Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2084579	04/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Summit Pediatrics	134 Foothills Parkway, Chelsea, 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
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 a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Laboratory Manager/Testing Personnel 2 (LM /TP2), the laboratory failed to ensure the Laboratory Director (or designee) and the TP signed the attestation statements for one of the six 2024-2025 PT events reviewed. The findings include: 1. A review of the 2024-2025 API PT records revealed the Laboratory Director (or designee) and the TP failed to sign the attestation statements for the 2025 Hematology third event. 2. During the exit conference on 04-08-2026 at 1:19 PM, the LM/TP2 confirmed the above findings.
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 Temperature and Humidity logs, the Sysmex XP-300 Instruction For Use (IFU), the patient test records and interview with the Laboratory Manager/Testing Personnel 2 (LM/TP2), the laboratory failed to document the corrective action when the humidity was outside manufacturer's acceptable limits. The surveyor noted humidity was out of range for 56 out of 455 testing days from December 2024 through March 2026. The findings include: 1. A review of the Temperature Control and Humidity logs revealed the humidity was outside manufacturer's acceptable limits when Sysmex XP-300 Hematology analyzer was in operation for the following days. A) December 2024, 8days B) January 2025, 10 days C) February 2025, 8 days D) March 2025, 7 days E) November 2025, 1 day F) December 2025, 12 days G) February 2026, 4 days H) March 2026, 6 days 2. A review of the Sysmex XP-300 IFU revealed on Chapter 14 Technical Information, page 14-1, Operating Environment, Relative Humidity: 30-85 percent 3. A review of the patient test records revealed 444 specimens were performed during the days when the humidity was outside manufacturer's specification. 4. During the exit conference on 04-08-2026 at 1:19 PM, LM/TP2 confirmed the above findings.
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 Laboratory Manager/Testing Personnel 2 (LM/TP2), the laboratory failed to label EightCheck 3WP X-TRA 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 LM/TP2 on 04-08-2026 at 9:17 AM, the surveyor observed the following EightCheck 3WP X-TRA Hematology controls for Sysmex XP-300 analyzer, stored in the laboratory refrigerator. Levels 1, 2 and 3 Lot Number: 60760710, 60760711, 60760712 Expiration Date: 06-24-2026 Open Expiration Date: Not written The surveyor inquired if the above QC vials were currently being used prior to patient testing. LM/TP2 confirmed the QC vials were currently in use. 2. Review of manufacturer's package insert for the EightCheck 3WP X-TRA Hematology control for Sysmex analyzers with 3-Part Differentials" (AQ578643G), 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 re-capped." 3. LM/TP2 confirmed the above findings during the exit conference on 04-08-2026 at 1:19 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on a review of the Sysmex XP-300 Maintenance Log, and an interview with the Laboratory Manager/Testing Personnel 2 (LM/TP2), the laboratory failed to document the monthly and quarterly maintenances. The surveyor noted 14 out of the 22 months reviewed from June 2024 through March 2026. The findings include: 1. A review of the Sysmex XP-300 Maintenance Logs revealed a place to document monthly and quarterly maintenances for the analyzer. However, there was no documentation of performance for the following months. A) 2024 - June, August, November, December B) 2025 - March, July, August, September, October, November, December C) 2026 - January, February 2. A further review of the Sysmex XP-300 Maintenance Log revealed the manufacturer's maintenance specifications. A) Monthly (or every 1500 samples) - Clean RBC and WBC Transducer, Clean Waste Chamber B) Quarterly (or every 4500 samples) - Clean Sample Rotor Valve (SRV) 3. LM/TP2 confirmed the above findings during the exit conference on 04-08-2026 at 1:19 PM.
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 a review of the post analytical report and an interview with the Laboratory Manager (LM), who is also Testing Personnel 2 (TP2), the laboratory failed to ensure "reference intervals" or "normal" values for Complete Blood Count (CBC) analytes were included on CBC test report from the date of the last survey, 04-03-2024 through the date of the current survey, 04-08-2026. The findings include: 1. The post analytical review of patient's test report revealed no "reference intervals" or "normal" values for CBC parameters included in the report. 2. During the exit conference on 04-08-2026 at 1:19 PM, the LM/TP2 confirmed the above findings.