

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2144058	(X3) Date Survey Completed 09/24/2024
Name of Provider or Supplier Rgv Endocrine Center	Street Address, City, State 1900 S Jackson Road, Ste 1, 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
D0000	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Pentra 400 User Manual, the laboratory's records, and staff interview, the laboratory failed to have documentation of performing the required bimonthly maintenance procedures on the Pentra 400 chemistry analyzer for four of fourteen months from June 2023 to August 2024. Findings include: 1. A review of the Pentra 400 User Manual (1300107504) revealed the following: "Bimonthly Procedures (Every Two Months) - To Check Glycol Level Check the cooling unit glycol level on a bimonthly basis (every two months). - To Replace Filter Replace the filter at the back of the instrument on a bimonthly basis (every two months)." 2. A review of the laboratory's records from June 2023 to August 2024 revealed the laboratory failed to have documentation of performing the required bimonthly maintenance procedures on the Pentra 400 chemistry analyzer (serial number: 301C4-1481) for the following months: - August 2023 - October 2023 - December 2023 - February 2024 3. Further review of the laboratory's records revealed the laboratory estimated performing 7,200 chemistry tests annually. 4. In an interview on 9/24/24 at 11:03 a.m. in the break room, after review of the records, the technical supervisor (as indicated on the CMS 209 form) confirmed the above findings.</p>
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 random review of patient test reports from July to December 2023 and staff interview, the laboratory failed to provide documentation of the reference intervals for Urine Creatinine and Urine Albumin on the final reports for eight of eight patient's reports reviewed. Findings include: 1. A random review of patient test reports from July to December 2023 revealed the following 8 patient's reports without reference intervals for Urine Creatinine and Urine Albumin: Specimen ID: 230711028 Resulted: 7/18/23 Specimen ID: 230726032 Resulted: 7/26/23 Specimen ID: 230810005 Resulted: 8/10/23 Specimen ID: 230825006 Resulted: 8/25/23 Specimen ID: 231103026 Resulted: 11/3/23 Specimen ID: 231103034 Resulted: 11/3/23 Specimen ID: 231106033 Resulted: 11/6/23 Specimen ID: 231213003 Resulted: 12/13/23 2. In an interview on 9/24/24 at 11:03 a.m. in the break room, after review of the records, the technical supervisor (as indicated on the CMS 209 form) confirmed the above findings.