Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2033072	12/16/2021
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
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 record review and staff interview, the laboratory failed to perform control testing using at least two levels of control each day of patient routine chemistry and hematology testing from July 2021 to December 2021. Findings include: 1) Review on 12/16/2021 of control records from July 2021 through December 16, 2021 for the i-STAT Chem8+ test cartridge revealed two levels of control material were tested once for lot #s H21136, H21167C, H21183, H21226, and H21294B on 7/27/21, 7/28/21, 8 /25/21, 10/1/21, and 11/22/21 respectively. 2) Interview on 12/16/2021 at 11:15 a.m. with Staff A (testing personnel) revealed that the current control practice was to perform two levels of control materials once for each new lot of Chem8+ test cartridges before use. 3) Interview on 12/16/2021 at 11:15 a.m. with Staff B (Director of Clinical Operations) revealed the laboratory did not develop an IQCP to support the the control testing practices by the laboratory. 4) The laboratory has performed a combined total of 2,178 routine chemistry and hematology tests since July 2021. Chem8+ test cartridge includes the following analytes: sodium, potassium, chloride, ionized calcium, total carbon dioxide, glucose, blood urea nitrogen, creatinine, and hematocrit.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to approve the procedure manual used by the laboratory. Findings include: 1) Interview with the Staff B (Director of Clinical Operations) on 12/16/2021 at 11:45 a.m. revealed the laboratory used the test device's operator manual as their procedure manual. 2) Review on 12/16/2021 of the operator manual revealed it was not signed and dated for approval by the LD.