| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 09D2035109 | 10/29/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gwu Medical Faculty Associates | 2150 Pennsylvania Avenue, Nw Pft Lab 3-133, Washington, DC | |

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 |
|---|---|
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records and interview with the testing person (TP), the lab director (LD) failed to attest that PT was performed in the same manner as patient testing when performing blood gas analysis. Findings: 1. Review of PT records on the day of the survey 10/29/24 at 2:00 PM showed that the LD did not review and sign the API Chemistry 3rd PT event performed on 9/10/24 nor the API Chemistry 2nd PT event performed on 6/4/24 2. Review of PT records on the day of the survey 10/29/24 at 2:00 PM showed the LD did not review and sign the API Chemistry 2nd and 3rd events performed in 2023. 3. The TP confirmed on the day of the survey 10/29/24 at 2:00 PM that the LD failed to attest that PT was performed in the same manner as patient testing when performing blood gas analysis. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3) |

| | |
|---|---|
| | Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based review of the written procedure manual and interview with the testing person (TP), the lab failed to maintain all internal quality control (QC) records. Findings: 1. The lab failed to retain the blood gas analyzer internal QC reports when QC failures occurred, since the last survey performed in 2022. 2. The blood gas analyzer performs an internal QC check every thirty minutes. 3. The blood gas analyzer failed internal QC on 7/30/24. 4. The TP stated on the day of the survey 10/29/24 at 2:00 PM that when the sensor and solution pack fail the QC check the analyzer is shut down. He will then complete the manufacturer "credit request form" to get a replacement solution pack. Once the request is completed and sent to the manufacturer all documentation is thrown away. 5. The "Retention of Documents" procedure states that the lab will retain all QC and calibration records in the QA notebook for two years. 6. The TP confirmed on the day of the survey 10/29/24 at 2:00 PM that the lab failed to retain the blood gas analyzer internal QC reports when QC failures occurred, since the last survey performed in 2022. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the written procedure manual and interview with the testing person (TP), the lab failed to document temperatures for all areas of the lab. Findings: 1. The lab did not document the room temperature when performing blood gas analysis since the last survey in the 2022. 2. Review of the manufacturer specifications for the blood gas analyzer states that the optimal temperature range for the sensor cassette and the solution pack storage is between 5-25 Degrees Celsius and the optimal operating temperature range for the analyzer is between 12-28 Degrees Celsius. 3. The TP confirmed on the day of survey 10/29/24 at 2:30 PM that the lab did not document the room temperature when performing blood gas analysis since the last survey in 2022. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based review of the written procedure manual and interview with the testing person, the laboratory failed to document the expiration dates of hematology reagents and quality control materials. Findings: 1. The laboratory failed to document the expiration dates of the arterial blood gas reagent cassettes, solution packs, and quality control materials since the last survey in the year 2022. 2. The "Installation and Cleaning procedure" states that the lab will maintain a record of all cassette, solution packs, and the record will be maintained for two years. 3. The testing person confirmed on the day of the survey 10/29/24 at 1:00 PM that the expiration dates of hematology reagents and quality control materials was not documented since the last survey in year 2022. |
| **D5419** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(e)<br><br>Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based review of the written procedure manual and interview with the testing person, the laboratory failed to document the lot numbers of hematology reagents and quality control materials. Findings: 1. The laboratory failed to document the lot numbers of the arterial blood gas reagent cassettes, solution packs, and quality control materials since the last survey in the year 2022. 2. The "Installation and Cleaning procedure" states that the lab will maintain a record of all cassette, solution packs, and the record will be maitained for two years. 3. The testing person confirmed on the day of the survey 10/29/24 at 1:00 PM that the lot numbers of hematology reagents and quality control materials was not documented since the last survey in the year 2022 |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the written procedure manual and interview with the testing person, the laboratory failed to document the cleaning and disinfections of the blood gas analyzer. Findings: 1. The laboratory did not document the cleaning and disinfections of the blood gas analyzer every 30 days since the last survey in the year 2022. 2. The "Installation and Cleaning" procedure states that the lab will keep a log of the cleaning and disinfections of the blood gas analyzer and the record will be maintained for two years. The "Retention of Documents" procedure states that maintenance records will be kept in the QA book for two years. 3. The testing person confirmed on the day of the survey 10/29/24 at 1:00 PM that the lab failed to document the cleaning and disinfections of the blood gas analyzer every 30 days since the last survey in the year 2022. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1) |

