Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0487467	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Nocona General Hospital	100 Park Rd, Nocona, 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
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 laboratory policy, proficiency testing records, the Centers for Medicare & Medicaid Services (CMS)-209 laboratory personnel report, and interview with facility personnel, the laboratory failed to include 2 of 11 testing personnel who routinely perform patient testing in proficiency testing for 2022 and 2023. The findings included: 1. Based on review of the laboratory policy "Paperless / Electronic Proficiency Testing", stated the following: "Testing ... 3.The specimens will be placed on the next patient run and treated as routine tests. Proficiency specimens must be tested the same number of times and in the same manner as patient specimens are routinely tested." 2. Based on a review of proficiency testing records and the CMS-209 laboratory personnel report, all proficiency testing events from the 2022 through 2 events in 2023 were performed by Testing Person 1 (TP-1), Testing Person 3 (TP-3), Testing Person 4 (TP-4), Testing Person 5 (TP-5), Testing Person 6 (TP-6), Testing Person 7 (TP-7), Testing Person 8 (TP-8), or Testing Person 10 (TP-10): 2022 Chemistry-Core - 1st Event was performed by TP-1, TP-3, TP-4, TP-7, TP-10 2022 Hematology/ Coagulation- 1st Event was performed by TP-1, TP-4 2022 Microbiology - 1st Event was performed by TP-1, TP-3, TP-4, TP-8, TP-10 2022 Chemistry-Core - 2nd Event was performed by TP-1, TP-4, TP-5 2022 Hematology/ Coagulation- 2nd Event was performed by TP-1, TP-4 2022 Microbiology - 2nd Event was performed by TP-1, TP-4 2022 Chemistry-Core - 3rd Event was performed

	by TP-1, TP-4 2022 Hematology/ Coagulation- 3rd Event was performed by TP-1 2022 Microbiology - 3rd Event was performed by TP-1, TP-4 2023 Hematology/ Coagulation - 1st Event was performed by TP-1 and TP-4 2023 Chemistry-Core - 1st Event was performed by TP-1, TP-4, TP-5, TP-6, TP-7 2023 Chemistry-Core - 2nd Event was performed by TP-1, TP-3, TP-4, TP-7 Testing Persons 9 and 11 did not participate in proficiency testing in 2022 and 2023. 3. During an interview at 12:10 pm on 07/10/2023, the Technical Consultant/TP-1 confirmed the above findings.
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 laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to review and evaluate the ungraded results obtained on proficiency testing for 2 of 3 events in 2022 (hematology event 1 and 3) and 1 of 1 events in 2023 (microbiology event 1). The findings included: 1. Review of the laboratory's PT policy "Paperless / Electronic Proficiency Testing" revealed: "Testing ... 5. Returned results will be evaluated ASAP. A score of 80% for each analyte and an overall score of 80% in each specialty must be attained. Failure to achieve an overall satisfactory score of two consecutive events or two out of three events is an unsuccessful performance. 6. Remedial action and documentation will be made for each unacceptable result." The policy failed to address ungraded proficiency testing results. 2. Review of the API 2022 Hematology 1st and 3rd Events revealed the following PT results: 2022 Event 1 EDUCATIONAL BLOOD CELL IDENTIFICATION Analyte/Method: Basophil (DIF) (%) Sample- DIF-01 Performance- Not Graded Analyte/Method: Eosinophil (DIF) (%) Sample- DIF-01 Performance- Not Graded Analyte/Method: Lymphocyte (DIF) (%) Sample- DIF-01 Performance- Not Graded Analyte/Method: Lymphocyte, reactive (DIF) (%) Sample- DIF-01 Performance- Not Graded Analyte/Method: Monocyte (DIF) (%) Sample- DIF-01 Performance- Not Graded Analyte/Method: Neutrophil, segmented (DIF) (%) Sample- DIF-01 Performance- Not Graded Analyte /Method: Platelet estimate (DIF) Sample- DIF-01 Performance- Not Graded Analyte /Method: Blood Cell ID (Educational) Samples- ECI-01, ECI-02, ECI-03, ECI-04, ECI-05 Performance- Not Graded 2022 Event 3 BLOOD CELL IDENTIFICATION Analyte/Method: Blood Cell Identification Sample- BCI-14 Performance- Not Graded EDUCATIONAL BLOOD CELL IDENTIFICATION Analyte/Method: Basophil (DIF) (%) Sample- DIF-03 Performance- Not Graded Analyte/Method: Lymphocyte (DIF) (%) Sample- DIF-03 Performance- Not Graded Analyte/Method: Monocyte (DIF) (%) Sample- DIF-03 Performance- Not Graded Analyte/Method: Neutrophil, segmented (DIF) (%) Sample- DIF-03 Performance- Not Graded Analyte/Method: Platelet estimate (DIF) Sample- DIF-03 Performance- Not Graded Analyte/Method: Blood Cell ID (Educational) Samples- ECI-11, ECI-12, ECI-13, ECI-14, ECI-15 Performance- Not Graded Further review of the event revealed the API performance review was signed by the laboratory director. No documentation of result evaluation of Samples DIF-01, ECI-01, ECI-02, ECI-03, ECI-04, ECI-05, DIF-03, ECI-11, ECI-12, ECI-13, ECI-14, and ECI-15 by the laboratory director was provided. 3. Review of the API 2023 Microbiology 1st Event revealed the following PT results: Analyte /Method: BioFire FilmArray RP2.1/Influenza A Sample- RSP-04 Performance- Not Graded Further review of the event revealed the API performance review was signed

