

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0067049	(X3) Date Survey Completed 11/04/2025
Name of Provider or Supplier Urology Group Of Western New England Pc	Street Address, City, State 61 Locust St, 1st Floor, Northampton, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview the laboratory failed to have a procedure manual available to laboratory personnel. Findings include: 1. Surveyor observation of the laboratory on 10/29/2025 at 10:30 AM revealed the laboratory did not have a procedure manual in the laboratory available for use by laboratory personnel. Surveyor was unable to review the procedure manual for content as it was not there. 2. Staff interview with the Practice Manager and Medical Assistant (MA) on 10/29/2025 at 10:30 AM confirmed the above findings. The MA stated, "I think the Laboratory Director has it and is reviewing it, but I am not sure."</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure testing personnel (TP) received documented training prior to reporting results on</p>

patient samples in the specialty of Hematology. Findings include: 1. Record review on 10/28/2025 of the laboratory's TP records revealed 3 of 5 new TP did not have documented training records. Specifically TP1, TP2 and TP3. 2. Staff interview with the Medical Assistant and the Practice Manager (PM) on 10/28/2025 confirmed the above TP did not have documented training records and are reporting out patient test results. The PM stated, "They are transfers from our other lab and received their training at the other location." 3. The laboratory performs 45 Hematology tests annually.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the Technical Consultant failed to ensure new testing personnel (TP) received competency assessment twice during the first year of testing patient specimens in the specialty of Hematology. Findings include: 1. Record review on 10/28/2025 of the laboratory's TP records revealed: a. 2 of 5 new TP received competency assessment only once during the first year of testing patient samples. Specifically TP1 and TP2. b. 1 of 5 new TP did not receive any competency assessment during the first year of testing patient samples. Specifically TP3. 2. Staff interview with the Medical Assistant and the Practice Manager (PM) on 10/28/2025 confirmed the above TP did not have the required documented competency assessment during the first year of testing patient samples. The PM stated, "The old TC was on medical leave and did not return. He used to take care of all of this." 3. The laboratory performs 45 Hematology tests annually.