DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Notice to the Public of Limitation of CLIA Certificate

Date May 29, 2025

Title Notice to the Public of Limitation of AllCells, LLC's CLIA Certificate

Notice to the Public of Limitation of AllCells, LLC's CLIA Certificate, 22D2126670

The Centers for Medicare & Medicaid Services (CMS) is providing notice that on June 13, 2025, the AllCells, LLC's CLIA certificate, located at 1250 Hancock St, Quincy, MA 02169, will be limited for the analyte hematocrit (HCT) due to their failure to meet CLIA requirements.

The laboratory was notified on May 29, 2025. When a laboratory's CLIA certificate is limited, it will not be permitted to perform any testing for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, in the testing area it is limited. The laboratory may continue to perform parallel testing on specimens if needed to implement corrective actions; however, the laboratory may not report any test results during the period of limitation. CMS is committed to patient safety and quality of care.

The report of findings associated with this sanction is available through the CMS Freedom of Information Officer. For additional information, please contact FOIA request@cms.hhs.gov.

As of August 18, 2017, public notice of revocations, suspension, and limitations will be posted on the Survey & Certification website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Termination-Notices.html.

For more information, please visit <u>www.medicare.gov</u>. To learn more about the termination process, please visit www <u>https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html</u>.