Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0933357	06/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Guajira Family Clinic & Diabetes Care	1900 S Jackson Rd Ste 9, Mcallen, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's proficiency testing records from 2023, 2024 and 2025, and staff interview, the laboratory failed to ensure 4 of 6 testing personnel participated in proficiency testing for hematology. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the facility identified 6 personnel who performed hematology testing. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2023 (events 2 and 3), 2024 (events 1, 2, and 3) and 2025 (event 1) determined only testing personnel #1 and #6 participated in proficiency testing. The records showed: a) 2023 Event 2 performed by testing personnel #1 b) 2023 Event 3 performed by testing personnel #1 c) 2024 Event 1 performed by testing personnel #1 d) 2024 Event 2 performed by testing personnel #1 e) 2024 Event 3 performed by testing personnel #1 f) 2025 Event 1 performed by testing personnel #1 and #6 3. The technical consultant confirmed the finding in an interview conducted on 06/11/2025 at 0950 hours in the reception area.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute's chemistry proficiency testing records from 2024 and staff interview, the laboratory failed to have documentation of evaluating proficiency testing results returned as "not graded" by the proficiency testing agency. The findings included: 1. A review of the laboratory's American Proficiency Institute's chemistry proficiency testing records from 2024 (events 1, 2 and 3) identified that the proficiency testing agency returned a result of "not graded" for 3 of 5 samples tested for Total Bilirubin as part of 2024 Event 1. They were: Sample Performance CH-01 Acceptable CH-02 not graded CH-03 not graded CH-04 Acceptable CH-05 not graded 2. Further review of the records determined the facility failed to have documentation of evaluating the 3 'not graded' results. 3. The technical consultant confirmed the findings in an interview conducted on 06/11/2025 at 0940 hours in the reception area.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 review of the manufacturer's instructions for the Medonic M-series hematology analyzer, review of the laboratory's procedures, review of patient test records from March - April 2025, and staff interview, the laboratory failed to have documentation of a procedure to address flags on complete blood count (CBC) results. The findings included: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (May 2022, Article no. 1504611) identified the following flags, descriptions and corrective actions to perform: a) Flag: BD Description: The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Corrective Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. b) Flag: NM Description: There was no mode in the WBC distribution between the LYM-L and GRAN-H settings. Corrective Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. c) Flag: OM Description: There was

	only one mode in the WBC distribution between the LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis b blood smear is recommended. Corrective Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. d) Flag: TM Description: There were more than two modes in the WBC distribution between the LYM-L and GRAN-H settings. Corrective Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 3. A review of the laboratory's procedures determined the facility failed to have documentation of a procedure to verify flagged results. 4. A review of patient test records from March - April 2025 identified 3 patient results with flags which were reported to the provider without the results being verified: a) date: 3/25/2025 ID: 28704 Flag: OM (first run) Flag: BD (second run) b) date: 3/29/2025 ID: 15442 Flag: BD (first run) Flag: BD (second run) Flag: BD (third run) c) date: 4/16/2025 ID: 90049 Flag: OM (first run) Flag: OM (second run) 5. The technical consultant confirmed the findings in an interview conducted on 06/11/2025 at 1230 hours in the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance records for the TOSOH AIA-900 analyzer from 2023, 2024 and 2025 and staff interview, the laboratory failed to have documentation of performed trimonthly maintenance every three months. The findings were: 1. A review of the laboratory's maintenance records for the TOSOH AIA-900 analyzer from 2023, 2024 and 2025 identified the manufacturer required the following maintenance to be performed every three months: clean instrument surfaces after any spills clean diluent/wash reservoirs with 1:100 dilution of Clorox Rinse reservoirs with Reagent Grade Type 1 water Replace worn or damaged B/F Wash Probe Tip 2. Further review identified trimonthly maintenance was performed at the following times: January 2023 August 2023 (7 month gap) January 2024 (5 month gap) May 2024 (4 month gap) July 2024 (2 month gap) November 2024 (4 month gap) February 2025 (3 month gap) June 2025 (4 month gap) 3. The technical consultant confirmed the findings in an interview conducted on 06/11/2025 at 1200 hours in the reception area after she reviewed the records.
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 calibration records for the Medonic M-series hematology analyzer from 2023 and 2024, and staff interview, the laboratory failed to ensure calibrations were performed every six months as required. The findings included: 1. A review of the laboratory's policy titled "Instrument Operation and Maintenance" (approved by the laboratory director on 04 /22/1998) determined it was the laboratory's policy to perform instrument calibrations every six months. 2. A review of the laboratory's calibration records for the Medonic M-series hematology analyzer from 2023 and 2024 identified the laboratory performed calibrations at the following times: August 2023 June 2024 (10 month gap) September 2024 (3 month gap) November 2024 (2 month gap) 3. The technical consultant confirmed the findings in an interview conducted on 06/11/2025 at 1110 hours in the reception area.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records for Sodium, Potassium, and Chloride performed on the Dimension RXL analyzer in 2023, 2024 and 2025, and staff interview, the laboratory failed to have documentation of performed the required calibration verifications every 6 months. The finding included: 1. A review of the laboratory's calibration verification records for the Dimension RXL analyzer for the analytes of Sodium, Potassium and Chloride determined the verifications were performed on the following days: June 2023 February 2024 (8 month gap) Note: Calibration verification has not been performed from February 2024 to June 11, 2025 (the day of the survey) resulting in a gap of 16 months. 2. The technical consultant confirmed the findings in an interview conducted on 06/11/2025 at 1028 hours in the reception area.
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 the the laboratory's critical value log from 2024 and 2025, review of patient test records from May 2025, and staff interview, the laboratory failed to have documentation of following its policy for the notification of critical values. The findings included: 1. A review of the laboratory's policy titled "Policy for Calling and Reporting Critical Values" (approved by the laboratory director on 12/23/2021) determined: "All critical/panic values will be immediately repeated, called to the provider, and include the providers name, who communicated the critical and at what time and date was it communicated. This will be included in a Critical/Panic designated log." The policy then defined the following critical values: White blood cell: less than 2.5 or greater than 25 Hemoglobin: less than 7.5 or greater than 18 Hematocrit: less than 24 or greater than 55 Platelet: less than 75 or greater than 800 2. A review of the laboratory's critical value log identified the laboratory last documented the notification of a critical value in 2024. 3. A review of the patient test records from May 2025 identified the following critical value: a) date: 5/02/2025 test: platelet value: 52 The laboratory did not have documentation of following its policy for the notification of the critical value. 4. The technical consultant confirmed the findings in an interview conducted on 06/11/2025 at 1230 hours in the laboratory.