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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 03D0871525 | (X3) Date Survey Completed 08/12/2022 |
| Name of Provider or Supplier Presidio Health Associates Llc Db a Cat | Street Address, City, State 2611 N Warren Ave, Tucson, AZ | |
| 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 |
|---------------------------|---|
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review of the laboratory's refrigerator temperature logs and interview with the lead Registered Respiratory Therapist (RRT-1) on August 11, 2022, the laboratory failed to follow their "Corrective Action Plan" when the reagent refrigerator is not with in the established temperature range. The findings include: 1. Review of the refrigerator temperature logs for eight (8) days in 2021 and 2022, two (2) of the (8) days were not within established range: 08/18/2021 34 degrees Fahrenheit (range 35-46) 07/09/2022 34 degrees Fahrenheit (range 35-46) 2. The laboratory had no corrective actions documented or communication documented regarding the out of range temperatures or the assessment of the stability of the Abbott iStat blood gas cartridges. 3. The laboratory RRT-1 confirmed by interview on August 12, 2022 at 10:30 a.m., the lack of documentation of corrective action for temperature failures. 4. The laboratory reports performing 3,250 blood gas analysis annually.</p> |
| D6030 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p> |

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on personnel record review, laboratory policy and procedure review, and by interview with the lead Registered Respiratory Therapist (RRT-1) on August 12, 2022, the laboratory director failed to follow established policy and procedures for Ten (10) policy and procedures reviewed. The findings include: 1. The laboratory performs Blood gas analysis on the Abbott istat point of care analyzer. 2. Ten (10) of (10) policies and procedures reviewed, state the activities will be "conducted by the laboratory Director (LD) or their designee". 3. The LD performs the functions of Technical Consultant and Clinical Consultant. The laboratory has no documentation of delegation of authority or designation of responsibilities to the RRT-1 for conducting the initial training and competency's of the (11) RRT performing blood gas testing personnel. 4. The laboratory records revealed the RRT-1 conducted five (5) of (5) initial training and competency's for testing personnel, and conducted six (6) of (10) annual competency's for blood gas analysis testing personnel in 2022. 5. The RRT-1 confirmed by interview on August 12, 2022 at 10:30 a.m., the LD did not follow the laboratory's policy and procedure for conducting the training and competency of (11) of (11) RRT testing personnel. 6. The laboratory reports performing 3,250 blood gas analysis annually.