	by the laboratory director. No documentation of result evaluation of Sample RSP-04 by the laboratory director was provided. 4. During an interview at 12:10 pm on 07/10 /2023, the Technical Consultant confirmed the above findings.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to correctly evaluate and document corrective action for unacceptable results for 3 of 3 events in 2022 (event 1, 2, 3) for the chemistry specialty, 1 of 3 events in 2022 (event 2) for the hematology specialty and 1 of 1 event in 2023 (event 1) for the chemistry specialty. The findings included: 1. Review of the laboratory's PT policy "Paperless / Electronic Proficiency Testing" revealed: "Testing ... 5. Returned results will be evaluated ASAP. A score of 80% for each analyte and an overall score of 80% in each specialty must be attained. Failure to achieve an overall satisfactory score of two consecutive events or two out of three events is an unsuccessful performance. 6. Remedial action and documentation will be made for each unacceptable result." 2. Review of API PT records for 2022 and 2023 chemistry and hematology testing revealed the following: Chemistry 2022 Event 1 Analyte: pCO2 (Blood Gas) (mmHg) Sample: BG-02 Laboratory result: 51 Expected result: 64-76 No documentation of corrective action for this unacceptable result. Analyte: pCO2 (Blood Gas) (mmHg) Sample: BG-05 Laboratory result: 58 Expected result: 59-70 No documentation of corrective action for this unacceptable result. Analyte: pH (Blood Gas) Sample: BG-02 Laboratory result: 7.17 Expected result: 7.07-7.16 No documentation of corrective action for this unacceptable result. Analyte: pO2 (Blood Gas) (mmHg) Sample: BG-02 Laboratory result: 39 Expected result: 1-24 No documentation of corrective action for this unacceptable result. Chemistry 2022 Event 2 Analyte: pCO2 (Blood Gas) (mmHg) Sample: BG-10 Laboratory result: 48 Expected result: 49-59 No documentation of corrective action for this unacceptable result. Analyte: pH (Blood Gas) Sample: BG-08 Laboratory result: 7.60 Expected result: 7.61-7.70 No documentation of corrective action for this unacceptable result. Analyte: pH (Blood Gas) Sample: BG-09 Laboratory result: 7.10 Expected result: 7.11-7.20 No documentation of corrective action for this unacceptable result. Analyte: pH (Blood Gas) Sample: BG-10 Laboratory result: 7.20 Expected result: 7.22-7.31 No documentation of corrective action for this unacceptable result. Hematology /Coagulation 2022 2nd Event Analyte: Eosinophils (Hem-5c) (%) Sample: COU-07 Laboratory result: 9.2 Expected result: 5.3-8.5 No documentation of corrective action for this unacceptable result. Chemistry 2022 Event 3 Analyte: Troponin Sample: CM-12 Laboratory result: >115 Expected result: 88.30-108.99 No documentation of corrective action for this unacceptable result. Analyte: Troponin Sample: CM-14 Laboratory result: 1.60 Expected result: 0.57-1.50 No documentation of corrective action for this unacceptable result. Chemistry 2023 Event 1 Analyte: pCO2 (Blood Gas) (mmHg) Sample: BG-04 Laboratory result: 57 Expected result: 45-56 No documentation of corrective action for this unacceptable result. Analyte: pO2 (Blood

	Gas) (mmHg) Sample: BG-03 Laboratory result: 276 Expected result: 202-262 No documentation of corrective action for this unacceptable result. Analyte: Sample: Laboratory result: Expected result: No documentation of corrective action for this unacceptable result. 3. During an interview at 12:10 pm on 07/10/2023, the Technical Consultant confirmed the above findings. Word Key: pCO2- partial pressure of carbon dioxide mmHg- millimeters of mercury pO2- partial pressure of oxygen
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 direct observation, laboratory policy, patient final reports and confirmed in interview, the laboratory failed to define 4 of 14 panic values for patient results in their policy. Findings Included: 1. During a tour of the facility on 07/11/2023 at 09:30 a.m. revealed the laboratory performed arterial blood gas analysis on the Nova Prime analyzer (Serial Number: PP13210090C) and D-Dimer analysis on the Alere Triage Analyzer (Serial Number: 10982). 2. Review of laboratory policy, "Critical Value List" (Reviewed by the Laboratory Director on 06/19/2023) revealed the laboratory failed to define panic values on arterial blood gas (pH, PCO2, PO2) and d-dimer patient results. 3. Review of patient final reports revealed the following patient panic values documented by laboratory staff that were NOT defined in laboratory policy: a. Patient Medical Record Number: 236519 Test: D-Dimer Result: 1490 HC (High Critical) Resulted: 01/17/2023 b. Patient Medical Record Number: 225907 Test: D-Dimer Result: 3000 HC (High Critical) Resulted: 02/08/2023 c. Patient Medical Record Number: 237756 Test: Arterial Blood Gas- PCO2 Result: 57.8 HC (High Critical) Resulted: 06/09/2023 d. Patient Medical Record Number: 248333 Test: Arterial Blood Gas- PCO2 Result: 57.0 HC (High Critical) Resulted: 06/19/2023 e. Patient Medical Record Number: 225366 Test: D-Dimer Result: 1340 HC (High Critical) Resulted: 06/21/2023 f. Patient Medical Record Number: 237756 Test: Arterial Blood Gas- PCO2 Result: 72.9 HC (High Critical) Resulted: 07/11/2023 4. During an interview with the Technical Consultant (TC-1) on 07/13/2023 at 09:15 a.m. in the laboratory office, the TC confirmed the laboratory failed to define 4 of 14 panic values for patient results in their policy. Word Key: pH- Potential of Hydrogen PCO2-Partial Pressure of Carbon Dioxide PO2- Partial Pressure of Oxygen

