

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D0512004	<b>(X3) Date Survey Completed</b>  07/01/2024
<b>Name of Provider or Supplier</b>  Littleton Pediatric Medical Center	<b>Street Address, City, State</b>  206 W County Line Rd, Suite 110, Highlands Ranch, CO	
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>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's competency records, proficiency testing (PT) records, and an interview with the laboratory's technical consultant (TC1), the laboratory failed to rotate the testing of PT samples in the microbiology, hematology, and urology subspecialties between the four testing personnel (TPs) competent to and regularly performing testing in these subspecialties during all PT events from 2022 through 2024. The laboratory performs approximately 11,466 tests annually. Findings include: 1. A review of the laboratory's competency records showed that of the four TPs listed on form CMS-209, all four were competent to and regularly performed microbiology, hematology, and urology testing in the laboratory. 2. A review of the laboratory's PT attestations and records from 2022 through 2024 revealed that only one of four TPs competent to and regularly performing microbiology, hematology, and urology testing in the laboratory had participated in any events from 2022 through 2024. 3. An interview with TC1 on 07/01/2024 at approximately 11:00 A.M. confirmed that only one of the four TPs competent to and regularly performing microbiology, hematology, and urology testing in the laboratory had handled PT samples for these subspecialties from 2022 through 2024.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's competency records and policies, and an interview with the laboratory's technical consultant (TC1), the laboratory failed to establish and follow written policies to assess the competency of three out of three technical consultants (TCs) and two out of two clinical consultants (CCs), since the last survey on 08/13/2021. The laboratory performs approximately 11,466 tests annually. Findings include: 1. A review of the laboratory's records showed that there were no recorded assessments of consultant competency, since the last survey on 08/13/2021. 2. A review of the laboratory's policies and procedures revealed that there was no written policy for the assessment of consultant competency. 3. An interview with TC1 on 07/01/2024 at approximately 11:00 A.M. confirmed that the laboratory did not have a written policy to assess the competency of consultants and had not been doing so since the last survey on 08/13/2021.

**D5221**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's proficiency testing (PT) records, and an interview with the laboratory's technical consultant (TC1), the laboratory failed to evaluate and document the evaluation of PT results received from the the College of American Pathologists (CAP), since the laboratory's last survey on 08/13/2021. The laboratory performs approximately 11,466 tests annually. Findings include: 1. A review of the laboratory's PT records showed that no evaluation or documentation of PT results review were recorded when the laboratory received a score of less than 100% for any analytes. 2. An interview with TC1 on 07/01/2024 at approximately 11:00 A.M. confirmed that the laboratory did not document or perform any evaluation or corrective action of PT scores received from CAP.

**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 the laboratory's records, and an interview with the laboratory's technical consultant (TC1), the laboratory failed to have a written and approved policy or procedure for assessing the competency of laboratory staff, and handling laboratory communications and complaints, since the laboratory's last survey on 08/13/2021. The laboratory performs approximately 11,466 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that there were no written and approved policies or procedures for assessing the competency of

	<p>laboratory staff, and handling laboratory communications and complaints. 2. An interview with TC1 on 07/01/2024 at approximately 11:00 A.M. confirmed that the laboratory did not have written and approved policies or procedures for assessing the competency of laboratory staff, and handling laboratory communications and complaints.</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, and an interview with the laboratory's technical consultant (TC1), the current laboratory director (LD) failed to approve, sign, and date the laboratory's policies and procedures before allowing them to be used, since the last survey on 08/13/2021. The laboratory performs approximately 11,466 tests annually. Findings include: 1. A review of the laboratory's policies and procedures showed that none of the policies currently in use by the laboratory had been approved, signed, and dated by the current LD. 2. An interview with TC1 on 07/01/2024 at approximately 11:00 A.M. confirmed that the current LD had not approved, signed, and dated any of the policies and procedures, despite being used in the laboratory.</p>
<p><b>D5433</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's maintenance records and an interview with the laboratory's technical consultant (TC1), the laboratory failed to perform routine maintenance on the Horizon 642E centrifuge used in processing patient samples at least every two years- as recommended by the manufacturer- since the laboratory's last survey on 08/13/2021. The laboratory performs approximately 11,466 tests annually. Findings include: 1. A review of the laboratory's maintenance records showed that there were no service records present for the Horizon 642E centrifuge used in processing patient samples. 2. An interview with TC1 on 07/01/2024 at approximately 11:00 A.M. confirmed that the centrifuge had not been serviced since at least 2022- when TC1 was hired- and that no service records were present for the instrument.</p>
<p><b>D5779</b></p>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(a)</p>

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policy and procedure manual and an interview with the laboratory's technical consultant (TC1), the laboratory failed to establish and follow a written and approved policy or procedure for investigating laboratory errors, documenting corrective actions, and evaluating the effectiveness of the corrective actions taken, since the laboratory's last survey on 08/13/2021. The laboratory performs approximately 11,466 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that there was no written and approved policy or procedure for investigating laboratory errors, documenting corrective actions, or evaluating their effectiveness. 2. An interview with TC1 on 07/01/2024 at approximately 11:00 A.M. confirmed that the laboratory did not have a written and approved policy or procedure for investigating laboratory error and documenting corrective actions, and had not been evaluating their effectiveness.