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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 09D0665191 | (X3) Date Survey Completed 05/17/2022 |
| Name of Provider or Supplier Gw Medical Faculty Assc At Gwu | Street Address, City, State 2150 Pennsylvania Ave Nw Suite 2-207, 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 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to maintain all PT documents that is required when performing PT. Findings: 1. The lab performs Prostatic Specific Antigen (PSA) testing on the FastPack analyzer. 2. The lab failed to maintain all worksheets and raw data for the API 2121 Chemistry PT 1st, 2nd, 3rd events. 3. The lab failed to maintain all worksheets and raw data for the American Proficiency Institute (API) 2020 Chemistry PT 1st and 2nd events 4. The TP confirmed on the day of the survey at 2: 20 PM that the lab failed to maintain all PT documents that is required when performing PT testing.</p> |
| D3031 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including</p> |

instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of quality control procedures (QC) and interview with the nursing director, the lab failed to retain all QC performed during chemistry testing. Findings: 1. The lab performs Prostatic Specific Antigen (PSA) testing on the FastPack analyzer. 2. On January 21, 2020, testing person (TP) "A" performed the PSA QC twice. 3. The TP failed to keep the QC that did not pass and retained only the repeated QC. 4. The nursing director confirmed on the day of the survey at 3:20 PM that the TP failed to keep the QC that did not pass and retained only the repeated QC.

D5305

TEST REQUEST
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on review of the physician lab orders and interview with the director of nursing, the lab failed to ensure that patient test requisitions included the required identifiers needed for accurate and reliable Chemistry Prostatic Specific Antigen (PSA) testing. Findings: 1. Review of the physician lab order showed the order did not include the date of birth, sex, nor the age of the patient. 2. The physician lab order did not include the name of the test that was ordered nor the name and complete address where the test would be performed. 3. Review of the physician order showed the resulting agency as "Internal Lab, 123 Anywhere Street, Madison WI 53711". 4. The director of nursing confirmed on the day of the survey at 3:00 PM that the physician lab orders failed to include the required identifies needed for accurate and reliable Chemistry testing

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 the review of the written procedure manual, laboratory records, interview with the testing person (TP), and the director of nursing, the laboratory failed to perform and maintain six month calibration verification (CV) on the chemistry analyzer. Findings: 1. The lab performs Prostatic Specific Antigen (PSA) testing on the FastPack analyzer. 2. The TP stated on the day of the survey at 11:00 AM the lab performs CV procedure every six months. The TP stated that the lab receives the calibration materials in the mail when CV procedures need to be performed. 3. Review of laboratory records did not show that CV procedures were performed for the year 2121. 4. The director of nursing confirmed on the day of the survey at 3:20 PM that CV were not available.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on review of the written procedure manual and interview with the testing person (TP), the lab failed to perform comparison studies when performing chemistry testing. Findings: Repeat deficiency 1. The lab performs Prostatic Specific Antigen (PSA) testing on two different FastPack analyzers. 2. The lab written procedure for "Fastpack comparison of test results" states that the lab director will perform twice a year the comparison studies for the two analyzers. 3. The lab failed to perform the comparison studies for PSA testing. 4. The TP confirmed on the day of the survey at 2:30 PM that the lab director failed to perform the comparison studies for PSA testing.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:

Based on review of the patient's final report and interview with the director of nursing, the lab failed to ensure that the final report included the required identifiers needed for accurate interpretation of patient lab results. Findings: 1. The lab performs Prostatic Specific Antigen testing. 2. Review of the patient final report showed that the location where testing was performed was LabCorp and GW Medical Faculty Associates. The address was 2150 Pennsylvania Ave NW, Washington DC. 3. The final report did not have a date and time in the "collection date and collection time" area of the final report. 4. The final report did not include the test report date nor the run time the report was printed. 5. The final report did not include the test result, nor the unit of measurement needed for interpretation of the PSA result. 6. The director of nursing confirmed on the day of the survey at 3:00 PM that the lab failed to ensure that the patient final report included the required identifiers needed for accurate interpretation of lab results.

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 review of the written procedure manual and interview with the testing person (TP), the laboratory director (LD) failed to perform comparison studies when performing chemistry testing. Findings: Refer to D5775 1. The lab performs Prostatic Specific Antigen (PSA) testing on two different FastPack analyzers. 2. The lab written procedure for "Fastpack comparison of test results" states that the lab director will perform twice a year the comparison studies for the two analyzers. 3. The lab failed to perform the comparison studies for PSA testing. 4. The TP confirmed on the day of the survey at 2:30 PM that the lab director failed to perform the comparison studies for PSA testing

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that 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 review of proficiency testing (PT) records and interview with the testing person (TP), the lab director (LD) failed to review and sign all PT performance evaluations for Prostatic Specific Antigen testing. Findings: 1. The LD failed to review and sign the PT performance evaluations for the American Proficiency Institute (API) Chemistry 2021 1st, 2nd, and 3rd events. 2. The LD failed to review and sign the PT performance evaluations for the API Chemistry 2020 1st, 2nd, and 3rd events. 3. On the day of the survey at 2:00 PM the TP printed the performance evaluations from the API website for the LD. The LD reviewed and signed the API Chemistry 2021 1st, 2nd, and 3rd events and the API Chemistry 2020 1st, 2nd, and 3rd events.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of quality assessment (QA) procedures and interview with the testing person (TP), the laboratory director (LD) failed to perform QA procedures to ensure the acceptability of PSA laboratory testing. Findings: 1. The TP stated on the day of the survey at 3:00 PM that QA procedures are performed monthly and the lab QA procedure states that the LD will perform monthly QA checks. 2. The LD failed to perform QA procedures for the year 2021 and from January-May of the year 2022. 3. The TP confirmed on the day of the survey at 3:20 PM that the LD failed to perform monthly QA procedures.

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 training and competency records and interview with the testing person (TP), the laboratory director acting as the technical consultant (TC) failed to perform annual competency assessment procedures on testing personnel (TP) performing Prostatic Specific Antigen testing. Findings: 1. The TC failed to perform competency procedures on the TP for the year 2021. 2. The TP stated on the day of the survey at 2:00 PM that she was not aware the TC needed to perform annual competency assessments. 3. The TP confirmed on the day of the survey at 2:00 PM that annual competency procedures for the year 2021 were not performed by the TC.