Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409049	08/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Health West Dickinson Clinic	2615 Fairway St, Dickinson, ND	

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
D0000	An on-site validation survey was completed on August 11, 2026 with the following standard level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, written policies and procedures, lack of competency assessment documentation and interview with the Technical Consultant (TC) #1, the laboratory failed to establish and follow written policies and procedures of assessing competency assessments for 4 of 4 TCs. Findings Included: 1) Review of the laboratory's submitted Form CMS 209 revealed 4 TCs in consultant roles. 2) Review of the laboratory's enterprise policy titled 'Sanford Policy Laboratory, Competency Program' revealed instruction for conducting six-element competency components for Testing Personnel (TPs), and not for consultant and/or supervisors. 3) No consultant competencies for the 4 TCs were provided by the laboratory. 4) In an interview on 8 /11/2026 at 2:30 PM, TC#1 confirmed the laboratory did not assess consultant competencies for consultants and/or supervisors, and did not have documentation on file.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory policy, patient testing records, and interview with the Technical Consultant (TC) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to follow manufacturer instructions to ensure Multiplex Vaginal Panels (MVP) testing was not performed on the Cepheid GeneXpert analyzer for patients under the age of 14, for 5 of 562 patients tested from January 1, 2025 to May 31, 2026. Findings Included: 1) During a laboratory tour on 8/11/2026 at 2:34 PM, one Cepheid GeneXpert analyzer (Serial Number 12055) was observed in operation, available for use for MVP testing. 2) Review of the manufacturer's instructions from Cepheid titled 'GeneXpert Power By CEPHEID INNOVATION Xpert Xpress MVP' revealed the following statements: Page 14 of 53 - "MVP test has been evaluated in patients 14 years of age and older (including pregnant women) Page 53 of 53 - "Revision History - Updated age of patients evaluated from 18 years of age to 14 years of age and older. Added limitation that false negative results can occur if level is outside the BV algorithm parameters for a positive result". 3) Review of the laboratory's policy titled 'Sanford Policy Laboratory Cepheid GeneXpert Xpert Xpress MVP' stated the following on page 10 of 11: "16. The Xpert Xpress MVP test performance has been evaluated in patients 14 years of age and older (including pregnant women)." 4) Review of patient testing records from January 1, 2025 to May 31, 2025 revealed the following 5 patients out of 562 MVPs tested, under the age of 14: a. Specimen ID: 98243178, Age: 2 b. Specimen ID: 98805123, Age:6 c. Specimen ID: 99351639, Age: 4 d. Specimen ID: 100667244, Age: 11 e. Specimen ID: 10795717, Age: 13 5) In an interview on 8/11/2026 at 2:40 PM, TC#1 confirmed the findings and stated the laboratory did not have a mechanism to ensure MVP testing was performed on patients above the age of 14 only.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, written policies and procedures, laboratory temperature continuous monitoring logs, and interview with the Technical Consultant (TC) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to define temperatures and humidity in accordance with manufacturer instructions for 2 of 2 years. Findings Included: 1) During a laboratory tour on 8/11/2026 at 2:34 PM, the following were observed stored for use or in operation: a. A box of 50 Remel BactiDrop Potassium Hydroxide (10%) ampoules, Lot Number 291777, Manufacturer storage temperature

	requirements 20 to 25 degrees Celsius. b. 1 Abbott Architect c4000 (Serial Number C461846), Manufacturer operating humidity requirements 10-85% relative humidity (non-condensing). c. 1 Sysmex XN-L 430 (Serial Number 12055), Manufacturer operating humidity requirements 10-85% relative humidity (non-condensing). 2) Review of the laboratory's written enterprise policy titled 'Sanford Policy Laboratory, Temperature and Humidity Monitoring' stated the following on page 1: "To ensure that refrigerators, freezers and the laboratory maintain appropriate temperature, humidity and measured and recorded, any out-of-range temperatures and/or humidity and the corresponding corrective actions are documented, and temperature and humidity logs are reviewed, signed and dated monthly in Epic ... 3. Procedure: 1. Set high and low limits according to manufacturers' requirements for the items stored in each area. (Quality control, reagent, test kits, etc.) 2. Record digital temperatures, from calibrated thermometers/hygrometers each day of operation for refrigerators, freezers and the laboratory ambient temperature and humidity, as applicable." 4) Review of the laboratory's continuous monitoring temperature and humidity logs revealed an acceptable temperature range of 15 to 25 degrees Celsius, and humidity range up to 95%. 5) In an interview on 8/11/2026 at 2:40 PM, TC#1 confirmed the acceptable temperature and humidity ranges of the laboratory were not defined as per manufacturer requirements.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on direct observation, review of quality control (QC) records, laboratory test records, and confirmed in interview with the Technical Consultant (TC) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to take corrective action since the last acceptable test run after QC failures on the Abbott Architect c4000 for 2 of 13 days (Random review between April 5 to April 18th, 2026). Findings Included: 1) During a laboratory tour on 8/11/2026 at 2:34 PM, 1 Abbott Architect c4000 (Serial Number C461846) was observed in use. 2) Review of the laboratory's QC records revealed the following QC failures requiring recalibration, for which a patient evaluation since the last acceptable test run was not completed: a. Analyte: Alanine Aminotranferase (ALT), QC failure/Recalibration Dates: 4/9/2026, 4/17/2026 Patient specimen IDs run on 4/8/2026: 11889417, 11881478, 11876058 Patient specimen IDs run on 4/16/2026: 12119217, 12118104, 12122670 b. Analyte: Triglycerides (TRIG), QC failure/Recalibration Dates: 4/9 /2026, 4/17/2026 Patient specimen IDs run on 4/8/2026: 11889417, 11881478, 11876058 Patient specimen IDs run on 4/16/2026: 12119217, 12118104, 12122670 3) In an interview on 8/11/2026 at 2:40 PM, TC#1 confirmed the findings the laboratory did not conduct corrective actions by performing patient evaluation to the last acceptable test run when QC failures requiring recalibration occurred.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)

	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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, written policies and procedures, lack of delegation of responsibilities/duties, and interview with the Technical Consultant (TC) #1, the laboratory director (LD) failed to ensure signed delegation of responsibilities for 4 of 4 TCs. Findings Included: 1) Review of the laboratory's submitted Form 209 revealed 4 TCs in consultant roles. 2) Review of the laboratory's enterprise policy titled 'Sanford Policy CLIA Moderate Complexity West Dickinson' stated the following on page 1 and 2 of 7: "Laboratory Director Responsibilities: ...2) The laboratory director may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications. If the laboratory delegates these responsibilities, he/she remains responsible for ensuring that all duties are properly performed ... 5) The laboratory director delegates the following responsibilities to the technical staff. They must: a. Ensure that proficiency testing samples are tested as required under Subpart H of the Federal Registry. b. Ensure that proficiency testing results are returned within the time frames established by the proficiency testing program c. Ensure an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. d. Ensure that quality control and quality assurance programs are established and maintained to assure the quality of the laboratory services provided and to identify failures in quality as they occur. e. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. f. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly." 3) No delegation of responsibilities and duties for the TCs, signed by the LD, were provided by the laboratory. 4) In an interview on 8/11/2026 at 2:30 PM, TC#1 confirmed the laboratory did not have documentation on file of the delegation of responsibilities and duties for each consultant, signed by the LD.