Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0871525	11/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Presidio Health Associates Llc Dba Cat	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) attestation statements for 2018 and interview with the laboratory personnel, the laboratory failed to have the director or a qualified designee sign the attestation statements for the 2nd and 3rd events of PT performed under the specialty of Chemistry. Findings include: 1. The PT attestation statements noted above did not have the signature either of the director or an individual that would qualify as a designee; a technical consultant meeting the qualifications under CLIA regulation 493.1409. 2. The laboratory personnel acknowledged that the attestation statements indicated above lacked the signature of the director or designee.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of current manufacturer's quality control (QC) and calibration verification (CalVer) assay information sheets for the i-Stat blood gas analyzer for review and interview with the laboratory personnel, the laboratory failed to retain the

	records indicated above for a minimum of two years. Findings include: 1. Based on the laboratory's IQCP policies, the laboratory performs monthly liquid QC for blood gas testing and performs 2. The laboratory failed to provide the Control Value Assignments Sheets (CLEW Sheets) that indicated the correct control target values and ranges for the CG8+ control cartridges utilized for the following months: November 2018 (lot # W18268), January 2019 (lot #W18339), and July 2019 (lot #W19200243). 3. The laboratory failed to provide the Calibration Verification Assignment Sheets (CLEW Sheets) that indicates the manufacturer's acceptable ranges for the CalVer performed on February 1, 2018 (lot #219W172600240) 4. The laboratory personnel acknowledged that the documents indicated above could not be located on the day of the survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) scores for 2018 and 2019 and interview with the laboratory personnel, the laboratory failed to provide a documented review of the PT results for 2018 and 2019 for the sub-specialty of routine chemistry and the specialty of hematology. Findings include: 1. No documented reviews, including a written comment and signature, were presented during the survey to indicate that the laboratory director or designee reviewed the results for the testing events indicated above for blood gas testing. 2. There must be evidence of a review of the PT scores for each event even if the laboratory received a score of 100%. 4. The laboratory personnel acknowledged that there were no documented reviews of the PT scores for the events listed above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of a documented annual quality assessment (QA) review for 2018 and as indicated in the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory failed to provide a documented annual QA review for 2018. 1. The laboratory's policy indicated that the following areas are to be reviewed on an annual basis: Test procedures Package Inserts Instrument Manuals Policy or processes not covered by the QA review Normal Ranges Reportable Ranges Limitations of test methods. 2. The facility personnel acknowledged that the documented annual review could not be located.