Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0556637	02/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Altitude Pulmonary And	435 Arden Ave Ste 310, Glendale, CA	

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 interview with the laboratory staff, review of laboratory personnel reports (CMS209, LAB116), patient test reports, College of American Pathologists (CAP) Blood Gas Analysis proficiency testing (PT) records from 2018 to 2019, for 6 out of 6 testing events results reviewed from the 1st testing event of 2018 through the 3rd testing event of 2019, it was determined that proficiency testing samples had not been tested by personnel routinely testing patients specimen. The findings included: 1. Based on interview with the laboratory staff on 02/28/2020, review of the laboratory's CAP (account # 7197025-01) PT records from the 1st testing event of 2018 through the 3rd testing event of 2019, there were four testing personnel who routinely perform blood gas analysis, but only one testing person and the Laboratory Director not listed in CMS 209 and LAB 116 performed the proficiency testing samples. 2. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2), Sodium (Na+), Potassium (K+), Calcium (Ca +2), and Hematocrit (Hct) which the laboratory failed to utilize personnel who routinely test patient specimens to perform PT samples. Q1, 2018 Q2, 2018 Q2, 2019 03/06/2018 06/29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology

	(Hct). 4. The laboratory staff affirmed (02/28/2020 at approximately 9:00 a.m.) that only 1 out 4 testing personnel for blood gas and the Laboratory Director not performing routine patient specimens performed all PT samples for 6 out of 6 testing events.
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 interview with the laboratory staff on February 28, 2020, review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records from 2018 to 2019, for 6 out of 6 testing events results reviewed from the 1st testing event of 2018 through the 3rd testing event of 2019, it was determined that the laboratory failed to document that the individual testing or examining the PTsamples and the Laboratory Director attested to the routine integration of the Blood Gas PT samples into the patient workload utilizing the laboratory's routine methods. The findings included: 1. Based on interview with the laboratory staff on 02/28/2020, the laboratory participated in CAP (account # 7197025-01) Blood Gas (pH, pCO2, pO2), Na +, K+, Ca +2, and Hematocrit) PT program from the 1st testing event of 2018 through the 3rd testing event of 2019. 2. Review of 6 out 6 Blood Gas PT events reviewed from 2018 to 2019 indicated that the Laboratory Director and testing staff did not sign the attestation page to document they attested to the routine integration of PT samples in routine patient workload utilizing the laboratory's routine methods. 3. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2, Na+, K+, Ca +2, Hematocrit (Hct) which the Laboratory Director and testing staff failed to sign the attestation page to document they attested the routine integration of PT samples in routine patient workload utilizing the laboratory's routine methods. Q1, 2018 Q2, 2018 Q2, 2019 03/06/2018 06/29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 4. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 5. The laboratory staff affirmed (02/28/2020 at approximately 9:00 a.m.) that the Laboratory Director and testing staff failed to sign the attestation page to document the routine integration of PT samples in routine patient workload utilizing the laboratory's routine methods.
