

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404029	(X3) Date Survey Completed 01/13/2021
Name of Provider or Supplier Smdc Medical Center - Essentia Health	Street Address, City, State 502 East 2nd Street, Duluth, MN	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure corrective actions were taken when laboratory equipment operating temperatures fell outside of established parameters. The laboratory performs approximately 100 histopathology tests annually. Findings are as follows: 1. The laboratory performed histopathology testing as indicated on the Clinical Laboratory Improvements (CLIA) Application for Certification Form CMS-116, and confirmed by Laboratory Technical Manager during a tour of the laboratory on 1/13/21, at 8:05 a. m. 2. A Microm HM550 Cryostat was observed as present and available for use during the tour. 3. The operating temperature range for the Microm HM550 Cryostat was established in the "Frozen Section - Interoperative Consultation" procedure and the Microm HM550 Cryostat - Miller Dwan Histology Lab Temperature Log, both located in the on-line Histopathology Procedure Manual, as being -22 to -27 degrees Celsius. 4. The operating temperature was higher than the upper limit of the range established in procedure for 49 of 105 days on which patient testing occurred, from</p>

January 2019 through July, 2019. No evidence of corrective actions could be located in the records provided. 5. In an interview on 1/13/21, at 11:15 a.m., the Laboratory Technical Manager confirmed the above finding. .

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 document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure 19 of 46 testing personnel were evaluated for a Chemistry test procedure competency in 2020. Findings are as follows: 1. The laboratory performed Chemistry testing as indicated on the Clinical Laboratory Improvements (CLIA) Application for Certification Form CMS-116, and confirmed by Laboratory Technical Manager during a tour of the laboratory on 1/12/21, at 9:35 a. m. 2. An Abbott i-STAT chemistry analyzer was observed as present and available for use during the tour. 3. Competency assessments for testing performed on the i-STAT analyzer were not included in the on-line Laboratory Technical Competency evaluation records completed in 2020 for 19 of 46 testing personnel. 4. The laboratory was unable to provide the missing evaluations upon request. 5. In an interview on 1/12 /21, at 11:45 a.m., the Laboratory Technical Manager confirmed the above finding. .