Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0683776	04/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Broaddus Hospital	# 1 Health Care Drive, Philippi, 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 Broaddus Hospital on April 1 and April 2, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of laboratory personnel records, lack of documentation, interview with the technical supervisor (TS), and interview with the laboratory director (LD), the laboratory failed to document the competency of 9 of 9 testing personnel (TP) for the performance of a white blood cell count with manual differential in 2023 and 2024. Findings: 1. Review of 2023 and 2024 hematology TP competency assessment records revealed no documented competency for the performance of a white blood cell count with manual differential for 9 of 9 TP in hematology. 2. During an interview with the TS, 4/1/25 at 9:00 AM, the TS agreed that no documented competency assessment for the performance of a white blood cell count with manual differential could be located for the TP. 3. An exit interview with the LD, 4/2/25 at 4: 00 PM, confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, an interview with the technical supervisor (TS), and an interview with the laboratory director (LD), the laboratory failed to document the evaluation of ungraded results received from API in 3 of 3 Hematology events and 3 of 3 Microbiology events of 2024. Findings: 1. Review of API 2024 PT records for the three Hematology events revealed no evaluation of the educational RBC Morphology (DIF-01, DIF-02, DIF-03) results in the three events. 2. Review of API 2024 PT records for Microbiology revealed no evaluation of the ungraded results for Educational Susceptibility (Events 1,2, and 3), Blood Culture Susceptibility Interpretation (Event 2), and Gram Stain results (Events 1,2, and 3). 3. During an interview with the TS, 4/1/25 at 10:00 AM, the TS agreed that no documented evaluation could be located for the ungraded results received from API. 4. An exit interview with the LD, 4/2/25 at 4:00 PM, confirmed the findings.
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 quality control (QC) and calibration records, laboratory analyzer records, final patient reports, reagent verification documents, direct observation in the laboratory, and staff interviews, the laboratory failed to ensure quality control materials were not used after the expiration date in Chemistry (refer to D5417); failed to document verification of PT and APTT reference intervals (refer to D5421); failed to perform and document the calibration of pipettes used to prepare reagents and perform patient testing in Chemistry and Immunohematology (refer to D5433); and failed to ensure patient results were not released until quality control was acceptable (refer to D5481).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) 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. This STANDARD is not met as evidenced by: Based on direct observation, review of Abbott Alinity ci chemistry analyzer records, interview with the technical supervisor (TS), and interview with the laboratory director (LD), the laboratory failed to ensure that external quality control (QC) and calibration materials were not used beyond the expiration date established by the manufacturer for 11 of 15 vials in use. Findings: 1. During a tour of the Chemistry

	laboratory, 4/2/25 at 8:00 AM, the state surveyor examined the chemistry QC and calibration materials currently in use from the refrigerator and identified 15 opened vials that had the date opened on the container. None of the vials had a labeled expiration date. The TS stated there was a reference chart attached to the chemistry Alinity ci analyzer that states how many days opened QC and calibration materials have before they are expired. Comparison between the opened QC and calibration materials and the reference chart identified that 11 of 15 vials of QC materials were expired. 1. Bilirubin Calibrator (65189FD01A) opened 2/22/25, stable for 7 days 2. Bilirubin Calibrator (65189FD01B) opened 2/22/25, stable for 7 days 3. CO2 Calibrator (72065FD01A) opened 3/1/25, stable for 30 days 4. CO2 Calibrator (72065FD01B) opened 3/1/25, stable for 30 days 5. Immunoassay Plus QC (10501T) opened 3/16/25, stable for 10 days 6. Immunoassay QC (64990T) opened 3/21/25, stable for 10 days 7. Immunoassay QC (64991T) opened 3/21/25, stable for 10 days 8. Immunology QC (85753T) opened 3/16/25, stable for 10 days 9. Immunology QC (85751T) opened 3/16/25, stable for 10 days 10. Multiqual QC (45971T) opened 3/20 /25, stable for 2 days 11. Multiqual QC (45973T) opened 3/20/25, stable for 2 days 2. Review of daily QC and calibration records on the Abbott Alinity ci chemistry analyzer revealed daily QC and routine calibrations were performed using expired materials and accepted for patient testing purposes in March and April 2025. Refer to D5481. 3. During an interview with the TS, 4/2/25 at 8:45 AM, the TS confirmed that expired QC and calibration materials had been used and stated that patient chemistry results had been released. 4. An exit interview with the LD, 4/2/25 at 4:00 PM, confirmed the findings.
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 a review of the Sysmex CA-660 coagulation analyzer quality control (QC) records, reagent verification records, lack of documentation, and interview with the technical supervisor (TS), and an interview with the laboratory director (LD), the laboratory failed to document the (b)(1)(ii)verification of the reference interval/range for one of one new lot of Innovin PT and one of one new lot of Actin APTT reagents in 2025. Findings: 1. Review of coagulation QC records (March 2025) for coagulation testing identified Innovin lot 564667A (expiry 8/1/27) for PT testing and Actin lot 575016A (expiry 10/14/26) for APTT testing currently in use on the Sysmex CA-660 analyzer 2. Review of the performance specification verification records (January 2025) for the current Innovin (lot 564667A) and Actin (lot 575016A) reagents revealed no verification documentation for the appropriateness of the reference intervals for the laboratory's patient population. 3. During an interview with the technical supervisor (TS), 4/2/25 at 9:00 AM, the TS agreed that no verification documentation for the reference intervals used in PT and APTT testing could be located. 4. An exit interview with the LD, 4/2/25 at 4:00 PM, confirmed the findings.