D2121	HEMATOLOGY CFR(s): 493.851(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 interview with the laboratory staff, review of College of American Pathologists (CAP) Blood Gas Analysis proficiency testing (PT) records from 2018 to 2019, for 6 out of 6 testing events results reviewed from the 1st testing event of 2018 through the 3rd testing event of 2019, it was determined that the laboratory failed to attain a score of at least 80% for Hematocrit (Hct), a subspecialty of Hematology, 2nd PT event of 2018. The findings included: 1. Based on interview with the laboratory staff on 02/28/2020, review of the laboratory's CAP (account # 7197025-01) PT records from the 1st testing event of 2018 through the 3rd testing event of 2019, the laboratory failed to maintain satisfactory performance with the PT program by failing to obtain a score of at least 80% acceptable response. 2nd testing event of 2018, Hct (20%) Kit # 31250072 CAP Result Mean Expected Spec # Result HCT-06 42 32.2 30-35 HCT-07 25 19.8 18-21 HCT-08 43 42.1 39-45 HCT-09 20 24.8 23-27 HCT-10 32 41.3 38-44 2. The laboratory tested and reported 3 out of 3 Hct patient test results (Q2, 2018) on 06/29/2018, the day the laboratory failed the Hct proficiency testing. Accession # 16722 5090 4644 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28/2020 at approximately 9:00 a.m.) the unsatisfactory PT performance for Hct, Q2, 2018.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff, review of College of American Pathologists (CAP) Blood Gas Analysis proficiency testing (PT) records from 2018 to 2019, for 6 out of 6 testing events results reviewed from the 1st testing event of 2018 through the 3rd testing event of 2019, it was determined that the laboratory failed to document the evaluation and verification of the unacceptable responses to evaluate the laboratory's performance and to identify any problems that required corrective action for Hematology Hematocrit (Hct), 2nd PT event of 2018, Sodium (Na+), and Potassium (K+) 2nd PT event of 2018 and 2019. The findings included: 1. Hematology (Hct) a. The laboratory reported an unacceptable result for 4 out of 5 Hct PT challenges, resulting in a score of 20% during the 2nd event of 2018. b. Review of the result summary provided by CAP showed that the laboratory's reported results were higher than the expected mean for HCT 06 and 07, but lower than the expected mean for HCT 09 and 10 without performance review and corrective action documented for Hematology Hct. CAP Result Mean Expected Spec # Result HCT-06 42 32.2 30-35 HCT-07 25 19.8 18-21 HCT-08 43 42.1 39-45 HCT-09 20 24.8 23-27 HCT-10 32 41.3 38-44 c. The laboratory tested and reported 3 out of 3 Hct patient test results (Q2, 2018) on 06/29/2018, the day the laboratory failed the Hct proficiency testing. Accession # 16722 5090 4644 d. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 1,103 tests for the subspecialty of Hematology (Hct). e. The laboratory staff affirmed (02/28/2020 at approximately 9:00 a.m.) there was no corrective action documentation and verifications were recorded for Hct, Q2, 2018. 2. Routine Chemistry (Na+, K+) a. Review of the result summary provided by CAP for 2nd event of 2018 and 2019, specimens AQ 10 Na+ and K+ reported a result code 42 (No credit assigned due to absence of response) which the program indicated under "Actions Laboratories

	Should Take when a PT Result is Not Graded." CAP has a requirement under Actions Laboratories Should Take when a PT Result is Not Graded: "The laboratory is required to use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the Kit Instructions and/or the Result Form. Document Corrective Actions to prevent future failures." b. The laboratory tested and reported 10 out of 10 Na+ and K+ patient test results (Q2- 2018 and 2019) on 06/29/2018 and 07/11-15/2019, the day the laboratory received 1 out of 5 exceptional code 42 proficiency testing results without documentation of performance review and corrective action. 06/29/2018 07/11/2019 Accession # Accession # 16722 49485 5090 07/15/2019 4644 Accession # 49238 49897 49192 30407 13116 5408 c. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21 /2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry. d. The laboratory staff affirmed (02/28/2020 at approximately 10:00 a.m.) there was no documentation of performance review and corrective action for Na+ and K+ proficiency testing exceptional code 42, Q2- 2018 and 2019.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on February 28, 2020, review and the lack of documentation of policies and procedures (P/P) for Specimen Submission, Handling, and Referral, it was determined that the laboratory failed to establish policies and procedures for patient preparation, specimen collection, labeling, including patient name or unique patient identifier and appropriate specimen source, storage and preservation, conditions for specimen transportation, processing, acceptability, rejection, and referral. The findings included: 1.. The laboratory has no P /P for the following: a. Patient preparation b. Specimen collection c. Specimen labeling, including patient name or unique patient identifier and appropriate specimen source d. Specimen storage and preservation e. Conditions for specimen transportation f. Specimen processing g. Specimen acceptability and rejection h. Specimen referral 2. