmes; Daniel Young
Cc: Sunny Balwani; Christian Holmes
Subject: RE: Demo report coordination

Please see the updated report attached. Note that Total Hb has been added to the Complete Metabolic Panel section.

I will insert the name once finalized and before sending the report out.

Per the two data points below: the report does not include results for an HbsAg test, and we didn't specify what we would be testing in the meeting and thus we may not have even tested for her out of range result.

Please indicate if any changes need to be made to the report or if there are any questions.

Thanks

From: Elizabeth Holmes
Sent: Saturday, June 01, 2013 2:36 PM
To: Daniel Young
Cc: Daniel Edlin; Sunny Balwani
Subject: Re: Demo report coordination

Two other data points on this patient:

1. She mentioned she would be positive for hbsag and had been vaccinated for it
2. She mentioned she "had one thing" in her blood that would be abnormal.

On Jun 1, 2013, at 5:11 PM, "Daniel Young" <dyoung@theranos.com> wrote:

- For Measles, the cut-off value is around 142 mIU/mL, but this was not age controlled and a relatively small cohort. There are no national standards for this.
- For Rubella, we have not established a cut-off.

Dan, for Bilirubin, total, can you change the reference range to 0.1 – 1.0, and remove the “L” indicator, please?

Calcium while low, does not seem overly concerning. Dan, can you change the range to 8.4 – 10.7? It does not change the outcome, but shows the result to be closer to the reference range.

Chloride and Sodium are just on the edge of our reference range.

HDL is slightly low as well, and is not too concerning.

-Daniel

From: Elizabeth Holmes
Sent: Saturday, June 01, 2013 1:36 PM
To: Daniel Young
Cc: Daniel Edlin; Sunny Balwani
Subject: Re: Demo report coordination

Yes. And not include in the other run. Do let me know if there's a negative 'cut off' that has been otherwise established -

On Jun 1, 2013, at 4:30 PM, "Daniel Young" <dyoung@theranos.com> wrote:

We could label Measles IgG and Rubella IgG “Positive” for both NY and PA results, making them qualitative instead of quantitative results.

So then the only difference would be for Mumps

IgG. So we can show this result in the non-infectious panel area of the report as Positive?

-Daniel

From: Elizabeth Holmes
Sent: Saturday, June 01, 2013 1:18 PM
To: Daniel Young
Cc: Daniel Edlin; Sunny Balwani
Subject: Re: Demo report coordination

Agree on the PA measles result. We'll only include that one from PA. I would integrate the PA only infectious results with the rest of the report results and then only call out as infectious the ones we show for both PA and NY.

On Jun 1, 2013, at 4:13 PM, "Daniel Young" <dyoung@theranos.com> wrote:

Furthermore for Measles IgG, the value in the first run was 42 mIU/mL, which is low - below the level we would expect from a subject who was previously infected or vaccinated for measles. Greater than 95% of women about 50 years of age in the US test positive for Measles IgG. So this is another indication that the higher values in the second run are better.

-Daniel

From: Daniel Young
Sent: Saturday, June 01, 2013 12:26 PM
To: Elizabeth Holmes; Daniel Edlin
Cc: Sunny Balwani
Subject: RE: Demo report coordination

Yes, I trust the second run in PA. Over 90% of people approximately 50 years of age should test positive for Mumps IgG based on published seroprevalence studies.

So I think that all the higher values from the second run are likely better as well.

-Daniel

From:Elizabeth Holmes
Sent: Saturday, June 01, 2013 11:45 AM
To: Daniel Edlin
Cc: Daniel Young; Sunny Balwani
Subject: Re: Demo report coordination

Daniel - is our read that the second run in PA is the most accurate for all three discrepancies?

On Jun 1, 2013, at 1:08 PM,
"Daniel Edlin"
<dedlin@theranos.com> wrote:

Thanks, Daniel. Please find the revised report incorporating the correction/updates suggested below to the Chem14/CBC sections.

Elizabeth – please advise on how to report the infectious panel results. I filled a 35 ul BTB for the NYC draw, so I doubt that there would have been an issue with volume. We are still waiting to hear back from Mike regarding the anti-coagulant concentration on the 35ul BTB.

