Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0857452	05/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Alabama Pediatrics	2815 Independence Drive, Birmingham, AL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a lack of Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the laboratory failed to enroll in an approved Microbiology Urine Culture Colony Count (UCCC) PT program from the date of the last survey, 07-25-2024, through the date of the current survey, 05-19-2026. The findings include: 1. A review of PT records revealed the laboratory had no evidence of PT enrollment for the Microbiology UCCC test performed in the laboratory for approximately 22 months. 2. TP1 confirmed the above findings during the exit conference on 05-19-2026 at 2:30 PM.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) Proficiency Testing (PT) records, the lack of Quality Assurance (QA) Policies and Procedures (P&P), and an interview with Testing Personnel 1 (TP1), the laboratory failed to: (I) enroll in an approved PT program for the Microbiology Urine Culture Colony Count (UCCC); (II) implement a QA policy specifying the evaluation of Microbiology UCCC to ensure accuracy of testing. This surveyor noted missing enrollment and documentation occurred from the date of the last survey, 07-25-2024, through the date of the current survey, 05-19-2026. The findings include: 1. A review of PT records revealed the laboratory had no documentation of the PT enrollment for the Microbiology UCCC. 2. A review of the QA policy and procedure manual revealed no written documentation on how the laboratory ensures the accuracy of the Microbiology UCCC test. 3. TP1 confirmed the above findings during the exit conference on 05-19-2026 at 2:30 PM.
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 reviews of the Monthly Room Temperature (RT) and Humidity logs, the Medonic M-Series Hematology analyzer User's Guide, patient testing logs and an interview with Testing Personnel 1 (TP1), the laboratory failed to record the RT and Humidity 9 of the 26 testing days in March 2025. The findings include: 1. A review of the RT and Humidity logs revealed TP did not record RT and Humidity for the following days when the Medonic M-Series Hematology analyzer was operated. A) March 21-22, 2025 B) March 24-29, 2025 C) March 31, 2025 2. A review of the Medonic M-Series User's Guide revealed on page 83 the following specifications. A) Temperature - 64 - 90 degrees Fahrenheit (18 - 32 degrees Celsius) B) Humidity (noncondensing) - Up to 80% 3. A review of the patient testing logs revealed 93 Complete Blood Count (CBC) were performed when the RT and Humidity were not documented. 4. TP1 confirmed the above findings during the exit conference on 05-19-2026 at 2:30 PM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on surveyor's laboratory tour observation, review of manufacturer's package insert and confirmed in an interview with the Testing Personnel 1 (TP1), the laboratory failed to label Boule Hematology Quality Control (QC) materials with revised expiration dates for 3 of 3 control vials upon opening. Findings Included: 1. During the laboratory tour of the facility with the TP1 on 05-19-2026 at 8:13 AM, the surveyor observed the following Boule Hematology controls for Medonic M-Series analyzer, stored in the laboratory refrigerator. Levels Low, Normal, High Lot Number: Expiration Date: 22602-5K:07-13-2026 Open Expiration Date: Not written The surveyor inquired if the above QC vials were currently being used prior to patient testing. TP1 confirmed the QC vials were currently in use. 2. Review of manufacturer's package insert for the Boule Hematology Control revealed the following instructions, "Storage and shelf life after first opening Opened and recapped vials ... will retain stability for 14 days if stored at 2-8 C after being recapped." 3. TP1 confirmed the above findings during the exit conference on 05-19-2026 at 2:30 PM.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of the pipette maintenance records, the Policy and Procedure (P&P) Manual and an interview with the Testing Personnel 1 (TP1), the laboratory failed to perform and document the annual pipette check for the Piccolo Minipet, a 100 microliter fixed-volume micropipette. This was noted for one out of one pipette being used from the date of the last survey, 07-25-2024 to the date of the current survey, 05-19-2026. The findings include: 1. A review of the 2024-2026 pipette maintenance records revealed the Piccolo Minipet had no documentation of the annual pipette check . 2. A review of P&P manual revealed the laboratory's instructions for an annual check of the pipette. 3. TP1 confirmed the above findings during the exit conference on 05-19-2026 at 2:30 PM.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

	This STANDARD is not met as evidenced by: Based on a review of the Piccolo Total Bilirubin (TBil) Quality Control (QC) records and an interview with the Testing Personnel 1 (TP1), the laboratory failed to monitor the shifts and trends of test performance over time. The surveyor noted there was no documentation of Levey-Jennings (L-J) charts or peer group data for approximately 22 months from the date of the last survey, 07-25-2024 through 05-19-2026. The findings include: 1. A review of the Piccolo TBil QC records revealed no evidence of L-J charts or peer group data being available for review for the following months. A) 2024 - July - December B) 2025 - January - December C) 2026 - January through May 2. TP1 confirmed the above findings during the exit conference on 05-19-2026 at 2:30 PM.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the Laboratory Director failed to ensure the laboratory was enrolled in an approved PT program for the Microbiology Urine Culture Colony Count (UCCC), moderate complexity test. The surveyor noted no documentation of the PT enrollment for the Microbiology UCCC test from the date of the last survey, 07-25-2024, through the date of the current survey, 05-19-2026. The findings include: 1. A review of the API PT records revealed a lack of enrollment and documentation for the Microbiology UCCC test for approximately 22 months. 2. The TP1 confirmed the above findings during the exit conference on 05-19-2026 at 2:30 PM.