

Theranos Statement on Transparency
July 8, 2015

We believe the general public has a right to assurance of the safety, efficacy, and accuracy of all lab tests. And there is no greater and more comprehensive standard for this – throughout the world -- than FDA review. We strongly disagree that there is any higher bar for ensuring the integrity of a diagnostic test than FDA review. Anyone who would suggest otherwise is simply not aware of the rigor of FDA's review process. The FDA review process is designed to comprehensively assess and ensure the safety, accuracy, and efficacy of tests. The real issue here is the need for regulation of lab developed tests – which we believe is critical for public health, safety, and engagement in laboratory testing to realize a world in which preventive care can become a reality. Theranos is establishing a new paradigm in transparency in lab testing by committing to FDA review of all of its laboratory-developed tests, publishing its lab proficiency testing scores, customer satisfaction scores, guest visit times, prices, and more as it works to realize this vision for preventive care.