

Message

From: Adam Rosendorff [/O=Theranos Organization/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/CN=Recipients/CN=Adam Rosendorff92]
Sent: 10/1/2014 11:48:44 PM
To: Sunny Balwani [sbalwani@theranos.com]
CC: Maximillion Fosque [mfosque@theranos.com]
Subject: RE: ``FW: Physician Call Needed Before 4pm

On further review, [REDACTED] (DOB [REDACTED]) is a different patient from [REDACTED] (DOB [REDACTED]), according to the MD office. This resolves the patient identifier issue.

However, for [REDACTED] (DOB [REDACTED]), the 9/19 Testosterone result is 280 ng/dL, and the 9/26 Testosterone result is 705 ng/dL. These are really different...

Thanks,

Adam

From: Adam Rosendorff
Sent: Wednesday, October 01, 2014 4:07 PM
To: Sunny Balwani
Subject: FW: ``FW: Physician Call Needed Before 4pm

Sunny

Please see below.

Thanks,

Adam

From: Adam Rosendorff
Sent: Wednesday, October 01, 2014 4:05 PM
To: Elena Scheer
Cc: Christian Holmes; Maximillion Fosque; arosendorff@[REDACTED]
Subject: RE: ``FW: Physician Call Needed Before 4pm

Elena/Christian

I just got off the phone with Dr Palmer.

He is concerned that the patient, [REDACTED] (DOB [REDACTED]), may have had his lab results mixed up with another [REDACTED] (DOB [REDACTED]) - apparently his office has been receiving reports for the only [REDACTED] they have with both DOBs.

Specifically, on the 9/26 visit, the Testosterone (total) was 705 ng/dL and the Vitamin D (25-OH) was 50.9 ng/mL. These results appeared on a lab report for [REDACTED] with DOB [REDACTED]

On the prior visit, which was 9/19, the Testosterone (total) was 280 ng/dL (accessioned and appearing with the [REDACTED] DOB!!!), and the Vitamin D was 38.8 ng/mL. There is also a further total testosterone test for this same visit on 9/19 for [REDACTED] ([REDACTED] DOB as well), with a result of 309 ng/mL. Both testosterone values (280 and 309 ng/dL) are quite different from the testosterone value for 9/26 (705 ng/dL). The Vitamin D value (38.8 ng/mL), is also quite different from the 9/26 value (50.9 ng/mL)

The inaccurate DOB means that the specimen was not adequately identified, which is a CLIA violation.

Further, the significant discrepancies between results separated by only a week, raises grave concerns for both the accuracy and potential intra-individual precision of the assay, if indeed the two specimens belong to the same patient (see previous point).

Finally, as lab director, I need to sign off on proficiency testing/ AAP for Vitamin D and Testosterone, which have both been in production for almost a year, without (to my knowledge), a fully executed AAP plan and data. This data needs to be shared also with our QA/QC director, and be available for CLIA inspections.

Thanks,

Adam

From: Elena Scheer
Sent: Wednesday, October 01, 2014 3:29 PM
To: Adam Rosendorff
Subject: ``FW: Physician Call Needed Before 4pm
Importance: High

Hi Adam,

Can you call the Dr. below as soon as possible? All info is below.

Thanks,

Elena

From: Maximillion Fosque
Sent: Wednesday, October 01, 2014 3:28 PM
To: Elena Scheer; Daniel Edlin
Cc: Christian Holmes
Subject: RE: Physician Call Needed Before 4pm

Sure.

On the first part, it is reported twice because Total TST is a component of Free TST, and thus we display it in that set of results as well.

Thanks,

Max

From: Elena Scheer
Sent: Wednesday, October 01, 2014 2:21 PM
To: Daniel Edlin; Maximillion Fosque
Cc: Christian Holmes
Subject: Physician Call Needed Before 4pm
Importance: High

Hi all,

I just spoke with Dr. Palmer about patient [REDACTED] (DOB [REDACTED]) two visits. He has questions about the testosterone values and why they are reported twice on each report. He also wants to discuss how the testosterone results are quite different for each visit. He is seeing the patient at 4pm and would like to hear back before then.

His phone number is [REDACTED]

Can I pass along to Adam?

Thanks,

Elena

Elena Scheer

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