

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1073299	(X3) Date Survey Completed 01/30/2020
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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2018 Hematology (events 1,2,3) and Hematology 2019 (events1, 2,3), and confirmed in interview with facility perspnnel, the laboratory failed to</p>

participate in 2 of 3 events in 2018. The findings were: 1. A review of the laboratory's API proficiency testing records from 2018 Hematology (events 1,2,3 and 2019 Hematology (events 1,2,3) revealed the laboratory failed to participate in the following 2 of 3 events: 2018 Hematology (event 1) 2018 Hematology (event 2) 2. An interview with the technical consultant on 01/30/2020 at 09:35 hours in an office area, after review of the records, confirmed the findings.

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 laboratory's policy, laboratory quality control records from 2019 and staff interview, it was revealed the laboratory failed to have documentation of verified new lots of controls prior to placing them into use. The findings were: 1. Review of laboratory policy titled "Quantitative CBC control Verification Policy" (approved and signed by the laboratory director (10/01/15) under Policy: " It is the policy of this lab to validate quantitative controls prior to replacing them into use for patient testing" it states "New controls shall be run once a day for 5 days along with current controls. If current controls are within range and new controls are within their range, then new controls will be acceptable for use for patient testing." 2. A review of the laboratory's quality control records from May 2019 to January 2020 revealed the laboratory performed quality control testing utilizing 3 different lots of control material. Lot 77500 N expiration 08/26/2019 Lot 67500 L expiration 08/26/2019 Lot 87500 H expiration 08/26/2019 Lot 078100 N expiration 11/18/2019 Lot 068100 L expiration 11/18/2019 Lot 088100 H expiration 11/18/2019 Lot 078700 N expiration 02/10/2020 Lot 068700 L expiration 02/10/2020 Lot 088700 H expiration 02/10/2020 3. A review of the laboratory's quality control records from May 2019 to January 2020 revealed the laboratory failed to have documentation verifying 1 of 3 lots. The lots without documentation of verification were: Lot 078700 N expiration 02/10/2020 Lot 068700 L expiration 02/10/2020 Lot 088700 H expiration 02/10/2020 4. An interview with the technical consultant on 01/30/2020 at 1040 hours in the office area confirmed the finding.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing records and interview with facility personnel, the Laboratory Director failed to ensure the laboratory was enrolled in an approved proficiency testing program (three testing events per year) for the regulated analytes in the specialty of hematology for the first and second event of 2018. (refer to D2123)