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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0900539 | (X3) Date Survey Completed 04/23/2024 |
| Name of Provider or Supplier Health Texas Medical Group | Street Address, City, State 810 Se Military Drive, San Antonio, 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 |
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| D0000 | An announced validation survey was conducted on 04/23/2024. |
| D5783 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) results (January 2023 to February 2023), review of patient reports and confirmed in interview, the laboratory failed to document evaluation of all patient test results after QC failures since the last acceptable QC run for three of three occurrences. Findings included: 1. Random review of the laboratory's chemistry quality control (January 2023 to March 2023) determined the following days QC was out of acceptable range the following three days: January 2023: a. Date/Time performed: 01/13/2023; 11:47 AM Analyte: Sodium QC: DXC Set 4 Multiquel 1 Lot Number: 45951 Result: 126 mmol/L Acceptable range: 104.4 - 116.40 mmol/L Comment: "recalibrated, reran QC" February 2023: a. Date/Time performed: 02/13/2023; 5:54 PM Analyte: PSA QC: DXC Set 3 Immune 1 Lot Number: 85321 Result: 0.37 ng/mL Acceptable range: 0.24 - 0.36 ng/mL Comment: "cal and rerun ..." b. Date/Time performed: 02/24/2023; 11:13 AM Analyte: Calcium QC: DXC Set 4 Multiquel 3 Lot Number: 45953 Result: 11.9 mg/dL Acceptable range: 11.95 - 12.65 mg/dL Comment: "recal, rerun qc" 2. The laboratory was asked to provide documentation of evaluation of all patient test since the last acceptable QC. None was provided. 3. Review of patient reports from</p> |

the stated days determined the following patients were not evaluated: January 2023 a. Analyte: Sodium Date tested: 01/12/2023 Patients tested: 12 (Refer to Patient Alias List 1 for patient information.) February 2023 a. PSA Date tested: 02/13/2023 Patients tested: 21 (Refer to Patient Alias List 1 for patient information.) b. Calcium Date tested: 02/23/2023 Patients tested: 15 (Refer to Patient Alias List 1 for patient information.) 4. The technical consultant confirmed the findings during an interview on 04/23/2023 at 1500 hours in the office. Key: mmol/L: Millimoles per liter PSA: Prostate Specific Antigen ng/ml: nanograms per milliliter mg/dL: milligrams per deciliter