Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0536156	02/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
San Juan Medical Group Inc	622 West Maple St Ste B, Farmington, NM	

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	Based upon the onsite validation survey conducted from 02/13/2023 to 02/15/2023, this facility was found to be IN compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed with standard level deficiencies cited.
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 direct observation, review of manufacturer's instructions, laboratory records, and confirmed in staff interview, the laboratory failed to ensure laboratory room temperatures were defined according to manufacturer's specifications for 6 of 6 months (09/2021-11/2021 and 09/2022-11/2022). Findings included: 1. During a tour of the laboratory room on 02/13/2023 at 1:40 pm, one Tosoh G8 Glycohemoglobin Analyzer (Serial number 15869205) was observed. 2. Review of the manufacturer's instructions titled "TSKgel G8 Variant Hsi" (Revision 2.0; 08/19/2021) stated "7. Specimens ... Specimens may be stored up to twenty four hours at room temperature 10-25C" (50-77F)." 3. Review of the laboratory forms, titled "Daily Temperature /Hydrometer Checks", dated from 09/2021 through 11/2021 and 09/2022 through 11 /2022, stated "Room Temperature (large lab) 68-86F" (20-30C)." The laboratory's room temperature upper limit of 86F exceeded the manufacturer's specified upper limit of 77F. 4. During an interview on 02/14/2023 at 2:30 pm in the conference room,

	after review of the above records, the Laboratory Director (as listed on Centers for Medicare & Medicaid Services (CMS)-209 FORM; signed by the Laboratory Director on 02/01/2023) confirmed the findings. Word key: C = degrees Celsius F = degrees Fahrenheit
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 review of laboratory policies, laboratory records, and confirmed in staff interview, the laboratory failed to have documentation of performance of verification studies to include reportable range and normal reference range for 1 of 1 assay performed on the Tosoh G8 Glycohemoglobin Analyzer (Serial number 15869205) prior to patient testing. Findings included: 1. Review of the laboratory policy titled "Quality Assessment Plan" (reviewed by the Laboratory Director on 09/13/2022) stated: a. "New Testing ... Reportable Range ... The kit does not need to hit the max of the analyte. It does however need to test the reportable range to an extent to confirm linearity." b. "New Testing ... Reference range: The reference range given in the package insert will be used as the patient reference range." 2. Review of the laboratory policy titled "Tosoh G8 Glycohemoglobin Analyzer" (reviewed by the Laboratory Director on 09/22/2022) stated "REPORTABLE RANGE/LINEARITY: 3.1 - 19.0%". Review of the laboratory record titled "sAS1C Accuracy, Reportable Range, and Linearity" (signed by the Laboratory Director on 11/07/2019) revealed the following results: Lyphocheck Hemoglobin A1C Linearity Set; Lot 34710 Expiration date 06/30/2021 ID 0008 - Level 01 result: "---% SA1C TOO LOW" (Expected Value 2.7% - 3.8%) ID 0009 - Level 01 result: "---% SA1C TOO LOW" Level 02 mean result: 4.70% (Expected Value 4.1% - 5.1%) Level 03 mean result: 5.95% (Expected Value 5.5% - 6.5%) Level 04 mean result: 9.90% (Expected Value 8.4% - 10%) Level 05 mean result: 14.2% (Expected Value 12% - 15%) ID 0008 - Level 06 result: "---%" (Expected Value 16% - 22%) ID 0009 - Level 06 result: "---%" The laboratory verified a reportable range of 4.7% to 14.2%. The laboratory failed to verify the reportable range of 3.1% - 19% stated in the laboratory policy. 3. During an interview on 02/14/2023 at 1:05 pm in the conference room, the surveyor requested documentation of the studies to verify the laboratory's normal reference range. No documentation was provided. The Laboratory Director, after review of the above records, confirmed the laboratory failed to perform verification studies to include reportable range and normal reference range for the Tosoh G8 Glycohemoglobin Analyzer. Word key: A1C = glycated hemoglobin
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed

