Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D2115767	08/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Delgiacco Medical Llc	Vi Medical Foundation Bldg, Charlotte Amalie, VI	

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 review of 2024 and 2025 American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) program attestation documentation and interview with the laboratory consultant, the laboratory testing personnel failed to sign the attestation for two of three events. Findings: 1. Review of AAB.-MLE M3 2024 and AAB.-MLE M1 2025 events showed no signature by the testing personnel analyzing the PT specimens. 2. Interview with the laboratory consultant on 8/25/2025 at 1:00 PM confirmed the individual testing the PT specimens failed to attest to the routine integration of the samples in the patient workload.
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 observation, review of documentation, and interviews, the laboratory failed to ensure a step-by-step procedure for usage of sodium citrate tubes on the DxH 520 hematology analyzer for complete blood cell counts (Refer to D5403), failed to ensure the hematology controls were labeled with a preparation and expiration date (Refer to D5415); and failed to ensure hematology quality control were not used when they had exceeded their expiration date (Refer to D5417).
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 review of the laboratory's procedure manual and interview with the testing person (TP) and the laboratory consultant, the laboratory failed to have a step-by-step procedure for usage of sodium citrate specimen tubes (blue top) on the Beckman Coulter DxH 520 hematology analyzer. Findings: 1. Review of the laboratory's procedure manual showed no step-by-step procedure for usage of sodium citrate specimen tubes on the Beckman Coulter DxH 520 analyzer for complete blood cell count (CBC) testing. 2. Interview on 8/25/2025 at 9:30 AM with the TP confirmed, "On request, I do draw blue top tubes (citrate) and walk the results back to the nurses." 3. Interview with the laboratory consultant on 8/25/2025 at 12:00 PM confirmed the laboratory reported out approximately 2 patient results with sodium citrate tubes. 4. The laboratory reports out approximately 2000 CBC tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observation of the Beckman Coulter DxH 500 Series Control level I, II, III hematology quality control (QC) vials, review of the Beckman Coulter DxH 500 Series Control package insert, review of the "Daily Temperature and Control Log," and interview with the testing personnel (TP) and the laboratory consultant, the laboratory failed to document open and revised expiration dates on three of three hematology QC vials for complete blood cell counts. Findings: 1. Observation on 8/25 /2025 at 9:20 AM of the Beckman Coulter DxH 500 Series Control lot (251751) level I, II, III hematology QC vials located in the refrigerator showed six vials (two of each level) with no documentation of an opened and revised expiration date. 2. Review of DxH 500 Series Control package insert (manufacturer's instructions) stated, "16* Open Vial Days, *Assumes that the Instructions for Use section of the Consumable IFU/Setting Sheet is performed a maximum of 16 times within 16 days, provided that are handled properly." 3. Review of the "Daily Temperature and Control Log," showed Beckman Coulter DxH 500 Series Control lot (251751) level I, II, III hematology QC vials were put into use on 8/4/2025. The log showed the laboratory used the QC on 8/20/2025, 8/21/2025, and 8/25/2025, which was past the opened expiration date of 16 days. The laboratory reported 11 patients on 8/20/2025, 4 patients on 8/21/2025, and 4 patients on 8/25/2025. 4. Interview with the laboratory consultant on 8/25/2025 at 12:00 PM confirmed the laboratory failed to document the opened and revised expiration dates on the QC vials currently in use. 5. The laboratory reports approximately 2000 complete blood cell counts annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observation of the Beckman Coulter DxH 500 Series Control level I, II, III hematology quality control (QC) vials, review of the Beckman Coulter DxH 500 Series Control package insert, review of the "Daily Temperature and Control Log," and interview with the testing personnel (TP) and the laboratory consultant, the laboratory used QC past the expiration date for three of three days for complete blood cell counts. Findings: 1. Observation on 8/25/2025 at 9:20 AM of the Beckman Coulter DxH 500 Series Control lot (251751) level I, II, III hematology QC vials located in the refrigerator showed six vials (two of each level) with no open and revised expiration date. 2. Review of DxH 500 Series Control package insert (manufacturer's instructions) stated, "16* Open Vial Days, *Assumes that the Instructions for Use section of the Consumable IFU/Setting Sheet is performed a maximum of 16 times within 16 days, provided that are handled properly." 3. Review of the "Daily Temperature and Control Log," showed Beckman Coulter DxH 500 Series Control lot (251751) level I, II, III hematology QC vials were put into use on 8 /4/2025. The log showed the laboratory used the QC on 8/20/2025, 8/21/2025, 8/25 /2025 which was past the opened expiration date of 16 days. The laboratory reported 11 patients on 8/20/2025, 4 patients on 8/21/2025, and 4 patients on 8/25/2025. 4. Interview with the laboratory consultant on 8/25/2025 at 12:00 PM confirmed the laboratory failed to ensure expired QC was not used past the expiration date for three of three days. 5. The laboratory reports approximately 2000 complete blood cell counts annually.

