

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0700623	(X3) Date Survey Completed 09/25/2018
Name of Provider or Supplier Childersburg Primary Care	Street Address, City, State 33637 Us Hwy 280, Childersburg, 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
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of patient test reports and instrument printout of results, a review of quality assurance records (QA) and laboratory logs, a review of policies and procedures, and an interview with Testing Personnel (TP) #6, the surveyor determined the laboratory failed to follow its policy and procedure, "Panic Value Procedure," to rerun a patient's sample, when a critical platelet count was obtained on Patient I on 3/21/17. The laboratory staff failed to identify possible errors in its system processes and take corrective actions when the patient was sent to a reference laboratory for additional testing, which resulted in a normal platelet count from a specimen drawn at the reference laboratory on the same day as the laboratory's specimen draw and testing. This affected 1 of 9 patient test reports reviewed by the surveyor. The findings include: 1. A review of Patient I's instrument printout of CBC testing (Complete Blood Count), dated 3/21/17 at 1445 (2:45 PM) revealed a platelet count of 49.0 x 10 E3/ul. The platelet count was circled on the instrument printout. The normal range for platelets was indicated as 150 - 450. The instrument printout was noted with two sets of initials; one was the testing personnel and the other identified later in an interview as the nurse practitioner. 2. A review of the laboratory's "Panic Value Procedure" revealed: "... 1. Rerun sample to assure that accurate results were obtained. 2. If results remain in the critical range, immediately notify the ordering provider for additional instructions." The panic values for platelets were listed as less than 100 (x10 E3/ul) and greater than 700. This policy was signed by the Laboratory Director, but was not dated. There was no documentation the specimen was repeated for accuracy. 3. A review of the daily lab log for 3/21/17 revealed a note the platelet</p>

count for Patient I was abnormal, and was sent out for testing. 4. In an interview with TP #6 on 9/25/18 at 1:39 PM, the testing personnel stated the report was given to the nurse practitioner, who reviewed it and requested a send out for testing. The surveyor requested to review the send-out test report. The reference laboratory's report, dated 3/21/17 (specimen date) and 3/22/17 (result date) revealed a normal (150-379) platelet count of 216. At this time, the surveyor asked if the specimen had been sent to the reference laboratory. TP #6 stated a new specimen was drawn at the reference laboratory. The surveyor asked if the laboratory had repeated the specimen internally for accuracy. TP #6 stated the specimen had not been repeated at the laboratory; although the procedure was to rerun the specimen, and show the physician the initial result and the repeated result. TP #6 further stated the nurse practitioner was shown the initial result (panic value) of Patient I, and the nurse practitioner requested a sent out test for the patient.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on a review of patient test reports and instrument printout of results, a review of quality assurance records (QA) and laboratory logs, a review of policies and procedures, and an interview with Testing Personnel (TP) #6, the surveyor determined the laboratory failed to accurately report the Red Blood Cell Count (RBC) for patient A on 1/30/17. Although the laboratory staff performed a chart review of the patient's medical record for quality assessment checks, the laboratory failed to identify the error in recording and reporting. The laboratory further failed to follow its policy and procedure, "Panic Value Procedure," to rerun a patient's sample, when a critical platelet count was obtained on Patient I on 3/21/17. These failures affected 2 of 9 patient test reports reviewed by the surveyor. The findings include: 1. A review of Patient A's test report, dated 1/30/17, and printed from the electronic system on 9/25/18, revealed the RBC was resulted as $50.6 \times 10^6/\text{ul}$ (microliters). 2. A review of patient A's instrument printout, included in the quality assurance records, revealed the RBC was $5.06 \times 10^6/\text{ul}$. 3. Further review of the QA records revealed the laboratory had performed a quality assessment on the patient's chart in January of 2017. Patient A's record was one of three records reviewed by the laboratory staff. The quality assessment form included a column for "Test Results" under the section, "PATIENT CHART" and this was marked "y" (yes) by the laboratory staff. The laboratory staff failed to identify the error in recording (transcription error) and reporting. 4. In an interview on 9/25/18 at 2:00 PM, TP #6 explained checking the medical record for accuracy of recording/reporting was included in the quality assessment review. TP #6 stated she failed to realize the decimal point had been entered in the incorrect place, resulting in an erroneous result for the RBC for Patient A. The testing personnel stated in an earlier interview (at 9:45 AM), the laboratory staff manually enters test results into the computer system. 5. A review of Patient I's instrument printout of CBC (Complete Blood Count) testing, dated 3/21/17 at 1445 (2:45 PM) revealed a platelet count of $49.0 \times 10^3/\text{ul}$. The platelet count was circled on the instrument printout. The normal range for platelets was indicated as 150 - 450. The instrument printout was noted with two sets of initials; one was the testing personnel and the other identified later in an interview as the nurse practitioner. 6. A review of the laboratory's

"Panic Value Procedure" revealed: "... 1. Rerun sample to assure that accurate results were obtained. 2. If results remain in the critical range, immediately notify the ordering provider for additional instructions." The panic values for platelets were listed as less than 100 ($\times 10^3/\text{ul}$) and greater than 700. This policy was signed by the Laboratory Director, but was not dated. There was no documentation the specimen was repeated for accuracy. 7. A review of the daily lab log for 3/21/17 revealed a note the platelet count for Patient I was abnormal, and was sent out for testing. 8. In an interview with TP #6 on 9/25/18 at 1:39 PM, the testing personnel stated the report was given to the nurse practitioner, who reviewed it and requested a send out for testing. The surveyor requested to review the send-out test report. The reference laboratory's report, dated 3/21/17 (specimen date) and 3/22/17 (result date) revealed a normal (150-379) platelet count of 216. At this time, the surveyor asked if the specimen had been sent to the reference laboratory. TP #6 stated a new specimen was drawn at the reference laboratory. The surveyor asked if the laboratory had repeated the specimen internally for accuracy. TP #6 stated the specimen had not been repeated at the laboratory; although the procedure was to rerun the specimen, and show the physician the initial result and the repeated result. TP #6 further stated the nurse practitioner was shown the initial result (panic value) of Patient I, and the nurse practitioner requested a sent out test for the patient. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor