Clinical Laboratory Improvement Amendments (CLIA) Guidance During COVID-19 Emergency

CMS issued important guidance ensuring that America’s clinical laboratories are prepared to respond to the threat of the 2019 Novel Coronavirus (COVID-19.) CMS is committed to taking critical steps to ensure America’s clinical laboratories are prepared to respond to the COVID-19 threat and other respiratory illnesses by implementing flexibilities around requirements for a Clinical Laboratory Improvement Amendments (CLIA) certificate during public health emergencies.

While there is no formal waiver authority under CLIA, CMS continue to exercise flexibilities under current regulations and through enforcement discretion to address temporary and remote testing sites, use of alternate specimen collection devices, and implementation of laboratory developed tests. Our hope is that this guidance provides the steps needed for all U.S. Labs wanting to apply for a CLIA certificate to test for COVID-19.

Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency

Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency