

To: Elizabeth Holmes[eholmes@theranos.com]
From: Sunny Balwani
Sent: Tue 9/30/2014 6:06:40 AM
Importance: Normal
Subject: Fwd: Customer Issue - GM
Received: Tue 9/30/2014 6:06:41 AM
[image001.png](#)

Begin forwarded message:

From: Daniel Young <dyoung@theranos.com>
Date: September 29, 2014 at 10:22:35 PM PDT
To: Maximillion Fosque <mfosque@theranos.com>, Sunny Balwani <sbalwani@theranos.com>
Cc: Chinmay Pangarkar <cpangarkar@theranos.com>, Christian Holmes <cholmes@theranos.com>
Subject: RE: Customer Issue - GM

Ok – looks fine.

Based on the individual tip date for the fingerstick sample, there were 4 tips reporting OORL, and two reporting invalid. Our algorithm interprets this an OORL result. It is possible that a processing error occurred, but we really do not have direct evidence of any errors based on this data.

From the patient history, given the medication and other factors that we do not fully know, there could have been some unusual trends in this analyte. There was also a significant gap between the 2nd and 3rd assay measurements.

-Daniel

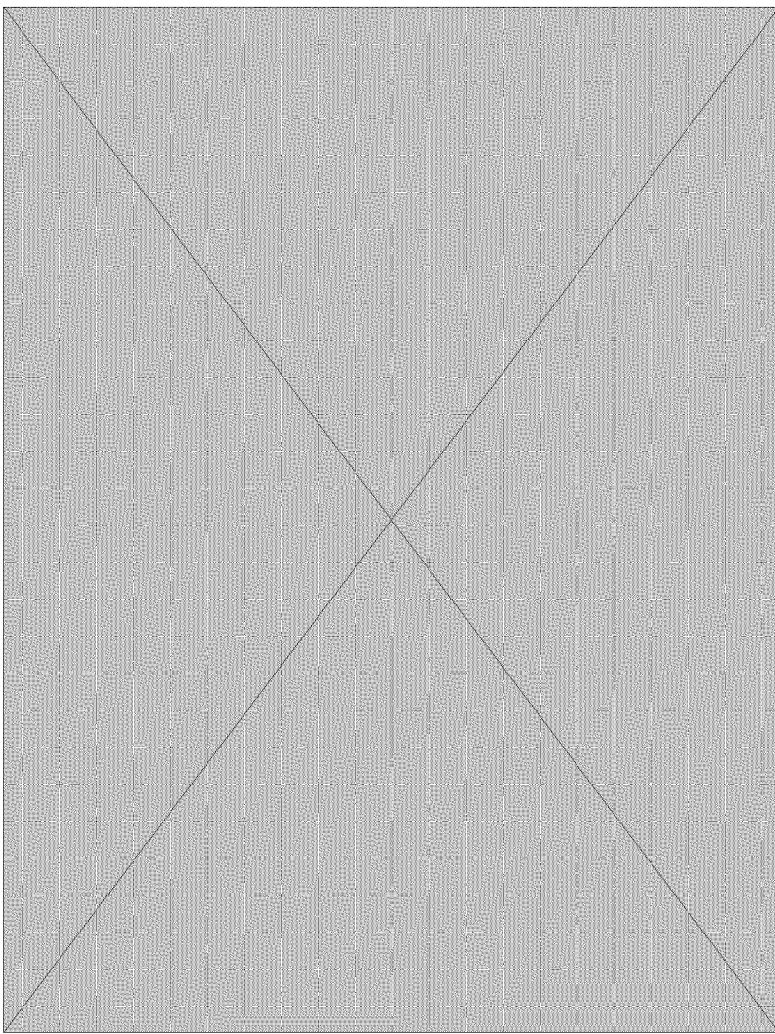
From: Maximillion Fosque
Sent: Monday, September 29, 2014 10:18 PM
To: Daniel Young; Sunny Balwani
Cc: Chinmay Pangarkar; Christian Holmes
Subject: RE: Customer Issue - GM

Finger stick

From: Daniel Young
Sent: Monday, September 29, 2014 10:17 PM
To: Maximillion Fosque; Sunny Balwani
Cc: Chinmay Pangarkar; Christian Holmes
Subject: RE: Customer Issue - GM

Is this the fingerstick or venous sample?

From: Maximillion Fosque
Sent: Monday, September 29, 2014 10:16 PM
To: Sunny Balwani
Cc: Daniel Young; Chinmay Pangarkar; Christian Holmes
Subject: RE: Customer Issue - GM



From: Sunny Balwani

Sent: Monday, September 29, 2014 9:46 PM

To: Maximillion Fosque

Cc: Daniel Young; Chinmay Pangarkar; Christian Holmes

Subject: Re: Customer Issue - GM

Did the first sample show hemolysis or other issues?

