Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2100196	07/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mon Health Wedgewood Primary Care	1300 Fort Pierpont Dr Suite 101, Morgantown, 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 Mon Health Wedgewood Primary Care & Psychiatry on July 27, 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.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to assess the annual competency of 2 of 8 testing personnel (TP) in 2020 and the six month competency of 1 of 8 TP in 2020. Findings: 1. Review of TP personnel files revealed no annual competency for TP2 and TP3 for 2020. 2. Review of TP personnel files revealed no six month competency for TP4 for December 2020. TP4 hired date 6/29/2020. 3. An interview with the laboratory supervisor, on 7/27/21 at approximately 9:30 AM, confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on review of quality control (QC) documents, patient test results, and interview the laboratory failed to ensure that quality control materials for the ACT2Diff Hematology analyzer were not being used after expiration date. Findings: 1. Review of QC daily printouts from the ACT2Diff hematology analyzer (October 2020 thru February 2021) identified QC lot 068100, 078100, 088100 Lot Expiration 10/27/2020 programmed into the analyzer as QC for 10/28/2020 and 10/30/2020. 2. Review of patient test results revealed 3 patients had CBCs reported 10/28/2020 and no patient CBCs ran 10/30/2020. 3. An interview with the laboratory manager, 7/27/21 at approximately 10:30 AM, confirmed the findings.