Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0923623	05/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Donald R Schneider Md & Zachary R Schneider Md	2538 Davidsonville Road, Gambrills, 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) 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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 9/25/2018 for not ensuring that proficiency testing attestation statements were signed by the laboratory director. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the LD signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of hematology PT records for 6 PT events in 2019 and 2020 showed that the LD did not sign the attestation statement for the 3rd event of 2019. 2. During an interview on 5/13/2021 at 3:15 PM, the LD confirmed that the attestation statement was not signed by the LD.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on procedure manual and record review and interview with the laboratory director (LD), the laboratory did not establish written policies and procedures for

	assessing the testing personnel as defined in subpart M- CFR 493.1413(b)(8) through (9). Findings: 1. A review of the laboratory's competency assessment records from 2019 and 2020 showed that the laboratory's "Clinical Laboratory Clinical Performance Review" worksheet included 4 categories: "Blood specimen collection"; "Specimen Handling"; "Test performance"; and "Documentation" and check boxes to indicate whether each is "Satisfactory" or "Needs Improvement." This worksheet did not include all of the required elements for evaluating the competency of the testing personnel and assuring that they maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. 2. The LD stated in an email on 5/3/21 that "We do have a competency checklist that we have used in our regular evaluations in the past but there was no competency policy written." 3. During an interview on 5/13/2021 at 3:15 PM, the LD confirmed that the laboratory did not establish and follow written policies and procedures to assess employee competency.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 did not provide the testing personnel with written policies and procedures for performing quality control (QC) and documenting corrective actions when results of QC did not meet the laboratory's criteria for acceptability. Findings: 1. The laboratory uses a CDS Medonic M-Series hematology analyzer to perform hematology testing. 2. Procedure manual review showed that the current QC procedure does not include written instructions for what steps to take if hematology QC is unacceptable, or how to document corrective actions taken; and 3. Part of the QC procedure reviewed refers to the previous hematology analyzer which is not currently in use. 4. During an interview on 5/13/2021 at 3:15 PM, the LD confirmed that the procedure manual did not contain procedures for how to perform QC and document corrective actions when QC is not acceptable.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on temperature log record review and interview with the laboratory director (LD), the laboratory failed to document corrective action when freezer temperatures were out of range. Findings: 1. Temperature records were reviewed from October through December, 2019 and from September through October, 2020. 2. The temperature range for the laboratory freezer is less than or equal to -15 degrees Celsius. 3. In October, 2019 laboratory freezer temperatures were out of range 2 out of 23 times recorded. 4. In November, 2019 laboratory freezer temperatures were out of range 6 out of 21 times recorded. 5. In December, 2019 laboratory freezer temperatures were out of range 7 out of 22 times recorded. 6. In September, 2020 laboratory freezer temperatures were out of range 21 out of 21 times recorded. 7. In October, 2020 laboratory freezer temperatures were out of range 22 out of 22 times recorded. 8. There were no corrective actions documented for these dates. 9. During an interview on 5/13/2021 at 3:15 PM, the LD confirmed that there were no corrective actions documented for the days that the laboratory freezer temperatures were out of range.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the lot numbers and expiration dates of reagents and control materials used for hematology testing were documented. Findings: 1. Review of the laboratory's "Medonic CA 620 Reagent Log" from 1/17 /2019 to 9/14/2020 showed that 3 out of 15 times the identity of the item being logged was not documented; and 2. The "Dilt" logged on 9/14/2020 did not have the "Date Opened," "Lot Number," or "Expiration Date" documented. 3. During an interview on 5/13/2021 at 3:15 PM, the LD confirmed that documentation of lot numbers and expiration dates of reagents and QC material used for hematology testing was incomplete.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

	be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on procedure manual and quality control (QC) record review and interview with the laboratory director (LD), the laboratory did not ensure that all corrective actions were documented when hematology QC was unacceptable. Findings: 1. The laboratory uses a CDS Medonic M-Series hematology analyzer to perform hematology testing. 2. The laboratory uses a "Control Performance Log" to document whether hematology QC is acceptable by requiring the testing person to put a check mark to document that QC is "IR" (in range) or "OR" (out of range) under the columns labeled "HIGH," "NORMAL," and "LOW." There is space at the bottom of the form for the user to document "Date OR" "COMMENTS" and "Corrective action." 3. A review of "Control Performance Logs" from October through December, 2019 and October through November, 2020 showed that on 12 occasions QC was marked as "OR" but no corrective actions were documented. 4. During an interview on 5/13/2021 at 3:15 PM, the LD confirmed that corrective action had not been documented when hematology QC was out of range.