

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0506359	(X3) Date Survey Completed 10/21/2021
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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were 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 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, review of the manufacturer's instructions, review of laboratory's temperature charts and staff interview it was determined the laboratory failed to monitor the temperature for storage of BD Vacutainer Blood Collection Tubes. Findings included: 1. Surveyor's observations on 10/21/2021 at 1100 hours in the laboratory's storage room revealed the following BD vacutainer tubes stored in an under the countertop cabinet: 5 boxes (500 count) of K2 EDTA Blood Collection Tubes Lot 1098465, Expiration 2022-08-31 3 boxes (300 count) of SST Blood</p>

Collection Tubes Lot 1102114, Expiration 2022-03-31 3 boxes (300 count) of Serum /Blood Collection Tubes Lot 0119111, Expiration 2022-04-30 2. Review of the manufacturer's instructions for storage of BD Vacutainer Blood Collection Tubes revealed required storage temperature to be 4-25C. 3. Review of the laboratory's temperature monitoring charts revealed no documentation of temperature monitoring for the room the Vacutainer Tubes were stored in. 4. In an interview at 1100 hours in the laboratory's storage room the Technical Consultant (as described on CMSForm 209 signed by laboratory director on 10/16/2021) stated that the temperature was not monitored for the room the tubes were stored in. This confirmed the findings.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Beckman Coulter Act diff 2 hematology analyzer quality control records and staff interview it was determined the laboratory's quality control procedures failed to monitor over time the accuracy and precision of test performance. Findings included: 1. Review of the Beckman Coulter Act diff 2 hematology analyzer's January 2021 Levi Jennings charts monitoring over time quality control performance of Lot 069100 revealed the charts had only one documented data point of quality control performance. 2. Review of the Beckman Coulter Act diff 2 hematology analyzer daily quality control records for Lot 069100 for January of 2021 revealed quality controls were performed on: 01/14/2021 01/15 /2021 01/18/2021 01/19/2021 01/20/2021 01/21/2021 01/22/2021 01/25/2021 Note: All of the above should have appeared as data points on the Levi Jennings charts. 3. In an interview at 1030am in the conference room the Technical Consultant (as described on CMS Form 209 signed by laboratory director on 10/16/2021), after review of the data, confirmed the findings