

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0235608	(X3) Date Survey Completed 10/05/2021
Name of Provider or Supplier Doctors Urgent Care Dr Vic Wood Inc	Street Address, City, State 24 Homestead Avenue, Wheeling, WV	
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	An announced, on site, recertification survey was conducted at Doctors Urgent Care Dr Vic Wood Inc on October 5, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to return the proficiency testing (PT) results for one of two 2021 American Proficiency Institute (API) testing events within the required timeframe. Findings: 1. Review of API PT records for 2021 revealed the following score: 2021 2nd Hematology event - 0% failure to participate 2. An interview with the laboratory manager, 10/5/21 at approximately 11:00 AM, confirmed the laboratory failed to return the results for API 2021 2nd Hematology testing event and the laboratory received a 0% failure to participate score.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

	<p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to assess the annual competency of two of two testing personnel (TP) for the year 2020. Findings: 1. Review of TP records revealed no annual competency for TP1 and TP2 for 2020. 2. Interview with the laboratory manager, 10/5/21 at approximately 12:30 PM, confirmed the findings.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to document the (2) room temperature and (3)humidity of the room containing the Medonics analyzer for 9 of 9 months in 2021. Findings: 1. Review of temperature logs revealed a lack of room temperature and humidity monitored and documented for the Medonics analyzer January 2021 thru September 2021. 2. An interview with the laboratory manager, 10/5/21 at approximately 11:55 AM, confirmed the findings.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to document the Medonics analyzer maintenance for 9 of 9 months in 2021. Findings: 1. Review of policies and procedures(P&P) identified a "Medonic M-Series Cleaning Procedure" that included a daily, monthly, six month, and as needed maintenance schedule for the analyzer. 2. No documentation of the daily, monthly, six month, or as needed maintenance could be located for January 2021 thru September 2021. 3. An interview with the laboratory manager, 10/5/21 at approximately 11:45 AM, confirmed the findings.</p>
<p>D6064</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <p>Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the West Virginia license verification source and interview, the laboratory had 1 of 2 testing personnel (TP2) performing laboratory testing that did not possess a current WV laboratory license as required by the state rule WV 64 CFR 57 Clinical Laboratory Technician and Scientist Licensure and Certification rule. Findings: 1. Review of WV license verification source identified the following for TP2: WV license 04856 expiration of 2-1-2021 2. An interview with TP2, on 10/5/21 at approximately 10:30 AM, confirmed that TP2 had an expired WV lab license and had been continuing to test patients from February 2021 thru date of survey.