D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation, interview with the technical supervisor (TS), and interview with the laboratory director (LD), the laboratory failed to ensure the established maintenance protocol for calibration of equipment was followed for 17 of 17 pipettes in use Findings: 1. A tour of the laboratory, 4/1/25 at 11:00 AM, identified 17 pipettes in use in the chemistry and Immunohematology departments (12 fixed volume MLA, 4 adjustable volume MLA, 1 ID Tipmaster). 15 of 17 pipettes had a label attached stating "last calibration 4/28/24, calibration due 10/28/24", one had a label attached stating "last calibrated 5/1/24, calibration due 11/1/24", and the ID Tipmaster pipette had no label. 2. During an interview with the TS, 4/1/25 at 11:30 AM, the TS stated that no documentation of current pipette calibrations could be located. 3. An exit interview with the LD, 4/2/25 at 4:00 PM, confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of Abbott Alinity chemistry analyzer quality control (QC) and calibration records, interview with the technical supervisor (TS) and interview with the laboratory director (LD), the laboratory failed to ensure the quality control material evaluated in Chemistry did not exceed the acceptability criteria (expiration date) before releasing patient results in March and April 2025. Findings: 1. A tour of the chemistry laboratory, 4/2/25 at 8:00 AM, identified 11 expired quality control and calibration materials in use. Refer to D5417. 2. Review of March and April 2025 daily QC and calibration records on the Abbott Alinity ci analyzer revealed the following daily QC and routine calibrations performed using expired materials and accepted for patient testing: 1.Bilirubin Calibrator (65189FD01A, 65189FD01B) opened 2/22/25, expired 3/1/25, calibrations accepted on 3/2/25, 3/9 /25, 3/10/25, 3/24/25, and 3/25/25 2. CO2 Calibrator (72065FD01A, 72065FD01B) opened 3/1/25, expired 4/1/25, calibration accepted on 3/28/25 3. Immunoassay Plus QC (10501T) opened 3/16/25, expired 3/26/25, accepted on 3/27/25, 3/28/25, 3/29/25, 3/30/25, 3/31/25, 4/1/25 4. Immunoassay QC (64990T, 64991T) opened 3/21/25, expired 3/31/25, accepted on 4/1/25 5. Immunology QC (85753T, 85751T) opened 3 /16/25, expired 3/26/25, accepted on 3/27/25, 3/28/25, 3/29/25, 3/30/25, 3/31/25, 4/1 /25 6. Multiqual QC (45971T, 45973T) opened 3/20/25, expired 3/22/25, accepted on 3/23/25, 3/24/25, 3/25/25, 3/26/25, 3/27/25, 3/28/25, 3/29/25, 3/30/25, 3/31/25, 4/1/25 3. During an interview with the TS, 4/2/25 at 8:45 AM, the TS confirmed that expired

	QC and calibration materials had been used and stated that patient chemistry results had been released. 4. An exit interview with the LD, 4/2/25 at 4:00 PM, confirmed the findings.
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 a review of Paragon laboratory information system (LIS) final patient reports, Chemistry laboratory policies and procedures, and interview with the laboratory director (LD), the laboratory failed to ensure comments provided to authorized persons for estimated glomerular filtration rate (eGFR) result interpretation were accurate and reflective of the method performed. Findings: 1. Review of 3 Paragon LIS patient reports from day of survey revealed the following comment for the eGFR test result: "If patient is African American multiply eGFR by 1.210." 2. Review of "Reference Interval(s), Clinical Decision Point(s), or Cutoff(s), & Result Comments" laboratory policy identified the final report comment for eGFR as stating "The CKD-EPI equation was used to calculate this eGFR result. Result reporting will go to 90 mL/min/BSA to aid in interpretation according to CKD classification grades" and lists 6 classification stages. 3. During an interview with the laboratory director (LD), 4/2/25 at 2:20 PM, the LD agreed the result comment for eGFR in Paragon was inconsistent with the race-free equation comment stated in the current policy. 4. An exit interview with the LD, 4/2/25 at 4:00 PM, confirmed the findings.