Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0675742	05/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Covington Pediatrics	614 West Bypass, Andalusia, AL	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2021 API (American Proficiency Institute) proficiency testing (PT) records, personnel records, and an interview with Testing Personnel (TP) #2 and the Laboratory Director, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed moderate complexity Hematology testing on patients. This was noted on seven of nine surveys events reviewed. The findings include: 1. A review of API attestation statements revealed the employee listed as TP #2 on the previous Form CMS-209 (Laboratory Personnel Report) from the 6/26/2018 survey had signed the attestation as the testing personnel and had performed all the testing on the following Hematology surveys: 2018-Event #3, 2019-Events #1 and #2, and 2020-Event #1 [Records for the 2019-Event #3 were not available, and were printed during the survey; the attestation statement was not signed. Refer to D3037.] 2. A review of API attestation statements revealed TP #2 listed on the current Form CMS-209 had signed the attestation as the testing personnel and had performed all the testing on the following Hematology surveys: 2020-Event #2 (while being supervised by TP #4), 2020-Event #3, and 2021-Event #1. 3. A review of the personnel files of testing personnel listed on the current Form CMS-209 revealed, TP #1 and #4 had been qualified to perform moderate complexity Hematology testing since the previous survey (on 6/26/2018). TP #3 was a recently hired employee, trained to perform Hematology testing on 10/5/2020. There was no record of TP #1, #3 or #4 performing PT. 4. During an interview on 5/5/2021 at 12:05 PM, the TP #2 confirmed she had performed all the Hematology proficiency testing because she was "in charge of the

	lab"; TP #4 had supervised her performing the PT on 2020-Event #2, because "it was her first time". (The surveyor noted TP #2 was hired and trained in September 2017.) TP #2 further confirmed the person "in charge of the lab" (listed as TP #2 on the previous Form CMS-209) had also performed all the PT in late 2018 thru early 2020. 5. During an interview with the Laboratory Director on 5/5/2021 at 12:15 PM, the surveyor reviewed PT deficiencies, and explained all testing personnel listed on the CMS-Form 209 must periodically participate in the performance of proficiency testing, not just the person "in charge of the lab". .
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2021 API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel (TP) #2 and the Laboratory Director, the surveyor determined the laboratory failed to ensure proficiency testing records for one of nine surveys were retained for at least two years. The findings include: 1. A review of API PT records revealed no results (scores) with review sheet, no program forms, no attestation statement and no instrument printouts for the 2019-Event #3 survey. 2. During an interview on 5/5/2021 at 12:05 PM, TP #2, confirmed she was unable to find these records, so she printed scores, program forms, and the attestation statement (unsigned) from the API website. TP #2 confirmed she was unable to find the instrument printouts, and the original signed attestation statement. 3. During an interview on 5/5/2021 at 12:15 PM, the surveyor reviewed PT deficiencies with the Laboratory Director. .
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 reviews of API (American Proficiency Institute) proficiency testing records, Sysmex XP-300 Hematology quality control and calibration records, inadequate quality assurance documentation, and interviews with Testing Personnel #2, the Practice Manager and the Laboratory Director (who also serves as one of the Technical Consultants), the surveyor determined the laboratory failed to implement an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the quality of the analytic systems. These systemic failures were noted to occur during a nine-month period in 2020. The findings include: 1. Refer to D2007, D5437, D5441, D5447, and D5791. .
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 reviews of the Sysmex XP-300 Hematology calibration records, and an interviews with Testing Personnel #2, the Practice Manager, and the Laboratory Director, the surveyor determined the laboratory failed to ensure calibrations were performed with the frequency required by the manufacturer in 2020 - 2021. The findings include: 1. A review of Sysmex XP-300 calibration records revealed the following: A) 11/4/2019: Documentation of an acceptable calibration with an expiration date in early May 2020 B) The next calibration was performed during a service call on 9/14/2020; this calibration expired on March 2021. 2. During an interview on 5/5/2021 at approximately 2:30 PM, the surveyor asked if calibrations had been performed every six months, as required by the manufacturer. The Office Manager and Testing Personnel stated Sysmex may not have been performing calibrations in early 2020 due to COVID-19. When asked about the calibration due in March 2021, the Office Manager stated there was confusion on whether the laboratory had a current service agreement; the Manager stated they did and had provided Sysmex with a copy of it. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the Sysmex XP-300 Hematology Quality Control (QC) records and an interview with the Laboratory Director, the surveyor determined the laboratory failed to review and monitor for shifts and trends to assess accuracy and precision of test performance over time in 2020- 2021. The findings include: 1. A review of the QC records for the Sysmex XP-300 Hematology analyzer revealed the daily QC printouts were retained for the 2018 - 2021 survey period. The laboratory had elected to submit the QC data to the Sysmex Insight website (the Sysmex Interlaboratory

