Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0871525	(X3) Date Survey Completed 11/13/2024
Name of Provider or Supplier Presidio Health Associates Llc Dba 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2022, 2023 and 2024 and interview with the testing personnel (TP-1), the laboratory failed to test PT samples by testing personnel who routinely perform patient testing in the laboratory, using the laboratory's routine methods. Findings include: 1. The laboratory participates in 3 PT events annually for testing performed in the specialties of Chemistry and Hematology. 2. The CMS-209, Laboratory Personnel Form presented during the survey conducted on 11/13/24 listed 17 testing personnel who routinely perform patient testing. 3. Interview with testing personnel during the survey confirmed that the PT samples were not rotated among the 17 testing personnel in the laboratory and that the same testing personnel: initals "SP" performed PT testing for every PT event from 2022-2024. 4. The TP-1 interviewed on 11/13/24 at 11:30 AM confirmed that the same individual participated in each testing event as indicated above.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on information the Proficiency Testing (PT) provider furnished to the State

	Agency, the laboratory failed to to attain an overall testing event score of at least 80 percent for the regulated analytes, pH and PCO2 Blood Gas, during the 3rd testing event of 2022 resulting in an unsatisfactory PT performance.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and interview with the testing personnel, the laboratory failed to undergo appropriate training and employ the technical assistance necessary to correct the PT failures for the regulated analytes, pH and PCO2 Blood Gas during the 3rd event of 2022.
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) records from 2022 through 2024 and interview with the testing personnel (TP-1), the laboratory failed to provide a documented review of PT results from the 1st and 2nd testing events of 2024, 1st and 3rd testing events of 2023, and the 3rd testing event of 2022. Findings include: 1. The laboratory performs patient testing on the i-STAT under the specialties of Chemistry and Hematology. The laboratory performs 3,500 tests annually. 2. No evidence, either by written comment or signature, was presented during the survey conducted on 11/13/2024 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 1st and 2nd testing events of 2024. 3. No evidence, either by written comment or signature, was presented during the survey conducted on 11/13/2024 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 1st and 3rd testing events of 2023. 4. No evidence, either by written comment or signature, was presented during the survey conducted on 11/13/2024 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 3rd testing event of 2022. 5. The TP-1 interviewed on 11/13/24 at 11:30 AM confirmed the PT results indicated above were not reviewed by laboratory personnel.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general

	laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) results, lack of Quality Assessment (QA) records and interview with the testing personnel (TP-1), the laboratory failed to review the effectiveness of corrective actions taken to resolve problems found with unsatisfactory PT scores and prevent recurrence of the problems. Findings include: 1. The laboratory utilizes the i-STAT for patient testing under the specialties of Chemistry and Hematology with an test volume of 3, 500. 2. PT records reviewed during the survey from the 3rd event of 2022 indicated the laboratory received unsatisfactory scores of 60% for the following regulated analytes: pH and PCO2 Blood Gas. The laboratory failed to perform and document any corrective actions. 3. The laboratory failed to provide documentation of a review of the effectiveness of the corrective action taken to resolve problems identified with the unsatisfactory PT scores, including but not limited to, evidence the problem was resolved, a revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general systems quality assessment reviews with appropriate staff. 4. The TP-1 interviewed on 11/13/24 at 12:00 PM confirmed the laboratory lacked a QA process to include a review of the effectiveness of the corrective actions taken for the PT errors indicated above.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the testing personnel (TP-1), the laboratory failed to rotate control material testing among all operators who perform patient testing. Findings include: 1. The laboratory performs patient testing using the I-Stat under the specialties of Chemistry and Hematology with an annual test volume of 3,250. 2. The CMS-209, Laboratory Personnel Form presented during the survey conducted on 11/13/24 listed 17 testing personnel who routinely perform patient testing. 3. No documentation was presented for review to indicate the laboratory rotated control material testing among all operators who perform patient testing. 4. The TP-1 interviewed on 11/13/2024 at 12:15 PM confirmed the laboratory failed to rotate control material testing among all operators who perform patient testing.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation from 2023 and 2024 and interview with the testing personnel (TP-1), the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. The laboratory's Quality Assessment Plan states, "All QA Activities are fully documented and retained for a minimum of two years. A Laboratory Quality Assurance-General Form is used to document most QA efforts. In addition to the general form, there are four Supervisory Monthly Checklists. These checklists provide a means of data collection throughout the year and serve to facilitate individual annual QA reviews. These checklists are used to document supervisory oversight of several major laboratory functions in addition to documenting communication breakdowns and complaints, and include: Patient Test Management-Twice Annual Chart Audit Record Proficiency Testing-Tracking Sheet Maintenance, Calibration, and Quality Control-Tracking Sheet Communications, Complaints, Problems, and Personnel-Tracking Sheet" 2. No QA documentation from June 2023 through the survey date (11 /13/24) was presented for review to indicate the laboratory followed the established policy referenced above to ensure accurate and reliable test reporting. 3. The TP-1 interviewed on 11/13/24 at 12:00 PM confirmed the laboratory failed to produce evidence of QA documentation from June 2023 onwards. 4. The laboratory performs 3,500 tests annually under the specialties of Chemistry and Hematology.