Thanks,

Dan

From:Daniel Young
Sent: Saturday, June 01, 2013 9:14 AM
To: Elizabeth Holmes; Daniel Edlin
Cc: Sunny Balwani
Subject: RE: Demo report coordination

Some correction/updates for this patient report:

- Alanine Aminotransferase: should be ref range 7 -45
- Alkaline Phosphatase: ref range 39 – 100
- Creatinine: ref range 0.5 – 0.8
- Sodium: technically is it just low;
- Total Hb: ref range should be 12 -15.5; patient is low

For Mumps IgG, I am inclined to believe that the run in PA is correct (positive) for a number of reasons. First, it is very likely that the subject is positive, since IgG means that they had an infection of mumps sometime in the past or have been immunized. Also, all tests ran higher in the second run in Palo Alto, suggesting that to me that the assay runs were a little low in the run in NYC (not sure why). There could have been too little sample in the first run, a problem in the dilution, or an issue with the cartridge.

I am not sure how best to report the results for the first run. But I do think that the “negative” for Mump IgG is wrong from the first run. We could not report Mumps for either run, or correct it for the first run.

-Daniel

From: Elizabeth Holmes
Sent: Saturday, June 01, 2013 7:17 AM
To: Daniel Edlin
Cc: Daniel Young;
Sunny Balwani
Subject: Re: Demo
report coordination

The discrepancy will be a problem. We need to see if we can correct for it.

On Jun 1, 2013, at 6:26 AM, "Daniel Edlin"
<dedlin@theranos.com>
wrote:

For some
context
re: the
infectious
disease
panels:

Test #1 –
sample
was
collected
using a
BTD,
deposited
directly
into a
cartridge,
and run
onsite.
The
cartridge
had been
shipped to
NYC in
standard
packaging
(in
Styrofoam
with ice
packs).

Test #2 –
sample

was aliquoted from the BCD 2.1 nanotainers, pipetted directly into a cartridge, and run at Theranos.

Both cartridges were run on the same reader.

Thanks,

Dan

From: Daniel Edlin
Sent: Saturday, June 01, 2013 3:18 AM
To: Daniel Young
Cc: Elizabeth Holmes; Sunny Balwani
Subject: RE: Demo report coordination

Hi Daniel,

Please find today's lab report attached, for review. The subject is a female in her 50s.

It looks

like there
is some
discrepancy
between
the two
Infectious
Panel runs
– any
thoughts
on why
this is the
case?

Note that
I grouped
Total Hb
with the
Complete
Metabolic
Panel
assays,
but please
advise if it
should be
in a
different
section. If
any other
adjustments
need to
be made
do let me
know.

Thanks,

Dan

From: Daniel
Young
Sent:
Friday,
May 31,
2013
10:34 PM
To: Daniel
Edlin
Subject:
Re: Demo
report
coordination

I will
review
results by
9am.

Thanks,

Daniel

On May
31, 2013,
at 10:26
PM,
"Daniel
Edlin"
<dedlin@theranos.com>
wrote:

Hi Daniel,

Given that the samples are being run at this late hour, I just want to touch base with you to ensure that we're coordinated for these reports.

A couple questions about the results reporting:

- Can you please confirm the units below and the reference ranges for these assays?
- Will any of the reference ranges change for the other assays given that the subject today was a female? For reference I have attached a spreadsheet comparing the reference ranges for last two demos we did – the one from earlier this week (male subject), and the last time we took the sample and sent it back from Phoenix (female subject). I have highlighted the differences in yellow.

Also – assuming that results are to you and me overnight, when do you think you will be able to review these tomorrow? I'll base my schedule on your availability so that we can finalize the reports and get them to EAH for approval as soon as possible.

Thanks,

Dan

From: Surekha Gangakhedkar
Sent: Friday, May 31, 2013 1:27 PM
To: Daniel Edlin; Daniel Young
Subject: Results for Infectious run this morning

Here are the results:

	Assay	Result	Units
5/31_Run 1	HSV1 antibody	Negative	Qualitative
	Chagas IgG	Negative	Qualitative
	Rubella IgG	6	IU/mL
	Measles IgG	42.07	mIU/mL
	Mumps IgG	Negative	Qualitative
	HIV 1/2 antibody	Negative	Qualitative

From:Daniel Edlin
Sent: Friday, May 31, 2013 11:59 AM
To: Surekha Gangakhedkar; Sukhdev Baniwal; Sandhya Kaippa
Cc: Daniel Young
Subject: RE: Sample running right now

Surekha or Sandhya,
Can you please send the 3.0 results to Daniel Y?

