Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1003967	07/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ridgewood Medical Clinic	219 W Kingsley Rd Ste 336, Garland, TX	

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 laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 review of laboratory policy, quality control (QC) records, corrective action documentation, patient reports, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for 17 of 17 patients in 2023 (December) and 21 of 21 patients in 2024 (May through July) on the Drew 3 hematology analyzer. Findings included: 1. Review of the laboratory policy titled "Quality Control Policy" stated: "II. Standards for Controls: A. Quantitative analysis ... 2. When one of both levels of QC fail, the first step is to repeat the control which exceeded acceptable limits. If the control is still out of range, check the reagent of the failing analyte for dating and stability. If fresh QC and/or fresh reagents do not bring the QC into range, recalibrate per the manufacturer's instructions. Record the problem and the corrective action. If the issue is unable to be resolved, call the technical service department of the equipment manufacturer for further instructions or to schedule repair/maintenance. 3. When a QC failure occurs, patient reports released since the last acceptable test run must be

evaluated to determine if there is significant clinical difference in patient results. If specimen stability allows, repeat testing for all patients involved." The policy did not include evaluation of patients when test systems adjustments were performed for QC failures since the last acceptable QC run. 2. Review of Drew 3 QC records and corrective action documentation revealed troubleshooting and test system adjustments performed for the following sampling of QC test events in 2023 (December) and 2024 (May through July): Low control: Lot #EX1023L Normal control: Lot #EX1023N High control: Lot #EX1023H 12/04/2023 Low control 10:59 hours QC failed for the WBC, RBC, HGB, HCT, MCV, MCHC, PLT analytes and the automated differential parameters: LYM#, GRA#, LYM%, GRA% 11:01 hours QC was repeated and failed for the MCH and MCHC analytes 11:04 hours QC was repeated and failed for the MCH and MCHC analytes 11:52 hours QC was repeated and passed Normal control 11:54 hours QC failed for the WBC, RBC, HGB, HCT, MCV, MCH, PLT analytes and the automated differential parameters: LYM#, GRA#, LYM%, GRA% 11:55 hours QC was repeated and passed Corrective action documentation revealed the following: Repeat Controls "yes" New Control "NO" New Diluent "yes" New Detergent "yes" Calibrate "-" Bleach Baths "yes" Call Service "yes" Comments "Run N rn [sic] L" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (12/03/2023): Patient IDs: 04.04.2009, 3.10.1961, 04.22.2015 12/15/2023 High control 11:16 hours QC failed for the HCT analyte 11:18 hours QC was repeated and failed for the HCT analyte 11:27 hours QC was repeated and failed for the HCT analyte 12:20 hours QC was repeated and passed 12:23 hours QC was repeated and passed 13:01 hours QC was repeated and passed Corrective action documentation revealed the following: Repeat Controls "yes" New Control "no" New Diluent "no" New Detergent "no" Calibrate "-" Bleach Baths "Yes" Call Service "-" Comments "Ran H 3x"; "called service"; "Bleach Bath" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (12/14/2023): Patient IDs: 08.21.1995, 3.21.2004, 03.16.2021, 8.26.1984, 11.23.1975 Low control: Lot #EX1024L Normal control: Lot #EX1024N High control: Lot #EX1024H 12/27/2023 Normal control 11: 21 hours QC failed for the RBC analyte 12:46 hours QC was repeated and passed 13: 47 hours QC was repeated and passed High control 12:47 hours QC failed for the RBC and HCT analytes 12:49 hours QC was repeated and failed for the RBC and HCT analytes 13:00 hours QC was repeated and failed for the HCT analyte 13:48 hours QC was repeated and failed for the HCT analyte 13:50 hours QC was repeated and failed for the HCT analyte 13:57 hours QC was repeated and failed for the HCT analyte Corrective action documentation revealed the following: Repeat Controls "yes" New Control "yes" New Diluent "yes" New Detergent "yes" Calibrate "-" Bleach Baths "Yes" Call Service "yes" Comments "Ran H 3 times"; "called service"; "ok to run" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (12/26/2023): Patient IDs: 4.8.51, 05.02.1963 Low control: Lot #EX1024L Normal control: Lot #EX1024N High control: Lot #EX1024H 12/30/2023 Low control 10:54 hours QC failed for the RBC, HCT, MCH, and MCHC analytes 10:56 hours QC was repeated and failed for the automated differential parameter: LYM% 11:21 hours QC was repeated and failed for the WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV analytes and the automated differential parameters: LYM#, MID#, GRA#, LYM%, GRA% 11:25 hours QC was repeated and passed Corrective action documentation revealed the following: Repeat Controls "yes" New Control "NO" New Diluent "NO" New Detergent "NO" Calibrate "-" Bleach Baths "Yes" Call Service "-" Comments "Ran L 2 times, did bleach bath pass 3rd time" The following patients were not evaluated to ensure accurate and reliable test results since the last

