

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2108787	(X3) Date Survey Completed 09/27/2022
Name of Provider or Supplier Manchin Clinic Of Bridgeport	Street Address, City, State 409 West Main Street, Bridgeport, 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, routine recertification survey was conducted at Manchin Clinic of Bridgeport on September 27, 2022, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to ensure that quality control (QC) materials used for hematology testing were not utilized beyond the expiration date for 22 of 47 days of patient testing. Findings: 1. QC record review (July 2022 thru date of survey) identified 47 days of patient testing. 2. QC record review revealed 22 of the 47 days had lots of expired QC materials documented on the analyzer printouts (8/15, 8/16, 8/17, 8/18, 8/19, 8/22, 8/23, 8/24, 8/25, 8/26, 8/29, 8/30, 8/31, 9/1, 9/2, 9/7, 9/8, 9/9, 9/12, 9/13, 9/14, 9/15). 3. An interview with the technical consultant, 9/27/22 at approximately 11:00 AM, confirmed the findings.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview the laboratory failed to establish a system to monitor and assess the quality control (QC) system to ensure materials are not utilized beyond the expiration date for 22 of 47 days of patient testing. Findings: 1. QC record review (July 2022 thru date of survey) identified 47 days of patient testing. 2. QC record review revealed 22 of the 47 days had lots of expired QC materials documented on the analyzer printouts (8/15, 8/16, 8/17, 8/18, 8/19, 8/22, 8/23, 8/24, 8/25, 8/26, 8/29, 8/30, 8/31, 9/1, 9/2, 9/7, 9/8, 9/9, 9/12, 9/13, 9/14, 9/15). 3. No documentation of corrective action could be located. 4. An interview with the technical consultant, 9/27/22 at approximately 11:00 AM, confirmed the findings.

D6064

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:
Based upon review of personnel files, primary source verification, and interview the laboratory testing personnel that perform moderate complexity testing on the ACT2 Diff hematology analyzer failed to possess a current West Virginia laboratory license as required by the West Virginia 64 CSR 57 Clinical Laboratory Practitioner Licensure and Certification. Findings: 1. A review of testing personnel records and the WV licensure verification portal identified that one of one laboratory testing personnel (TP1) had no valid laboratory license at the time of survey. 2. Review of testing records revealed that TP1 had been testing patient specimens from 7/18/22 thru date of survey. 3. An interview with TP1 and the technical consultant, 9/27/22 at approximately 9:15 AM, confirmed the findings.