Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2157832	08/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Monmouth Medical Center Vantage Point	100 Route 36 East, Suite 1m, West Long Branch, NJ	

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
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 the surveyor review of the Proficiency Testing (PT) records and interview with the Director of Laboratory Operations (DLO), the laboratory failed to maintain the attestation statements provided by College of American Pathologists (CAP) for Hematology and ReticulocyteTesting with the LD and analyst's signature. The findings include: 1. The attestation statements were not signed by the LD and analyst for Hematology events FH9-C-2021, FH2-B-2022, FH9-B-2023 and FH9-A-2023. 2. The attestation statements were not signed by the LD and analyst for Reticulocyte event. FT4-A-2023. 3. The DLO confirmed on 8/2/23 at 11:00 am the attestation statements for the above events were not signed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Director of Laboratory Operations (DLO) ,the laboratory failed to have a procedure for performing correlation studies for Hematology tests performed on the Sysmex XN 10 analyzers From February 2023 to the date of survey. The DOL confirmed on 8/2 /23 at 11:00 am that the laboratory did not have a procedure for performing correlation studies.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: A. Based on surveyor review of the Insight Quality Control Report (IQCR) for the Sysmex XN10 analyzers and interview with Director of Laboratory Operations (DLO) the laboratory failed to document corrective action for Precision from 10/12/22 to 11 /21/22 . The findings include: 1. The IQCR states "if your Coefficient of Variation (CV) is 1.5 times greater than the group CV, your result is presented in bold and an investigation is warranted." 2. Basophil % Level 1 had a value of 5.3 in bold on the IQCR report for lot # 2283 Period 1 for Sysmex XN10 Serial #81457. 3. There was no evidence for corrective action for the above mentioned CV. 4. The DLO confirmed on 8/223 at 11:00 am the laboratory failed to document all corrective action. B. Based on surveyor review of the Insight Quality Control Report (IQCR) for the Sysmex XN10 analyzers and interview with Director of Laboratory Operations (DLO) the laboratory failed to document corrective action for Accuracy Code Bias from 8/2/22 to 1/16/23. The findings include: 1. The IQCR had accuracy bias code for Fluorescent Platelet Count (PLT- F) from 8/2/22 to 1/16/23. 2. There was no documented corrective action for the above mentioned code. 3. The DLO confirmed on 8/223 at 11:00 am the laboratory failed to document all corrective action.