| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 30D2033072 | 08/24/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dmc Primary Care | 6 Tsienneto Rd, Ste 301, Derry, NH | |

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 |
|---|---|
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and staff interview, the laboratory (lab) failed to enroll in an approved proficiency testing program in 2021, 2022, and 2023 for 6 of 6 chemistry and hematology analytes performed by the lab and listed in Subpart I. Findings include: 1. Review on 8/24/2023 the lab's test menu revealed the lab performs testing for the following analytes: sodium, potassium, chloride, glucose, blood urea nitrogen, and hematocrit. 2. Review on 8/24/2023 of the lab's American Proficiency Institute PT records from 2021, 2022 and 2023 revealed the enrollment was for a CLIA identification number of a different lab, not the CLIA ID for the Compliance lab. The lab could not provide PT records with the Compliance lab's CLIA identification number. 3. Interview on 8/24/2023 at 12:00 p.m. with the Director of Clinical Operations confirmed the lab did not have PT enrollment for the Compliance lab's CLIA identification. |
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>The laboratory must verify the accuracy of any analyte or subspecialty without |

| | |
|---|---|
| | analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory (lab) failed to verify the accuracy in 2022 and 2023 for 3 of 3 chemistry analytes performed by the lab and not listed in subpart I. Findings include: 1. Review on 8/24/2023 the lab's test menu revealed the lab performs testing for the following analytes: ionized calcium, creatinine, and total carbon dioxide. 2. Review on 8/24/2023 of proficiency testing records revealed the PT enrollment for ionized calcium, creatinine, and total carbon dioxide was for the wrong laboratory (CLIA identification number 30D0084805). There was no additional documentation that the lab had verified accuracy twice a year for these three analytes. 3. Interview on 8/24/2023 at 12:00 p.m. with the Director of Clinical Operations confirmed the lab's PT enrollment did not include the CLIA identification number for this laboratory. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory (lab) failed to perform calibration verification for chemistry and hematology analytes in 2022 and 2023. Findings include: 1. The lab could not provide documentation on 8/24/2023 that calibration verification had been performed in every 6 months in 2022 and 2023 for the following analytes: sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, total carbon dioxide, and hematocrit. 2. Review on 8/24 /2023 of the lab's procedure manual revealed no instructions to perform calibration verification every 6 months. 3. Interview on 8/24/2023 at 12:15 p.m. with 2 of 2 Clinical Nurse Leads confirmed the lab had not performed calibration verifications. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES |

| | |
|---|---|
| | CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the Technical Consultant (TC) failed to maintain records for semi-annual competency assessments of testing personnel performed in 2022 and 2023. Findings include: 1. Review on 8/24/2023 of personnel records revealed 7 testing personnel (TP) new since the previous survey completed on 12/16/2021. The laboratory (lab) could not provide documentation at the time of survey on 8/24/2023 of competency assessments of current and previous testing personnel performed in 2022 and 2023. 2. Interview on 8/24/2023 at 10:15 a.m. with 2 of 2 Clinical Nurse Leads confirmed above finding. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the Technical Consultant (TC) failed to maintain records for annual competency assessments of testing personnel performed in 2022 and 2023. Findings include: 1. Review on 8/24/2023 of personnel records revealed 7 testing personnel (TP) new since the previous survey completed on 12/16 /2021. The laboratory (lab) could not provide documentation at the time of survey on 8 /24/2023 of competency assessments of current and previous testing personnel performed in 2022 and 2023. Further review of personnel records revealed hire dates for some personnel exceeded 2 years. 2. Interview on 8/24/2023 at 10:15 a.m. with 2 of 2 Clinical Nurse Leads confirmed above finding. |
| **D6066** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(4)(ii)<br><br>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, laboratory (lab) failed to have documentation of training for 7 of 7 new testing personnel performing chemistry and hematology testing who were hired in 2021, 2022, and 2023. Findings include: 1. 1. Review on 8/24/2023 of personnel records revealed 7 testing personnel (TP) new since the previous survey completed on 12/16/2021. The laboratory (lab) could not provide documentation at the time of survey on 8/24/2023 of training documentation for these 7 new TP who would have been trained after the previous survey in 2021. 2. |

| | |
|---|---|
| | Interview on 8/24/2023 at 10:15 a.m. with 2 of 2 Clinical Nurse Leads revealed the hire dates may not be exact start dates for their moderate complexity test training and could not provide documentation when testing personnel completed training. |