To: Sunny Balwani[sbalwani@theranos.com]; Adam Rosendorff[arosendorff@theranos.com]
From: Mark Pandori
Sent: Thur 4/17/2014 1:05:32 AM
Importance: Normal
Subject: slides pt, aap
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aap_pt_th_mwp_v1.pptx

Attached, a slide show I put together giving an overview of AAP and how it works and why it is better than PT.

I am happy to add to this. I purposely avoided getting into the technical aspects of passing and failing.

We can certainly add criteria etc.

If ok, I aim to present this at Staff Meeting on Thursday.

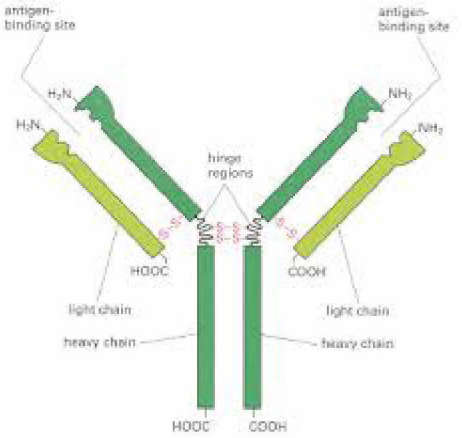
Thanks.

Mark Pandori

File Produced in Native Format

Proficiency Testing & Quality Assessment of Theranos Methods

theranos



CMS (the Center for Medicare and Medicaid Services) (aka “CLIA”)

-requires that all tests for certain “regulated” analytes are evaluated for *accuracy* on a routine basis

-3 external challenges per year, minimum of 5 samples

-private agencies provide synthetic, preserved, specimen panels

PT continued,

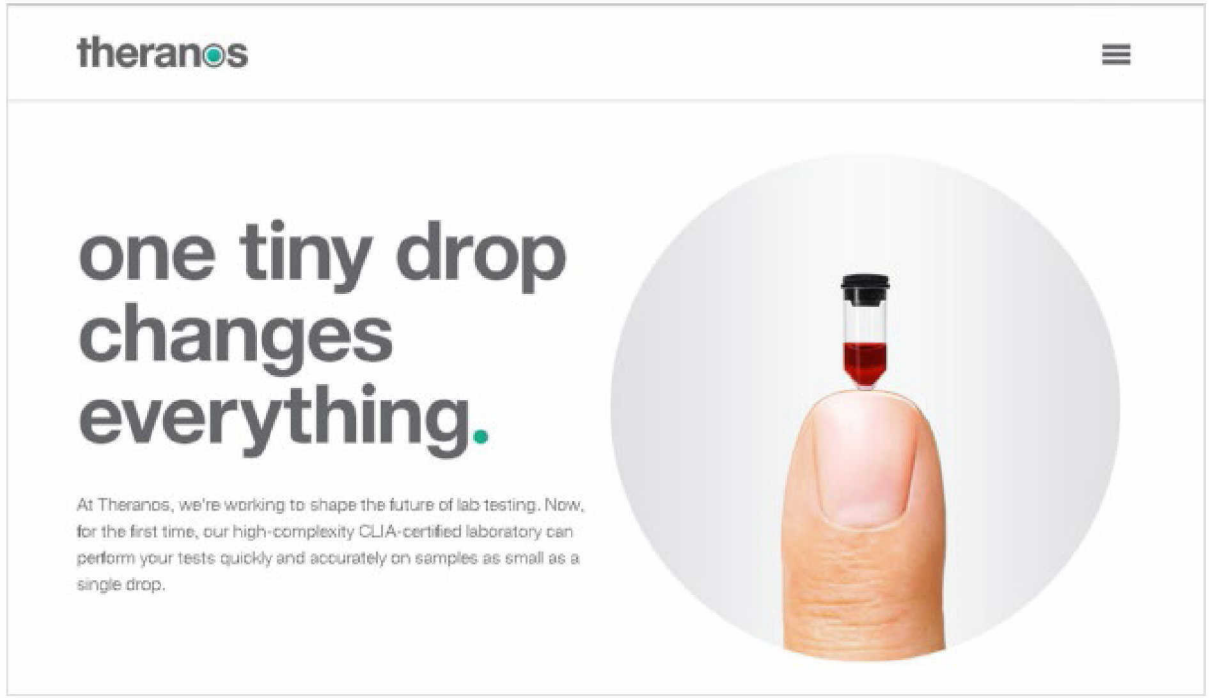
-panels are tested by multiple laboratories on various types of equipment to generate acceptable ranges on a per method basis

-your lab is compared to peer groups on the basis of equipment

Theranos tests have no peer groups

Normal process of PT is therefore *not* appropriate!

Additionally, the synthetic matrix of many commercially available PT samples is not an appropriate one for many Theranos tests.



How is PT performed then, on Theranos tests?

The CLSI (The **Clinical & Laboratory Standards Institute**):

Refers to the use of an "AAP" or Alternative Assessment Protocol

This is an alternative way to assess the ongoing performance of a laboratory test when standard PT is inappropriate

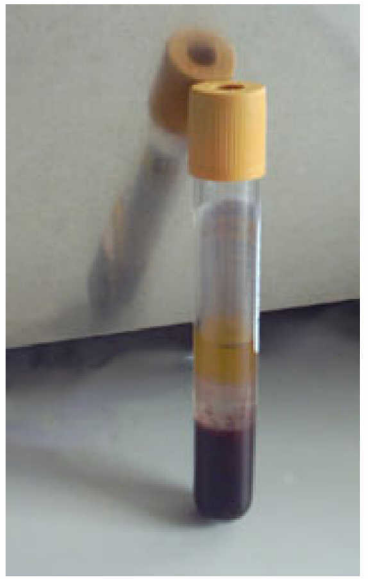
Particularly important for laboratories who have no peers…such as us!

Our AAP:

-Includes comparison of a predicate, FDA approved method (for which there is external assessment available), to the Theranos methods

-Uses *actual* clinical specimens; 5 or more specimens are tested by predicate and by the Theranos method

-Includes monthly (or greater frequency) performance



vs.

The Theranos AAP is superior to standard PT, and will provide even *more* Quality Assurance:

-Performed more frequently (works as a "canary in a coal mine", closer to real-time monitoring)

-*Typical PT does not*.

-Is performed using actual clinical specimens

-Allows certain variables to be tracked that might affect lab testing, which normal PT would not allow (due to frequency)

-Passing an AAP event is just as rigorous as PT; in fact it is more rigorous due to increased frequency.

Results

-If the AAP showed anything wrong with a test, it can be captured and repaired in near-real time

-Back up testing can be engaged temporarily

-ultimate safety for the patient

Questions?