

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D0101910	<b>(X3) Date Survey Completed</b> 07/02/2019
<b>Name of Provider or Supplier</b> Ridgefield Pediatric Associates	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5441</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document when quality controls (QC) were out of range and establish QC procedures to monitor QC shifts and trends in the speciality of hematology. Findings include: 1. Record review of the laboratory's quality control (QC) records on 7/8/19 revealed the following: a) The laboratory failed to monitor QC results over time to monitor shifts and trends. b) The laboratory failed to document corrective action when QC is out of range; specifically on 12/22, 12/31 in 2018 and on 1/13/19. 2. Staff interview with testing personnel #1 on 7/8/19 at 12:45 PM confirmed: a) The laboratory does not have a mechanism in place to monitor QC shifts and trends. b) The laboratory failed to document corrective action when the QC was out of range for the above dates. 3. The laboratory performs 358 Complete blood count tests annually.</p>
<b>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p>

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to check each lot and shipment of media for its ability to support growth and, as appropriate, select or inhibit specific organisms in the specialty of microbiology. Findings include: 1. Record review of the quality control records for BBLSelect Strep Agar (SSA) on 7/8/19 revealed the laboratory failed to document the ability of the media to support growth, select or inhibit specific organisms for each lot number and shipment in 2017 and 2018. 2. Staff interview with testing personnel #1 (TP1) on 7/8/19 at 1:50 PM confirmed the laboratory did not check each new lot number or shipment of SSA media for their ability to support growth and, as appropriate, select or inhibit specific organisms. TP # 1 stated the laboratory relied on the manufacturer's certificate of analysis and documented only the physical condition of the media when received. 3. The laboratory performs 2462 cultures annually in the specialty of microbiology.