

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2190639	(X3) Date Survey Completed 08/09/2022
Name of Provider or Supplier Tennova Walk-In Clinic North	Street Address, City, State 700 Paul Huff Pkwy Nw, Cleveland, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of the Sysmex XN-330 calibration records and interview with the technical consultant, the laboratory failed to follow the manufacturer's requirements for CBC instrument calibration frequency in 2021 and 2022. The findings include: 1. Review of the Sysmex XN-330 calibration records states, "Following installation calibration, the operator is requested to verify the instrument calibration every 6 months or on an 'as needed' basis, and maintain good QC practices, to ensure the accuracy of the system." 2. Review of the Sysmex XN-330 calibration records revealed calibration was not performed from January 2021 until January 2022, resulting in the laboratory not following manufacturer's requirements. 3. Interview with technical consultant on August 9, 2022 at 12:30 PM confirmed the above findings. =====</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p>

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

===== Based on review of the quality control (QC) and patient records, lack of an Individualized Quality Control Plan (IQCP), and interview with the technical consultant, the laboratory failed to perform QC each day of patient testing or develop and implement an IQCP prior to February 2021, for the iSTAT analyzers. The findings include: 1. Review of the QC and patient records revealed iSTAT QC performed when new lots of cartridges were started and every 30 days. 2. No IQCP was available for review at the time of survey on August 9, 2022. 3. Interview on August 9, 2022 at 12:30 p.m. with the technical consultant confirmed the laboratory does not perform QC daily with patient testing but follows the manufacturer's instructions for performance of QC frequency and does not have an IQCP in place for the iSTAT analyzer.

=====