

## Bad Blood: The Rise and Fall of a 9 Billion Dollar Diagnostic Disrupter and What the Profession of Laboratory Medicine Didn't Do (But Should Have) to Stop It

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In an age of fake news, we in the laboratory are not immune. In recent years, we have seen fake quality, fake laboratories, and fake diagnostic manufacturers. The most bizarre and outrageous tale of this kind is the rise and fall of Theranos. The story of Theranos contains lessons for the medical laboratory field, many of which remain unexplored. Why was Theranos allowed to proceed to testing patient samples with un-approved, un-cleared devices and methods? Why were the professional associations in the US so deferential, while the European professional associations were skeptical? Why was so much venture capital poured into a company that refused to reveal its technical designs? The answers reveal that truth is stranger than fiction. And sometimes failure is more spectacular than anything we might imagine. What was once a 9 billion dollar valuation – a “unicorn” in Silicon Valley parlance – burned through hundreds of millions of dollars in what is now known as fraudulent attempt to sell a “disruption” of the laboratory testing marketplace. The “fake it ‘til you make it” culture of Silicon Valley start-ups, while relatively benign when applied to car ride sharing applications or instant photo-sharing, proved itself to be a dangerous approach to developing new devices for medical laboratory testing. Millions of tests were proven unreliable. Patients were mis-diagnosed. When finally inspected, Theranos laboratories were found wanting in the most basic ways, with improperly-set QC protocols, with inappropriate responses to QC outliers, and with patient results released even when QC was notably out-of-control. Theranos eventually shuttered its laboratories, announced an exit from the laboratory testing market, and tried to reinvent itself as a diagnostic design company. But that only delayed the inevitable. As legal woes mounted, and the venture capital funding dried up, Theranos was forced to shed staff, until it was a mere shell of its former self. Finally, the company simply ran out of money and expired. The chronicle of Theranos is discussed in the 2018 book, *Bad Blood*, and the details reveal some unexpected heroes. Laboratory professionals, it turns out, were among the only people who had ethical qualms about faking test results. Laboratory professionals helped to sound the alarm, helped blow the whistle, helped to leak information to reporters. If the laboratory professionals hadn't acted, Theranos might still be in operation today, churning out millions of erroneous results to patients. In truth, the Theranos story may be an example of the unusual strength of our medical laboratory profession. And yet another reason why we must preserve our profession in order to assure patients get the right care.