D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random review of patient test reports from the Beckman Coulter DxH 520 hematology analyzer and interview with the laboratory consultant, the laboratory failed to include an identification number or unique patient identifier on six of six patient reports. Findings: 1. Review of six of six patient reports form the Beckman Coulter DxH 520 hematology analyzer showed last name of the patient and run date and time. The laboratory failed to include a unique patient identifier to ensure positive patient identification. 2. Interview with the laboratory consultant on 8/25/2025 at 1:00 PM confirmed the laboratory failed to include an identification number or unique patient identifier on six of six patient reports. 3. The laboratory reports out approximately 2000 complete blood cell count tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of documentation and interviews, the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing (Refer to D6007); failed to ensure verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method (Refer to D6013); and failed to ensure the quality control program was maintained to assure the quality of laboratory services and identify failures (Refer to D6020).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by:

	Based on observation, review of documentation, and interviews, the laboratory director failed to ensure quality laboratory services for preanalytic, analytic, and postanalytic phases of testing. Findings: 1. The laboratory director failed to ensure a step-by-step procedure for usage of sodium citrate tubes on the DxH 520 hematology analyzer for complete blood cell counts (Refer to D5403). 2. The laboratory director failed to ensure the hematology controls were labeled with a preparation and expiration date (Refer to D5415). 3. The laboratory director failed to ensure hematology quality controls were not used when they had exceeded their expiration date (Refer to D5417). 4. The laboratory director failed to include a unique patient identifier on the patient report to ensure positive patient identification (Refer to D5805).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of performance specification for one of one Beckman Coulter DxH 520 hematology analyzer for complete blood cell counts and interviews with the laboratory consultant and Beckman Coulter service representative, the laboratory director failed to ensure the verification procedures for accuracy, precision, reportable range and normal patient values were adequate. Findings: 1. Review of the performance specifications for the Beckman Coulter DxH 520 hematology analyzer showed no reportable range and normal value verification. 2. The laboratory director failed to approve the Beckman Coulter DxH 520 hematology analyzer performance specifications for accuracy and precision. 3. Phone interview on 8/25/2025 at 12:00 PM with the Beckman Coulter service representative confirmed, "I performed the accuracy and precision. It was up to the laboratory to perform reportable range and reference intervals." 4. Interview with the laboratory consultant on 8/25/2025 at 12:30 PM confirmed the laboratory director failed to ensure the verification of performance specifications for accuracy, precision, reportable range, and normal values were adequate. 5. The laboratory results approximately 2000 complete blood cell count tests annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's written procedure, quality control data, patient data, and laboratory's test volume, the laboratory director failed to ensure the quality control program was maintained to assure the quality of laboratory services and identify failures for four of four complete blood cell count (CBC) patient results. Findings: 1. Review of the laboratory's written procedure titled "St Thomas & St Croix Cancer Specialists Lab Procedure Manual and Standard Operating Procedures Quality Assessment Plan" showed Quality control records will be checked to verify

	QC has been performed as scheduled and appropriate action was taken if MORE THAN TWO controls were out of range. 2. Review of the Beckman Coulter DxH 520 hematology analyzer quality control data and patient data showed: 8/25/2025 at 8:04 AM - abnormal low level (lot 352517511) red blood cell parameter was out of range. The normal level (lot 352517512) was analyzed on 8/25/2025 at 8:06 AM and the red blood cell parameter was out of range. 08/25/2025 - four patients were analyzed and resulted. 3. Interview with the laboratory consultant on 8/25/2025 at 1:00 PM confirmed the laboratory director failed to ensure the quality control program was maintained to assure the quality of laboratory services and identify four of four failures. 4. The laboratory reports approximately 2000 CBC patient results annually.