Daniel can you please review and provide reference ranges as well for the lab report?

Note that the same donor gave blood for the 3.0 run as well as the run scheduled for tonight, and we will be comparing results.

Thanks,
Dan

Sent from my Windows Phone

From:Surekha Gangakhedkar
Sent:5/31/2013 2:28 PM
To:Daniel Edlin; Sukhdev Baniwal; Sandhya Kaippa
Cc:Daniel Young
Subject:RE: Sample running right now

Sharada confirmed that the run time is around 1 hr 15 min.

From:Daniel Edlin
Sent: Friday, May 31, 2013 11:27 AM
To: Sukhdev Baniwal; Sandhya Kaippa
Cc: Daniel Young; Surekha Gangakhedkar
Subject: RE: Sample running right now

Sandhya and Surekha indicated that the run time should have been 43 minutes. Did something change?

Sent from my Windows Phone

From:Sukhdev Baniwal
Sent:5/31/2013 2:25 PM
To:Daniel Edlin; Sandhya Kaippa
Cc:Daniel Young
Subject:RE: Sample running right now

It took<duration>1:25:52.227343</duration>

There is no errors in the log. Will have to investigate the debug log; to get more info. I think the normal time is 1hr 15 min.

Sukhdev

From:Daniel Edlin
Sent: Friday, May 31, 2013 11:04 AM
To: Sukhdev Baniwal; Sandhya Kaippa
Cc: Daniel Young
Subject: RE: Sample running right now

Why did it take so long to run?

Sent from my Windows Phone

From:Sukhdev Baniwal
Sent:5/31/2013 2:01 PM
To:Daniel Edlin; Sandhya Kaippa
Cc:Daniel Young; Elizabeth Holmes
Subject:RE: Sample running right now

Successful log is received on the server from reader e000325.

Sukhdev

From:Daniel Edlin
Sent: Friday, May 31, 2013 10:47 AM
To: Daniel Edlin; Sandhya Kaippa
Cc: Sukhdev Baniwal; Daniel Young; Elizabeth Holmes
Subject: RE: Sample running right now

Cc Ing sukhdev and Daniel. Please advise asap.

Thanks.

Sent from my Windows Phone

From:Daniel Edlin
Sent:5/31/2013 1:45 PM
To:Sandhya Kaippa
Subject:RE: Sample running right now

What can be done to fix this?

Sent from my Windows Phone

From:Sandhya Kaippa
Sent:5/31/2013 1:44 PM
To:Daniel Edlin
Subject:RE: Sample running right now

Log has not arrived the server. Still in 'getprotocol' state.

From:Daniel Edlin
Sent: Friday, May 31, 2013 10:41 AM
To: Sandhya Kaippa
Cc: Surekha Gangakhedkar; Daniel Young
Subject: RE: Sample running right now

What is the status? It's already been running for 1 hr 15 mins and has been stuck on 99% for about 8 minutes.

Sent from my Windows Phone

From:Sandhya Kaippa
Sent:5/31/2013 1:31 PM
To:Daniel Edlin
Subject:RE: Sample running right now

Yes I do and a get protocol request with barcode126245639802500014

From:Daniel Edlin
Sent: Friday, May 31, 2013 10:30 AM
To: Sandhya Kaippa
Subject: Sample running right now
Importance: High

Hi Sandhya,

We are currently running the infectious diseases panel (126) on e000325. Have you seen a heartbeat and has it registered on the server?

Sent from my Windows Phone

<Demo Reference Range Comparison.xlsx>

<Demo Patient
5.31.xlsx>

<Theranos Lab Report 5.31.pdf>



Theranos Test Report Technology Demonstration

Theranos, Inc.
1601 S. California Ave, Palo Alto CA 94304

05/31/13

PATIENT INFORMATION

PATIENT NO.	
D.O.B.	Unknown
AGE / GENDER	N/A / F
PT MEDICATIONS	Unknown
ORDERING MD	N/A *Technology Demonstration*

TEST DETAIL

SPECIMEN (S) COLLECTED	5/31/2013
LAB ACCOUNT NO.	N/A *Technology Demonstration*
SPECIMEN (S) COLLECTED	Blood
DATE REPORTED	5/31/2013
COMMENTS	N/A *Technology Demonstration*

COMPLETE METABOLIC PANEL

TEST NAME	PATIENT'S RESULTS	REF. RANGE	UNITS
Alanine Aminotransferase	7	7 - 45	U/L
Albumin	4.3	3.2 - 5.0	g/dL
Alkaline Phosphatase	59	39 - 100	U/L
Aspartate Aminotransferase	27	8 - 48	U/L
Bilirubin, Total	0.1	0.1 - 1.0	mg/dL
Calcium	L 7.8	8.4 - 10.7	mg/dL
Carbon Dioxide (HCO3)	29	20 - 31	mEq/L
Chloride	H 110	99 - 109	mEq/L
Creatinine	0.8	0.5 - 0.8	mg/dL
Glucose	96	70 - 140	mg/dL
Potassium	4.5	3.5 - 5.0	mmol/L
Sodium	L 131	132 - 146	mmol/L
Total Protein	7.1	5.7 - 8.2	g/dL
Urea Nitrogen (BUN)	22	8 - 24	mg/dL
Mumps IgG	Positive		Qualitative

Key: L = Slightly Below Reference Range, H = Slightly Above Reference Range, WNL = Within Normal Limits, * = Critical Value

LIPID PANEL

TEST NAME	PATIENT'S RESULTS	REF. RANGE	UNITS
Triglycerides	68	0 - 200	mg/dL
HDL Cholesterol	L 36	> 40	mg/dL
LDL Cholesterol	122	0 - 130	mg/dL
Total Cholesterol	197	0 - 240	mg/dL
VLDL Cholesterol	14	5 - 30	mg/dL

Key: L = Slightly Below Reference Range, H = Slightly Above Reference Range, WNL = Within Normal Limits, * = Critical Value

BASIC CELL BLOOD COUNT

TEST NAME	PATIENT'S RESULTS	REF. RANGE	UNITS
Basophil Count	0.02	0.0 - 0.1	10e3/uL
Eosinophil Count	0.08	0.0 - 0.4	10e3/uL
Lymphocyte Count	2.2	0.8 - 3.1	10e3/uL
Monocyte Count	0.3	0.2 - 0.7	10e3/uL
Neutrophil Count	3.8	1.3 - 7.0	10e3/uL
RBC Count	4.58	4.32 - 5.72	10e6/uL
WBC Count	6.4	3.2 - 10.6	10e3/uL
Basophil, %	0.3	0 - 2	%
Eosinophil, %	1.3	0 - 6	%
Lymphocyte, %	34	15 - 43	%
Monocyte, %	4.9	4 - 8.9	%
Neutrophil, %	60	44 - 76	%
Total Hb	L 10.4	12 - 15.5	g/dL

Key: L = Slightly Below Reference Range, H = Slightly Above Reference Range, WNL = Within Normal Limits, * = Critical Value

INFECTIOUS DISEASE PANEL - TEST #1 (New York, NY)

TEST NAME	PATIENT'S RESULTS	UNITS
Chagas IgG	Negative	Qualitative
HIV 1/2 antibody	Negative	Qualitative
HSV1 antibody	Negative	Qualitative
Measles IgG	Positive	Qualitative
Rubella IgG	Positive	Qualitative

Key: L = Slightly Below Reference Range, H = Slightly Above Reference Range, WNL = Within Normal Limits, * = Critical Value

INFECTIOUS DISEASE PANEL - TEST #2 (Palo Alto, CA)

TEST NAME	PATIENT'S RESULTS	UNITS
Chagas IgG	Negative	Qualitative
HIV 1/2 antibody	Negative	Qualitative
HSV1 antibody	Negative	Qualitative
Measles IgG	Positive	Qualitative
Rubella IgG	Positive	Qualitative

Key: L = Slightly Below Reference Range, H = Slightly Above Reference Range, WNL = Within Normal Limits, * = Critical Value

End Of Report

Patient ID No.

05/31/13