

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0665191	(X3) Date Survey Completed 01/08/2020
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) did not ensure that proficiency attestation statements were signed to show that the testing person and lab director attests PSA testing was performed in the same manner as patient testing. Findings: 1. The lab is enrolled in a proficiency testing program with a provider. The provider sends the lab unknown samples to test, after testing the lab reports results to the provider to be evaluated (scored); 2. The lab director and testing person did not sign the attestation statement for PSA proficiency testing event one of 2019, event three of 2018 and event two of 2018; and 3. This was confirmed during interview with Lab Staff Member #1, in the afternoon, on the day of survey.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) did not ensure that PSA chemistry proficiency testing results were reviewed by the lab director and staff. Findings: 1. The lab is enrolled in a proficiency testing program with a provider. The</p>

provider sends the lab unknown samples to test, after testing the lab reports results to the provider to be evaluated (scored); 2. The lab director did not review, sign and date the scored results obtained from the proficiency test provider for the second event of 2018; 3. The lab did not maintain the proficiency test providers evaluation (showing each test result and the proficiency test providers score for each reported test result) for the first event of 2019; and 4. This was confirmed with Lab Staff Member #1 during interview in the afternoon on the day of survey.

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:
A. Based on record review and interview, the laboratory (lab) written procedure for patient specimen collection for PSA (chemistry) testing, did not state that the lab collects patient blood in heparin green top vacutainer tubes. Findings: 1. The laboratory written procedure for collection of patient blood for PSA testing did not state that patient specimens for PSA testing are collected in heparin green top vacutainer tubes; and 2. This finding was confirmed during interview with Lab Staff Member #1, in the afternoon, on the day of survey. B. Based on record review, the laboratory written procedure did not define weekly quality control testing for PSA testing, to ensure that whenever patient testing was performed, the external (liquid) quality control testing was performed within the previous seven days. Findings: 1. The written procedure states that quality control testing is performed weekly, but did not define weekly. During interview with staff on the day of survey, it was determined that weekly testing means quality control testing is performed at any time during the week, even if quality control checks exceed 7 days from the previous quality control check; and 2. The written procedure did not provide instructions to suspend weekly quality control testing only if no patient testing was performed after seven days (from the last acceptable control results) and then test controls on the same day patient testing is resumed; C. Based on record review and interview, the laboratory did not have corrective action procedures to ensure problems are identified, documented, corrected and a written action plan is put in place to monitor corrections to ensure the problem was resolved. Findings: 1. The lab did not have written procedures to document and correct problems identified in the lab; 2. The lab did not have a written

	<p>corrective action plan when the refrigerator temperatures failed to meet the labs criteria for acceptability. See D5785 for additional findings; 3. The laboratory did not have written procedure to check the previous week of patient (PSA) test results for accuracy when a quality control failure is identified, since the quality control may have failed at any time after the last acceptable control result; and 4. This was confirmed during interview with lab staff member #1 in the afternoon on the day of survey.</p>
<p>D5775</p>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) did not perform biannual comparison studies between the two chemistry analyzers, used to perform PSA (chemistry) testing, as stated in the labs written procedure. Findings: 1. The laboratory written procedure states that the lab performs biannual comparison studies between the two chemistry analyzers used to test patient blood samples for PSA; 2. In 2018 and 2019, the lab records showed that only one comparison study was performed each year (not two); and 3. This was confirmed during interview with Lab Staff Member #1 in the afternoon on the day of survey.</p>
<p>D5779</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) did not take and document corrective action when proficiency test results were unacceptable. Findings: 1. The lab was enrolled in a proficiency test (PT) program for PSA (chemistry) testing. A provider sends unknown samples to the lab three times during the year (each shipment is a PT event). The lab tests the samples and reports the results to the provider to evaluate the results for accuracy. The provider reports the evaluation (score) to the lab; 2. In 2018, the lab obtained unsuccessfully for the second event. During interview with Lab Staff Member #1 on the day of survey, it was reported that the provider did not evaluate the results because they were not submitted to the provider in time for evaluation; and 3. The lab did not have a corrective action plan describing the problem and how it will ensure that proficiency test results will be reported to the provider in a timely manner.</p>
<p>D5785</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p>

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory (lab) did not take corrective actions when the temperature of the refrigerator used to store PSA (chemistry) test reagents failed to meet the laboratory's criteria for acceptability. Findings: 1. The acceptable temperature range for the refrigerator was 35 to 46 F; 2. On March 26, 25, 23, 22, 21 and 20, 2019 the temperature was reported as 34 F and no corrective action plan was taken and documented; 3. On March 29, 28 and 27, 2019 the temperature was reported as 32 F (freezing) and no corrective action plan was taken and documented, including a visual reagent check and remedial quality control testing to ensure the freezing temperature did not damage the activity of test reagents; and 4. This was confirmed during interview with Lab Staff Member #1 in the afternoon on the day of survey.