Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1081896	01/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Guajira Family Clinic & Diabetes Care	505 Angelita St Unit 18 & 19, Weslaco, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 the laboratory's verification studies performed on the ABX Micros 60 hematology analyzer in March 2025, review of patient test reports, and staff interview, the laboratory failed to have documentation of verifying 1 of 1 sets of patient normal ranges. The findings included: 1. A review of the laboratory's verification records for the ABX Micros 60 hematology analyzer (serial number: 311CS100950) performed in March 2025 determined the laboratory failed to have documentation of verifying 1 of 1 sets of patient normal ranges. 2. A review of patient test reports from December 2025 identified the laboratory had the following set of patient normal ranges in use: White Blood Cell 3.5 - 10 Red Blood Cell 3.8 - 5.8 Hemoglobin 11 - 16.5 Hematocrit 35 - 50 Mean Corpuscular Volume 80 - 97 Mean Corpuscular Hemoglobin 26.5 - 33.5 Mean Corpuscular Hemoglobin Concentration 31.5 - 35.0 Red cell distribution width 10 - 15 Mean Platelet Volume 6.5 - 11 Lymphocyte percent 17 - 48 Lymphocyte count 1.2 - 3.2 Monocyte percent 4 - 6 Monocyte count 0.3 - 0.8 Granulocyte percent 43 - 76 Granulocyte count 1.2 - 6.8 3. The laboratory stated it performed 360 tests annually. 4. The technical consultant confirmed the findings in an interview conducted on 01/14/2026 at 0930 hours in the break room.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's ABX Micros 60 analyzer records from March 2025 to January 2026, and staff interview, the laboratory failed to have documentation of performing 1 of 1 calibrations on the ABX Micros 60 hematology analyzer. The findings included: 1. A review of the laboratory's policy titled "Instrument Operation and Maintenance" determined: "Calibration of laboratory instruments will be every six months..." 2. A review of the laboratory's records for the ABX Micros 60 analyzer from March 2025 to January 2026 identified a calibration was performed upon installation in March 2025. No calibration had been performed since (a time lapse of 9 months). 3. The technical consultant confirmed the findings in an interview conducted on 01/14/2026 at 0900 hours in the break room.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology quality control records from May 2025 to December 2025, and staff interview, the laboratory failed to have documentation of verifying 4 of 4 new lots prior to use. The findings included: 1. A review of the laboratory's ABX Minotrol 16 hematology control records from May 2025 to December 2025 determined the following lots were placed into service: Lot number: 5097 Lot number: 5153 Lot number: 5209 Lot number: 5265 2. Further review of the laboratory's quality control records determined the laboratory failed to

	have documentation of verifying each of the 4 lots prior to placing them into service. 3. The technical consultant confirmed the findings in an interview conducted on 01/14 /2026 at 0930 hours in the break room.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by:
D5813	TEST REPORT CFR(s): 493.1291(g) (g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records from May 2025 to December 2025, and staff interview, the laboratory failed to have documentation of the notification of 1 of 2 critical values. The findings included: 1. A review of the laboratory's policy titled "Critical Values" determined: "The laboratory Personnel will immediately notify the requester or user about lab results in the 'Critical Value' or 'Panic Range'." The policy defined 'Critical Value' as: WBC: less than 2.0 or greater than 20.0 HGB: less than 7.5 or greater than 18 HCT: less than 25 or greater than 55 PLT: less than 50 or greater than 800. 2. A review of the laboratory's policy titled "Reporting Critical Values" determined: "It is the policy of this laboratory to document the reporting of critical values. Document: - who was notified - when the person was notified - by who was the person notified." 3. A review of patient test records from May 2025 to December 2025 identified 2 patient results which met the laboratory's criteria as a 'Panic Value'. The test date, patient identification numbers, and results were: July 29, 2025 DOB: 11/30/97 PLT: 842 September 12, 2025 Sample ID: 90152 HCT: 55.2 4. A review of the laboratory's critical value log from May 2025 to December 2025 determined the laboratory failed to have documentation of the notification of the critical value for sample ID 90152. 5. The technical consultant confirmed the findings in an interview conducted on 01/14 /2026 at 0920 hours in the break room. Key WBC - white blood cell HCT- hematocrit HGB - hemoglobin PLT - platelet DOB - date of birth
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 policies, review of the laboratory records from May 2025 to December 2025, and staff interview, the laboratory director failed to ensure the quality assurance plan was followed by documenting the monthly review for 8 of 8 months. The findings included: 1. A review of the laboratory's policy titled "Quality Assurance Plan" determined the following: "Our laboratory uses this Quality Assurance Program to improve the laboratory services were provide to our physicians and patients. We will perform a quality review at least monthly and review the results with the Laboratory Director or Technical Consultant for their approval." 2. A review of the laboratory's records from May 2025 to December 2025 determined the laboratory failed to have documentation the review of records as required by its quality assurance plan for 8 of 8 months. The months were: May 2025 June 2025 July 2025 August 2025 September 2025 October 2025 November 2025 December 2025 3. The technical consultant confirmed the findings in an interview conducted on 01/14 /2026 at 0915 hours in the break room.