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2), Na+, K+, Ca +2, and Hematocrit (Hct) which the laboratory failed to establish P /P for patient preparation, specimen collection, labeling, including patient name or unique patient identifier and appropriate specimen source, storage and preservation, conditions for specimen transportation, specimen processing, acceptability, rejection, and referral. 03/06/2018 06/29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21 /2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests

	for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28 /2020 at approximately 10:00 a.m.) that the laboratory has no P/P for Specimen Submission, Handling, and Referral.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, it was determined that the Condition for Analytic Systems was not met as mandated by CLIA in Subpart K of Title 42 of the Code of Federal Regulation. The findings included: 1.The laboratory failed to establish the procedure manual in all phases of testing for GEM 3500 blood gas analysis prior to reporting patient test results (See D5401). 2. The laboratory failed to establish the procedure manual for GEM 3500 from pre-analytic, analytic, and post-analytic phases of clinical testing that met the required requirements for 493.1251(b) (1), (3)-(14) (See D5403). 3. The laboratory failed to ensure the procedure manual for GEM 3500 was approved, signed, and dated by the Laboratory Director before the laboratory utilized the new blood gas analyzer (See D5407). 4.The laboratory failed to ensure the procedure manual for GEM 3000 was maintained and dated for its initial use and discontinuance (See D5409). 5. The laboratory failed to monitor the humidity condition of the environment where it installed the GEM 3500 blood gas analyzer for optimum function (See D5413) 6. The laboratory failed to establish and verify the performance specifications, including accuracy, precision, and reportable range, on both the "loaner" and current GEM 3500 blood gas analyzers (See D5421). 7. The laboratory failed to ensure it established GEM 3500 preventive maintenance (PM) policies and procedures, and unscheduled repairs when needed to maintain optimum operating characteristics (See D5433). 8.The laboratory failed to ensure documentation that two levels of control materials were performed each day of testing for blood gas analysis (pH, pCO2, pO2), Na+, K+, Ca+2, and Hct, or an alternative "Individual Quality Control Plan" (IQCP) was established (See D5445). 9. The laboratory failed to ensure it maintained a record system that identifies who performed the blood gas test (See D5787).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on February 28, 2020, lack of Instrumentation Laboratory Worldwide (ILW) GEM 3500 blood gas analyzer policies

	and procedures, review of quality control records, patients reports, test requisitions, and analyzer printouts, it was determined that from March 6, 2018 to February 28, 2020, the laboratory failed to establish its GEM 3500 blood gas analyzer policies and procedures (P/P) covering the required components for pre-analytic, analytic and post-analytic phases of clinical testing. The findings included: 1. The laboratory has no written P/P in all phases of clinical testing for GEM 3500 blood gas analyzers, both the "loaner" GEM 3500 (SN # 09080376) utilized from 03/06/2018 to 06/28/2018 and current GEM 3500 (SN # 18039486) utilized after 06/28/2018 which replaced its previous GEM 3000 blood gas analyzer. 2. Random patient sampling covering the period from 03/06/2018 to 06/29/2018, the laboratory tested and reported 8 out of 8 blood gas patient test results utilizing both the "loaner" and current GEM 3500 blood gas analyzers without an established P/P in all phases of clinical testing. "Loaner" "Current" GEM 3500 03/06/2018 06/29/2018 Accession # Accession # 4889 16722 8649 5090 1413 4644 4494 24437 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28 /2020 at approximately 10:00 a.m.) that the laboratory failed to establish its GEM 3500 blood gas analyzer policies and procedures (P/P) in all phases of clinical testing from pre-analytic, analytic and post-analytic process.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on February 28, 2020, and review of laboratory records, the laboratory failed to provide the procedure manual that met all the applicable requirements for Blood Gas Analysis utilizing Instrumentation Laboratory Worldwide (ILW) GEM 3500 analyzer. The findings included: 1. At the time of inspection, the laboratory failed to provide the procedure manual for GEM 35000 from pre-analytic, analytic, and post-analytic phases of clinical testing, such as: a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen

	acceptability and rejection as described in 493.1242. b. Step-by-step performance of the procedure, including test calculations and interpretation of results. c. Preparation of solutions, calibrators, controls, reagents, and other materials used in testing. d. Calibration and calibration verification procedures. e. The reportable range for test results for the test system as established or verified in 493.1253. f. Control procedures. g. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. h. Limitations in the test methodology, including interfering substances. i. Specific source of Reference Intervals (Normal Values). j. Specific source for imminently life-threatening test results, or panic or alert values. k. Pertinent literature references. l. The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. m. Description of the course of action to take if a test system becomes inoperable. 2. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2) Na+, K+, Ca +2, and Hematocrit (Hct) which the laboratory failed to provide the procedure manual that met all the applicable requirements for Blood Gas Analysis utilizing GEM 3500 analyzer. 03/06/2018 06/29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28/2020 at approximately 10:00 a.m.) the laboratory failed to provide the procedure manual that met all the applicable requirements for Blood Gas Analysis utilizing GEM 3500 analyzer in all phases of clinical testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on February 28, 2020, and review of laboratory records, the current Laboratory Director failed to meet the standard requirement to approve, sign, and date the all policies and procedures (P/P) before the laboratory utilized the new GEM 3500 blood gas analyzer. The findings included: 1. At the time of inspection, there was no available P/P for the new Instrumentation Laboratory Worldwide GEM 3500 blood gas analyzer which replaced the GEM 3000. There was no P/P approved, signed, and dated by the Laboratory Director for the "loaner" GEM 3500 (SN # 09080376) utilized from 03/06/2018 to 06/28/2018 and current GEM 3500 (SN # 18039486) after 06/28/2018 blood gas testing. 2. . Random patient sampling covering the period from 03/06/2018 to 06/29/2018, the laboratory tested and reported 8 out of 8 blood gas patient test results utilizing both the "loaner" and current GEM 3500 blood gas analyzers without an approved, signed, and dated P /P before the laboratory utilized both the "loaner" and current GEM 3500 blood gas analyzers. "Loaner" "Current" GEM 3500 03/06/2018 06/29/2018 Accession # Accession # 4889 16722 8649 5090 1413 4644 4494 24437 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated

	by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28/2020 at approximately 10:00 a.m.) that the laboratory failed to provide an approved, signed, and dated P/P before the laboratory utilized both the "loaner" and current GEM 3500 blood gas analyzers.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on February 28, 2020, and review of laboratory records, the laboratory failed to ensure it maintained the copy of the dated GEM 3000 blood gas analyzer policies and procedures (P/P) for its initial use and discontinuance. The findings included: 1. The laboratory failed to provide the discontinued GEM 3000 P/P dated with initial use and discontinuance when the laboratory started to utilize the "loaner" GEM 3500 (SN # 09080376) in 03/06/2018, and the current GEM 3500 (SN # 18039486) in 06/29/2018. 2. . Random patient sampling covering the period from 03/06/2018 to 06/29/2018, the laboratory tested and reported 8 out of 8 blood gas patient test results utilizing both the "loaner" and current GEM 3500 blood gas analyzers without maintaining the copy of GEM 3000 blood gas analyzer P/P, dated with its initial use and discontinuance prior 03/06/2018. "Loaner" "Current" GEM 3500 03/06/2018 06/29/2018 Accession # Accession # 4889 16722 8649 5090 1413 4644 4494 24437 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28/2020 at approximately 10:00 a.m.) that the laboratory failed to ensure it maintained the copy of the dated GEM 3000 blood gas analyzer policies and procedures (P/P) for its initial use and discontinuance.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records, and interview with the laboratory staff on February 28, 2020, it was determined that the laboratory failed to define criteria for the humidity condition of the environment where it installed the GEM 3500 blood gas analyzer. The findings included: 1. The laboratory failed to

