

## **Provider Notification 12/04/2020 - CMS Takes Action to Protect Integrity of COVID-19 Testing**

Dear Provider,

The Centers for Medicare & Medicaid Services (CMS) is taking every action to ensure that U.S. laboratories are fit to deliver reliable, accurate and timely patient results regarding COVID-19. Since August 12, 2020, CMS has issued 171 cease and desist letters to laboratories across the country that lack the appropriate certifications for COVID-19 testing. A recent record check completed by CMS revealed that the facilities did not hold the proper Clinical Laboratory Improvement Amendments of 1988 (CLIA) certifications. Of these 171 letters issued, thirty-four percent went to facilities conducting laboratory testing without a CLIA certificate and sixty-six percent went to laboratories that were performing COVID-19 testing outside the scope of their existing CLIA certification. Having the appropriate CLIA certification is imperative as it verifies that laboratories meet federal performance, quality, and safety standards to properly diagnose, prevent and treat diseases. The letters ordered the laboratories to stop immediately to safeguard the integrity of COVID-19 testing and to protect patients from potential endangerment if provided inaccurate or unreliable test results.

Any facility that conducts COVID-19 testing is considered a “laboratory” and must therefore be certified under CLIA. CMS implemented an expedited review process at the onset of the public health emergency and has more recently released a quick-start [guide](#), which helps laboratories with the application process. To prevent false results that could adversely alter diagnosis, treatment and contribute to the further spread of COVID-19, it is imperative that facilities apply for CLIA certification and operate within the scope of that certification.

Following receipt of the letters, laboratories are required to provide CMS an attestation certifying they have ceased testing. The letters provide non-certified laboratories with information on how to become CLIA certified and encourages certified laboratories to obtain the proper CLIA certification to resume testing. CMS has taken this action to promote compliance with CLIA and to keep patients safe.