Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1073299	**(X3) Date Survey Completed** 01/25/2022
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**
D0000	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's quality control records from 2021, and staff interview, it was revealed the laboratory failed to have documentation of verifying 4 of 5 lots quality control material. The findings include: 1. A review of the laboratory's hematology quality control records from 2021 revealed the laboratory placed the following lots of 4C-ES control into use: 689000 expiration: 2/15/2021 696000 expiration: 5/21/2021 678000 expiration: 8/30/2021 684000 expiration: 11/22/2021 690000 expiration: 2/14/2022 2. Further review of the laboratory's hematology revealed the laboratory failed to have documentation of verifying 4 of the 5 lots. They were: 689000 expiration: 2/15/2021 696000 expiration: 5/21/2021 684000 expiration: 11/22/2021 690000 expiration: 2/14/2022 3. The laboratory was asked to provided documentation of verifying the identified lots of control material. No documentation was provided. 4. An interview with the technical consultant on 01/25/2022 at 1149 hours in the break room - after her review of the records- confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 6 testing personnel to perform moderate complexity testing (refer to D6065). The findings include: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/25 /2022) revealed the laboratory identified 6 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for 1 of 6 testing personnel. The laboratory failed to have documentation of education for testing personnel #6 as listed on Form CMS 209. Testing personnel #6 was employed by the laboratory May 24, 2020 to April 30, 2020. 3. The laboratory was asked to provide documentation of education. No documentation was provided. 4. An interview with the technical consultant on 01/25/2022 at 1100 hours in the break room - after her review of the records- confirmed the findings.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 6 testing personnel to perform moderate complexity testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/25/2022) revealed the laboratory identified 6 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for 1 of 6 testing personnel. The laboratory failed to have documentation of education for testing personnel #6 as listed on Form CMS 209. Testing personnel #6 was employed by the laboratory May 24, 2020 to April 30, 2020. 3. The laboratory was asked to provide documentation of education. No documentation was provided. 4. An interview with the technical consultant on 01/25/2022 at 1100 hours in the break room - after her review of the records- confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 1 of 6 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/25/2022) revealed the laboratory identified 6 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training 1 of 6 testing personnel. The laboratory failed to have documentation of training for testing personnel #6 as listed on Form CMS 209. Testing personnel #6 was employed by the laboratory May 24, 2020 to April 30, 2020. 3. The laboratory was asked to provide documentation of training. No documentation was provided. 4. An interview with the technical consultant on 01/25 /2022 at 1100 hours in the break room - after her review of the records- confirmed the findings.