	monitor the humidity condition of the environment where it installed GEM 3500 blood gas analyzer to protect it from condition that could adversely affect patient test result. 2. The Instrumentation Laboratory Worldwide manufacturer for GEM 3500 recommended 5-90% humidity specification for optimum function of the blood gas analyzer. 3. Random patient sampling covering the period from 03/06/2018 to 07/15 /2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2), Na+, K+, Ca +2, and Hematocrit (Hct) without monitoring the humidity condition of the environment where it installed the GEM 3500 blood gas analyzer. 03/06/2018 06/29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 4. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 5. The laboratory staff affirmed (03/05 /2020 at approximately 11:00 a.m.) through email communication that the laboratory failed to monitor the humidity condition of the environment where it installed the GEM 3500 blood gas analyzer for optimum function.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of GEM 3500 blood gas analyzer performance specification records, review of patients reports, and interview with the laboratory staff on February 28, 2020, it was determined that prior to reporting Blood Gas (pH, pCO2, pO2), Sodium (Na+), Potassium (K+), Calcium (Ca+2), and Hematocrit (Hct) patient results utilizing both the "loaner" and current GEM 3500 which replaced the GEM 3000, the laboratory failed to document and demonstrate that it could obtain performance specifications, including accuracy, precision, and reportable range, comparable to that of the analyzer's manufacturer. The findings included: 1. At the time of inspection, the laboratory failed to provide the performance specification records, including accuracy, precision, and reportable range, on both the "loaner" GEM 3500 (SN # 09080376) utilized in 03/06/2018 to 06/28/2018, and the current GEM 3500 (SN # 18039486) utilized in 06/29/2018. 2. Random patient sampling covering the period from 03/06 /2018 to 06/29/2018, the laboratory tested and reported 8 out of 8 blood gas patient test results utilizing both the "loaner" and current GEM 3500 blood gas analyzers without performing the accuracy, precision, and reportable range for both the "loaner" and current GEM 3500 which replaced the GEM 3000 blood gas analyzer. "Loaner" "Current" GEM 3500 03/06/2018 06/29/2018 Accession # Accession # 4889 16722 8649 5090 1413 4644 4494 24437 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103

	tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28 /2020 at approximately 9:30 a.m.) that the laboratory failed to provide the performance specification records, including accuracy, precision, and reportable range, on both the "loaner" and current GEM 3500 blood gas analyzers.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on February 28, 2020, and review of laboratory records, the laboratory failed to provide an established GEM 3500 scheduled preventive maintenance (PM) policies and procedures (P/P), records and unscheduled repairs when needed to maintain optimum operating characteristics in 2018, 2019, and 2020. The findings included: 1. At the time of inspection, the laboratory failed to provide an established GEM 3500 scheduled preventive maintenance (PM) policies and procedures (P/P), records and its unscheduled repairs when needed to maintain optimum operating characteristics for 2018, 2019, and 2020 when the laboratory replaced its GEM 3000 with a "loaner" GEM 3500 (SN # 09080376) utilized in 03/06/2018 to 06/28/2018, and the current GEM 3500 (SN # 18039486) utilized in 06/29/2018. 2. Random patient sampling covering the period from 03/06/2018 to 06/29/2018, the laboratory tested and reported 8 out of 8 blood gas patient test results utilizing both the "loaner" and current GEM 3500 blood gas analyzers without an established GEM 3500 scheduled preventive maintenance (PM) policies and procedures (P/P), records and unscheduled repairs when needed to maintain optimum operating characteristics . "Loaner" "Current" GEM 3500 03/06 /2018 06/29/2018 Accession # Accession # 4889 16722 8649 5090 1413 4644 4494 24437 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28/2020 at approximately 9:30 a.m.) that the laboratory failed to provide an established GEM 3500 scheduled preventive maintenance (PM) policies and procedures (P/P), records and unscheduled repairs when needed to maintain optimum operating characteristics in 2018, 2019, and 2020.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review and the lack of documentation of quality control materials of different concentration on each day of testing for GEM 3500 blood gas analysis, and interview with the laboratory staff on February 28, 2020, it was determined that the laboratory failed to that each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in 493.1256 (d)(3) "At least once each day patient specimens are assayed or examined perform the following for whichever is more stringent." The laboratory also had not instituted an alternative "Individual Quality Control Plan" (IQCP) including Risk Assessment, Quality Control and Quality Assessment. The findings included: 1. The laboratory failed to provide documentation to show that two levels of control material were performed each day of testing for blood gas analysis (pH, pCO2, pO2), Sodium (Na+), Potassium (K+), Calcium (Ca+2), and Hematocrit (Hct) in 2018, 2019, and 2020. 2. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2), Na+, K+, Ca +2, and Hct with no documentation for quality control materials being performed each day of testing. 03/06/2018 06/29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28/2020 at approximately 10:30 a.m.) that the laboratory failed to provide documentation to show that two levels of control material were performed each day of testing for blood gas analysis (pH, pCO2, pO2), Na+, K+, Ca+2, and Hct.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on observation of the GEM 3500 blood gas analyzer in the laboratory, review of the laboratory personnel report (CMS 209 and LAB 116), patients test records, the lack of documents, and interview with the laboratory staff, the laboratory failed to maintain a record system that identifies who performed the test. The findings include: 1. The laboratory failed to provide documentation that identifies who utilized the GEM 3500 "loaner" (SN # 09080376) in 03/06/2018 to 06/28/2018 and current GEM 3500 (SN# 18039486) in 06/29/2018 to 02/28/2020 to test and report blood gas (pH,

	pCO2, and pO2), Sodium (Na+), Potassium (K+), Calcium (Ca+2), and Hematocrit (Hct) patient test results. 2. The laboratory personnel report (signed and dated by the Laboratory Director on 02/21/2020) included four testing personnel operating the GEM 3500 blood gas analyzer. 3. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2), Na+, K+, Ca +2, and Hematocrit (Hct) which the record system was unclear or failed to identify who performed the test. 03/06/2018 06 /29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 4. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 5. The laboratory staff affirmed (02/28/2020 at approximately 9:00 a.m.) that the laboratory failed to maintain a record system that identifies who performed the test.
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 interview with the laboratory staff on February 28, 2020, and review of laboratory records, it was determined that the laboratory failed to 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. The findings included: 1. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified with the failure in establishing the procedure manual in all phases of testing for GEM 3500 blood gas analysis prior to reporting patient test results (See D5401). 2. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified with the failure in establishing the procedure manual for GEM 3500 from pre-analytic, analytic, and post-analytic phases of clinical testing that met the required requirements for 493.1251(b) (1), (3)-(14) (See D5403). 3. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified with the failure in ensuring the procedure manual for GEM 3500 was approved, signed, and dated by the Laboratory Director before the laboratory utilized the new blood gas analyzer (See D5407). 4.The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified with the failure in ensuring the procedure manual for GEM 3000 was maintained and dated for its initial use and discontinuance (See D5409). 5. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified with the failure in monitoring the humidity condition of the environment where it installed the GEM 3500 blood gas analyzer for optimum function (See D5413). 6. The laboratory failed to ensure it established the ongoing mechanism to monitor, assess, and correct

	problems identified with the failure in establishing the performance specification, including accuracy, precision, and reportable range, on both the "loaner" and current GEM 3500 blood gas analyzers (See D5421). 7. The laboratory failed to ensure it established the ongoing mechanism to monitor, assess, and correct problems identified with the failure in establishing GEM 3500 preventive maintenance (PM) policies and procedures, and unscheduled repairs when needed to maintain optimum operating characteristics (See D5433). 8.The laboratory failed to ensure it established the ongoing mechanism to monitor, assess, and correct problems identified with the failure in establishing the documentation of two levels of control material were performed each day of testing for blood gas analysis (pH, pCO2, pO2), Na+, K+, Ca+2, and Hct, or an alternative "Individual Quality Control Plan" (IQCP) was established (See D5445). 9. The laboratory failed to ensure it established the ongoing mechanism to monitor, assess, and correct problems identified with the failure in maintaining a record system that identifies who performed the blood gas test (See D5787).
