Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2047970	09/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sartell Pediatrics	111 2nd Street South, Sartell, 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
D0000	. The Zarminali Pediatrics laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on September 16, 2026. The following condition-level deficiencies were cited: 493.1409 Laboratories Performing Moderate Complexity Testing: Technical Consultant 493.1421 Laboratories Performing Moderate Complexity Testing: Testing Personnel The following standard-level deficiencies were cited: 493.1253 Establishment and Verification of Performance Specifications 493.1291 Test Report 493.1411 Technical Consultant Qualifications 493.1413 Technical Consultant Responsibilities 493.1423 Testing Personnel Qualifications .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete all required Performance Verification (PV) activities prior to reporting patient test results for one of one Routine Chemistry analytes performed by the laboratory in 2024, 2025, and 2026. Findings are as follows: 1. The laboratory performed Routine Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:05 a.m. on 09/16/26. 2. A Reichert Unistat Bilirubinometer instrument was observed as present and available for use

	during the tour. The laboratory performed Neonatal Bilirubin (NBili) testing using this device. This testing was implemented prior to 2024. 3. Reference interval verification was required for new non-waived tests as established in the PV procedure found in the Lab Procedure Manual.. 4. An NBili test report reviewed on date of survey did not include a reference interval (RI) as indicated below. Patient: MRN xxxx290 Age: 13 months Date: 05/11/26 Analyte: NBili RI on Report: (blank) 5. In an interview at 3:35 on 09/16/26, the LD confirmed the above finding. In an interview at 3:40 p.m. on 09 /16/26, Testing Personnel 3 indicated a reference interval for patients older than 5 days had not been established. .
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of seventeen reported Hematology reference intervals was consistent between a procedure and a patient test report in 2026. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:05 a.m. on 09/16/26. 2. An Alcor miniiSED analyzer was observed as present and available for use during the tour. The laboratory performed Erythrocyte Sedimentation Rate (ESR) testing using this analyzer. 3. The female reference interval (RI) listed in the miniiSED (ALCOR) Erythrocyte Sedimentation Rate procedure, located in the Lab Procedure Manual, was not consistent with that included on a female patient test report as indicated below. Patient: MRN xxxx154 Age: 11 years Gender: Female Date: 05/11/26 Analyte: ESR RI in Procedure: 0-20 RI on Report: 0-15 4. In an interview at 3:25 p.m. on 09/16/26, the LD confirmed the above finding. In an interview at 3:35 p.m. on 09/16/26, Testing Personnel 3 indicated the incorrect reference range for a male patient had been selected during manual data entry of the test result. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on review of personnel records, laboratory records and interview with laboratory personnel, the laboratory failed to ensure one of two personnel performing Technical Consultant responsibilities met the qualification requirements of of 493. 1411 to perform the functions specified in 493.1413. Findings are as follows: The laboratory failed to ensure one of two personnel performing Technical Consultant responsibilities was qualified to perform these activities. See D6035. .
D6035	TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:
. Based on observation, record review, and interview with the laboratory personnel, the laboratory failed to ensure one of two personnel performing Technical Consultant (TC) responsibilities in 2025 and 2026 met the TC qualification requirements of 42 CFR 493.1411. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:05 a.m. on 09/16/26. 2. The following moderate complexity analyzers and equipment were observed as present and available for use during the tour: Medonic M Series hematology analyzer Reichert Unistat Bilirubinometer instrument Alcor miniised ESR analyzer AmScope microscope (urine sediment, KOH, and vaginal wet preparation examinations) The laboratory also

	performed moderate complexity Group A Streptococcus testing using a Quidel Solana instrument in 2025. 3. The TC was responsible for evaluating testing personnel competency as established in the Competency Assessment procedure found in the Lab Procedure Manual. 4. Testing Personnel 3 (TP3) performed semiannual competency evaluations for TP2 on 08/11/25 and former TPAA on 02/10/26 as indicated on the 6 month Laboratory Testing Training Checklist documents found in personnel records. 5. TP3 did not possess the required minimum education credential of an Associate Degree as a Medical Laboratory Technician to qualify as a TC. 6. In an interview at 12:25 p.m. on 09/16/26, the LD confirmed the above finding. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually during the first year of patient specimen testing for one of three testing personnel (TP) hired in 2025. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:05 a.m. on 09/16/26. 2. The following moderate complexity analyzers and equipment were observed as present and available for use during the tour: Medonic M Series hematology analyzer Reichert Unistat Bilirubinometer instrument Alcor miniised ESR analyzer AmScope microscope (urine sediment, KOH and vaginal wet preparation examinations) 3. Competency evaluation of new testing personnel was required after 6 months of patient testing and annually thereafter as established in the Competency Assessment procedure found in the Lab Procedure Manual. 4. TP1 received an initial competency evaluation in September 2025 as indicated on the Laboratory Personnel Competency Assessment Tracking/Evaluation form found in personnel records. 5. Semi-annual competency evaluation documentation for TP1 was not found during review of 2026 laboratory records. The laboratory was unable to provide the missing competency evaluation upon request. 6. In an interview at 12:20 p.m. on 09/16/26, the LD confirmed the above finding. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least annually for one of two tenured testing personnel (TP) in 2025. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:05 a.m. on 09/16/26. 2. The following moderate complexity analyzers and equipment were observed as present and available for use during the tour: Medonic M Series hematology analyzer Reichert Unistat Bilirubinometer instrument Alcor miniised ESR analyzer Amscope

	microscope (urine sediment, KOH, and vaginal wet preparation examinations) The laboratory also performed moderate complexity Group A Streptococcus testing using a Quidel Solana instrument in 2025. 3. Competency evaluation of testing personnel was required after 6 months of patient testing and annually thereafter as established in the Competency Assessment procedure found in the Lab Procedure Manual. 4. A 2025 annual competency assessment was not found for TP3 during review of laboratory records. The laboratory was unable to provide the missing competency assessment upon request. 5. In an interview at 12:20 p.m. on 09/16/26, the LD confirmed the above finding. .
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 records, laboratory records 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 moderate complexity test performance. Findings are as follows: The laboratory failed to obtain an equivalency evaluation of foreign credentials for one testing personnel performing moderate complexity testing in 2025 and 2026. 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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to obtain a foreign credential equivalency evaluation for one of one testing personnel with foreign credentials who was performing moderate complexity testing in 2025 and 2026. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:05 a.m. on 09/16/26. 2. The following moderate complexity analyzers and equipment were observed as

	present and available for use during the tour: Medonic M Series hematology analyzer Reichert Unistat Bilirubinometer instrument Alcor miniised ESR analyzer The laboratory also performed moderate complexity Group A Streptococcus testing using a Quidel Solana instrument in 2025. 3. Former Testing Personnel AA (TPAA), hired on 08/18/25, performed the above moderate complexity testing through 07/10/26. 4. West African education credentials were found for TPAA in personnel records. The credential was generated by the T.I. Ahmadiyya Secondary School, P.O. Box 3419, Kumasi, Ghana, and entitled West African Senior School Certification Examination. 5. An evaluation of foreign credentials was not found with the education document. The laboratory was unable to provide the required evaluation upon request. 6. In an interview at 12:25 p.m. on 09/16/26, the LD confirmed the above finding. .