CND Life Sciences™

CND INSIGHTS

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Why Diagnostic Testing Reliability Matters

Richard J. Morello
Chief Executive Officer

Perhaps there has been no other time in the last century when the topic of laboratory testing has been more prevalent in our daily lives than today and more critical to the health of the planet. The COVID-19 pandemic has exposed the massive importance of large-scale clinical testing capacity and availability in the midst of a global contagion, but has also underscored the critical necessity of testing *standards*, *quality*, and *accuracy*. The ability to overcome this calamity and return billions of people to social and economic normalcy continues to rest materially in the hands of those providing tests assumed to be reliable, and it is a key moment for all diagnostic laboratories and companies to realize the roles they play and the responsibilities they bear within our healthcare system.

The Clinical Laboratory Improvement Amendments (CLIA), passed by Congress in 1988 and administered by CMS, set the new US quality standards and regulatory oversight for most laboratories that perform testing on human specimens including blood, body fluid, and tissue for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health. Over the last two decades, the Food and Drug Administration (FDA) has also increased its scope of active regulation of more advanced tests (e.g., molecular diagnostics in oncology) that may have more serious therapeutic implications for patients. As a whole, the agencies have established rigorous quality and safety requirements for the millions of diagnostic tests conducted every day. While there are no perfect systems of regulatory oversight, these bodies have set parameters for good laboratory standards that should yield higher quality and more accurate test performance for physicians and their patients.

With the COVID-19 pandemic, the industry and public at large have seen the consequences of rushed test development and a loosening of standards in the face of a time-sensitive crisis. A test that cannot reliably reproduce results, maintain purported sensitivity and specificity levels, sustain integrity across different test collection and storage environments, or comply with overall performance claims can have disastrous consequences. While an infectious disease of this magnitude may be the extreme case, laboratories of all types that play roles in supporting diagnostic and therapeutic decisions of physicians and patients have serious obligations to uphold the highest levels of quality and accuracy.

As a relatively new and growing anatomical pathology lab, the team at CND Life Sciences takes our CLIA-certification and quality expectations quite seriously. Our culture and philosophy are grounded in the experience of our three physician founders, who have more than 80 years of collective patient care under their belts. They know the vital importance of receiving a reliable test result to help make a sound diagnostic judgment and recommend an optimal treatment path for their patients. For every skin-based test we perform, there is a patient and family awaiting potentially life-altering results. With this in mind, it is our job to conduct our processes and protocols accordingly, and to drive and maintain laboratory and operating excellence no matter what conditions we face.

As we have learned with disease screening and antibody testing for COVID-19, wide variations in false negative and false positive results from different laboratories can create real conundrums for patients and public health. Time will tell how the multitude of testing organizations we are counting on will meet the unprecedented challenge of the COVID-19 pandemic. We are certainly rooting for them to show us the way.