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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>45D1072570 | <b>(X3) Date Survey Completed</b><br><br>08/12/2022 |
| <b>Name of Provider or Supplier</b><br><br>Etmc Physician Group, Inc   | <b>Street Address, City, State</b><br><br>18118 Fm 344w, Flint, TX         |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | An onsite survey conducted 08/12/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.  |
| <b>D5783</b>              | <p><b>CORRECTIVE ACTIONS</b><br/>CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of laboratory policy, quality control (QC) records, and confirmed in interview, the laboratory failed to perform patient remediation to the last acceptable QC when QC failed to meet the laboratory's established criteria for acceptability for four out of four QC failures reviewed in November 2021 and June to July of 2022. The findings include: 1. Review of the laboratory policy titled "Hematology - Laboratory Policy and Procedure" did not include steps for patient remediation to the last acceptable QC when QC failed to meet the laboratory's established criteria for acceptability. Surveyor queried on 8/12/2022 at 11:00 hours if patient remediation to the last acceptable QC was performed for QC issues that could not be resolved with basic repeat testing; testing person (TP) 1 stated that it was not part of the laboratory's standard operating procedure. 2. Review of QC records and the "Quality Control Review" worksheets from November 2021 and June to July of 2022 had the following four QC failures that could not be resolved with repeat testing: November 2021: Three QC failures that could not be resolved with repeat testing. 11/4/2022: Problems identified: "Normal and High Control - High RBC" Corrective Action: "Remixed and</p> |

repeated, then zapped apertures 10x and startups. All within range." The last acceptable QC was on 11/3/2022, with the following 21 patients ran. ID: 12061961 ID: 09121937 ID: 08271986 ID: 05011952 ID: 12201970 ID: 09211988 ID: 11291969 ID: 11071943 ID: 06201955 ID: 06181943 ID: 02031970 ID: 12111945 ID: 09071948 ID: 06151928 ID: 02051962 ID: 03041967 ID: 03101950 ID: 05041981 ID: 06121927 ID: 10151965 ID: 01041978 11/11/2021: Problems identified: "N (normal) control - H (high) RBC Corrective Action: "Ongoing issue - Bleached Baths, zapped apertures. Changes all check valves and filters" The last acceptable QC was on 11/10/2021, with the following eight patients ran. ID: 11041949 ID: 08121982 ID: 02231945 ID: 09011941 ID: 05271946 ID: 09141944 ID: 11241954 ID: 12191961 11/22/2021: Problems Identified: "N (normal) control - H (high) RBC" Corrective Actions: "Ran reproducibility due to ongoing issue. Adjusted RBC calibration factor." The last acceptable QC was on 11/19/2021 with the following ten patients ran: ID: 11081934 ID: 01131969 ID: 01151954 ID: 08171953 ID: 10271970 ID: 08251967 ID: 11271947 ID: 09041943 ID: 05221940 ID: 09071932 July 2022: One QC failure that could not be resolved with basic repeat testing. 7/18/2022 Problems identified: L (low) control - Regional flags, L MCH and MCHC, \*'s, M's, on Diff Corrective Actions: Zapped apertures 10 x ...bleached baths. Repeated without flags and within range. The last acceptable QC was on 7/6/2022, with the following five patients ran. ID: 11151933 ID: 09211951 ID: 08191950 ID: 04211954 ID: 10061944 3. In an interview on 8/12/2022 at 11:40 hours, in the breakroom, TP 1 confirmed the laboratory did not remediate patients to the last acceptable QC when QC fails to meet the laboratory's established acceptability and could not be resolved with basic repeat testing.

**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 Centers for Medicaid and Medicare Services (CMS) 209 personnel form, inter- laboratory communication, and confirmed in an interview, the technical consultant (TC) 1 failed to perform annual competency assessments for one of one testing personnel in 2020 and 2021 The findings include: 1. Review of the CMS-209 personnel form had the following two personnel listed: TP 1 - qualified under 493.1423(b)(2) TC 2 - qualified under 493.1411(b)(2)(ii) With the laboratory director (LD) fulfilling the roles of clinical consultant (CC) and TC 1. 2. Review of inter-laboratory communication in September 2021, delegated the duty of 'control checks' to TC 2; whereas remediation of issues, quality problems, lab errors, and staff competencies, would remain with the acting LD as TC 1. Surveyor queried for the annual competency assessments for 2020 and 2021, 8/12/2022 at 09:08, and none was provided. 3. In an interview on 8/12/2022 at 09:10 hours, TP 1 confirmed that annual competency assessments had not been performed for the testing persons in 2020 and 2021.