Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0933357	04/25/2023
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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing records from 2021 3rd event through 2023 1st event,and staff interview, the laboratory failed to attain an acceptable score of 80% or higher for the analyte Chloride in the 2022 Chemistry Core 1st Event and the analyte Sodium in the 2022 Chemistry Core 3rd Event resulting in unsatisfactory analyte performance. The findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records found the laboratory obtained a score of 60% for the analyte Chloride in the 2022 Chemistry Core 1st Event and a score of 20% for the analyte Sodium (NA) in the 2022 Chemistry Core 3rd Event. 2 . During interview of the technical consultant conducted April 25, 2023 at 12:31 PM, she confirmed that the laboratory failed to achieve satisfactory performance for Chloride and Sodium in the two testing events.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on review of policies and procedures, the proficiency testing records from 2021 3rd event through 2023 1st event, patient test records and staff interview, the laboratory failed to take remedial action when failures occurred in two of three Chemistry proficiency testing events in 2022. The findings included: 1. Review of the policy titled PROFICIENCY TESTING found: "Use the "Proficiency Testing Troubleshooting Checklist" and the "Proficiency Testing Remedial Action Log Sheet" to help resolve and document failed proficiency testing." 2. Review of the American Proficiency Institute (API) proficiency testing records found the laboratory obtained a score of 60% for the analyte Chloride in the 2022 Chemistry Core 1st Event and a score of 20% for the analyte Sodium (NA) in the 2022 Chemistry Core 3rd Event. The laboratory did not use the "Proficiency Testing Troubleshooting Checklist" and the "Proficiency Testing Remedial Action Log Sheet" to document corrective actions in the failed proficiency testing events. 4. During interview of the technical consultant conducted April 25, 2023 at 12:31 PM, she confirmed that she did not utilize the "Proficiency Testing Troubleshooting Checklist" and the "Proficiency Testing Remedial Action Log Sheet" to document corrective actions in the failed proficiency testing events.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observations, review of proficiency testing records, patient test counts and interview of facility personnel, the laboratory failed to verify the accuracy of their results for Prostate Specific Antigen (PSA) at least twice annually in 2022. The laboratory tested 697 patient specimens for PSA in 2022. The findings included: 1. Observations made during the tour of the laboratory conducted March 20, 2023 at 4: 22 PM found the laboratory used the Siemens Dimension to test patient specimens for PSA, and was currently using lot FB3245. 2. Review of patient test counts found the laboratory tested 697 patient specimens for PSA in 2022. 2. During interview of testing person one on the CMS- 209 conducted April 25, 2023 at 11:58 AM, he confirmed the laboratory did not participate in a proficiency testing program for PSA or have another means of verifying the accuracy of results at least twice annually.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's own written policy, proficiency testing records, and confirmed in interview, the laboratory director failed to ensure that an approved corrective action plan that included training or technical assistance and remedial actions was taken when proficiency testing failures occurred in the 1st and 3rd Chemistry Core testing events of 2022. (See D 2087 and D 2094)