	Quality Assurance Program) as a method of monitoring the QC for shifts and trends over time. 2. The surveyor reviewed the Sysmex Insight reports from 8/20/2018 thru 1 /3/2020. For dates thereafter, no Sysmex Insight reports were available. Testing Personnel #2 printed six reports covering the time period of 12/30/2019 thru 5/5/2021 on the day of the survey at the surveyor's request. 3. A review of the Sysmex Insight reports revealed a nine-month period with notifications from Sysmex of positive biases that required action for Hemoglobin, MCH (Mean Corpuscular Hemoglobin) and MCHC (Mean Corpuscular Hemoglobin Concentration) on the following reports: A) Lot #9365: 12/30/2019 thru 4/6/2020 B) Lot #0084: 4/6/2020 thru 6/26/2020 C) Lot #0168: 6/22/2020 thru 9/23/2020 There was no documentation of investigation and corrective action until September 2020 when the laboratory failed the 2020-Event #2 Hematology proficiency testing (performed on 7/27/2020). (Refer to D5791.) 4. During interviews on 5/5/2021 at 12:15 PM and 3:20 PM, the surveyor asked the Laboratory Director if she was aware of the notifications of QC bias for Hemoglobin, MCH and MCHC in the 2020 Sysmex Insight reports. The Director explained her main focus during 2020 was COVID-19, so she had depended on the person running the laboratory; the Testing Personnel (TP) listed as TP #2 on the previous Form CMS-209 (Laboratory Personnel Report) from the 6/26/2018 survey failed to notify the Director of any QC problems. When the laboratory received failing scores for the Red Blood Cell indices (MCH and MCHC) on the 2020-Event #2 survey, the current lab supervisor investigated and notified the Director; Sysmex was called and performed service on the Hematology instrument on 9/14/2020. The Director did not know whether patient testing and care had been affected during the nine-month period of QC bias. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Hematology quality control (QC) records and an interview with Testing Personnel #2, the surveyor determined the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on one day in December 2020. The findings include: 1. A review of the Hematology records revealed no documentation of QC on 12/3/2020. 2. During an interview on 5/5/2021 at 2:45 PM, Testing Personnel #2 confirmed no QC was performed on 12/3/2020, and three patient CBC's (Complete Blood Counts) were run. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on reviews of API (American Proficiency Institute) proficiency testing (PT) records, Sysmex XP-300 Hematology quality control (QC) and calibration records, a lack of quality assurance (QA) documentation of problems found during the survey process, and interviews with Testing Personnel #2, the Practice Manager and the Laboratory Director (who also serves as one of the Technical Consultants), the surveyor determined the laboratory failed to implement an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the quality of the analytic systems. These systemic failures in the specialty of Hematology were noted to occur in 2020 and 2021. The findings include: (I) Proficiency testing: 1. A review of laboratory records revealed no QA procedures were implemented to ensure proficiency testing (PT) records were retained for at least two years (Refer to D3037), and PT was rotated to verify proficiency for all testing personnel who performed patient testing (Refer to D2007). 2. A review PT results revealed the QA procedures did not include reviews for biases in the SDI's (Standard Deviation Index) to determine if investigation and corrective actions were required (see below). A) A review of the 2020-Event #1 survey (performed on 3/19/2020) revealed the laboratory failed to review and investigate the significance of the positive bias in the SDI for Hemoglobin. [MCH (Mean Corpuscular Hemoglobin) and MCHC (Mean Corpuscular Hemoglobin Concentration) were not reported in this survey.] B) A review of the 2020-Event #2 survey (performed on 7/27/2020) revealed significant positive biases in the SDI's for Hemoglobin, MCH (with a failing score of 0%), and MCHC (with a failing score of 20%). Sysmex performed service on the Hematology instrument on 9 /14/2020; a clot was removed from the RBC (Red Blood Cell) transducer and a calibration was performed. (II) Hematology: 1. Calibrations: A review of laboratory records revealed no QA procedures were implemented to ensure calibrations were performed every six months as required by the manufacturer in 2020 - 2021. The surveyor noted a calibration was not performed in early May 2020 as required (due to COVID-19). The laboratory further failed to ensure a calibration was performed in a timely manner in March 2021. (Refer to D5437.) 2. Quality Controls: A review of laboratory records revealed no QA procedures were implemented to ensure shifts and trends in the quality control (QC) results were monitored. (Refer to D5441.) A review of the Sysmex Insight reports revealed a nine-month period (January thru September 2020) with notifications from Sysmex of positive biases that required action for Hemoglobin, MCH and MCHC. These reports were not printed until the day of the survey, thus there was no documentation of review; the surveyor further noted there was no documentation of corrective actions implemented until September 2020. (See above) (III) Quality Assurance (QA) 1. The laboratory records included monthly QA reviews, however the procedures were inadequate to monitor, assess, and, when indicated, correct problems identified in the quality of the analytical systems. There was no documentation of the above noted problems until September 2020. 2. In an interview with the Laboratory Director on 5/5/2021 at 3:20 PM, the surveyor reviewed the above noted findings, and the lack of quality assurance reviews required to assess and correct failures in the quality of the analytical system for nine months from January thru December 2020; the surveyor also discussed ongoing problems in 2021 (missed calibration and no documentation of review on the 2021 Sysmex Insight reports). The surveyor also noted a lack of reviews in 2020 to determine if patient CBC (Complete Blood Count) results, and patient care was impacted by the above noted problems. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	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. This CONDITION is not met as evidenced by: Based on reviews of API (American Proficiency Institute) proficiency testing records, Sysmex XP-300 Hematology quality control and calibration records, a lack of quality assurance documentation, and interviews with Testing Personnel #2, the Practice Manager and the Laboratory Director (who also serves as one of the Technical Consultants), the surveyor determined the Technical Consultants failed to fulfill their responsibilities to provide technical and scientific oversight of the laboratory in 2020 and 2021. The findings include: 1. Refer to D6036. .
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on reviews of API (American Proficiency Institute) proficiency testing records, Sysmex XP-300 Hematology quality control and calibration records, a lack of quality assurance documentation, and interviews with Testing Personnel #2, the Practice Manager and the Laboratory Director (who also serves as one of the Technical Consultants), the surveyor determined the Technical Consultants failed to fulfill their responsibilities to provide technical and scientific oversight of the laboratory in 2020 and 2021. The findings include: 1. Refer to D5400, D5437, D5441, D5447 and D5791. SURVEYOR ID #32258 Licensure and Certification Surveyor