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: I. Based on direct observation, manufacturer's instructions, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure the proper storage conditions of 1 of 1 BioFire Respiratory Panel 2.1 kits were maintained according to manufacturer's instructions. The findings included: 1. During a tour of the laboratory on 07/11/2023 at 2:50 pm, the surveyor observed the following in a second laboratory room next to the main laboratory: 1 BioFire Respiratory Panel 2.1 kit; lot # 0483623, expiration date 02/24/2024 2. Review of the manufacturer's instructions labeled on the box of the kit revealed a temperature requirement of 15-25C. 3. Review of the laboratory's environmental records revealed no documentation of temperature monitoring of the second laboratory room. The laboratory was asked to provide documentation, and none was provided. 4. During an interview on 07/11/2023 at 2:50 pm, the Phlebotomist confirmed that temperature was not monitored and documented in the second laboratory room. II. Based on direct observation, review of manufacturer's instructions, environmental logs, laboratory records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer requirements for Remel reagents for 5 of 5 months in 2019 (random review February-June). The findings included: 1. During a tour of the laboratory on 07 /11/2023 at 2:50 pm, the surveyor observed a BioFire FilmArray Torch in a second laboratory room next to the main laboratory. 2. Review of FilmArray Torch Operator's Manual revealed: "CHAPTER 4: PERFORMANCE SPECIFICATIONS FilmArray Torch System Specifications ... Operations Specification 15C to 30C @ 20 to 80% relative humidity (non-condensing)" 3. Review of the laboratory's environmental records revealed no documentation of temperature or humidity monitoring of the second laboratory room. The laboratory was asked to provide documentation, and none was provided. 4. Review of laboratory records revealed the placed the BioFire FilmArray Torch into use in November 2021. Further review of records revealed the laboratory performed an annual volume of 463 tests on the BioFire FilmArray Torch. 5. During an interview on 07/11/2023 at 2:50 pm, the Phlebotomist confirmed that temperature and humidity were not monitored and documented in the second laboratory room.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on direct observation and staff interview, the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, and poured/expiration dates. The findings included: 1. During a tour of the laboratory on 07/11/2023 at 11:37 am, the surveyor observed the following in the blood bank laboratory area: 2 unlabeled coplin jars 1 coplin jar labeled "DI WATER" The laboratory failed to label the secondary containers with the identification, lot numbers, concentration, and poured/expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. 2. During the exit interview on 07/11/2023 at 1:49 pm, the Technical Consultant confirmed the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, and poured/expiration dates.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of maintenance records and confirmed in interview, the laboratory failed to perform monthly maintenance for 2 of 6 months reviewed in 2022 (December) and 2023 (January). The findings included: 1. Review of the "NGH BLOOD BANK CELL WASHER AND REFRIGERATOR MAINTENANCE" logs from November 2022 through April 2023 revealed the following months the laboratory failed to perform monthly maintenance on the cell washer: December 2022 January 2023 2. During an interview on 07/11/2023 at 10:28 am, the Technical Consultant after review of maintenance records confirmed the laboratory failed to perform monthly cell washer maintenance.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to

	identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory records, and confirmed in interview the laboratory failed to perform calibration verification for the Beckman Coulter UNICEL DXH 600 hematology analyzer every 6 months as required in 2022 and 2023. The findings included: 1. Review of the laboratory's policy " CALIBRATION UNICEL DXH 600" revealed: "Calibration is to be performed every 6 months using Coulter S-cal calibrator. Calibration is reviewed and a printout is to be retained. Alternate times calibration is to be performed At installation or relocation of instrument After replacement of any major component If controls are consistently out of limits" 2. Review of Beckman Coulter UNICEL DXH 600 hematology analyzer calibration records revealed the last calibration verification was performed 08/27/2021 There were no calibration verification records for 02/2022, 02/2022, 02/2023 (every 6 months). 3. During an interview on 07/11/2023 at 4:00 pm, the Technical Consultant stated he could not find the calibration records for 2022 and 2023, confirming the above findings.
