

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404029	(X3) Date Survey Completed 09/21/2022
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to perform calibration verification on a Chemistry analyzer at least once every 6 months in 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Manager during a tour of the laboratory at 8:05 a.m. on 09/21/22. The LM indicated the Abbott i-STAT handheld analyzer was used for moderate complexity blood gas testing during the tour. 2. i-STAT calibration</p>

	<p>verification was required every six months as indicated in the Abbott iSTAT Calibration Verification procedure found in the healthcare platform MediaLab. 3. The most recent calibration verification was performed in December 2021 as indicated in laboratory records. Documentation of a calibration verification performed in 2022 was not found on date of survey, 09/21/22. The laboratory was unable to provide the missing documentation upon request. 4. In an interview at 10:30 a.m. on 09/21/22, the POC Coordinator confirmed the above finding. .</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure Hematology and Histopathology test result reports included the name and address of the laboratory location. Findings are as follows: 1. The laboratory performed Intrauterine Insemination preparations (IUI) and Tissue Grossing (Gross) under the Hematology and Pathology specialties, respectively, as confirmed by the Laboratory Manager during a tour of the laboratory at 8:05 a.m. on 09/21/22. 2. The address of the laboratory location was not included on the IUI and pathology test result reports reviewed on date of survey. See below Test Patient MRN Date of result IUI Ending in 681 09/15/22 Gross Ending in 957 09/18/22 3. In an interview at 10:00 a.m. on 09/21/22, the Pathology General Supervisor confirmed the Pathology finding, In an interview at 12:20 p.m. on 09/21/22, the Hematology General Supervisor confirmed the Hematology finding. .</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: . Based on review of personnel documents and interview with laboratory personnel, the laboratory failed to ensure staff performing moderate complexity testing meet the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: The laboratory failed to obtain an equivalency evaluation of foreign credentials for 1 testing personnel performing moderate complexity Chemistry testing in 2021 and 2022. See D6065. .</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p>

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to obtain a foreign credential equivalency evaluation for 1 of 1 testing personnel with foreign credentials who was performing moderate complexity Hematology testing between January 2021 and September 2022. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Manager (LM) during a tour of the laboratory at 8:05 a.m. on 09/21/22. The LM indicated the Roche Coagucheck-Pro device was used for moderate complexity INR testing during the tour. 2. Testing Personnel 20 (TP20) was listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as an employee performing moderate complexity testing. The LM indicated TP20 performed INR testing using the Coagucheck-Pro device. 3. Education credentials provided by the laboratory indicated TP20 completed education in Poland. The credential "Swiadestwo Dojrzalosci Liceum Medycznego" in Polish translated to "Secondary School Maturity Certificate Medicine" in English. 4. The CLIA Compliance Policy, found in the healthcare platform Media Lab, indicated the laboratory complied with all CLIA requirements for testing personnel. 5. An equivalency evaluation of TP20's foreign credentials was not found in personnel records. The laboratory was unable to provide the equivalency evaluation upon request. 6. In an interview at 11:15 a.m. on 09/21/22, the LM confirmed the above finding. .