

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0679887	(X3) Date Survey Completed 04/30/2019
Name of Provider or Supplier Svmg Urology Worcester	Street Address, City, State 85 Prescott Street Suite 403, Worcester, MA	
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	A CLIA recertification survey was conducted for the Wayne B. Glazier, MD, PC Urology laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review and confirmed through an interview on 4 /30/19 at 10:24 AM with the technical supervisor, the laboratory failed to ensure that five (5) out of six (6) testing personnel routinely tested proficiency testing samples as evidenced by the following: 1. A review of proficiency testing record attestation statements for calendar years 2017 and 2018 (six testing events) revealed that only one (testing person number 3) of the personnel performing moderate complexity testing was also performing proficiency testing samples based on the documented signature on the attestation forms. 2. The technical supervisor interviewed confirmed that only one out of the six testing personnel was routinely performing proficiency testing samples. .</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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)</p>

-- (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 record review and interview, the laboratory failed to perform calibration verifications every six months or, as appropriate, as evidenced by the following: a) A review of quality control records for calendar years 2017 and 2018 was performed. The review revealed that calibration verifications of at least 3 points were not performed once every six months for one (1) of one (1) chemistry analytes requiring calibration verification on the Qualigen chemistry analyzer. Six month calibration verifications for Prostate Specific Antigen (PSA) were not available for calendar years 2017 and 2018. b) The Technical Consultant interviewed on 4/30/19 10:10 AM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months for PSA. c) The laboratory performs approximately 264 PSA tests annually.