Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1082418	03/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Manchin Clinic South Llc	181 Middletown Loop, Whitehall, 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	A routine recertification survey was performed at Manchin Clinic South LLC on March 22, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) under 42 CFR 493. Specific deficiencies cited are explained below.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory director (LD) and testing personnel (TP) failed to sign the attestation statement for 2 of 3 hematology proficiency testing (PT) events in 2023. Findings: 1. Review of 2023 American Proficiency Institute (API) PT records revealed no attestation statement signed by the LD and TP for the 1st and 3rd hematology testing event in 2023. 2. An exit interview with the LD, technical consultant, and TP, 3/22/24 at 3:30 PM, confirmed the findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed

	by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory filed to maintain a copy of proficiency testing (PT) records for 2 of 3 testing events in 2023. Findings: 1. Review of American Proficiency Institute (API) PT records revealed no records for the processing and examination of PT samples for the 1st and 3rd hematology testing events of 2023. 2. An exit interview with the laboratory director, technical consultant, and testing personnel, 3/22/24 at 3:30 PM, confirmed the findings.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to document and retain the corrective action taken for unacceptable analyte scores in hematology for the 1st and 2nd American Proficiency Institute (API) proficiency testing events of 2023. Findings: 1. Review of the 1st 2023 API PT event records identified an unacceptable analyte score of 0% for WBC DIFF (#0765). No documentation of the corrective action taken could be located. 2. Review of the 2nd 2023 API PT event identified an unacceptable analyte score of 20% for MCV. No documentation of the corrective action taken could be located. 3. An exit interview with the laboratory director, technical consultant, and testing personnel, 3/22/24 at 3: 30 PM, confirmed the findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to retain analyzer printouts for quality control and patient results in Hematology for two of two months in 2023. Findings: 1. The technical consultant (TC) stated during an interview, 3/22/24 at 9:00 AM, that the quality control records and patient analyzer printouts for March 2023 and April 2023 (two months requested by the surveyor to

	review) could not be located. 3. An exit interview with the laboratory director, technical consultant, and testing personnel, 3/23/24 at 3:30 PM, confirmed the failure of the laboratory to retain analytic systems records for the required 2 years.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records, lack of documentation, and staff interviews, the laboratory failed to perform and document calibration procedures (refer to D5437); failed to perform and document calibration verification procedure (refer to D5439); failed to document corrective action taken when patient results fall outside established operating parameters (refer to D5781); and failed to document the corrective actions taken for problems identified in the quality assessment of the analytic systems (refer to D5791). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to document and perform calibration of the AcT diff 2 analyzer at the frequency specified by the laboratory in 2022 and 2023. Findings: 1. Review of P&P identified the frequency of calibration for the AcT diff 2 analyzer as every six months, as a step in resolving QC issues, and after major maintenance. 2. Review of calibration records revealed calibrations performed on 12/27/2021 and 3/15/2024. No documentation of calibrations performed between these two dates could be located. 3. Review of 2021 calibration records revealed a documented calibration on 12/27/2021. No documentation of a calibration could be located from 12/27/2021 thru 3/15/2024. 4. An interview with the technical consultant, 3/23/24 at 9:15 AM, confirmed the lack of required calibration for the AcT

	diff 2 in 2022 and 2023. 5. An exit interview with the laboratory director, technical consultant, and testing personnel, 3/23/24 at 3:30 PM, confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to meet the calibration verification requirements for the AcT diff 2 hematology analyzer in 2022 and 2023. Findings: 1. Review of calibration records (2022 thru date of survey) revealed no calibrations documented as performed on the AcT diff 2 analyzer for 2022 and 2023. Refer to D5437. 2. An exit interview with the laboratory director, technical consultant, and testing personnel, 3/23/24 at 3:30 PM, confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to document corrective actions taken when (b)(1)(i)