On Sep 29, 2014, at 5:55 PM, "Maximillion Fosque" <mfosque@theranos.com> wrote:

Aliquot from EDTA vacutainer run on Edison

From: Daniel Young

Sent: Monday, September 29, 2014 5:55 PM

To: Maximillion Fosque; Chinmay Pangarkar

Cc: Sunny Balwani; Christian Holmes

Subject: RE: Customer Issue - GM

We need the raw tip counts for both events.

Also, what kind of sample was used in the second case?

From: Maximillion Fosque

Sent: Monday, September 29, 2014 5:53 PM

To: Daniel Young; Chinmay Pangarkar

Cc: Sunny Balwani; Christian Holmes

Subject: FW: Customer Issue - GM

All,

A doctor's office has reported a potential discrepancy with our hCG results.

On or around 9/3 or 9/4, a patient got hCG results from another lab of 160 mIU/mL. Within 48 hours, the patient came to Walgreens (visit date 9/5), and we collected 1 EDTA CTN. We reported results of OORL (<7.82 mIU/mL). Due to this, medications were discontinued. However, the patient returned on 9/19, with the same test ordered (along with Progesterone). We then reported hCG results of 2150.01 mIU/ML (aliquot to CTN and run on Edison).

The office is inquiring as to why the first result was reported as Negative, where in fact it is likely it should have been a positive value.

9/5 CTN: 0000000000134072
9/19 CTN: 0000000000175430

Please let me know what information can be pulled to assist in this investigation.

Thanks,
Max

From: Sunny Balwani

Sent: Monday, September 29, 2014 4:45 PM
To: Maximillion Fosque
Subject: FW: Customer Issue - GM

can you please look this up and send me details.

From: Kimberly Alfonso

Sent: Monday, September 29, 2014 3:04 PM
To: Christian Holmes
Cc: Sunny Balwani
Subject: Customer Issue - GM

Please see below.

Still need info on HCG inquiry from last month too (re: August 20 with 600,000 result from Margaret Gossett, NP).

From: Eric M. Nelson

Sent: Monday, September 29, 2014 2:53 PM
To: Mike Phebus
Cc: Kimberly Alfonso
Subject: FW: Labs-issue-hcg

Mike and Kimberly,

Please see below detailed hcg issue from a fertility office here in Scottsdale.

Thanks,
Eric

From: Allison Martin [<mailto:backdesk1@ivfphoenix.com>]

Sent: Monday, September 29, 2014 2:26 PM
To: Eric M. Nelson
Subject: RE: Labs

Eric,
Thank you so much for dropping off the new order sheets! I am sorry I was unavailable at that time!
We will call the support line, but also wanted to give you a heads up on what happened with the lab. We sent a patient of ours in for her 48 hour repeat on her QBhcg. Her initial test came back at 160 (run at a different lab), and when we sent her back in for her repeat with your lab the results came back at <7.82. Because her test came back negative, we had her discontinue her current medications and began getting her ready for her

next cycle.

A few weeks later she went back in for another QBhcg and it came back at over 2000. We brought her in and I scanned her, and there was in fact a baby, and a heartbeat.

Our concern is your lab told us she had a negative pregnancy, we relayed that to our patient and continued our protocol as she wasn't pregnant.

Our patients initials are GM. Date of service was 9/5/14 at 9:12am for a QBhcg which came back at a <7.82
Please pass this along, to ensure that this does not happen to any further patients/clients.

Thank you,

Allison Martin
IVF Phoenix & the office of
Dr John L Couvaras, MD FACOG

O: 602.765.2229

E: backoffice1@ivfphoenix.com

<image001.jpg>

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Thank you.

From: Eric M. Nelson [<mailto:ericon@theranos.com>]

Sent: Monday, September 29, 2014 11:25 AM

To: Allison Martin

Subject: Re: Labs

Hi Allison,

I just left new materials at the front desk of your office. Please note the new reproductive health panel and monitoring panel on the back of the test menu. For an issue please call clinician support 1 855 843 7200.

Also, you can email me the details and I will send on to my manager. Please include the patients initials only. If you can also include other important details like dates, time of visit etc., that would be helpful.

Thanks,
Eric

Sent from my iPhone

On Sep 29, 2014, at 10:04 AM, "Allison Martin" <backdesk1@ivfphoenix.com> wrote:

Good morning,

I hope this email finds you well! We have been sending more of our patients over to your lab for testing, and we are in need of some more order forms! If you could please direct me in how

I can get some more for our office!

Also, we needed to know who we could speak with about an incident we had with a patient and your lab? Is there a manager we could contact? Or what is the best way to go about this?
Thank you and have a good day!

Thank you,

Allison Martin

IVF Phoenix & the office of
Dr John L Couvaras, MD FACOG

O: 602.765.2229

E: backoffice1@ivfphoenix.com

<image001.jpg>

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Thank you.