

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1018247	(X3) Date Survey Completed 09/09/2021
Name of Provider or Supplier Etmc Physician Group, Inc	Street Address, City, State 1000 E 5th Street, Suite 200, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies, the laboratory's quality control (QC) records from July 2020 to August 2021, the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of an IQCP (Individualized Quality Control Plan) to lessen the frequency of quality control testing for the Chem8+ cartridge on the Abbott i-STAT analyzer in 2020. Findings: 1. A review of the laboratory's policy titled 'Procedure for i-STAT' revealed the following: "With each new cartridge lot: Run controls" 2. Further review of the laboratory's policy manual revealed the following notation: "i-STAT Chem8+ Cartridges As of 6 /2020 all Chem8+ cartridges are no longer waived and are classified as a moderately complex laboratory test." 3. A review of the laboratory's QC records from July 2020</p>

to August 2021 revealed the laboratory failed to have documentation of running 2 levels of external QC material each day of patient testing, as required per CFR 493.1256. 4. A review of the laboratory's records revealed the laboratory failed to have documentation of an IQCP to lessen the frequency of quality control testing from 2 levels of external QC material each day of patient testing to running QC material with each new cartridge lot. 5. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/9/21 at 11:40 a.m. in the break room, after review of the records, confirmed that an IQCP was not implemented for the i-STAT Chem8+ testing.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's quality control records for the Abbott i-STAT analyzer from July 2020 to August 2021, a random review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of running two levels of quality control material each day of patient testing for 52 of 52 days reviewed between July 2020 to August 2021 for testing on the Abbott i-STAT Chem8+ cartridge. Findings include: 1. A review of the laboratory's quality control records for the Abbott i-STAT analyzer (Serial number: 333949) from July 2020 to August 2021 revealed the laboratory failed to have documentation of running two levels of quality control material each day of patient testing for 52 of 52 days reviewed using the Chem8+ cartridges. 2. Further review of the laboratory's quality control records for the Abbott i-STAT analyzer revealed the laboratory runs two levels of control material with every new lot of Chem 8+ cartridges 3. Testing person #1 was asked on 9/9/21 at 11:00 a.m. to provide documentation of an IQCP, defining the laboratory's quality control procedure for running QC material with each new lot of Chem8+ cartridges. No documentation was provided. (Refer to D5445) 4. A random review of patient test records from July 2020 to August 2021 revealed the following four patient's samples were result on days when there was no documentation of two levels of quality control material run on the Abbott i-STAT Chem8+ cartridge: Date: 12/23/20 Patient: 051414 Date: 01/15/21 Patient: 051414 Date: 3/16/21 Patient: 042220 Date: 4/9/21 Patient: 022480 5. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/9/21 at 11:20 a.m. in the break room, after review of the records, confirmed the above findings. Key: QC = Quality Control

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's quality control records, and staff interview, it was revealed that the laboratory director failed to ensure a quality control program was established and maintained for the testing that the laboratory performs. (Refer to D5445, D5447)

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS form, a review of the competency assessment form and staff interview, it was revealed that the competency assessment forms used by the technical consultant failed to indicate which test systems (analyzers, tests) four of four testing personnel were competent to perform in 2019 and 2020. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory listed four testing personnel performing moderate complexity testing. 2. A review of the competency assessment forms revealed the forms failed to indicate which test systems the laboratory's four testing personnel (TP #1, TP #2, TP #3, TP #4) were competent to perform in 2019 and 2020. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/9/21 at 9:30 a.m. in the break room, after review of the records, confirmed the above findings.