Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0193463	09/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Barnes-Kasson County Hospital	2872 Turnpike Street, Susquehanna, PA	

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 by the Pennsylvania State Agency for Barnes Kasson County Hospital on 9/23/2025 and 9/24/2025. The laboratory was found out of compliance with the following conditions: 493.1250 Condition: Analytic Systems 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: A. Based on record review, lack of documentation, and interview with Technical Supervisor (TS)#1, the laboratory failed monitor and document temperature and humidity to ensure operating conditions were met when 1 of 1 chemistry test (Whole Blood Glucose) was performed from 9/27/2023 to 9/24/2025. Findings include: 1. On the day of the survey, 9/24/2025 at 11:00 am, review of the laboratory's Glucose Meter policy stated, " Use the test strips at temperatures between 16 to 35 degrees Celcius. Use the test strips between 10 - 80% relative humidity." 2. The laboratory failed to provide documentation for temperature and humidity readings taken to ensure operating conditions were met for 1 of 1 chemistry test (Whole Blood Glucose) performed in the emergency room from 9/27/2023 to 09/25/2025. 3. TS #1 confirmed the findings above on 9/24/2025 at 12:00 pm. B. Based on lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to document the Quality Control (QC) performed for 1 of 1 chemistry test and 3 of 3 virology tests performed from 9/27/2023 to 9/24/2025:. Findings include: 1. On the days of the survey, 9/23/2025 and 9/24/2025, the laboratory failed to provide documentation of QC performed for the following 1 of 1 chemistry test and 3 of 3 virology tests performed from 9/27/2023 to 9/24/2025: -Icotest: Siemens - COVID: Cobas Liat -