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 direct observation, review of the laboratory's IQCP (Individualized Quality Control Plan), laboratory records, and confirmed in interview, the laboratory failed to include a risk assessment in their IQCP for 1 of 1 BioFire FilmArray Torch analyzer. The findings included: 1. During a tour of the laboratory on 07/11/2023 at 2:50 pm, the surveyor observed a BioFire FilmArray Torch in a second laboratory room next to the main laboratory. 2. Review of the laboratory's IQCP revealed no risk assessment to include, at minimum, an evaluation of the following five components: Specimen Test system Reagent Environment Testing personnel The laboratory was asked to provide a risk assessment, and none was provided. 3. Review of laboratory records revealed the placed the BioFire FilmArray Torch into use in November 2021. Further review of records revealed the laboratory performed an annual volume of 463 tests on the BioFire FilmArray Torch. 4. During an interview on 07/11/2023 at 1:49 pm, the Technical Consultant confirmed the above findings.
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 review of patient manual differential forms, patient final reports, and confirmed in staff interview the laboratory failed to ensure 3 of 5 patients' manual differential results were transcribed accurately to the final test report (July 2023). The findings included: 1. A random review of manual differential forms from July 7- July 11, 2023, revealed the following patient manual differential results documented: Patient ID: 959522 Date: 07/07/2023 Differential report form: Seg: 55 Lymph: 37 Mono: 5 Eos: 3 A review of the patient's final report revealed the manual differential report was resulted as: Segs: 55.0 Lym: 37.0 Mono: 8.0 Patient ID: 959539 Date: 07 /10/2023 Differential report form: Seg: 58 Lymph: 8 Mono: 8 Eos: 26 Aniso: 1+ A review of the patient's final report revealed the manual differential report was resulted as: Segs: 58.0 Lym: 8.0 Mono: 6.0 Eos: 26.0 Anisocytosis: 1+ Patient ID: 959648 Date: 07/11/2023 Differential report form: Seg: 49 Band: 12 Lymph: 32 Mono: 7 Aniso: 1+ A review of the patient's final report revealed the manual differential report was resulted as: Segs: 49.0 Band: 15.0 Lym: 32.0 Mono: 7.0 Anisocytosis: 1+ The above final report test results did not reflect results on the manual differential form. The laboratory failed to ensure test results were transcribed accurately when entered in the patient final report. 2. During an interview on 01/26/2023 at 1:13 pm, the Technical Consultant-2, after review of the records, confirmed the above findings. Word key: Seg/Segs: segmented neutrophil Lymph/Lym: lymphocyte Mono: monocyte Eos: eosinophil Aniso: anisocytosis
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 review of Centers for Medicare & Medicaid Services (CMS) 209 form, personnel records and confirmed in interview, the technical consultant (TC) failed to perform annual competencies for 3 of 3 testing personnel (TP-5, TP-6 and TP-7) in 2021 and 2022 who performed arterial blood gas testing. Findings Included: 1. Review of CMS 209 for submitted at time of survey (07/10/2023) revealed the following testing persons (TP) who performed arterial blood gas testing (moderate complexity): TP-5 TP-6 TP-7 2. Review of personnel records revealed the laboratory failed to have documentation of annual competency assessment for 2021 and 2022 by the technical consultant (TC) for TP-5, TP-6 and TP-7 in arterial blood gas testing. 3. During an interview on 07/11/2023 at 02:15 p.m. in the laboratory office, the TC was asked to provide documentation of annual competency assessment for TP-5, TP-6 and

	TP-7. The TC provided documentation titled "Prime Plus Training Checklist", performed by TP-5, but no competency documentation was provided. This confirmed the above findings.