

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2017196	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Pediatric & Family Medicine	Street Address, City, State 3905 Webb Road, Chattanooga, TN	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 proficiency testing (PT) record's attestation statements for 2018 and an interview with the contract consultant, the laboratory failed to ensure the laboratory director signed the attestation statements in the first, second, and third events for complete blood count (CBC) of 2018. Findings include: 1. There were no laboratory director's signatures on attestation statements for the first, second, and third PT events for CBC specimens from 2018 available to review. 2. In an interview, November 7, 2018, at 2:30pm, the contract consultant confirmed the missing laboratory director signatures on the attestation statements for first, second, and third PT events for CBC specimens from 2018 available to review.</p>
D3031	<p>RETENTION REQUIREMENTS 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</p>

activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of daily Hematology quality control records and interview with the contract consultant determined that the laboratory failed to retain daily Hematology quality control records for the Coulter AcTdiff complete blood count (CBC) analyzer for November 7 until December 31, 2016. The findings include: 1. Lack of review of daily Hematology quality control records determined that the laboratory failed to retain daily Hematology quality control records for the Coulter AcTdiff CBC analyzer for November 7 until December 31, 2016. 2. Interview with the contract consultant on November 7, 2018 at 1:00pm confirmed that the laboratory failed to retain daily Hematology quality control records for the Coulter AcTdiff CBC analyzer for November 7 until December 31, 2016.

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

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.

This CONDITION is not met as evidenced by:

Based on a review of the laboratory's procedure manual revealed no panic or alert values for the complete blood count (CBC) for 2016-2018 (Refer to D5403) and review of hematology calibration verification records for 2016 and 2018, a review of the manufacturer's instructions, the laboratory failed to perform hematology calibration verifications when due every six months in 2017 (Refer to D5439).

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 a review of the laboratory's procedure manual and interview with contract consultant, the laboratory failed to include panic or alert values for hematology complete blood count (CBC) for 2016-2018. Findings include: 1. Review of the laboratory's manual (dated May 2015 by laboratory director - LD) revealed no panic or alert values for CBC testing. 2. An interview on November 7, 2018, at 1:15pm, with the contract consultant confirmed the laboratory did not have any panic or alert values for CBC testing from 2016-2018.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
 CFR(s): 493.1255(b)

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; (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 hematology complete blood count (CBC) calibration verification records for 2016 and 2018, a review of the manufacturer's operator guide, review of quality control (QC) records, chart review, and an interview with the contract consultant, the laboratory failed to perform hematology calibration verifications when due every six months in 2017. Findings include: 1. Review of the CBC calibration verification records disclosed that hematology calibration verifications were performed on August 31, 2016, then not again until March 31, 2018. 2. The manufacturer's operator guide indicates, "When necessary or as regulated by your regulatory agency." 3. A review of QC records for November 7, 2016, until November 5, 2018, revealed missing CBC QC records from November 7 until December 31, 2016. 4. Review of 5 patient charts indicated that Patient #2-4 did not have supporting CBC calibration verifications from February 13, 2017, until February 9, 2018. 5. In an interview, on November 7, 2018, at 11:00am, the contract consultant confirmed the hematology instrument calibration verifications were due and not performed every six months in 2017.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the proficiency testing (PT) complete blood count (CBC) results and interview, the laboratory Director (LD) failed to ensure PT scores were returned within the timeframes for the first event of 2018 resulting in a zero percent score (Refer to D6017) and failed to ensure all proficiency testing (PT) records are reviewed and evaluated to identify problems that require corrective actions (Refer to D6018).

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare Services (CMS) Casper 155 report for proficiency testing (PT) scores for the first event of 2018 for complete blood count (CBC) including red blood cells (RBC), white blood cells (WBC), hemoglobin (hgb), hematocrit (hct), platelets (plt), and automated wbc differential (wbc diff) and an interview with the contract consultant, the laboratory director (LD) failed to ensure the PT CBC results are returned within the timeframes for the first event of 2018 resulting in a zero percent score. Findings include: 1. Review of the CMS Report 0155D for Proficiency Testing (PT) scores revealed the 2018 CBC scores for the first event were 0% due to missing the PT timeframes. 2. An interview on November 7, 2018, at 1:30pm, with the contract consultant confirmed the 2018 CBC scores including rbc, wbc, hgb, hct, plt, and wbc diff for the first event were 0% due to missing the PT timeframes.

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 2018 proficiency testing (PT) records, lack of quality assurance

	<p>(QA) records, and an interview with the contract consultant, the laboratory director (LD) failed to ensure all proficiency testing (PT) records are reviewed and evaluated to identify problems that require corrective actions for the first event for complete blood count (CBC) of 2018. Findings include: 1. Review of the lab's 2018 PT records for the first event for CBC revealed a 0% score. 2. There were no QA corrective actions documented for the first event PT CBC score of 0% score in 2018 by the lab director. 3. An interview on November 7, 2018, at 1:15pm, with the contract consultant confirmed a score of 0% without any PT or QA corrective actions documented for the first event PT CBC in 2018 by the lab director.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of Testing Personnel (TP) records, personnel report (Centers for Medicare Services - CMS 209), and an interview with the contract consultant, the Technical Consultant failed to perform semiannual TP competencies for complete blood counts (CBC) in 2018 (refer to D6053) and the Technical Consultant failed to perform and approve annual TP competencies for CBC in 2017 and 2018 (refer to D6054).</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of Testing Personnel (TP) records, personnel report (Centers for Medicare Services - CMS 209) and interview with the contract consultant determined the Technical Consultant failed to perform semiannual TP competencies for complete blood counts (CBC) in 2018. The findings include: 1. Review of TP records revealed the Technical Consultant failed to perform semiannual CBC competencies for TP# 2 due in January and July 2018. 2. Review of the laboratory personnel report revealed 2 of 2 testing persons performing CBCs in 2018. 3. Interview with the contract consultant on November 7, 2018 at 1:45pm confirmed that the Technical Consultant failed to perform semiannual CBC competencies for TP# 2 due in January and July 2018.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p>

This STANDARD is not met as evidenced by:
Based on review of Testing Personnel (TP) records, personnel report (Centers for Medicare Services - CMS 209) and interview with the contract consultant determined the Technical Consultant failed to perform and approve annual TP competencies for complete blood counts (CBC) in 2017 and 2018. The findings include: 1. Review of TP records revealed the Technical Consultant failed to perform and approve annual CBC competencies for TP# 1 due in 2017-2018. 2. Review of the laboratory personnel report revealed 2 of 2 testing persons performing CBCs in 2017-2018. 3. Interview with the contract consultant on November 7, 2018 at 1:45pm confirmed that the Technical Consultant failed to perform annual CBC competencies for TP# 1 due in 2017 and 2018.