

Mount Sinai Researchers Assess Accuracy of Commercially Available Lab Tests

Evaluation uncovers more variability than expected in basic blood tests of healthy adults

NEW YORK – March 28, 2016 /Press Release/ — Scientists from the Icahn School of Medicine at Mount Sinai performed an in-depth comparison of basic blood tests run by commercial laboratories to assess accuracy and variability, finding that testing service and time of collection significantly influenced results. Given that lab tests are used to help decide everything from disease diagnosis to whether a patient needs medicine or whether that medication is working, this study highlights the importance of knowing the accuracy and variability in test results.

The study, which was first designed in early 2015 with data collected last July, analyzed results from comparable blood tests on healthy adults conducted at LabCorp, Quest Diagnostics, and Theranos. Researchers collected multiple samples from the same individuals and controlled for variables such as age, sex, and time of blood collection, among many others, but still found that more than half of test results showed significant differences between test providers. Triglyceride levels and red blood cell counts were among the most consistent results, while white blood cell counts and overall cholesterol levels were among the most variable. Test results from Theranos were flagged as abnormal 1.6 times more often than those from LabCorp or Quest. Data from blood samples collected earlier in the day also showed significant differences compared to samples from the same subjects later in the day. The study was published today in the *Journal of Clinical Investigation*.

“While most of the variability we found was within clinically accepted ranges, there were several cases where inaccurate results would have led to incorrect medical decisions,” said Joel Dudley, senior author on the paper and Director of Biomedical Informatics at the Icahn School of Medicine at Mount Sinai. “We hope this study will inspire the biomedical community to take a critical look at all testing variables to ensure that lab results are as robust and reproducible as possible.”

The study focused on common blood tests, which typically return a single data point or a few data points. However, as Mount Sinai scientists showed, even standard blood tests can generate rich data for statistical analysis: this study collected 14 samples to generate 22 lab results for each of 60 subjects, leading to a total of more than 18,000 data points in this project alone. While most results were within normal ranges, having even a small amount of inaccurate data mixed in could lead to erroneous conclusions from scientific or clinical studies.

“These testing disparities occurred despite rigorous laboratory certification and proficiency standards designed to ensure consistency,” said co-senior author Eric Schadt, PhD, the Jean C. and James W. Crystal Professor of Genomics at the Icahn School of Medicine at Mount Sinai, and Founding Director of the Icahn Institute for Genomics and Multiscale Biology. “Our results suggest the need for greater transparency in lab technologies and procedures, as well as a much more thorough investigation of biological mechanisms that may contribute to more dynamic levels than we currently understand.”

Paper cited:

Brian A. Kidd et al. Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults. The Journal of Clinical Investigation. DOI: 10.1172/JCI86318

Disclosure: J.T. Dudley owns equity in NuMedii Inc. and has received consulting fees or honoraria from Janssen Pharmaceuticals, GlaxoSmithKline, AstraZeneca, and Lam Therapeutics. If you have questions regarding industry relationships, we encourage you to visit our website at <http://icahn.mssm.edu/> where Mount Sinai publicly discloses the industry relationships of our faculty.

About the Mount Sinai Health System

The Mount Sinai Health System is an integrated health system committed to providing distinguished care, conducting transformative research, and advancing biomedical education. Structured around seven hospital campuses and a single medical school, the Health System has an extensive ambulatory network and a range of inpatient and outpatient services—from community-based facilities to tertiary and quaternary care.

The System includes approximately 6,600 primary and specialty care physicians, 12-minority-owned free-standing ambulatory surgery centers, over 45 ambulatory practices throughout the five boroughs of New York City, Westchester, and Long Island, as well as 31 affiliated community health centers. Physicians are affiliated with the Icahn School of Medicine at Mount Sinai, which is ranked among the top 20 medical schools both in National Institutes of Health funding and by U.S. News & World Report.

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