

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315886	(X3) Date Survey Completed 01/28/2020
Name of Provider or Supplier Columbia Pediatric Clinic	Street Address, City, State 1600 Nashville Hwy, Columbia, 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
D0000	<p>Intakes: TN00050273 Surveys were performed on the following two laboratories as follows: 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>
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES 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 B quality assurance and proficiency testing records, Laboratory A quality assurance and proficiency testing records, and interviews with the director of Laboratory A, the director of Laboratory B, and the clinical manager, the Columbia Pediatric Clinic failed to ensure laboratories did not participate in communications or discussions across sites/locations concerning proficiency testing (PT) sample results until after the date the PT results were due in 2019. The findings include: 1) Review of Laboratory B quality assurance and proficiency testing records revealed the following: Presence of complete blood count (CBC) instrument printouts for proficiency testing samples from Laboratory A for 2019 event two. The printouts were faxed to Laboratory B prior to the PT program's results due date. Instrument printouts for 2019 event two were faxed to Laboratory B 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 A quality assurance records and proficiency testing event cutoff dates provided by the laboratory's PT provider 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 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. 3) Interviews with the director of Laboratory A, the director of Laboratory B, and the clinical manager on January 28, 2020 at 2:45 p.m. confirmed the Columbia Pediatric Clinic failed to ensure laboratories did not participate in inter-laboratory communication concerning PT results until after the date the PT results were due for 2019 event two Hematology. The interview also confirmed that Laboratory B received faxed proficiency testing instrument printouts from Laboratory A for 2019 event two. Furthermore, it was determined that Laboratory B faxed proficiency testing results to Laboratory A for 2018 event two and 2019 event two.

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 B failed to ensure Laboratory B 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 B quality assurance records, Laboratory B proficiency testing records, and interviews with the directors of Laboratory A and Laboratory B and the clinical manager, the director of Laboratory B failed to ensure Laboratory B did not participate in any inter-laboratory communication across sites/locations concerning proficiency testing (PT) results until after the date the PT results were due in 2019. The findings include: 1) Review of Laboratory B quality assurance records revealed the presence of complete blood count instrument printouts for proficiency testing sample numbers FH2-06, FH2-07, FH2-08, FH2-09, FH2-10 that were performed at a sister laboratory (Laboratory A). The date the proficiency testing CBC instrument printouts were faxed from Laboratory A to Laboratory B was May 28, 2019 for five of five proficiency testing samples. 2) Review of the laboratory's proficiency testing records revealed the results due date for 2019 event two was May 28, 2019. 3) Interviews with the director of Laboratory A, the director of Laboratory B and the clinical manager on January 28, 2020 at 2:45 p.m. during exit confirmed the director for Laboratory B failed to ensure Laboratory B did not participate in inter-laboratory communication with Laboratory A regarding proficiency testing results until after the PT results due date for 2019 event two.