

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2161340	(X3) Date Survey Completed 12/16/2020
Name of Provider or Supplier Daniella Rodriguez - Rico Md Pa	Street Address, City, State 4716 South Jackson Road, 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.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2019 and 2020, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 5 of 5 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2019 (events 2 and 3) and 2020 (events 1, 2, and 3) revealed the laboratory failed to have documentation of the laboratory director signing 5 of 5 attestation statements. The review showed: 2019 event 2 signed by Technical Consultant 2019 event 3 signed by Technical Consultant 2020 event 1 signed by Technical Consultant</p>

	<p>2020 event 2 signed by Technical Consultant 2020 event 3 no signature 2. A review of the laboratory's policies revealed the facility failed to have a policy which stated the laboratory director delegated this responsibility to the Technical Consultant. 3. An interview with the Technical Consultant on 11/16/2020 at 1000 hours in the break room - after his review of the records- confirmed the findings.</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: A review of the manufacturer's instruction for the Sysmex XP-300 hematology analyzer, review of the laboratory's policies, review of patient test records, and staff interview, revealed the laboratory failed to have documentation of a policy to address flags on CBC results. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Document number 1051-CFL, Revision 2 June/2014) under the section titled "Histogram Flags" revealed: AG - The particle count equal to or less than the LD exceeds a prescribed range. Probable cause is platelet agglutination, which does not alter the WBC count, but may result in decrease platelet count. 2. The laboratory was asked to provide documentation of a policy to resolve AG flags and/or platelet counts prior to reporting the results to the provider. No documentation was provided. 3. A sampling of patient test records from 12/04/2020 to 12/15/2020 identified the following patient results with AG flags where no corrective action was performed and the flagged results were reported: a) 12/04/2020 Sample ID: 11-23-2019 b) 12/07/2020 Sample ID: 12-27-2019 c) 12/09/2020 Sample ID: 08/01/2019 d) 12/15/2020 Sample ID: 09/19/2019 4. An interview with the technical consultant on 12/16/2020 at 1200 hours in the break room - after his review of the records- confirmed the findings. Key CBC - complete blood count WBC- white blood cell</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it</p>

can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's patient normal ranges currently in use, review of the laboratory's verification studies, and staff interview, it was revealed the verification studies performed did not verify the normal ranges currently in use. The findings were: 1. A review of patient normal ranges hematology testing revealed the following examples of the ranges currently in use: WBC 6.0-15.0 RBC 4.00-5.40 Hemoglobin 10.8-14.7 Hematocrit 33.0-40.0 Platelet 142-350 2. A review of the laboratory's studies on the Sysmex XP-300 analyzer revealed the ranges were verified by the studies: WBC: 3.0 - 14.6 RBC: 3.77 - 5.13 Hemoglobin 10.0-14.4 Hematocrit 30.5-41.3 Platelet 139 - 455 3. The laboratory was asked to provide documentation of studies which verified: WBC RBC Hemoglobin Hematocrit No documentation was provided 4. An interview with the Technical Consultant on 12/16/2020 at 1110 hours in the break room - after his review of the records- confirmed the findings. Key WBC - white blood cell RBC - red blood cell