

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2068197	<b>(X3) Date Survey Completed</b>  12/05/2019
<b>Name of Provider or Supplier</b>  Columbia Pediatric Clinic	<b>Street Address, City, State</b>  1003 Reserve Blvd Ste 110, Spring Hill, 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>D0000</b>	<p>Intakes: TN00049973 Surveys were performed on December 5, 2019 and January 28, 2020 on the following two laboratories: On December 5, 2019, a recertification survey was performed on Columbia Pediatric Clinic, 44D2068197, located at 1003 Reserve Blvd., Suite 110, Spring Hill, TN 37174 (Laboratory A). On January 28, 2020, a complaint survey was performed on Columbia Pediatric Clinic, 44D0315886, located at 1600 Nashville Hwy., Columbia, TN 38401 (Laboratory B). Laboratory A performs complete blood count with differential on the Horiba ABX Micros 60 and neonatal bilirubin on the Unistat Bilirubinometer. Laboratory B performs complete blood count with differential on the Horiba ABX Micros 60, neonatal bilirubin on the Unistat Bilirubinometer, urine microscopy and wet prep. Both laboratories are enrolled and participate in proficiency testing with the same proficiency testing program, the College of American Pathologists (CAP).</p>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Columbia Pediatric Clinic failed to ensure its laboratories did not participate in any communications or discussions across sites/locations concerning proficiency testing (PT) sample results until after the date the PT results were due (Refer to D2011).</p>

**D2011**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based on review of Laboratory A quality assurance and proficiency testing records, Laboratory B quality assurance and proficiency testing records, and interview with the director of Laboratory A, the Columbia Pediatric Clinic failed to ensure laboratories did not participate in inter-laboratory communications concerning proficiency testing sample results until after the date the PT results were due in 2018 and 2019. The findings include: 1) Review of Laboratory A quality assurance records and proficiency testing event cutoff dates provided by the laboratory's proficiency testing program revealed the following: Presence of complete blood count (CBC) instrument printouts for proficiency testing samples from Laboratory B for 2018 event two and 2019 event two. The printouts for both events were faxed to Laboratory A prior to the PT program's results due date. Instrument printouts for 2018 event two were faxed to Laboratory A on May 25, 2018 (PT sample numbers FH2-06, FH2-07, FH2-08, FH2-09, FH2-10). The PT results for 2018 event two had an assigned due date by the PT provider for May 29, 2018. Instrument printouts for 2019 event two were faxed to Laboratory A on May 28, 2019 (PT sample numbers FH2-06, FH2-07, FH2-08, FH2-09, FH2-10). The PT results for 2019 event two had an assigned due date by the PT provider for May 28, 2019. 2) Review of Laboratory B quality assurance and proficiency testing records revealed the presence of complete blood count (CBC) instrument printouts for proficiency testing sample numbers FH2-06, FH2-07, FH2-08, FH2-09, and FH2-10 for 2019 event two that were performed at Laboratory A. The fax date on the printouts was May 28, 2019 (five of five proficiency testing CBC instrument printouts). The results due date for 2019 event two Hematology was May 28, 2019. 3) Interview with the director of Laboratory A on December 5, 2019 at 2 p. m. confirmed Columbia Pediatric Clinic failed to ensure Laboratory A did not participate in inter-laboratory communication with Laboratory B until after the date PT results were due to the PT provider for event two 2018 and 2019. The interview also confirmed that Laboratory A received faxed instrument printouts for proficiency testing results from Laboratory B for events 2018 event two and 2019 event two. Furthermore, during interviews conducted on January 28, 2020 at 2:45 pm at Laboratory B it was determined that Laboratory A faxed proficiency testing results to Laboratory B for 2019 event two.

**D5016**

**ROUTINE CHEMISTRY**

CFR(s): 493.1210

If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:  
The laboratory failed to perform calibration of the Bilirubinometer instrument (Refer to D5437), failed to perform calibration verification of the Bilirubinometer instrument (Refer to D5439), and failed to have an effective quality assessment process for the Bilirubinometer instrument (Refer to D5793).

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, review of manufacturer's instruction manual, laboratory records, and interview with the laboratory liaison, the laboratory failed to follow manufacturer's instructions for calibration in 2018 and 2019. The findings include: 1. Observation of the laboratory on December 5, 2019 at 9:00 a.m. revealed the Reichert Unistat Bilirubinometer on the counter in use for pediatric patient testing for total bilirubin. (Serial number 09943-0817). 2. Review of the manufacturer's instruction manual revealed that the Bilirubinometer is to be calibrated at least every six months, or earlier if indicated by quality control data, using stable assayed glass calibration cuvette. 3. Review of laboratory records revealed no records were present for calibration of the Bilirubinometer in 2018 or 2019. 4. Interview with the laboratory liaison on December 5, 2019 at 12:20 p.m. confirmed the laboratory failed to follow the manufacturer's instructions for calibration of the Bilirubinometer every six months in 2018 and 2019.