	in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the user manual for the Horiba ABX Micros 60 (hematology instrument), review of laboratory procedure, sample stability study for Complete Blood Counts (CBC), laboratory sample collection logs, patient result records, and interview with the laboratory director, the laboratory failed to establish performance specification to include accuracy, precision, analytical sensitivity, and specificity for the modified sample stability and handling of the hematology samples collected in an EDTA Becton Dickenson vacutainer blood collection tube prior to resulting 1 of 425 patients from October 2022 to February 2023. Findings included: 1. Review of the Horiba ABX Micros 50 user manual, under section labeled "Sample Stability" stated; "Fresh Whole Blood specimens are recommended! The ICSH (International Committee for Standardization in Hematology) defines a Fresh blood specimen as 'one processed within 4 hours after collection'. Well mixed Whole Blood specimens, collected in EDTA anti-coagulant and run within eight hours after collection, provide the most accurate results for all parameters. The White cell size distribution may shift when specimens are assayed between 5 and 20 minutes after collection and more than 8 hours after collection." 2. Review of the laboratory Procedure titled, "ABX Micros 60 procedure" stated; "SPECIMEN 2 ml (min) EDTA anticoagulated blood sample not more than 24 hours old." The "not more than 24 hours old" was crossed out and a handwritten note stated, "Extended to 4 days per QA study and Medical Director Review 12/29/17". The facility failed to have the laboratory director sign the amended procedure. 3. Review of the sample stability study for the CBC test revealed that the study consisted of 10 patient samples, originally collected on 12/18/2017 and re-tested again on 12/21/2017. The laboratory failed to include defined criteria or limits of acceptability for their specimen stability comparison study. The facility failed to establish performance specification studies to include to include accuracy, precision, analytical sensitivity, and specificity for the modified sample stability and handling of the hematology samples collected in an EDTA Becton Dickenson vacutainer blood collection tube. The laboratory failed to perform a 4-day (96 hours) sample stability and handling study, as stated on the handwritten note in their hematology procedure. 4. Review of the patient collection log and patient's CBC test results from October 2022 to Feb 13, 2023, revealed patient (ID# 209039) was collected on Friday, November 18, 2022 at 9:31 am and analyzed and reported on Monday, November 21, 2022 at 5:17 pm, 79 hours and 46 mins from the time of collection. 5. During an interview on 02/15/2023 at 1:15 pm, the laboratory director stated, "I was under the impression that the stability was good", confirming the findings above.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, manufacturer's instructions, calibration verification records, and confirmed in staff interview, the laboratory failed to document corrective actions taken when Tosoh G8 calibration verification results deviated from the laboratory's performance specifications for 4 of 4 events (06/02/2021, 12/01/2021, 06/02/2022, and 12/02/2022). Findings included: 1. Review of the laboratory policy titled "Tosoh G8 Glycohemoglobin Analyzer" (reviewed by the Laboratory Director on 09/22/2022) stated "REPORTABLE RANGE/LINEARITY: 3.1 - 19.0%". 2. Review of manufacturer's instructions for the Lyphochek Hemoglobin A1C Linearity Set stated "Expected Values for Hemoglobin A1C (%NGSP) Level 1: 2.7 - 3.8% Level 2: 4.1 - 5.1% Level 3: 5.5 - 6.5% Level 4: 8.4 - 10% Level 5: 12 - 15% Level 6: 16 - 22% Ranges reflect typical values for this product." 3. Review of the laboratory calibration verification records, dated 06/02/2021, 12/01/2021, 06/02/2022, and 12/02/2022, revealed the following: a. Tosoh G8 Calibration Verification signed by the Laboratory Director on 06/02/2021: Lyphocheck Hemoglobin A1C Linearity Set; Lot 34730 Expiration date 11/30/2022 ID 0005 - Level 01 result: "---% SA1C TOO LOW" (Expected Value 2.7% - 3.8%) Level 02 mean result: 4.5% (Expected Value 4.1% - 5.1%) Level 03 mean result: 5.8% (Expected Value 5.5% - 6.5%) Level 04 mean result: 9.9% (Expected Value 8.4% - 10%) Level 05 mean result: 14.3% (Expected Value 12% - 15%) ID 0008 - Level 06 result: "---%" (Expected Value 16% - 22%) b. Tosoh G8 Calibration Verification signed by the Laboratory Director on 12/01/2021: Lyphocheck Hemoglobin A1C Linearity Set; Lot 34747 Expiration date 08/31/2023 ID 0006 - Level 01 result: "---% SA1C TOO LOW" (Expected Value 2.7% - 3.8%) Level 02 mean result: 4.2% (Expected Value 4.1% - 5.1%) Level 03 mean result: 5.7% (Expected Value 5.5% - 6.5%) Level 04 mean result: 9.5% (Expected Value 8.4% - 10%) Level 05 mean result: 13.6% (Expected Value 12% - 15%) ID 0006 - Level 06 result: "---%" (Expected Value 16% - 22%) c. Tosoh G8 Calibration Verification signed by the Laboratory Director on 06/02/2022: Lyphocheck Hemoglobin A1C Linearity Set; Lot 34740 Expiration date 08/31/2023 ID 0005 - Level 01 result: "---% SA1C TOO LOW" (Expected Value 2.7% - 3.8%) Level 02 mean result: 4.2% (Expected Value 4.1% - 5.1%) Level 03 mean result: 5.7% (Expected Value 5.5% - 6.5%) Level 04 mean result: 9.6% (Expected Value 8.4% - 10%) Level 05 mean result: 14.0% (Expected Value 12% - 15%) ID 0007 - Level 06 result: "---%" (Expected Value 16% - 22%) d. Tosoh G8 Calibration Verification signed by the Laboratory Director on 12/02/2022: Lyphocheck Hemoglobin A1C Linearity Set; Lot 34750 Expiration date 04/30/2024 ID 0005 - Level 01 result: "---% SA1C TOO LOW" (Expected Value 2.7% - 3.8%) Level 02 mean result: 4.6% (Expected Value 4.1% - 5.1%) Level 03 mean result: 5.9% (Expected Value 5.5% - 6.5%) Level 04 mean result: 10.0% (Expected Value 8.4% - 10%) Level 05 mean result: 14.7% (Expected Value 12% - 15%) ID 0007 - Level 06 result: "---%" (Expected Value 16% - 22%) The laboratory failed to document corrective actions taken when calibration verification results deviated from the laboratory's performance specifications. The laboratory failed to ensure the laboratory's detection limits for the Tosoh G8 Glycohemoglobin analyzer reached a lower limit of 3.1% and a higher limit of 19% as stated in their own policy. 4. Review

	of patients testing performed from 05/01/2022 through 12/31/2022 revealed the following two patient results reported above the laboratory's verified reportable range: a. ID 214113 reported 05/10/2022 Result: 16.10% b. ID 220940 reported 11/30/2022 Result: 15.50% 5. Review of the Test Utilization report revealed 5,004 A1C% tests were reported from 02/01/2022 - 02/01/2023. 6. During an interview on 02/14/2023 at 10:23 am in the conference room, after review of the above records, the Laboratory Director confirmed the findings. Word key: A1C = glycated hemoglobin NGSP = National Glycohemoglobin Standardization Program