

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0101910	(X3) Date Survey Completed 10/22/2025
Name of Provider or Supplier Ridgefield Pediatric Associates	Street Address, City, State 38-B Grove St, Ridgefield, CT	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow their established Quality Control (QC) procedure to verify the new lot of controls upon receipt in the specialty of Hematology. Findings include: 1. Record review on 10/22/2025 of the laboratory's "Hematology Quality Control for Beckman Coulter DxH520" procedure revealed "When receiving new set of controls, run each level of controls 5x to confirm they are running properly. Do not discard the old set (keep in use) for at least 24 hours, in case of any issues with the new set." 2. Record review on 10/22/2025 of the "Beckman Coulter cell check" QC package insert revealed the following: a. Three levels of quality controls, 'Abnormal Low, Normal and Abnormal High' are in use. b. Current lot in use are: 352517711/362517712/372517713 with an expiration date of 2025-12-05. 3. Record review on 10/22/2025 of the laboratory's "IQAP Cell Control Daily Data" revealed lack of documentation of controls are run 5x to confirm the new QC lot verification as follows: a. Control/Level: DxH 5Diff/ Abnormal Low/ Normal/ Abnormal High with lot numbers: 352517711/362517712 /372517713 respectively. b. Start date for the current QC lot documented as 10/10/2025. c. Only One data point for all three levels of controls on 10/10/2025. 4. Staff interview on 10/22/2025 at 12:30 PM with Testing Personnel #1 confirmed the laboratory failed to perform the new QC lot verification 5x run as established in their policy. 5. The laboratory performs 93 complete blood count tests annually in the specialty of hematology.</p>

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to establish and follow complete written policies and procedures for streptococcus selective agar (SSA) throat cultures prior to patient testing in the subspecialty of bacteriology. Findings include: 1. Record review on 10/22/2025 of the laboratory's SSA throat cultures policies and procedures revealed lack of documentation of the following procedural steps: a. Specimen type and criteria for specimen acceptability and rejection. b. Step by step performance of the procedure. c. Corrective action to be taken when control results fail to meet acceptable criteria. d. Limitations in the test methodology including interfering substances. e. Reference intervals. f. Actions to be taken if testing system becomes inoperable. 2. Staff interview on 10/22/2025 at 12:20 PM with Testing Personnel #1 confirmed the above findings. 3. The laboratory performs 3,703 SSA throat cultures annually in the subspecialty of bacteriology.

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 surveyor observation, record review and staff interview, the laboratory failed to define and provide evidence of monitoring and documenting humidity

requirements in the specialty of hematology. Findings include: 1. Surveyor observation on 10/22/2025 at 9:45 AM of the laboratory work bench area revealed a DxH 500 Hematology analyzer is in use. 2. Record review on 10/22/2025 of the laboratory's maintenance records for 2024 and 2025 revealed lack of documentation of humidity levels for the laboratory area. 3. Record review on 10/22/2025 of the 'DxH 500 Hematology analyzer' operators manual revealed an acceptable relative humidity requirement of up to 80% (non-condensing) while operational. 4. Staff interview on 10/22/2025 at 12:30 PM with Testing Personnel #1 confirmed the above findings. 5. The laboratory performs 93 complete blood counts annually in the specialty of hematology.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the Technical Consultant (TC) failed to approve the competency assessment of Testing Personnel (TP) that performs moderate complexity testing in the subspecialty of bacteriology. Findings include: 1. Record review on 10/22/2025 of the laboratory's 'Competency assessment of Laboratory Testing Personnel' forms for 9 of 9 TP's in 2024 and 11 of 11 TP's in 2025 revealed the following: a. Peer to peer competency assessments are being carried out among TP's. b. Lack of documentation of the TC's signature and date in the TP competency records. 2. Staff interview on 10/22/2025 at 10:00 AM with Testing Personnel #1 (TP#1) confirmed the above findings. TP#1 further commented that he/she was not aware that the TC must perform the competency assessments. 3. The laboratory performs 3,703 Streptococcus Selective Agar throat cultures annually in the subspecialty of bacteriology.