Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0933626	05/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cattail River Hematology & Oncology	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the individual testing or examining the PT samples signed the PT attestation statements, attesting that hematology PT specimens were run in the same manner as patient samples. Findings: 1. The laboratory currently has one testing person (TP) listed on the "Laboratory Personnel Report" (CMS-209). 2. A review of hematology instrument printouts from PT run between 2023 and 2025 showed that TP #1 ran the PT for five out of five PT events, however the attestation statements for these five PT events were signed by only the LD and not the TP who performed the PT testing. 3. During an interview on 05/02 /2025 at 12:30 PM, the LD confirmed that the attestation statements were not signed by the individual who performed the PT.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by:

	Based on procedure manual review and interview with the laboratory director (LD), the laboratory failed to update its procedure manual to include the implementation of a new hematology analyzer. Findings: 1. The laboratory validated and began testing with a new hematology analyzer, the "Medonic M-Series" on 06/29/2023. 2. A review of the approved procedure manual showed that it contained outdated information related to the previous "Beckman Coulter AcT Diff" hematology analyzer. This included a sheet titled, "Blood Value Limits: Beckman Coulter AcT Diff" which listed "Hematology Reportable Ranges Verified with Lin C Linearity Control" and "Patient Limits (Normal)," a "Coulter AcT Diff Maintenance Log," and a "Coulter AcT Maintenance Schedule." 3. The procedure manual also included generic procedures ("Patient Test Management [Record Keeping]" and "Quality Control") provided by Beckman Coulter. These generic procedures had blanks/gaps to allow the laboratory to "personalize" the procedure by writing in information specific to the laboratory ' s policies. The procedures had not been completed or filled out by the laboratory, to provide accurate information to testing personnel. 4. The laboratory had a copy of the "Medonic M-Series User ' s Manual" which was not approved (signed and dated) by the LD. 5. During an interview on 05/02/2025 at 12:30 PM the LD confirmed that the approved procedure manual had not been updated to reflect the testing currently performed in the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the laboratory director (LD), the laboratory failed to provide the testing personnel with written preanalytical, analytical, and post analytical policies and procedures for testing with the Medonic M-Series hematology analyzer. Findings: 1. Procedure manual review showed that the laboratory ' s approved procedure manual did not include: requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242; step-by-step performance of the procedure, including test calculations and interpretation of results; preparation of calibrators, controls, reagents,

	and other materials used in testing; calibration and calibration verification procedures; the reportable range for test results for the test system as established or verified in 493. 1253; control procedures; corrective action to take when calibration or control results fail to meet the laboratory ' s criteria for acceptability; limitations in the test methodology, including interfering substances; or a description of the course of action to take if a test system become inoperable. 2. The procedures included in the current procedure manual referred to the previous hematology analyzer which is not currently in use. Cross-refer to D5401 3. During an interview on 05/02/2025 at 12:30 PM the LD confirmed that the approved procedure manual failed to include updated preanalytical, analytical, and post analytical policies for performing hematology testing.