Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D2115767	09/24/2021
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) 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 record review and interview, the laboratory director failed to sign the attestation for five of seven hematology proficiency testing events reviewed. Findings: 1. Review of proficiency testing events 2020-2, 2020-3, 2021-1, 2021-2, and 2021-3 for hematology revealed no laboratory signature on the proficiency testing attestation statement. 2. In interview on September 24, 2021 at approximately 12:30 PM, Testing Personnel #1 confirmed that the laboratory director did not sign the proficiency testing attestation statements.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain hematology daily quality control records for five of seven days reviewed and daily background counts for six of seven days reviewed. Findings: 1. Quality control and background count records were reviewed for the following dates patient testing was performed: 07/20/2021, 05/10/2021, 04/08/2021, 03/25/2021, 02/23/2021, 09/15

	/2020, and 06/23/2020. 2. Quality control records were not available for 05/10/2021, 04/08/2021, 03/25/2021, 02/23/2021, and 09/15/2020. Daily background counts for the hematology instrument were not available for 05/10/2021, 04/08/2021, 03/25 /2021, 02/23/2021, 09/15/2020, and 06/23/2020. 3. In interview on September 21, 2021 at approximately 01:35 PM, Testing Personnel #1 confirmed that the quality control records and instrument background counts were not retained.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain instrument printouts for four of seven hematology proficiency testing events reviewed. Findings: 1. Review of proficiency testing events 2019-3, 2020-1, 2020-2, 2020-3, 2021-1, 2021-2, and 2021-3 for hematology revealed no instrument printouts for events 2020-3, 2021-1, 2021-2, and 2021-3. 2. In interview on September 21, 2021 at approximately 12:24 PM, testing personnel #1 (TP1) confirmed that there was no documentation of testing records for event 2020-2.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to review and evaluate unacceptable results obtained for two of six hematology proficiency testing events reviewed. Findings: 1. Review of proficiency testing events 2021-1 and 2019-3 for hematology revealed no evidence of review or evaluation of unacceptable results for percent Eosinophils. 2. In interview on September 21, 2021 at approximately 12:30 AM, Testing Personnel #1 confirmed there was no documentation of review or evaluation of the unacceptable results for the two proficiency testing events.
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 record review, lack of documentation, and interview, the laboratory failed to have a quality control procedure for one of one tests performed by the laboratory. Findings: 1. Review of procedures provided by the laboratory revealed no procedure addressing the laboratory's quality control for hematology testing including number and frequency of testing controls, control limits, criteria to determine acceptability, and corrective action to take if control results failed to meet the laboratory's criteria for acceptability. 2. On September 24, 2021 at approximately 11:50 AM, the laboratory director confirmed there was no control procedure for the hematology testing.
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 observation, record review, lack of documentation, and interview, the laboratory failed to document two of two temperatures for proper storage of reagents and test system operation. Findings: 1. During a tour of the laboratory on September 24, 2021 at approximately 10:30 AM, a refrigerator with hematology quality control was observed. The quality control was labeled with storage instructions for 2-8 degrees Celsius (C). 2. Review of the procedure for the hematology instrument in Chapter 3 "Specifications/Characteristics" under "Temperature, Ambient Operating" stated "The ambient operating temperature is 16 C to 34 C (61 F to 93 F). 3. The surveyor requested temperature charts for room temperature and the refrigerator. 4. On September 24, 2021 at approximately 10:44 AM, Testing Personnel #1 confirmed that the laboratory did not have documentation of temperature monitoring for room temperature or the refrigerator.
D5805	TEST REPORT CFR(s): 493.1291(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 record review and interview, the laboratory failed to include the name of the laboratory on two of two patient test reports reviewed. Findings: 1. Patient test reports were reviewed from 03/25/2021 and 07/20/2021. The name of the laboratory did not appear on the reports. 2. On September 24, 2021 at approximately 12:51 PM, Testing Personnel #1 confirmed the name of the laboratory did not appear on the test report.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to have documentation of qualifications for one of one testing personnel. (See D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to have documentation of qualifications for one of one testing personnel. Findings: 1. Review of personnel records for Testing Personnel #1 (TP1) revealed no diploma on file. 2. On September 24, 2021 at approximately 1:50 PM, TP1 confirmed that no diploma was on file.