	Influenza (Flu): Cobas Liat - Respiratory Synctical Virus (RSV): Cobas Liat 2. Review of laboratory records revealed the laboratory performed the following examinations: - 2: Ictotest from 9/27/2023-9/23/2025. -53: COVID from 1/17/2025 to 9/24/2025 -6: COVID/Flu/RSV from 1/17/2025 to 9/25/2025. 3. TS #1 confirmed the findings above on 9/23/2025 at 12:45 pm.
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 lack of documentation and interview with Technical Supervisor (TS) #1, the laboratory failed to establish and follow a written policy or procedure to assess employee competency for 2 of 2 TS for their supervisory duties performed (493.1413) from 9/27/2023 to 9/23/2025. Findings include: 1. On the day of survey, 9/23/2025 at 10:00 am, the laboratory failed to provide a written policy to assess the supervisory duties performed for 2 of 2 TS from 9/27/2023 to 9/23/2025. 2. TS #1 confirmed the above findings on 9/23/2025 at 1:00 pm.
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 observation of the laboratory, record review, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 from 9/27/2023 to 9/23 /2025. Refer to 5413, 5435, 5449, and 5775.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation in the laboratory, review of laboratory temperature records, and interview with Technical Supervisor (TS) #1, the laboratory failed to monitor room temperatures and humidity to ensure proper operating conditions for 2 of 2 instruments used to perform hematology and chemistry examinations from 9/27/2023 to 9/23/2025. Findings include: 1. On the day of survey, 9/23/2025, at 11:00 am, during the tour of the laboratory, the surveyor observed the following instruments in use in the laboratory: - Siemens Sysmex CA-600: system requirements 15C to 35C and humidity 30 to 85%. - Siemens Dimension EXL: system requirements 18C to 30C and humidity 20 to 80%. 2 . Review of the temperature records revealed the laboratory failed to monitor and document room temperatures and humidity to ensure operating conditions were met for 2 of 2 used for hematology and chemistry examinations from 9/27/2023 to 9/23/2025. 3. TS #1 confirmed the findings above on 9/23/2025 at 11:30 am.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to establish and maintain a maintenance /function check policy to ensure equipment used in the laboratory for patient testing provided accurate and reliable test results for 2 of 2 years from 9/26/2023 to 9/23 /2025. Findings include: 1. On the day of survey, 9/23/2025 at 12:30 pm, review of laboratory procedures revealed the laboratory failed to establish a policy for maintenance/function checks performed for equipment used in the laboratory for patient testing for 2 of 2 years from 9/26/2023 to 9/23/2025. 2. The laboratory failed to provide maintenance/function check records for 1 of 1 centrifuge used for coagulation testing (platelet poor plasma) and 2 of 2 timers used for critical steps in patient testing. 3. TS #1 confirmed the findings above on 9/23/2025 at 12:45 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with Technical Supervisor (TS) #1, the laboratory failed to document the positive and negative control each day of patient testing for 22 of 22 serum ketone examinations performed from 2/8/2024 to 9/9 /2025. Findings include: 1. On day of survey, 9/23/2025 at 10:50 am, review of testing logs revealed the laboratory failed to document the positive and negative controls each day of use for 22 of 22 serum acetone examinations performed from 2/8 /2024 to 9/9/2025. 2. TS #1 confirmed the findings above on 9/24/2025 at 11:15 am.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instruments for 2 of 2 studies performed from 9/27/2023 to 9/23/2025. Findings include: 1. On the day of the survey, 9/23/2025 at 11:30 am, the laboratory failed to provide documentation to define and evaluate the relationship between methodologies/instruments for the following 2 of 2 studies performed from 9/27/2023 to 9/23/2025: - Sure-Vue serum HcG kit vs Siemens Dimension EXL HcG - Manual and automated differential (Sysmex CA600) 2. The laboratory failed to provide documentation for the written criteria established for acceptable differences in test values when comparison studies are performed. 3. TS # 3 confirmed the findings above on 9/23/2025 at 1:30 pm.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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: A. Based on record review, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to establish and maintain written policies for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the postanalytic systems specified in 493.1291 for 2 of 2 years from 9/27 /2023 to 9/23/2025. Findings include: 1. On the day of survey, 9/24/2025 at 12:15 pm, the laboratory could not provide a procedure for the ongoing mechanism to monitor, assess, and correct problems found in the postanalytic system specified in 493.1291 for 2 of 2 years from 9/27/2023 to 9/23/2025. 2. The laboratory failed to provide records for the following periodic checks performed to verify the accuracy of the Laboratory's Information System (LIS) from 09/27/2023 to 09/23/2025: - Calculated Data - Patient results transmitted between instruments and LIS - Patient Specific data. 3. TS #1 confirmed during interview on 9/23/2025 at 12:50 pm, the laboratory did not have a process in place to monitor and evaluate the accuracy of information provided to clients. B. Based on policy and record review, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory failed to follow written policies for an ongoing mechanism to monitor and ensure the integrity of test results reported for 2 of 2 testing personnel (TP) from 9/27/2023 to 9/24/2025. Findings include: 1. On the day of survey, 9/24/2025 at 9:30 am, review of the laboratory's Procedural Guidelines policy stated, "All lab work will be reviewed by laboratory supervisor that is performed by persons not qualified to work as a general supervisor". 2. The

	laboratory failed to provide documentation of the review of 2 of 2 TP (CMS 209, #5 and #6, dated 9/9/2025) lab work as per policy. 3. TS #1 confirmed the above findings on 9/24/2025 at 12:30 pm.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with Technical Supervisor (TS) #1, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory in accordance with 493.1445 from 9/27/2023 to 9/23/2025. Refer to D6091, D6092, and D6106.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: A. Based on review of the laboratory's policy, proficiency testing results from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), and interview with Technical Supervisor (TS) #1, the laboratory director failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for 2 of 2 years from 9/27/2023 to 9/23/2025. Findings include: 1. On the day of survey, 9/23/2025, at 9:50 am, review of the Laboratory's policy titled, Proficency Testing, revealed the policy stated, "The Laboratory Medical Director reviews all results and corrective actions taken as necessary". 2. Review of AAB-MLE testing reports revealed the laboratory director failed to evaluate and identify problems that required corrective action for 2 of 2 years from 9/27/2023 to 9/23/2025. 3. TS #1 confirmed the findings on 9/23/2025 at 11:30 am. B. Based on review of the laboratory's policy, proficiency testing results from the College of American Pathologist (CAP), and interview with Technical Supervisor (TS) #1, the laboratory director failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for 6 of 6 testing events from 9/27/2023 to 9/23/2025. Findings include: 1. On the day od survey, 9/23/2025, at 9:50 am, review of the Laboratory's policy titled, Proficency Testing, revealed the policy stated, "Upon receipt of the summary reports provided by CAP, AAB, DOH, results are reviewed for discrepancies. Review includes referee concensus, all educational challenges and lack of referee consensus. Lack of referee consensus is reviewed with results obtained with majority or close to majority of responses. In addition, patterns and trends are looked for as they relate to prior summary reposonses." 2. Review of CAP testing reports revealed the laboratory failed evaluate 6 of 6 testing events from 9/27/2023 to 9/23 /2025 when the results were not graded by the PT agency. 3. TS #1 confirmed the findings on 9/23/2025 at 11:30 am.

