Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233778	06/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pocahontas Memorial Hospital	150 Duncan Road, Buckeye, 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 conducted at Pocahontas Memorial Hospital on June 23 & 24, 2026, by the West Virginia Office of Laboratory Services. The laboratory was surveyed under 42 CFR 493, Requirements for Laboratories and noncompliance was found. Specific deficiencies cited are explained below.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of validation records for the Sysmex XN-450 analyzer, lack of documented evaluation, and interview with the general supervisor (GS), the laboratory failed to verify the appropriateness of the manufacturer reference intervals (RIs) for the laboratory population before using the new analyzer for patient testing from March 11, 2025, thru date of survey. Findings: 1. Review of the 2025 Sysmex XN-450 analyzer validation records revealed no evaluation of specimens from the laboratory population to verify the appropriateness of the manufacturer reference intervals (normal values) for the 22 analytes tested in a complete blood count with automated differential (CBC/Diff). The analyzer was approved for patient testing by the laboratory director on March 11, 2025. 2. The GS stated, 6/24/26 at 9:15 AM, that the RIs reported on a CBC/Diff final report were based on the old Sysmex XS-1000i

	analyzer procedure and had not been updated when the new Sysmex XN-450 was put into use in March 2025. The GS could not locate the evaluation of the appropriateness of the manufacturer RIs for the Sysmex XN-450.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the "Statistics by Procedure" report, Medhost laboratory information system (LIS) patient reports, lack of required information, and interview with the general supervisor (GS), the laboratory failed to provide the (c)(2) name and address of the location where parathyroid hormone (PTH) testing was performed for 5 of 7 patients in June of 2026. Findings: 1. During an interview on 6/24/26 at 8:30 AM, the GS stated the laboratory sent all PTH testing out to a Laboratory Corporation of America reference laboratory. 2. Review of the "Statistics by Procedure" report for June 1, 2026 thru date of survey identified 7 patient results for PTH testing sent out to the reference laboratory in the timeframe reviewed. 3. Review of the 7 Medhost LIS patient reports revealed 5 reports had no name and address of the reference laboratory where the PTH testing was performed: 6/3/26 patient 1 6/16/26 patient 2 6/18/26 patient 3 6/22/26 patient 4 and patient 5 4. An interview with the GS, 6/24/26 at 9:40 AM, confirmed the lack of required name and location for the reference laboratory on 5 of 7 PTH results reports released in June.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of Medhost laboratory information system (LIS) patient reports, verification records for the Sysmex XN-450 hematology analyzer, and interview with the general supervisor (GS), the laboratory failed to provide reference intervals (RIs) for 2 of the 22 parameters tested in a complete blood count with automated differential (CBC/Diff) from March 11, 2025, thru date of survey. Findings: 1. Review of two CBC/Diff Medhost LIS reports from 6/22/26 (#9169 and #9231) revealed no stated RI for Immature Granulocyte % (IG%) and Immature Granulocyte # (IG#). 2. Review of the validation records for the Sysmex XN-450 identified the laboratory director approved the hematology analyzer for patient testing on 3/11/2025. No evaluation of the appropriateness of manufacturer reference intervals could be located. Refer to D5421. 3. During an interview on 6/24/26 at 9:00 AM, the GS

	confirmed the lack of reference intervals for IG% and IG# on the patient CBC/Diff reports.