**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 observation of the laboratory, review of the Reichert Bilirubinometer manufacturer's instruction manual, laboratory records, and interview with the laboratory liaison, the laboratory failed to perform calibration verification of the Reichert Bilirubinometer instrument in 2018 and 2019. The findings include: 1. Observation of the laboratory on December 5, 2019 at 9:00 a.m. revealed the Reichert Unistat Bilirubinometer on the counter in use for pediatric patient testing for total bilirubin. (Serial number 09943-0817). 2. Review of the manufacturer instructions for the Reichert Bilirubinometer revealed that the Bilirubinometer calibration can be verified using assayed glass cuvettes to check the mid and high points of the 0-40 mg/dL measuring range and that a sample cuvette filled with distilled water may be used to check zero. 3. Review of laboratory records revealed no records were present for verifying the calibration of the Bilirubinometer in 2018 or 2019. 4. Interview with the laboratory liaison on December 5, 2019 at 12:20 p.m. confirmed the laboratory uses the manufacturer's stated measuring range of 0-40 mg/dL and failed to perform calibration verification at least every six months using a low, mid and maximum value in 2018 and 2019.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory quality assessment plan, patient/quality control log for the Reichert Bilirubinometer and the manufacturer's quality control package insert, and interview with the laboratory director, the laboratory's quality assessment process was ineffective when it failed to detect the use of incorrect quality control ranges resulting in the performance of patient testing on dates when quality control was unacceptable in 2019 (fifteen of twenty-nine patients). The findings include: 1) Observation of the laboratory on December 5, 2019 at 9:00 a.m. revealed the Reichert Unistat Bilirubinometer on the counter in use for pediatric patient testing for total bilirubin. 2) Review of the laboratory's quality assessment plan revealed that review of quality control of instruments is done during the month of June. 3) Review of the log used for recording patient and quality control testing and the manufacturer's control package insert for lot numbers 44331 and 44332 revealed the following: Lot numbers 44331 (level one) and 44332 (level 2) in use during dates of 9.4.19 to 11.14.19. Quality control ranges in use during these dates were 6.8-7.5 mg/dL for level one and 17.9-19.8 for level two. The manufacturer's stated quality control ranges for these lots were 7.3-8.0 mg/dL for

level one and 19.0-21.0 for level two. Patient testing was performed on dates when quality control was unacceptable (patient number eight on 11.07.2019). Other dates where patient testing was performed with unacceptable quality control includes 09.06.2019, 09.09.19, 09.27.19, 09.30.19, 10.02.19, 10.03.19, 10.08.19, 10.15.19, 10.17.19, 10.22.19, 11.08.19. Patient testing was performed for 15 of 29 patients during this period (9.4.19 to 11.14.19) on dates when quality control was unacceptable. There was no documented review of the bilirubin patient/quality control logs by the laboratory director/technical consultant and no documented corrective actions. 4) Interview with the laboratory director on December 5, 2019 at 2:00 p.m. confirmed the laboratory's quality assessment process was ineffective when it failed to review bilirubin patient test/quality control logs, detect and correct problems with bilirubin quality control in 2019, resulting in the performance of patient testing on dates when quality control was unacceptable (fifteen of twenty-nine patients).

**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:  
The director of Laboratory A failed to ensure Laboratory A did not participate in any communications or discussions across sites/locations concerning proficiency testing (PT) sample results until after the date the PT results were due. (Refer to D6016)

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on review of Laboratory A quality assurance records, information provided by the laboratory's proficiency testing (PT) program, and interview with the director of Laboratory A, the director of Laboratory A failed to ensure Laboratory A did not participate in any inter-laboratory communication across sites/locations with Laboratory B concerning proficiency testing (PT) results until after the date the PT results were due in 2018 and 2019. The findings include: 1) Review of Laboratory A quality assurance records and proficiency testing event results due dates provided by the laboratory's proficiency testing program revealed the following: Presence of complete blood count (CBC) instrument printouts for proficiency testing samples from a sister laboratory (Laboratory B) for 2018 event two and 2019 event two. The printouts for both events were faxed prior to the PT program results due date as follows: 2018 event two with a fax date of May 25, 2018 on the instrument printouts (PT sample numbers FH2-06, FH2-07, FH2-08, FH2-09, FH2-10); results due date was May 29, 2018, five of five samples. 2019 event two with a fax date of May 28,

2019 on instrument printouts (PT sample numbers FH2-06, FH2-07, FH2-08, FH2-09, FH2-10); results due date was May 28, 2019, five of five samples. 2. Interview with the director of Laboratory A on December 5, 2019 at 2 p.m. confirmed the director of Laboratory A failed to ensure Laboratory A did not participate in inter-laboratory communication with Laboratory B regarding proficiency testing results until after the PT results due date for 2018 event two and 2019 event two.