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on February 28, 2020, the laboratory failed to have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner weather manually transcribed or electronically transmitted results and patient-specific information reported directly. The findings included: 1. The laboratory failed to perform manual or electronic system(s) validation study to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final blood gas test report destination. 2. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2), Na+, K+, Ca +2, and Hematocrit (Hct) without performing the manual or electronic system(s) validation study to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final blood gas test report destination. 03 /06/2018 06/29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21 /2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28 /2020 at approximately 11:00 a.m.) that the laboratory failed to perform the manual or

	electronic system(s) validation study to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final blood gas test report destination.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with the laboratory staff, the Laboratory Director failed to ensure the quality control programs were established and maintained (See D5400) as mandated by State and CLIA. The cumulative effect of the above deficient practices resulted in the Laboratory Director's inability to ensure the accuracy and reliability of patient test reporting.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on February 28, 2020, and review of laboratory records, it was determined that the Laboratory Director failed to ensure quality control activities were established and maintained by the laboratory to assure the quality of services provided and to identify failures in quality as they occur. The findings included: 1.The Laboratory Director failed to ensure it established the procedure manual in all phases of testing for GEM 3500 blood gas analysis prior to reporting patient test results (See D5401). 2. The Laboratory Director failed to ensure it established the procedure manual for GEM 3500 from pre-analytic, analytic, and post-analytic phases of clinical testing met the required requirements for 493.1251(b) (1), (3)-(14) (See D5403). 3. The Laboratory Director failed to ensure the procedure manual for GEM 3500 was approved, signed, and dated by the Laboratory Director before the laboratory utilized the new blood gas analyzer (See D5407). 4.The Laboratory Director failed to ensure the procedure manual for GEM 3000 was maintained and dated for its initial use and discontinuance (See D5409). 5. The Laboratory Director failed to ensure it monitors the humidity condition of the environment where it installed the GEM 3500 blood gas analyzer for optimum function (See D5413) 6. The Laboratory Director failed to ensure it established and verified the performance specifications, including accuracy, precision, and reportable range, on both the "loaner" and current GEM 3500 blood gas analyzers (See D5421). 7. The Laboratory Director failed to ensure it established GEM 3500 preventive maintenance (PM) policies and procedures, and unscheduled repairs when needed to maintain optimum operating characteristics (See D5433). 8.The Laboratory Director

	failed to ensure two levels of control materials were performed each day of testing for blood gas analysis (pH, pCO2, pO2), Na+, K+, Ca+2, and Hct, or an alternative "Individual Quality Control Plan" (IQCP) was established (See D5445). 9. The Laboratory Director failed to ensure it maintained a record system that identifies who performed the blood gas test (See D5787).
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform 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 review of testing personnel training records, review of the laboratory policy and procedures, and interview with the laboratory staff on February 28, 2020, the Laboratory Director failed to 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. The findings included: 1. Review of the personnel files and interview with the laboratory staff confirmed that the laboratory did not have a policy or procedure for evaluating annually the competencies of the laboratory personnel to assure that they are competent and maintain their competencies for all phases of testing. 2. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2), Na+, K+, Ca +2, and Hematocrit (Hct) which the Laboratory Director failed to 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. 03/06/2018 06/29 /2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 3. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 4. The laboratory staff affirmed (02/28/2020 at approximately 11:00 a.m.) that the Laboratory Director failed to 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.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on laboratory personnel competency record review and interview with the laboratory staff on February 28, 2020,the technical consultant who is also the Laboratory Director failed to ensure that laboratory personnel were evaluated for competency pursuant to the laboratory's established competency assessment checklist. The findings included: 1. Pursuant to the laboratory's established competency assessment checklist and assessments performed on 4 out of 4 testing personnel, one of the criteria used to evaluate testing personnel competency was observation of all phases of testing to show that all written steps of the procedure are followed without deviation. 2. At the time of inspection, there were no written steps of the procedures for all phases of testing from pre-analytic, analytic, and post-analytic process to satisfy the criteria that testing personnel reviewed and followed all the procedures. 3. According to the laboratory staff interviewed on February 28, 2020, there was no GEM 3500 procedure manual accessible for the testing personnel since the laboratory only upgraded the model of the blood gas analyzer from GEMM 3000 to GEM 3500. 4. Random patient sampling covering the period from 03/06/2018 to 07/15/2019, the laboratory tested and reported 15 out of 15 blood gas patient test results (pH, pCO2, pO2), Na+, K+, Ca +2 and Hematocrit (Hct) with competency assessments of testing personnel in question. 03/06/2018 06/29/2018 07/11/2019 Accession # Accession # Accession # 4889 16722 49485 8649 5090 07/15/2019 1413 4644 Accession # 4494 49238 24437 49897 49192 30407 13116 5408 5. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry (ph, pCO2, pO2, Na+, K+, Ca +2), and 1,103 tests for the subspecialty of Hematology (Hct). 6. The laboratory staff affirmed (02/28/2020 at approximately 11:00 a.m.) that there were no available procedures for all phases of testing to satisfy the criteria that all written steps of the procedures are followed without deviation. .