| | |
|---|---|
| | (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the written procedure, proficiency testing records, and interview with the testing person (TP), the lab failed to document corrective action procedures for all problems that occurred in the lab. Findings: 1. The lab did not document corrective action procedures when blood gas solution packs were not delivered to the lab from December 2023-March 2024 by the manufacturer. Which meant patient testing could not be performed in house. 2. The TP stated on the day of the survey 10/29/24 at 2:00 PM that problems in the lab were not documented nor corrective action procedures performed. 3. The TP confirmed on the day of survey 10/29/24 at 2:00 PM that the lab failed to document corrective action procedures for all problems that occurred in the lab. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the patient final reports and interview with the testing person (TP), the lab failed to have all required identifiers on the patient final report. Findings: 1. Review of ten patient reports between the year 2022 and the day of the survey on 10/29/24 at 2:00 PM showed the patient final reports did include the facility name where the test was performed nor the facility address. 2. The TP stated on the day of the survey 10/29/24 at 2:00 PM that he did not know that the facility name and address needed to be on the patient final report. 3. The TP confirmed on the day of the survey 10/29/24 at 2:00 PM that the lab failed to have all required identifiers on the patient final report. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing records and interview with the testing person, the lab director failed to attest that PT was performed in the same manner as patient testing when performing blood gas analysis. Findings: Refer to D2015 |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>A Based review of the written procedure manual, review of laboratory records, and interview with the testing person, the laboratory director failed to ensure that quality assessments procedures were performed and maintained to assure the overall quality of laboratory services performed. Findings: Refer to D5413, D5417, D5419, D5429, and D5781 Review of the written "Retention of Documents" procedure on the day of the survey 10/29/24 at 2:30 PM states that the LD will monitor instrument, quality controls, sensor cassettes, patient test records, and maintenance records for remedial action monthly by reviewing the QA notebook. B Based review of the written procedure manual, review of laboratory records, and interview with the testing person (TP), the laboratory director (LD) failed to ensure that quality assessments (QA) procedures were performed and maintained to assure the overall quality of laboratory services performed. Findings: 1. Review of the written procedure manual on the day of the survey 10/29/24 at 2:30 PM showed that the lab did not have a written procedure for the QA patient chart review. 2. The TP stated on the day of the survey 10/29/24 at 2:30 PM that the LD randomly reviews twelve patient charts per annual year and four patient charts per quarter year for QA. 3. The TP confirmed on the day of the survey at 2:00 PM that the LD did not have a written procedure for the QA patient chart review. |
| **D6024** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(7)<br><br>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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on review of the written procedure, proficiency testing records, and interview with the testing person , the lab director failed to ensure that testing personnel documented corrective action procedures for all problems that occurred in the lab.<br>Findings: Refer to D5781 |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based of review of the written procedure manual, competency records, and interview with the testing person (TP), the laboratory director (LD) failed to ensure that all testing persons performing blood gas analysis received annual competency procedures. Findings: 1. Based on review of the written "Competency Assessment" procedure and the "ABL FLEX CO-Ox Training Checklist" showed on the day of the survey 10/29/24 at 2:30 PM the LD did not perform annual competency procedures with the TP since the last survey in the year 2022. 2. The TP confirmed on the day of the survey 10/29/24 at 2:30 PM that the LD did not perform annual competency procedures for TP performing blood gas analysis since the last survey in the year 2022. |