	daily function checks failed on 3 of 18 days of patient testing; (b)(1)(ii) reference ranges were not programmed in the analyzer prior to 2/26/2024; and (b)(1)(ii) 113 of 132 patient results reviewed were released with flags on the AcT diff 2 analyzer. Findings: 1. Review of 18 daily function (background) checks for the AcT diff 2 analyzer revealed days the daily function checks were repeated multiple times due to failure of one or more of the parameters. No documentation identifying the reason for failure or the corrective actions taken could be located. 2. Review of patient results (2 /16/24 thru 2/25/24) revealed a lack of reference ranges (RR) on the AcT diff 2 printout. Testing personnel (TP) stated during an interview, 3/22/2024 at 10:00 AM, that the reference ranges were put into the analyzer by service on 2/26/24. Due to the lack of RR, two critical patient results were not flagged on the analyzer printout. One of the two critical results (from 2/16/24) was not identified and reported to the provider until 2/19/24. No documentation of corrective actions taken could be located. 3. Review of P&P identified the process to handle 1,2,3 or M histogram error flags on the Act diff 2, as follows: rerun the patient specimen and if flags are still present, notify the physician for decision of further testing. Review of 232 patient CBC results between January and March 2024 identified 113 records with 1,2,3 or M histogram error flags. No documentation of corrective actions taken could be located. This finding is a Repeat Deficiency from the previous survey. 4. An exit interview with the laboratory director, technical consultant, and testing personnel, 3/23/24 at 3:30 PM, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to have an analytic systems quality assessment (QA) system that identified, monitored, and corrected problems identified in Hematology testing. Findings: 1. Review of P&P identified "Quality Assessment Plan" stating "a summary and analysis of the findings, acceptable threshold for the findings, corrective action to be taken, responsible party, required date of completion and a follow-up review" would be performed and documented on the QA Monthly Checklist. 2. Review of Monthly QA checklists for July, October, and December 2023 revealed the following under "suggestion for correction." No documentation of corrective actions taken could be located. a. No quality control seen for AcT diff 2 (July) b. AcT diff 2 calibration completed 12/2021, due 6/2022 (July) c. No QC for Clinitek, Mono, H Pylori, hCG, A1C, Strep, Stratus Covid/FLU (waived testing July, October, December) d. QC lot numbers not updated in LIS (December) 3. An exit interview with the laboratory director, technical consultant, and testing personnel, 3/22/24 at 3: 30 PM, confirmed the failure of the analytic systems QA to identify problems and the lack of corrective action to address the problems identified.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.

	1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory director (LD) failed to maintain a copy of all proficiency testing records (refer to D2009 and D2015), ensure unsatisfactory proficiency testing (PT) results have corrective actions taken if needed (refer to D2128), retain all analytic systems records (refer to D3031), and assure analytic quality assessment program identified and corrected failures in quality (refer to D5791) to maintain acceptable levels of analytic performance for patient testing and assure the quality of laboratory services provided
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 record review, lack of documentation, and interview the laboratory director failed to ensure the analytic systems quality assessment (QA) system was maintained and that problems identified by the QA were monitored and corrected (Refer to D5791).
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory director failed to ensure that laboratory results were reported only when the analytic systems were functioning within the established parameters. Refer to D5781.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on record review, quality assurance records, and lack of documentation the technical consultant (TC) of the laboratory failed to provide technical oversight to ensure the established quality control program for the laboratory was maintained (refer to D6036), problems in the analytic test systems were identified and corrective action was taken whenever test systems deviated from established performance specifications (refer to D6042), and that patient test results were not reported until corrective action was completed (refer to D6044).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the technical consultant failed to provide adequate technical oversight of the analytic test systems. Refer to D5437, D5439, D5781, and D5791.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the technical consultant failed to ensure the quality control program established for the analytic systems was performed and maitained to ensure accurate, reliable test results. Refer to D5437, D5439, and D5791.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the technical consultant failed to ensure that patient results were not reported without the required corrective action taken in Hematology. Refer to D5781.