Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1073299	**(X3) Date Survey Completed** 11/18/2025
Name of Provider or Supplier Guajira Family Clinic	**Street Address, City, State** 404 S 18th Suite A, Edinburg, 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 American Proficiency Institute's proficiency testing records from 2023 (events 2 and 3), 2024 (events 1, 2, and 3) and 2025 (events 1 and 2), and staff interview, the laboratory failed to ensure 2 of 3 testing personnel participated in proficiency testing. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 3 testing personnel. 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 (events 1 and 2) identified that testing personnel number 1 (as listed on Form CMS 209) performed testing for 7 of 7 events. They were: 2023 event 2 2023 event 3 2024 event 1 2024 event 2 2024 event 3 2025 event 1 2025 event 2 3. Further review determined testing personnel number 2 and number 3 (as listed on Form CMS 209) did not participate in proficiency testing. 4. The technical consultant confirmed the findings in an interview conducted on 11/18/2025 at 0930 hours in the office.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 review of the laboratory's policies, review of the laboratory's calibration records for the Horiba Micros 60 hematology analyzer, and staff interview, the laboratory failed to have documentation of performing calibrations every six months for 1 of 2 events. The findings included: 1. A review of the laboratory's policy titled "Instrument Operation and Maintenance" (approved 3/4/2008) identified the following: "Calibration of all laboratory instruments will be every six months, every time there is a complete change in lot numbers, or when controls don't give the desired results." 2. A review of the laboratory's calibration records for the Horiba Micros 60 hematology analyzer determined calibration was performed in November 2024 upon installation of the instrument. The laboratory did not have documentation of another calibration being performed as of the day of the survey (12 months later). 3. The technical consultant confirmed the findings in an interview conducted on 11/18 /2025 at 0950 hours in the office.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Horiba Micros 60 hematology analyzer, review of patient test records from November 13, 2025, November 14, 2025 and November 17, 2025, and staff interview, the laboratory failed to have documentation of following manufacturer's instructions for the resolution of flags on 17 of 18 results. The findings included: 1. A review of the manufacturer's instructions for the Horiba Micros 60 hematology analyzer (RAB043JEN) under the section titled "6.3.2. Flags on WBC Distribution curve" identified the the following flags and correction actions to be taken to resolve the flags: a) L1 "Indicates an abnormal number of cells, in comparison with the Lymphocytes, in the 30fl to 60fl zone. The pathological elements which may be found in this area include: - Platelet aggregates - Nucleated Red Blood cells" b) M2 "Indicates an excessive number of cells in the 130fl to 160fl zone. The pathological elements which may be found in this area will include: - Lymphoblasts - Myelocytes - Atypical Lymphocytes - Basophilia" c) G1 "Indicates an excessive number of cells in the 160fl to 220fl zone. The pathological elements which may be found in this area will include: - Eosinophilia - Myelocytes - Neutrophil polynuclease" d) G2 "Indicates an excessive number of cells larger than 400fl. The pathological elements which may be found in this area will include: - Metamyelocytes - Many types of Large Immature Cells" 2. The manufacturer's instructions also included the corrective actions to perform when patient results were flagged: "All Anomalies and/or Abnormal distribution flags given by the ABX Micros 60 should be manually verified by the examination of a stained peripheral blood smear for the presence of pathological elements. As a result of the differential resistance of cytoplasmic membranes in the different cell types, pathological elements can be found in a number of different zones." 3. A review of patient test records from November 14 -17, 2025 identified 17 of 18 patient records with flagged results which were reported to the provider without the results being

	verified. They were: a) November 13, 2025 ID: 34152 Flags: G2 ID: 33183 Flags: G1G2 ID: 32014 Flags: G2 ID: 37461 Flags: M2G1G2 ID: 70320 Flags: M2G1G2 ID: 33640 Flags: G1G2 b) November 14, 2025 ID: 32623 Flags: G1G2 ID: 22617 Flags: G2 ID: 34292 Flags: G1G2 ID: 14780 Flags: G1G2 ID: 36072 Flags: G1G2 c) November 17, 2025 ID: 30361 Flags: G2 ID: 35530 Flags: M2G1G2 ID: 3057 Flags: G2 ID: 29373 Flags: G1G2 ID: 12748 Flags: G2 ID: 36887 Flags: M2G1G2 4. The technical consultant confirmed the findings in an interview conducted on 11/18/2025 at 1040 hours in the office.