

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0983924	<b>(X3) Date Survey Completed</b> 07/26/2019
<b>Name of Provider or Supplier</b> Hamilton Pediatrics	<b>Street Address, City, State</b> 6918 Shallowford Rd, Suite 226, Chattanooga, TN	
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>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of one of six proficiency testing (PT) records and an interview with the laboratory manager, the laboratory director failed to attest to the 2017 B event Hematology Complete Blood Count (CBC) attestation statement. Findings include: 1. There was no attestation/signature by the laboratory director on the 2017 B (2nd ) event for CBC. 2. In an interview, July 24, 2019, at 10:30am, the laboratory manager confirmed the missing Laboratory Director signature and attestation on the attestation statement for the 2017 B event for CBC.</p>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p>

	<p>This STANDARD is not met as evidenced by: Based on a review of complete blood count (CBC) patient test records and an interview with the lab manager, the laboratory failed to retain 2 of 5 hematology CBC patient reports from 2018-2019. Findings include: 1. There were no hematology CBC patient records (test reports) available for review for patient #2 (2/9/2018) and patient #3 (2/10/2019). 2. In an interview, on July 24, 2019, at approximately 12:30 PM, the lab manager stated the CBC patient records were not available for review for patient #2 (2/9/2018) and patient #3 (2/10/2019).</p>
<p><b>D5303</b></p>	<p><b>TEST REQUEST</b> CFR(s): 493.1241(b)</p> <p>The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.</p> <p>This STANDARD is not met as evidenced by: Based on a review of two of five patient records and an interview with the laboratory manager, the laboratory failed to obtain written or electronic orders of laboratory tests for 2 of 5 records for complete blood counts (CBC) test ordered on February 9, 2018 and February 10, 2019, within 30 days of testing. Findings include: 1. A records review revealed 2 of 5 patient records no orders or requisitions for a CBC test reported on patient #2 (2/9/2018) and patient #4 (2/10/2019). 2. An interview on July 24, 2019 with the laboratory manager confirmed no written or electronic order for CBCs reported for patients (#2 &amp; #4) during 2018-2019.</p>
<p><b>D5400</b></p>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Hematology specialty complete blood count (CBC) quality control (QC) records for 2017-2019 and interview with the lab manager, the laboratory failed to follow manufacturer's instructions (MI) to perform CBC calibrations every six months during 2017-2019 (Refer to D5439) and failed to perform Hematology CBC QC procedures from 2017-2019 (Refer to D5445) resulting in Immediate Jeopardy.</p>
<p><b>D5439</b></p>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;</p>

(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the complete blood count (CBC) quality control (QC) records for 2017-2019 and an interview with the laboratory manager, the laboratory failed to conduct calibration verifications every six months as required resulting in Immediate Jeopardy. Findings include: 1. Review of the QC records lacked CBC calibration verifications performed on the hematology instrument every six months per the manufacturer's instructions during 2017-2019. 2. In an interview, July 24, 2019, at approximately 11:15 AM, the laboratory manager confirmed the laboratory failed to perform calibration verifications every six months per the manufacturer's instructions during 2017-2019 resulting in Immediate Jeopardy.

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the complete blood count (CBC) quality control (QC) and patient audit records and an interview with laboratory manager, the laboratory failed to perform Hematology CBC QC procedures during 2017-2019 resulting in Immediate Jeopardy. Findings include: 1. CBC QC records for 2017-2019 lacked the QC for three of five CBC patients reported (#1- 8-24-2017, #4- 2/10/2019, and #5- 7-3-2019). 2. In an interview, July 24, 2019, at approximately 11:00 AM, the laboratory manager confirmed the laboratory did not perform the QC for three of five CBC patients reported (#1- 8-24-2017, #4- 2/10/2019, and #5- 7-3-2019) resulting in Immediate Jeopardy. 3. In a telephonic interview, July 29, 2019, at 11:55pm, the laboratory manager confirmed the unavailability of the CBC QC records for patients

tested from 2018 (August = 332, September = 139, October = 179, November = 170, and December = 98 patients) and 2019 (January = 170, February = 109, March = 176, April = 161, May = 160, June = 185, and July = 150 patients) for a total of 2029 patients without proof of QC for 12 months.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records and an interview with the laboratory manager, the laboratory director failed to document corrective actions during the Hematology complete blood cell (CBC) PT events for 2017-B and 2018-C. Findings include: 1. There were no corrective actions available for review for the unsatisfactory Hematology CBC PT events for 2017-B and 2018-C. 2. In an interview, on July 24, 2019, at approximately 11:00 AM, the laboratory manager confirmed no corrective actions were available for review for CBC PT events for 2017-B and 2018-C.