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff, review of College of American Pathologists (CAP) Blood Gas Analysis proficiency testing (PT) records from 2018 to 2019, for 6 out of 6 testing events results reviewed from the 1st testing event of 2018 through the 3rd testing event of 2019, it was determined that the Laboratory Director failed to ensure that all proficiency testing reports received were reviewed to identify any problems that required corrective action for Hematology Hematocrit (Hct), 2nd PT event of 2018, Sodium (Na+), and Potassium (K+) 2nd PT event of 2018 and 2019. The findings included: 1. Hematology (Hct) a. The laboratory reported an unacceptable result for 4 out of 5 Hct PT challenges, resulting in a score of 20% during the 2nd event of 2018. b. Review of the result summary provided by CAP

	showed that the laboratory's reported results were higher than the expected mean for HCT 06 and 07, but lower than the expected mean for HCT 09 and 10 without performance review and corrective action documented for Hematology Hct. CAP Result Mean Expected Spec # Result HCT-06 42 32.2 30-35 HCT-07 25 19.8 18-21 HCT-08 43 42.1 39-45 HCT-09 20 24.8 23-27 HCT-10 32 41.3 38-44 c. The laboratory tested and reported 3 out of 3 Hct patient test results (Q2, 2018) on 06/29 /2018, the day the laboratory failed the Hct proficiency testing. Accession # 16722 5090 4644 d. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 1,103 tests for the subspecialty of Hematology (Hct). e. The laboratory staff affirmed (02/28/2020 at approximately 9:00 a.m.) there was no corrective action documentation for the unsatisfactory Hct PT result, Q2, 2018. 2. Routine Chemistry (Na+, K+) a. Review of the result summary provided by CAP for 2nd event of 2018 and 2019, specimens AQ 10 Na+ and K+ reported a result code 42 (No credit assigned due to absence of response) which the program indicated under "Actions Laboratories Should Take when a PT Result is Not Graded." CAP has a requirement under Actions Laboratories Should Take when a PT Result is Not Graded: "The laboratory is required to use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the Kit Instructions and/or the Result Form. Document Corrective Actions to prevent future failures." b. The laboratory tested and reported 10 out of 10 Na+ and K+ patient test results (Q2- 2018 and 2019) on 06/29/2018 and 07/11-15/2019, the day the laboratory received 1 out of 5 exceptional code 42 proficiency testing results without documentation of performance review and corrective action. 06/29/2018 07/11 /2019 Accession # Accession # 16722 49485 5090 07/15/2019 4644 Accession # 49238 49897 49192 30407 13116 5408 c. Based on the annual test volume reported (CMS 116 and LAB 144a Testing Declaration, signed and dated by the Laboratory Director on 02/21/2020), the laboratory performed and reported approximately 4,412 tests for the subspecialty of Routine Chemistry. d. The laboratory staff affirmed (02/28 /2020 at approximately 10:00 a.m.) there was no documentation of corrective action for Na+ and K+ proficiency testing exceptional code 42, Q2- 2018 and 2019.