D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with Technical Supervisor (TS) #1, the Laboratory Director (LD) failed to ensure an appropriate corrective action plan was followed when the laboratory had unacceptable analyte performance for 3 of 6 testing events from 9/27/2023 to 9/23/2025. Findings include: 1. On the day of survey, 9/23/2025 at 12:33 pm, review of the laboratory's AAB-MLE PT records revealed the laboratory had unacceptable results for the following 3 of 6 AAB-MLE PT testing events from 9/27/2023 to 9/23/2025 : - AAB-MLE 2025 1st Event: 1 unacceptable for Troponin, misidentified element in urine, and incorrect White Blood Cell Count - AAB-MLE 2025 2nd Event: 1 unacceptable for White Blood Cell Count, misidentified element in urine - AAB-MLE 2024 3rd Event: 2 unacceptable for Troponin, 1 unacceptable for Glucose 2. The problem identified and corrective actions provided for the unacceptable analyte performance is as follows: - Troponin in 2025 was clerical error and in 2024 was clinically insignificant with no corrective action - Glucose in 2024 was clinically insignificant with no corrective action - Misidentified elements in urine was to review with director - White Blood Cell Count in 2025 was rounding issue with no corrective action 3. The laboratory failed to provide acceptable corrective action taken when unacceptable or unsatisfactory PT results were obtained. 4. TS #1 confirmed the findings above on 9 /23/2025 at 1:00 pm.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: A. Based on review of the laboratory's procedure manual and interview with Technical Supervisor (TS) #1, the laboratory director (LD) failed to ensure approved chemistry and laboratory information system (LIS) polices were available to testing personnel for 2 of 2 years from 9/27/2023 from 9/23/2025. Findings Include: 1. On the day of survey, 9/23/2025 at 10:30 am, review of the laboratory's current procedure manual revealed the LD failed to ensure an approved policy for operation of the Siemens Dimension EXL analyzer and the usage of the LIS was available to testing personnel for 2 of 2 years from 9/27/2023 to 9/23/2025. 2. TS#1 confirmed the findings on 9/23/2025 at 11:00 am.
D6178	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(4) (b)(4) Follow the laboratorys established policies and procedures whenever test systems are not within the laboratorys established acceptable levels of performance;

	This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and records, and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure testing personnel were following laboratory policies for handling of critical values for 1 of 1 patients for coagulation testing performed from 9/27/2023 to 9/23/2025. Findings include: 1. On the day of survey 9/23/2025 at 2:00 pm, review of the laboratory's Alert Values procedure states, "As good laboratory practice, all alert values must be repeated for verification unless there is established correlation with previous testing." 2. Review of patient instrument reports revealed that 1 of 1 patient result for coagulation testing was not repeated according to policy. The patient also did not have prior results for comparison. 3. TS #1 confirmed the above findings on 9/23/2025 at 3:10 pm. B. Based on review of laboratory policies and records, and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure testing personnel were following laboratory policies for calibration of 2 of 43 chemistry analytes performed from 9/27/2023 to 9/23/2025. Findings include: 1. On the day of survey 9/24/2025 at 10:00 am, review of patient instrument reports revealed that the following 2 of 43 chemistry analytes had patient results reported from reagent packs that had an expired calibration: -Lipase - Hemoglogin A1C 3. TS #1 confirmed the above findings on 9/24/2025 at 12:10 pm.