	acceptable QC run with test system adjustments performed (12/29/2023): Patient IDs: 11.18.1943, 2.29.1948, 11.05.1996, 08.01.1967, 10.14.1976, 8.7.54 Low control: Lot #EX0424L High control: Lot #EX0424H 05/15/2024 Low control 09:59 hours QC failed for the automated differential parameter: LYM% 10:02 hours QC was repeated and failed for the automated differential parameter: LYM% 10:05 hours QC was repeated and failed for the automated differential parameter: LYM# 10:31 hours QC was repeated and passed Corrective action documentation revealed the following: Repeat Controls "yes" New Control "NO" New Diluent "NO" New Detergent "NO" Calibrate "-" Bleach Baths "yes" Call Service "yes" Comments "Ran L 3 times"; "Bleach pass" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (05/14/2024): Patient IDs: 04.08.1951, 07.12.1968, 08.31.2019, 04.10.2010, 07.14.2015, 10.23.1966, 09.18.1973, 11.23.2016, 010995 06/13/2024 Low control 10:29 hours QC failed for the automated differential parameter: LYM# 11:10 hours QC was repeated and passed High control 10:37 hours QC failed for the HCT and PLT analytes 10:44 hours QC was repeated and failed for the PLT analyte 10:49 hours QC was repeated and failed for the PLT analyte 11:13 hours QC was repeated and passed Corrective action documentation revealed the following: Repeat Controls "yes" New Control "NO" New Diluent "NO" New Detergent "NO" Calibrate "-" Bleach Baths "yes" Call Service "no" Comments "Ran H 3 times" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (06/12/2024): Patient IDs: 03.09.1959; 07.26.1981, 051581, 03.26.2003, 05.13.86, 10.02.2003 07/02/2024 Low control 09:25 hours QC failed for the PLT analyte and automated differential parameters: LYM# and LYM% 09:27 hours QC failed for the MCV analyte 10:14 hours QC was repeated and passed High control 09:30 hours QC failed for the HCT analyte 10:17 hours QC was repeated and failed for the HCT analyte 10:20 hours QC was repeated and failed for the HCT analyte 10:35 hours QC was repeated and failed for the HCT analyte Corrective action documentation revealed the following: Repeat Controls "yes" New Control "NO" New Diluent "NO" New Detergent "NO" Calibrate "NO" Bleach Baths "yes" Call Service "YES" Comments "Run controls"; "H dindnt [sic] pass [XX] say ok to Run" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (07/01/2024): Patient IDs: 5.23.2005, 4.22.1951, 6.14.2004, 2.2.1973, 03.06.1998, 02-14-1998 3. During an interview on 07/23/2024 at 12:20 pm, the Technical Consultant and Compliance Coordinator confirmed the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results. Word Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCHC - mean corpuscular hemoglobin concentration PLT - platelet LYM# - lymphocyte absolute GRA# - granulocyte absolute LYM% - lymphocyte percent GRA% - granulocyte percent MCH: mean corpuscular hemoglobin N - normal control L - low control H - high control RDW - Red cell distribution width MPV - Mean platelet volume MID# - combined value of the other types of white blood cells not classified as lymphocytes or granulocytes