

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2049842	(X3) Date Survey Completed 01/09/2023
Name of Provider or Supplier Etmc Physician Group Inc	Street Address, City, State 2401 Sse Loop 323, Tyler, TX	
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
D0000	An onsite survey conducted 01/09/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory documents, surveyor observations, the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to perform the verification of performance specifications for two of two analyzers used in patient testing from July 2021 to December 2022. The findings include: 1. In a tour of the laboratory on 1/9/2023 at 09:20 hours, the surveyor observed the following two analyzers used in patient care since July 2021: Hemochron Signature Elite: used for patient ACT (activated clotting time) testing. AVOXimeter: used for patient oxygen saturation (O2sat) testing. 2. Surveyor queried the technical consultant (TC) 2 for the verification studies for the Hemochron Signature Elite and the AVOXimeter, and none was provided. 3. Review of the CMS form 116, section VII "Non-Waived Testing" listed the total estimated annual test volume at 342. 4. In an interview on 1/9/2023 at 10:08 hours, in the office, the TC2 confirmed that the verification studies had not been performed for the Hemochron Signature Elite and the AVOXimeter.</p>

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of laboratory quality control (QC) documents and confirmed in an interview, the laboratory failed to have a mechanism in place to monitor QC for accuracy and precision over time for two of two tests, activated clotting time (ACT) and oxygen saturation (O2sat), performed from July 2021 to December 2022. The findings include: 1. Review of QC documentation for ACT and O2stat testing from July 2021 to December 2022 did not include a mechanism to monitor for accuracy and precision over time. 2. In an interview on 1/9/2023 at 11:29 hours, in the office, technical consultant 2 confirmed that the laboratory had not been monitoring QC for accuracy and precision over time.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control (QC) documents, patient test records, and confirmed in an interview, the laboratory failed to ensure the acceptability of QC results before reporting patient activated clotting time (ACT) results, for one of one patients tested on the Hemochron Signature Elite when QC was unacceptable in May 2022. The findings include: 1. Review of the QC form titled "Hemochron Weekly Control Log 2022" for May 2022 recorded the following QC failure that was unacceptable without resolution: May 20, 2022: Level 1: Lot C2DNL005, Exp 12/31/2022 Expected range 89-156 run 1 - "out of range" run 2 - 193 run 3 - 81 Surveyor queried if the controls ever came into acceptability on 5/20/2022, the technical consultant (TC)2 stated that QC was not re-run after the third attempt and that it was ran on 5/25/2022, to which the QC was within acceptable limits. 2. Review of patient testing records had the following patient ran between 5/20/2022 and 5/25/2022 when QC was out of acceptable limits: Test Date: 5/24/2022 MRN 081285351 3. In an interview on 1/9/2022 at 13:30 hours, in the office, TC2 confirmed that patient testing had occurred when QC was outside of acceptable limits.