

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0506359	(X3) Date Survey Completed 11/04/2019
Name of Provider or Supplier Ruben De Los Santos Md Pa	Street Address, City, State 1955 East Main Street, Eagle Pass, 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 out of compliance with the CLIA regulations. The condition not met was: D6033- 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were 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.
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 a review of the laboratory's American Association of Bioanalysts proficiency testing records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 3 of 6 attestation statements. Findings include: 1. A review of the laboratory's American Association of Bioanalysts proficiency testing records from 2018 (Q1, Q2, and Q3) and 2019 (Q1, Q2, and Q3) revealed the laboratory failed to have documentation of the laboratory director signing the following 3 attestation statements: 2018- Q3 2019- Q1 2019- Q3 2. The laboratory was asked to provide documentation of the laboratory director signing the above attestation statements. No documentation was provided. 3.</p>

An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 11/4/19) on 11/4/19 at 1:40 p.m. in the office, after review of the records, confirmed the above findings. THIS IS A REPEAT DEFICIENCY FROM THE PREVIOUS SURVEY CONDUCTED ON 9/4/2017

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing a competency assessment for 1 of 1 technical consultants. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/4/19) revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing a competency assessment of the technical consultant. 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 11/4/19 at 1:30 p.m. in the office revealed the laboratory did not assess the competency of the technical consultant. This confirmed the above findings.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, a review of the laboratory's patient reports, and staff interview, it was revealed the laboratory failed to ensure the reference intervals it provides to its clients are accurate. Findings include: 1. A review of the laboratory's 'Reference Intervals' policy (signed by the laboratory director on 1/3/2019) revealed the following: "Different limit ranges are used for male and female patient for the Hematology analyzer. Limits 1 is used for male patients, and limit 2 is used for female patients" WBC Limit 1 and Limit 2 range: 4.0 - 10.5 RBC Limit 1 range: 4.10 - 5.60 Limit 2 range: 3.80 - 5.10 HGB Limit 1 range: 12.5 - 17.0 Limit 2 range: 11.5 - 15.0 HCT Limit 1 range: 36 - 50 Limit 2 range: 34 - 44 MCV Limit 1 and Limit 2 range: 80 - 101 MCH Limit 1 and Limit 2 range: 27.0 - 34.0 MCHC Limit 1 and Limit 2 range: 32.0 - 36.0 RDW Limit 1 and Limit 2 range: 11.7 - 15.0 MPV Limit 1 and Limit 2 range: 7.8 - 11.0 PLAT Limit 1 and Limit 2 range: 140 - 450 GR Limit 1 and Limit 2 range: 1.8 - 7.8 LY Limit 1 and Limit 2 range: 0.7 - 4.5 MO Limit 1 and Limit 2 range: 0.1 - 1.0 GR# Limit 1 and Limit 2 range: 40.0 - 74.0 LY# Limit 1 and Limit 2 range: 14.0 - 46.0 MO# Limit 1 and Limit 2 range: 4.0 - 13.0 2. A random review of the laboratory's patient reports revealed the following female patients were resulted and the Limit 1 (male) reference ranges were listed on the final report: Patient ID: 004199111 Resulted 10/23/19 Patient ID: 000103628 Resulted 10/30/2019 Patient

ID: 001202496 Resulted 10/30/2019 4. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 11/4/19) on 11/4/19 at 2:45 p.m. in the office, after review of the records, confirmed the above findings. Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC- mean corpuscular hemoglobin concentration RDW- red cell distribution width MPV - mean platelet volume PLAT - platelet GR - granulocytes LY - lymphocytes MO - monocytes GR # - number granulocytes LY # - number lymphocytes MO # - number monocytes

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the laboratory's records, and staff interview, it was revealed the technical consultant failed meet the qualifications to provide technical oversight for the laboratory. Findings include: 1. The laboratory failed to have documentation of education to qualify the technical consultant (refer to D6035).

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service,

excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 1 technical consultants. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/04/19) revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel files revealed the laboratory failed to have documentation of education to qualify technical consultant # 1. The start date for the technical consultant is 1/2017. 3. The laboratory was asked to provide the required documentation. No documentation was provided. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 11/4/19 at 1:20 p. m. in the office, after review of the records, confirmed that he would need to get his transcripts and add them to his personnel file.