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From: Mark Pandori
Sent: Thur 4/17/2014 1:05:32 AM
Importance: Normal
Subject: slides pt, aap
Received: Thur 4/17/2014 1:05:33 AM
[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.

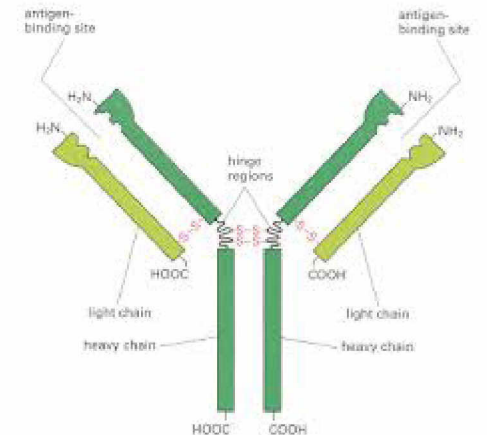
Thanks.

Mark Pandori

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Proficiency Testing & Quality Assessment of Theranos Methods



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,

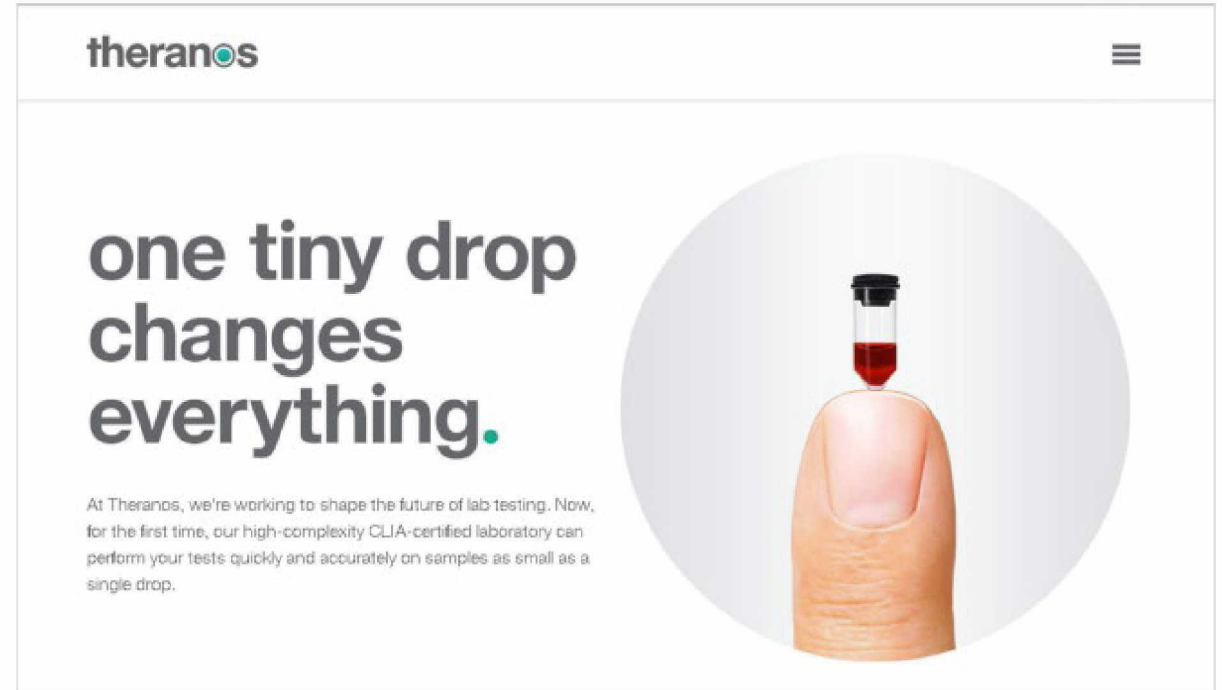
-panels are tested by multiple laboratories on various types of equipment to generate acceptable ranges on a per method basis

-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.

A screenshot of the Theranos website banner. The top left corner features the "theranos" logo in a lowercase, sans-serif font. The top right corner has a hamburger menu icon. The main content area is white and contains the headline "one tiny drop changes everything." in a large, bold, dark grey font. To the right of the headline is a circular graphic showing a small, clear glass vial with a black cap, containing a single drop of red liquid, positioned directly above a human fingertip. Below the headline, there is a paragraph of smaller text: "At Theranos, we're working to shape the future of lab testing. Now, for the first time, our high-complexity CLIA-certified laboratory can perform your tests quickly and accurately on samples as small as a single drop."

theranos

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changes
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At Theranos, we're working to shape the future of lab testing. Now, for the first time, our high-complexity CLIA-certified laboratory can perform your tests quickly and accurately on samples as small as a single drop.



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?

