Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	19D0906813	09/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Center For Pediatric & Adolescent Medicine	5040 West Main Street, Houma, LA	
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	A Recertification survey was conducted at Children's Pediatrics - CLIA ID # 19D0906813 on September 10, 2025. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were 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 CMS-209 form (Laboratory Personnel Report), policies, and personnel records; as well as interview with personnel, the laboratory failed to follow their competency assessment policy for one (1) of two (2) personnel serving as Technical Consultants. Findings: 1. Review of the laboratory's CMS-209 form revealed the following personnel served as Technical Consultants: a) Personnel 1 b) Personnel 6 2. Review of the laboratory's form "Point of Care Coordinator Training and Competency Assessment" revealed the following frequency for competency assessment of the Technical Consultant: *"Initial" *"6-month" *"Annual" 3. Review of personnel records for Personnel 6 revealed a 2024 competency assessment performed by the Laboratory Director of a sister facility; however, the laboratory failed to provide documentation of a competency assessment performed by the Laboratory Director of this facility. 4. In interview on September 10, 2025 at 1:10 p.m., Testing Personnel 1 confirmed a competency assessment for Personnel 6 was not performed as identified above.
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: I. Based on observation, review of the manufacturers' instructions and the laboratory's temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Findings: 1. Observation by surveyor during the laboratory tour on September 10, 2025 at 8:54 a.m. revealed the laboratory stored specimen collection supplies in the laboratory to include, but not limited to, the following: a) BBL Cultureswab Plus Collection and Transport System for Aerobes and Anaerobes - Manufacturer's storage requirements: 5-25 degrees Celsius b) BD Vacutainer C&S Transfer Straw Kit, C&S Preservative Plus Urine Tube - Manufacturer's storage requirements: 4-25 degrees Celsius c) Vacuette Tube 8 ml CAT Serum Sep Clot Activator - Manufacturer's storage requirements: 4-25 degrees Celsius 2. Review of the laboratory's temperature logs from April 2025 through September 2025 revealed the laboratory defined the acceptable room temperature limits as 18-27 degrees Celsius which exceeded the manufacturers' upper temperature limits. 3. In interview on September 10, 2025 at 8:59 a.m., Testing Personnel 1 confirmed the laboratory's acceptable room temperature upper limit exceeded the manufacturers' required limits as identified above. II. Based on observation, review of the manufacturers' instructions and the laboratory's temperature records, as well as interview with personnel, the laboratory failed to monitor the room temperature for eight (8) of eight (8) patient rooms where specimen collection supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on September 10, 2025 at 8:54 a.m. revealed the laboratory stored the following specimen collection supplies in patient rooms: a) BBL Cultureswab Plus Collection and Transport System for Aerobes and Anaerobes - Manufacturer's storage requirements: 5-25 degrees Celsius b) RAM Scientific EDTA K2 Safe-T Micro Capillary Blood Collection - Manufacturer's storage requirement "Store at room temperature." 2. Review of the laboratory's temperature logs from January 2025 through August 2025 revealed no documentation of room temperature monitoring in the patient rooms. 3. In interview on September 10, 2025 at 10:15 a.m., Testing Personnel 1 stated swabs and blood collection tubes were stored in patient rooms, but the rooms were not monitored for room temperature. She further stated the clinic had eight (8) patient rooms.
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: I. Based on observation, review of the manufacturer's instructions for use and the

	laboratory's maintenance records, as well as interview with personnel, the laboratory failed to perform monthly maintenance on the Sysmex XP-300 as required by the manufacturer for two (2) of eight (8) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on September 10, 2025 at 8:54 a.m. revealed the laboratory utilized a Sysmex XP-300 for Hematology testing. 2. Review of the manufacturer's "Sysmex XP-300 Automated Hematology Analyzer Quick Guide" section "Maintenance" revealed the following: * "Monthly Maintenance/or Every 1,500 Samples" - "Clean Waste Chamber (Rinse Sequence)" - "Clean Transducer (Rinse Sequence" 3. Review of the laboratory's Sysmex XP-300 maintenance logs from January 2025 through August 2025 revealed the laboratory did not perform monthly maintenance in February 2025 and August 2025. 4. In interview on September 10, 2025 at 12:28 p.m., Testing Personnel 1 stated they perform monthly maintenance when the analyzer alerts them. She confirmed monthly maintenance was not performed as identified above. II. Based on observation, review of the manufacturer's instructions for use and the laboratory's maintenance records, as well as interview with personnel, the laboratory failed to perform quarterly maintenance on the Sysmex XP-300 as required by the manufacturer for two (2) of three (3) quarters reviewed. Findings: 1. Observation by surveyor during the laboratory tour on September 10, 2025 at 8:54 a.m. revealed the laboratory utilized a Sysmex XP-300 for Hematology testing. 2. Review of the manufacturer's "Sysmex XP-300 Automated Hematology Analyzer Quick Guide" section "Maintenance" revealed the following: * "3-Month Maintenance/or Every 4,500 Samples" - "Clean the SRV" 3. Review of the laboratory's Sysmex XP-300 maintenance logs from January 2025 through August 2025 revealed the laboratory performed quarterly maintenance in February 2025 but did not perform quarterly maintenance when due in May 2025 and August 2025. 4. In interview on September 10, 2025 at 12:28 p.m., Testing Personnel 1 stated they perform quarterly maintenance when the analyzer alerts them. She confirmed quarterly maintenance was not performed as identified above.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Refer to D5413 I. 2. The laboratory failed to monitor the room temperature for eight (8) of eight (8) patient rooms where specimen collection supplies were stored. Refer to D5413 II.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by:

	Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to perform monthly maintenance on the Sysmex XP-300 as required by the manufacturer for two (2) of eight (8) months reviewed. Refer to D5429 I. 2. The laboratory failed to perform quarterly maintenance on the Sysmex XP-300 as required by the manufacturer for two (2) of three (3) quarters reviewed. Refer to D5429 II.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Refer to D5413 I. 2. The laboratory failed to monitor the room temperature for eight (8) of eight (8) patient rooms where specimen collection supplies were stored. Refer to D5413 II. 3. The laboratory failed to perform monthly maintenance on the Sysmex XP-300 as required by the manufacturer for two (2) of eight (8) months reviewed. Refer to D5429 I. 4. The laboratory failed to perform quarterly maintenance on the Sysmex XP-300 as required by the manufacturer for two (2) of three (3) quarters reviewed. Refer to D5429 II.