

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0933626	(X3) Date Survey Completed 06/14/2019
Name of Provider or Supplier Cattail River Hematology & Oncology	Street Address, City, State 3418 Olandwood Court #111, Olney, MD	
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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory (lab) director, the director did not document his review of the proficiency test providers evaluation for events the lab participated in 2019 and 2018. Findings: 1. The lab receives unknown proficiency samples from the proficiency test provider, for three separate events a year. The lab tests the samples and submits the results of the test to the provider. The proficiency test provider evaluates (scores) the test results and reports these results to the lab; 2. The lab director did not document that he reviewed the proficiency test providers evaluations for event 1 in 2019, event 3 in 2018, event 2 in 2018 and event 1 in 2018; and 3. This was confirmed during interview with the lab director upon exit on the day of survey.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory (lab) director, the lab</p>

director did not ensure that hematology quality control programs are maintained to ensure quality control failures are identified and corrected prior to testing patient samples. Findings: 1. The lab performs automated hematology testing on patient samples using an analyzer that reports the patient complete blood count and white blood cell differential; 2. The laboratory written procedure stated that the lab test three levels of control reagent (low, normal and high), evaluate the results of each quality control test and take corrective action when any control reagent result(s) fail to fall within the manufacturer's expected ranges (two standard deviations) prior to patient testing; 3. The laboratory tested patient specimens and reported the test results when the labs hematology quality control results failed to meet the labs criteria for acceptability ; 4. On May 1, 2019 the normal white blood cell (WBC) control result was 8.1 [acceptable range 8.3-9.7] and the high WBC control result was 17.4 [acceptable range 17.6-20.0], both control results failed to meet the laboratory's criteria for acceptability, but the lab tested and reported results for four patients; 5. On May 2, 2019 the normal white blood cell (WBC) control result was 8.2 [acceptable range 8.3-9.7] and the high WBC control result was 17.5 [acceptable range 17.6-20.0], both controls failed to meet the laboratory's criteria for acceptability, and in addition this was the second consecutive day of testing these control results failed, but the lab tested and reported results for four patients; 6. On May 6, 2019 the low white blood cell (WBC) control result was 2.8 [acceptable range 3.5-4.5], the normal WBC control result was 7.8 [acceptable range 8.3-9.7] and the high WBC control result was 17.3 [acceptable range 17.6-20.0], all three control results failed to meet the laboratory's criteria for acceptability, and in addition this was the third consecutive day of testing that the normal and high control reagent results failed, but the lab tested and reported results for eight patients; 7. On May 8, 2019 the high white blood cell (WBC) control result was 17.4 [acceptable range 17.6-20.0] and failed to meet the laboratory's criteria for acceptability, and in addition this was the fourth consecutive day of testing the control result failed, there was no corrective action report that stated patient testing was discontinued until the problem was corrected; 8. On May 16, 2019 the low WBC control result was 3.4 [acceptable range 3.5-4.5], this control result failed to meet the laboratory's criteria for acceptability, there was no corrective action report that stated patient testing was discontinued until the problem was corrected; 9. On May 20, 2019 the normal WBC control result was 8.2 [acceptable range 8.3-9.7], this control result failed to meet the laboratory's criteria for acceptability, there was no corrective action report that stated patient testing was discontinued until the problem was corrected; 10. On May 22, 2019 the normal WBC control result was 8.2 [acceptable range 8.3-9.7], this control result failed to meet the laboratory's criteria for acceptability, there was no corrective action report that stated patient testing was discontinued until the problem was corrected; 11. On May 24, 2019 the low WBC control result was 2.0 [acceptable range 3.5-4.5], the low red blood cell control result was 1.79 [acceptable range 2.02-2.52], the low hemoglobin control result was 3.1 [acceptable range 5.3-6.7] and the low hematocrit control result was 13.4 [acceptable range 14.2-19.6] these control results failed to meet the laboratory's criteria for acceptability, but the lab tested and reported results for one patient; 12. On May 31, 2019 the low WBC control result was 3.2 [acceptable range 3.5-4.5], this control result failed to meet the laboratory's criteria for acceptability, there was no corrective action report that stated patient testing was discontinued until the problem was corrected; 13. On May 29, 2019 the normal WBC control result was 8.2 [acceptable range 8.3-9.7], this control result failed to meet the laboratory's criteria for acceptability, there was no corrective action report that stated patient testing was discontinued until the problem was corrected; 14. On May 30, 2019 the normal WBC control result was 8.2 [acceptable range 8.3-9.7], this control result failed to meet the laboratory's criteria for acceptability, and in addition this was the second consecutive day of testing the control result failed, there

was no corrective action report that stated patient testing was discontinued until the problem was corrected; 15. The Daily Action log contained two entries for May 2019, the first for May 2, 2019 stated that patient results failed but were successfully retested and the second for May 20, 2019 stated that the startup failed; and 16. The monthly quality assurance report stated that in May 2019 there were no quality assurance problems, daily quality control was performed and that the monthly quality control graphs were reviewed, but two weeks later in June 2019, the lab finally identified the May quality failures. The lab director did not ensure that the quality control failures were identified and that corrective actions were taken (and documented) to resolve problems prior to patient testing.