Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2108787	07/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Manchin Clinic Of Bridgeport	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
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review of the Hematology Reportable Range Policy and patient test report and interview with technical consultant, the laboratory did not properly follow the post analytic assessment plan regarding the patient test reports. Finding include: 1. A Reportable Range Policy for the ACT Diff 2 was found within the laboratory quality assessment manual. The policy stated the following: " the acceptable ranges have been established and/or validated by the facility. The results that are greater than the high end of the validated reportable range will be reported as greater than the high end of the reportable range". The validated reportable range for WBC's was determined to be 1.4 to 8.1. This policy was signed as approved by the director on 2/1 /17 and reviewed by the director on 2/1/18. 2. A random selection of Hematology Patient Test Reports were chosen for review from 12/13/17 to 7/27/18. They are as follows: A. Patient test report #1 WBC reported as 11.2 on 12/13/17 B. Patient test report # 2 WBC reported as 12.9 on 12/28/17 C. Patient test report # 3 WBC reported as 10.4 on 12/29/17 D Patient test report #4 WBC reported as 17.7 on 7/27/18 3. During the exit interview with technical consultant at approximately 3:30PM, the technical consultant stated the 8.1 value found in the policy was an error and would need corrected.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the record review of the Quality Assessment Plan and interview with the testing personnel and technical consultant, the laboratory director did not consistently assure the quality of the laboratory services. Findings include: 1. The laboratory had established a Quality Assessment Plan which covered all aspects of the laboratory quality systems. Part of the plan were QA Reviews performed on a monthly schedule. Each QA Review had a signature line for director review. The forms were completed with data supporting the monthly review. However, the laboratory director proof of review signature line was blank from April 2018 through July 2018. 2. The testing person stated at 11:00 AM and the technical consultant agreed that the director was behind on his monthly review. There was a folder with sticky notes as reminders for him to review.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratories personnel records, quality assessment plan records and interview with testing personnel and technical consultant, the laboratory failed to ensure that testing personnel possessed a valid West Virginia Clinical Laboratory Practitioner Personnel license required by the state of West Virginia to be requested at the time the employee begins testing moderate complexity CLIA certified clinical testing. Findings Include: 1. The laboratory director did not ensure proper licensing of the only testing person conducting independent testing at the laboratory from Oct 2017 until July 2018. The WV Clinical Laboratory Personnel license initial application seeking a Point of Care Technicians license was dated April 11, 2018 with the Director signature date of July 17, 2018. The testing person was not issued the license until July 24, 2018. 2. The primary testing person performed patient testing from October 2017 until July 17, 2018 without a WV Clinical Laboratory Personnel License. 3. The technical consultant stated during an 11:45 AM interview that the primary testing person had been reminded to complete the application and supporting documentation should be found in the notes of the Monthly QA plan. However, review of the Oct through July QA plan items list pertaining to personnel showed no documentation to support the licensing reminder. The director did not sign off on the CLP application for the testing person until July, 2018. 4. The testing person stated at 10:30AM that she did not know that clincal laboratory personnel licensure was required to test specimens. 4. The WV Clinical Laboratory Practitioner Personnel Licensure Rule 64CSR 57 has a penalty section pertaining to expired licenses with a sliding fee scale. A copy of the fees needed to be submitted to the state for compliance with both CLIA and state CLP licensure are attached to this statement of deficiencies.