Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D2115767	06/14/2023
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
D0000	The Centers for Medicare & Medicaid Services (CMS) federal surveyor conducted an announced CLIA recertification survey at DelGiacco Medical LLC on June 14, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The findings were reviewed with the Laboratory Director and Testing Person #1 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1250; D5400: Analytic Systems
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 record review, written policies and procedures, and interview with the Laboratory Director and Testing Person #1, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: 1. The laboratory failed to follow written policy and procedure for patient hematology testing using the Beckman Coulter AcT Diff analyzer for three of three days of patient testing. Refer to D5401. 2. The laboratory failed to ensure the humidity was maintained as required by the manufacturer for the Beckman Coulter AcT Diff analyzer for two of two months. Refer to D5413. 3. The laboratory failed to demonstrate performance specifications prior to patient testing after the relocation for one of one analyzer. Refer to D5421. 4. The laboratory failed to perform two levels of control materials each day of patient hematology testing using the Beckman Coulter AcT Diff analyzer for three of three days of patient testing. Refer to D5447

D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 record review, written policy and procedure manual, and interview with Testing Person #1 (TP#1) and Laboratory Director (LD), the laboratory failed to follow written procedures for CBC (Complete Blood Count) testing for three of three days of patient testing. Findings include: 1. Interview with TP#1 on 06/14/2023 at 09: 40 AM confirmed the laboratory performed Complete Blood Count (CBC) testing using the Beckman Coulter AcT Diff Analyzer. 2. Review of the laboratory's written policy and procedures titled, "Lab Procedure Manual and Quality Assessment Plan" section "Machine StartUp and Daily Controls" stated: a. "Three levels of cell control material (low, normal, and high) are to be analyzed on a daily basis". b. "Review the control results to ensure they are within the acceptable ranges before analyzing patient samples". 3. Review of Quality Control (QC) records (AcT 5 Diff Control Plus Low Lot# 360523, Normal Lot# 370523, and High Lot# 380523) and patient testing records from 06/01/2023 through 06/06/2023 revealed the laboratory failed to follow written procedures for three of three days of patient testing. a. Low Control Lot# 360523 for Red Blood Cells (RBC) tested on 06/01/2023 at 09:00 AM failed with no documented corrective action. The value obtained was 2.17 X 10*6/L with an acceptable range of (2.22 - 2.56) X 10*6/L. b. Low Control Lot# 360523 for Hemoglobin (HGB) tested on 06/01/2023 at 09:00 AM failed with no documented corrective action. The value obtained was 5.4 g/dL with an acceptable range of (5.6 - 6.4) g/dL. c. Normal Control Lot# 370523 for RBC tested on 06/01/2023 at 09:01 AM failed with no documented corrective action. The value obtained was 4.4 X 10*6/L with an acceptable range of (4.49 - 4.79) X 10*6/L. d. Normal Control Lot# 370523 for HGB tested on 06/01/2023 at 09:01 AM failed with no documented corrective action. The value obtained was 12.9 g/dL with an acceptable range (13.4 - 14.4) g/dL. e. High Control Lot# 380523 for HGB tested on 06/01/2023 at 09:03 AM failed with no documented corrective action. The value obtained was 15.6 g/dL with an acceptable range (15.9 - 17.1) g/dL. f. Low Control Lot# 360523 for Hemoglobin (HGB) tested on 06/05/2023 at 09:05 AM failed with no documented corrective action. The value obtained was 5.4 g/dL with an acceptable range of (5.6 - 6.4) g/dL. g. Normal Control Lot# 370523 for HGB tested on 06/05/2023 at 09:08 AM failed with no documented corrective action. The value obtained was 12.8 g/dL with an acceptable range (13.4 - 14.4) g/dL h. Normal Control Lot# 370523 for RBC tested 06 /05/2023 at 09:08 AM failed with no documented corrective action. The value obtained was 4.4 X 10*6/L with an acceptable range of (4.49 - 4.79) X 10*6/L. i. High Control Lot# 380523 for HGB tested on 06/05/2023 at 09:10 AM failed with no documented corrective action. The value obtained was 15.4 g/dL with an acceptable range (15.9 - 17.1) g/dL. j. Low Control Lot# 360523 for Red Blood Cells (RBC) tested on 06/06/2023 at 08:49 AM failed with no documented corrective action. The value obtained was 2.20 X 10*6/L with an acceptable range of (2.22 - 2.56) X 10*6/L. k. Low Control Lot# 360523 for Hemoglobin (HGB) tested on 06/06/2023 at 08:49 AM failed with no documented corrective action. The value obtained was 5.3 g/dL with an acceptable range of (5.6 - 6.4) g/dL. l. Normal Control Lot# 370523 for HGB tested on 06/06/2023 at 08:51 AM failed with no documented corrective action. The

