

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0251828	(X3) Date Survey Completed 08/19/2026
Name of Provider or Supplier Morphis Pediatrics	Street Address, City, State 708 Medical Park Drive, Hartsville, SC	
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 onsite CLIA recertification survey was conducted on August 19, 2026, at the laboratory of Morphis Pediatrics by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare conditions of participation at 42 CFR Part 493, CLIA requirements for laboratories.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to follow manufacturer's instructions on storage and stability of 10 out of 10 cassettes used for LDX Cholesterol waived testing. Findings included: 1. During a tour of the laboratory on August 19, 2026, at 3:28 pm the surveyor directly observed the Abbott Point of Care Cholestech LDX Analyzer on the counter and 10 cassettes beside it. a. Cholestech LDX, Lipid Profile, Ref 97989, Lot C08 455090, expires(exp) 2027-06-30 2. The surveyor requested but the laboratory failed to provide documentation of what date and time the cassettes were stored at room temperature. Under storage and handling section in package insert it states "Write the new expiration date" the cassettes may be stored for up to 30 days at room temperature (48-86F/9-30C). Once cassettes have been stored at room temperature, they should not be returned to the refrigerator. 3. In an interview with testing personnel (TP1) on August 19, 2026, at 3:28 pm in the office the above findings were confirmed. Fahrenheit (F) Celsius (C)
D2007	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to examine or test proficiency samples with the same personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods for 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. Review of CMS 209 Personnel Report form reveals the following testing personnel: a. TP1 b. TP2 c. TP3 d. TP4 e. TP5 2. A review of American Proficiency Institute (API) records reveals TP1 performed the Hematology test for 2 out of 2 years: a. 2024 Hematology/Coagulation 1st Event, signed 03/26/2024 b. 2025 Hematology/Coagulation 1st Event, signed 03/24/2025 c. 2025 Hematology/Coagulation 2nd Event, signed 07/23/2025 d. 2025 Hematology/Coagulation 3rd Event, signed 11/04/2025 e. 2026 Hematology/Coagulation 1st Event, signed 03/24/2026 f. 2026 Hematology/Coagulation 2nd Event, signed 07/16/2026 3. In an interview with TP1 on August 19, 2026, at 3:28 pm in the office the above findings were confirmed.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory director and/or designee failed attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of API proficiency testing (PT) results reveals TP1 signed the attestation sheets for the following events: a. 2024 Hematology/Coagulation 1st Event, signed 03/26/2024 b. 2024 Hematology/Coagulation 3rd Event, signed 11/18/2024 c. 2025 Hematology/Coagulation 1st Event, signed 03/24/2025 d. 2025 Hematology/Coagulation 2nd Event, signed 07/23/2025 e. 2025 Hematology/Coagulation 3rd Event, signed 11/04/2025 f. 2026 Hematology/Coagulation 1st Event, signed 03/24/2026 g. 2026 Hematology/Coagulation 2nd Event, signed 07/16/2026 2. The surveyor requested but the laboratory failed to provide attestation sheets signed by the laboratory director. Attestation sheets lack the laboratory director's signature. 3. In an interview with TP1 on August 19, 2026, at 3:28 pm in the office the above findings were confirmed.
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 records review, lack of documentation, and staff interview, the laboratory failed to establish and/or follow written policies and procedures to assess the clinical consultant as required 493.1235 for the 3 out 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of CMS 209 Personnel Report (CLIA) form reveals: a. 1 Laboratory Director (LD) b. 1 Clinical Consultant (CC) c. 1 Technical Consultant (TC) d. 5 Testing Personnel (TP) 2. The surveyor requested but the laboratory failed to provide written policies and procedures to assess competency based on their federal regulatory responsibilities for the following positions: a. CC b. TC If they are performing patient testing, they are required to have the six required procedures in their competency assessment in addition to the regulatory responsibilities. No documentation was available on the day of survey. 3. In an interview with TP1 on August 19, 2026, at 3:28 pm in the office the above findings were confirmed.
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, lack of documentation, and staff interview, the laboratory failed to ensure the accuracy of test systems and are consistent with manufacturer's instructions. The equipment lacks documentation of performance verification for 3 out 3 pieces of equipment used in the laboratory. Findings included: 1. During a tour of the laboratory on August 19, 2026, at 3:28 pm the surveyor directly observed the following pieces of equipment: a. Room thermometer, Sunbeam b. Timers c. Centrifuge 2. The surveyor requested but the laboratory failed to provide the date the equipment performance verification was done. 3 out of 3 pieces of equipment lacked documentation of performance verification on the day of the survey. 3. In an interview with TP1 on August 19, 2026, at 3:28 pm in the office the above findings were confirmed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to ensure control material for moderately complex testing has not exceeded

	their expiration date or deteriorated or are of substandard quality for 3 out of 3 vials viewed (Low, Normal, and High). Findings included: 1. During a tour of the laboratory on August 19, 2026, at 3:28 pm the surveyor directly observed the following control regents for the Horiba Hematology analyzers: a. ABX Minotrol 16 1, Lot #61801601, exp. 26-09-26 b. ABX Minotrol 16 2, Lot#61801602, exp. 26-09-26 c. ABX Minotrol 16 3, Lot#61801603, exp. 26-09-26 2. The surveyor requested but the laboratory failed to provide the date the vials were opened and 3 out of 3 vials lacked documentation of open dates on the day of the survey. 3. In an interview with TP1 on August 19, 2026, at 3:28 pm in the office the above findings were confirmed.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on record review (proficiency testing, competency assessment records, and personnel records), lack of documentation and staff interview, the laboratory director failed to delegate to the technical consultant, clinical consultant, and testing personnel in writing the responsibilities as required in 493.1407 for each position for the 4 of 4 years reviewed (20203, 2024, 2025, and 2026). The laboratory director remains responsible for ensuring that all duties are properly performed. Findings included: 1. Review of API PT results reveals TP1 signed the attestation sheets for the following events: a. 2024 Hematology/Coagulation 1st Event, signed 03/26/2024 b. 2024 Hematology/Coagulation 3rd Event, signed 11/18/2024 c. 2025 Hematology/Coagulation 1st Event, signed 03/24/2025 d. 2025 Hematology/Coagulation 2nd Event, signed 07/23/2025 e. 2025 Hematology/Coagulation 3rd Event, signed 11/04/2025 f. 2026 Hematology/Coagulation 1st Event, signed 03/24/2026 g. 2026 Hematology/Coagulation 2nd Event, signed 07/16/2026 2. The surveyor requested but the laboratory failed to provide attestation sheets signed by the laboratory director. Attestation sheets lack the laboratory director's signature. If the laboratory director reapportions performance of his or her responsibilities, it must be in writing to an individual meeting the appropriate qualifications. 3. The surveyor requested but the laboratory failed to provide written policies and procedures to assess competency based on their federal regulatory responsibilities for the following positions: a. CC b. TC 4. In an interview with TP1 on August 19, 2026, at 3:28 pm in the office the above findings were confirmed.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on record review, lack documentation and staff interview, the laboratory failed

to assign a qualified clinical consultant for the 4 out of 4 years reviewed (2023, 2024, 2025, and 2026). Findings included: 1. Review of CMS 209 Personnel Report form reveals the following: a. 1 laboratory director (LD) b. 1 clinical consultant (CC) c. 1 technical consultant (TC) d. 5 testing personnel (TP) 2. The surveyor requested but the laboratory failed to provide documentation as required 493.1405 for the person assigned as the CC for moderately complex testing. 3. In an interview with TP1 on August 19, 2026, at 3:28 pm in the office the above findings were confirmed.