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Meaningful Drop-to-Drop Variation Seen in Blood; Study May Raise More Doubts for Theranos

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Test results from a single drop of blood are highly variable, according to a study published in the *American Journal of Clinical Pathology*. This variation between successive drops of fingerprick blood may be even greater than variation between fingerprick and venous blood samples. As a result, the authors say, tests may need to be run on six to nine drops of blood, rather than one.

This study's findings may affect many aspects of clinical testing. It could pose a problem for clinical decisions based on fingerprick tests, like anemia testing, and it could impact the future development of point-of-care diagnostics. Finally, this variability may also add momentum to the swirling of questions disputing the capabilities of Theranos' micro-sample technology.

"These data suggest caution when using measurements from a single drop of fingerprick blood," writes co-author Rebecca R. Richards-Kortum, Ph.D., from Rice University in Houston. "Our results show that people need to take care to administer fingerprick tests in a way that produces accurate results because accuracy in these tests is increasingly important for diagnosing conditions like anemia, infections and sickle-cell anemia, malaria, HIV and other diseases."

Fingerpricks are often used in point-of-care testing and are preferred over venipuncture because of patients' dislike of needles. Over the years, many tests have addressed the accuracy of results obtained from fingerstick samples versus venous blood, but few have assessed the variation in results between the successive drops of blood obtained from one fingerprick. The researchers were actually working on developing novel, low-cost platforms for low-resource settings when they observed wide variation in benchmark tests being performed on hospital-grade blood analyzers.

"A growing number of clinically important tests are performed using fingerprick blood," co-author Meaghan Bond, said in a statement. "It is important to understand how variations in fingerprick blood collection protocols can affect point-of-care test accuracy as well as how results might vary between different kinds of point-of-care tests that use fingerprick blood from the same patient."

In the study, the researchers analyzed the hemoglobin concentration, total white blood cell (WBC) count, three-part WBC differential, and platelet count in six successive drops (20 µL each) of blood. Samples were collected from one fingerprick from each of 11 donors, using best draw practices. Blood components were assessed with a hospital-grade hematology analyzer. A point-of-care hemoglobinometer was used to measure the hemoglobin concentration of 10 drops (10 µL each) of fingerprick blood from each of seven donors. Arm venipuncture samples were used as controls.

The researchers found that compared to venous controls, the successive drops of fingerprick blood had an average percent coefficient of variation (CV) that was higher by up to 3.4 times for hemoglobin, 5.7 times for WBC count, three times for lymphocyte count, 7.7 times for granulocyte count, and four times for platelets. For

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hemoglobin (using a point-of-care hemoglobinometer) the average percent for CV for fingerprick blood was up to five times higher for hemoglobin than venous blood.

Fluctuations in blood parameters are within published instrument variability when using volumes of fingerprick blood between 60 to 100 uL or greater. Recommending caution in using the results of these tests for clinical decision-making, such as determining anemia status, the authors suggest clinicians either accept the inaccuracy of fingerprick blood as a trade-off for easy blood collection; collect, read, and average multiple fingerprick samples (suggested six to nine blood drops), which adds accuracy but increases cost and time; or utilize venous blood.

Takeaway: While the current study did not utilize Theranos technology, new findings demonstrating wide variability in successive drops of fingerstick blood samples—and the resulting accuracy of test results— raises further questions about the company's closely-guarded testing mechanisms.

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