	value obtained was 12.7 g/dL with an acceptable range (13.4 - 14.4) g/dL. m. Normal Control Lot# 370523 for RBC tested 06/06/2023 at 08:51 AM failed with no documented corrective action. The value obtained was 4.4 X 10*6/L with an acceptable range of (4.49 - 4.79) X 10*6/L. n. High Control Lot# 380523 for HGB tested on 06/06/2023 at 08:52 AM failed with no documented corrective action. The value obtained was 15.1 g/dL with an acceptable range (15.9 - 17.1) g/dL. o. High Control Lot# 380523 for RBC tested on 06/06/2023 at 08:52 AM failed with no documented corrective action. The value obtained was 4.78 X 10*6/L with an acceptable range of (4.85 - 5.25) X 10*6/L. p. Examples of patient testing: Patient 544172 - test performed 06/01/2023 at 12:25 PM Patient 14597 - test performed 06/01 /2023 at 03:42 PM Patient 63248 - test performed 06/01/2023 at 02:40 PM Patient 14263 - test performed 06/05/2023 at 08:36 AM Patient 63641 - test performed 06/05 /2023 at 08:57 AM Patient 13647 - test performed 06/05/2023 at 09:12 AM Patient 63280 - test performed 06/05/2023 at 09:52 AM Patient 63676 - test performed 06/05 /2023 at 10:19 AM Patient 63478 - test performed 06/05/2023 at 10:22 AM Patient 14539 - test performed 06/05/2023 at 11:12 AM Patient 12729 - test performed 06/05 /2023 at 11:20 AM Patient 14827 - test performed 06/05/2023 at 11:22 AM Patient 63412 - test performed 06/05/2023 at 11:14 AM Patient 14115 - test performed 06/05 /2023 at 01:40 PM Patient 63614 - test performed 06/05/2023 at 01:30 PM Patient 14537 - test performed 06/06/2023 at 08:47 AM Patient 13548 - test performed 06/06 /2023 at 10:40 AM Patient 63596 - test performed 06/06/2023 at 12:25 PM Patient 14767 - test performed 06/06/2023 at 01:11 PM Patient 1666 - test performed 06/06 /2023 at 12:58 PM Patient 14821 - test performed 06/06/2023 at 01:32 PM Patient 63522 - test performed 06/06/2023 at 02:18 PM Patient 13455 - test performed 06/06 /2023 at 03:02 PM 4. Interview with LD on 06/14/2023 at 03:36 PM confirmed the findings as indicated above
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 review of records, manufacturer's instructions, and interview with the Laboratory Director (LD) and Testing Person #1 (TP#1), the laboratory failed to ensure the humidity was maintained as required by the manufacturer for the Beckman Coulter AcT Diff analyzer for two of two months. Findings include: 1. Interview with TP#1 on 06/14/2023 at 09:40 AM confirmed the laboratory performed Complete Blood Count (CBC) testing using the Beckman Coulter AcT Diff Analyzer. 2. On 06 /14/2023, a review of the manufacturer's "User Manual" under the section, "Specifications" stated, "Relative Humidity 30-80%". 3. On 06/14/2023, a review of laboratory records revealed no humidity readings for two of two months between 04 /11/2023 through 06/13/2023. 4. Interview with the LD on 06/14/2023 at 01:35 PM confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

	CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Laboratory Director (LD) and Testing Person #1 (TP#1), the laboratory failed to demonstrate performance specifications prior to patient testing after the relocation for one of one analyzer. Findings include: 1. Interview with TP#1 on 06/14/2023 at 09:40 AM confirmed the laboratory performed Complete Blood Count (CBC) testing using the Beckman Coulter AcT Diff Analyzer. 2. Interview with TP#1 on 06/14/2023 at 02:24 PM confirmed the laboratory relocated the Beckman Coulter AcT Diff analyzer to a different room on 04/10/2023. 3. On 06/14/2023, a review of records revealed no evidence the laboratory demonstrated performance specifications after the relocation and prior to patient testing. 4. Interview with the LD on 06/14/2023 at 02:47 PM, confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #1 (TP#1) and the Laboratory Director (LD), the laboratory failed to perform two levels of control materials each day of patient testing for three of three days of patient testing. Findings include: 1. Interview with TP#1 on 06/14/2023 at 09:40 AM confirmed the laboratory performed Complete Blood Count (CBC) testing using the Beckman Coulter AcT Diff Analyzer. 2. Review of Quality Control (QC) records and patient testing records from 05/08/2023 through 05/10/2023 revealed two levels of QC material were not performed each day of a patient testing for three of three days of patient testing. a. Patient 63249 - test performed 05/08/2023 at 08:44 AM b. Patient 63214 - test performed 05/08/2023 at 09:46 AM c. Patient 1726 - test performed 05/08/2023 at 11: 05 AM d. Patient 63596 - test performed 05/08/2023 at 12:09 PM e. Patient 63028 - test performed 05/08/2023 at 01:41 PM f. Patient 63676 - test performed 05/08/2023 at 01:43 PM g. Patient 14537 - test performed 05/09/2023 at 08:29 AM h. Patient 15085 - test performed 05/09/2023 at 08:37 AM i. Patient 1446 - test performed 05/09 /2023 at 09:11 AM j. Patient 63561 - test performed 05/09/2023 at 09:40 AM k. Patient 14350 - test performed 05/09/2023 at 10:00 AM l. Patient 63674 - test performed 05/09/2023 at 10:30 AM m. Patient 14922 - test performed 05/09/2023 at 09:42 AM n. Patient 12857 - test performed 05/09/2023 at 10:09 AM o. Patient 14515

	- test performed 05/09/2023 at 12:31 PM p. Patient 1666 - test performed 05/09/2023 at 01:44 PM q. Patient 63865 - test performed 05/09/2023 at 03:14 PM r. Patient 63631 - test performed 05/10/2023 at 08:59 AM s. Patient 63801 - test performed 05 /10/2023 at 01:35 PM 3. Interview with LD on 06/14/2023 at 03:34 PM confirmed the findings as indicated above.