

March 24, 2016

Dear Mr. Beauchamp,

Yesterday Theranos was made aware of a study (Kidd et al, "Evaluation of direct-to-consumer low-volume lab tests in healthy adults"), that may be published in the May 2016 edition of the *Journal of Clinical Investigation*, not from the *Journal of Clinical Investigation* itself or any of its authors, but through members of the media, including *The Wall Street Journal*, *The New York Times* and *The Washington Post*, who were provided with a draft copy of the study along with false and misleading statements.

Theranos believes in open access and greater transparency in lab testing. While the study shows that Theranos' results are in substantial agreement with other services offered by other companies, we have several significant concerns regarding the study's methods and conclusions, as well as the associated actions of its authors as summarized below.

The authors informed the media that they reached out to Theranos regarding this study by email and that the authors received no response from Theranos. Theranos has confirmed that no such emails, or any other correspondences, were received by any senior Theranos executive, as claimed by EE Schadt, one of the principal authors, to at least two journalists. This fact indicates that the authors are making false claims to the media to inappropriately bolster their credibility and that of their study.

It is unfortunate that the authors of this study did not in fact contact Theranos, as this would have allowed the company to provide accurate and comprehensive data and input on the study design and procedures, all of which would have led to a more credible study.

- 1) From the article proof that we were provided by the media (attached), it is alarming that one of the leading authors of this study (EE Schadt) failed to identify a potential conflict of interest, namely that he is on the scientific advisory board of a company named NuMedii Inc that may benefit from this publication. NuMedii is a bioinformatics company that is a potential competitor to Theranos. Such disclosures are required per JCI's stated policy regarding disclosure of potential conflicts by authors. No less alarming is the fact that the article does not disclose the extent of the other leading author's potential conflict of interest, including that Dr. Dudley also receives royalty payments from NuMedii, and his equity is valued at greater than 5% ownership of the company.
- 2) The authors make two major conclusions concerning: a) rejection rates and b) non-equivalence for lipid panels. However, there are fundamental

problems with this study that cast serious doubts on the validity of these conclusions, namely:

- a. The rejection rate reported from the study is not reliable due to the study design. Namely, the collection procedures do not reflect normal laboratory collection procedures or “real-world conditions” as suggested by the authors. For example, the collection of large amounts of venous sample (30mL) before collecting capillary samples is contrary to the Theranos CLIA lab collection procedures, and could negatively impact the quality of subsequent capillary blood collection, with clots and/or hemolysis (the exact reasons for sample rejection in this study at the Theranos lab). The collection practices employed in this study do not represent our normal practice and are contrary to the Theranos CLIA Lab Collection Procedures, thus invalidating the authors’ conclusions regarding “higher sample rejection rates”.
- b. Moreover, the authors fail to report how many finger pricks were performed at the first and second collection sites and whether or not they were on the same finger. The study was designed to circumvent the normal Theranos collection procedures. Such practices do not present normal practice, are contrary to the Theranos CLIA Lab Collection Procedures, and would have a negative effect on sample integrity. These fundamental problems with the conduct of the study reflect the lack of understanding of the study investigators concerning basic sample collection procedures that are critical for the integrity of their study and its conclusions.
- c. The faulty sample collection procedures also put in question all the subsequent laboratory testing comparisons, as it is well appreciated that pre-analytical factors, such as sample collection, are the major cause for lab test discrepancies.
- d. The study investigators failed to use any accepted reference methods for the tests being evaluated. As such, there is no “truth” from which to judge any test bias as the authors attempt to do.
- e. The authors present bias estimates, but fail to present any correlation data between the different laboratory results. Such a correlation analysis is a fundamental method used to compare quantitative test measurements.
- f. The attempt to use the rate of flagged test results to compare the “accuracy” of testing services is a flawed approach, as the discrepant patients were not further evaluated to discern whether they were truly abnormal.

These are just a few of the major problems with the conduct of this study that invalidate its central conclusions. There are many other problems with this study



that we are in the process of tabulating, but we wanted to open this important dialogue with you as soon as possible.

We do not believe that the actions of the authors present a sound or scientific way to engage with us about the efficacy of our technologies. It has produced a flawed and inaccurate study and we are disappointed that any journal would accept this study for publication.

We would like to offer the opportunity for you to speak directly with Theranos laboratory directors and scientists about the merits and accuracy of this study.

Sincerely,

Kingshuk Das, MD, Laboratory Director

A handwritten signature in black ink, appearing to read "K Das".

Donald Tschirhart, MD, Co-Laboratory Director

A handwritten signature in black ink, appearing to read "Donald Tschirhart".

Lisa Helfend, PhD, MD, Co-Laboratory Director, Clinical Consultant

A handwritten signature in black ink, appearing to read "Lisa Helfend".

Daniel L. Young, PhD, Laboratory Director

A handwritten signature in black ink, appearing to read "D L Young".