Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2002500	02/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Bemidji Clinic 1611 North	1611 Anne Street Nw, Bemidji, 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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. 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 hematology analyzer at least once every 6 months. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 02/01 /18 at 1:05 p.m. 2. The LD indicated the hematology analyzer had recently been replaced. The previous instrument in use was a Sysmex pocH-100i hematology

	analyzer 3. The laboratory exceeded the 6 month calibration verification (cal.) interval for the Sysmex pocH-100i hematology analyzer on one occasion in the time period reviewed;June 2016 through date of discontinuance, 01/23/18. See below Previous cal. Subsequent cal. Time elapsed 07/08/16 03/11/17 8 mo., 4 days The laboratory was unable to provide additional calibration verification records between 07/08/16 and 03/11/17. 4. In an interview on 02/01/17 at 5:15 p.m., the LD confirmed the calibration verification interval had been exceeded.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 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. This CONDITION is not met as evidenced by: . Based on review of personnel documents and interview with laboratory staff, 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 moderately complex Microbiology, Chemistry and Hematology testing. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (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 an equivalency evaluation of foreign education credentials for 1 testing personnel. Findings are as follows: 1. Testing Personnel 3 (TP3) was listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as an employee performing moderate complexity testing on patient specimens. Laboratory records indicated TP3 began training in the laboratory in June 2016. 2. Education credentials found in personnel records indicated TP3's education was obtained at the Medina College in Bulatok, Pagadian City, Philippines. 3. An equivalency evaluation of foreign credentials was not found in personnel records. The laboratory was unable to provide

	an equivalency evaluation upon request. 4. In an interview on 02/01/18 at 2:45 p.m., the Laboratory Director confirmed an equivalency evaluation of TP3's foreign education credentials had not been obtained.