Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0193463	10/27/2021
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
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on observation of the Blood Bank refrigerator and interview with General Supervisor (GS) #1, the laboratory failed to ensure that an area was designated in the blood bank refrigerator for quarantine blood products from 10/27/2019 to the date of survey. findings include: 1. On the day of survey, 10/27/2019, observation of the blood bank refrigerator revealed, there was no designated area for quarantine blood products in the blood bank refrigerator. 2. The GS#1 confirmed the finding above on 10/27/2021 at 11:35 a.m.
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 review of the laboratory procedure manual and interview with the general supervisor (GS) #1, the laboratory failed to establish a competency assessment procedure to assess the competency of 3 of 3 technical consultants from 10/27/2019 to the day of survey. Findings include: 1. On the day of survey, 10/27/2021, review of

	the laboratory clinical staff competency assessment policy revealed, the policy did not include the assessment of competency for 3 of 3 TC from 10/27/2019 to 10/27/2021. 2. The laboratory could not provide competency assessment records for 3 of 3 TC performed in 2019, 2020 and 2021. 3. The GS #1 confirmed the findings above on 10 /27/2021 around 9:20 a.m.
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: A. Based on review of the laboratory procedure manual and interview with the General Supervisor (GS)#1, the laboratory failed to include a general procedure for the validation of new test /analytes introduced to the laboratory from 10/27/2019 to the day of survey Findings include: 1. On the day of survey 10/27/2021, the laboratory could not provide a procedure for the validation of new test /analytes introduced to the laboratory From 10/27/2019 to the day of survey 2. The GS#1 confirmed the finding above on 10/28/2021 around 10:30 a.m. B. Based on review of the laboratory procedure manuals and interview with the General Supervisor (GS)#1, the laboratory failed to follow their microbiology procedures for sputum and wound cultures from 10/27/2019 to the day of survey. Findings include: 1. The procedures for sputum, wound cultures, and Collection, transport, and handling specimens state the following: - The sputum culture procedure under procedure states: "Heat Fix and stain gram stain smear. Read and report the gram stain." - The wound culture procedure under specimen set-up and procedure states: "Make a gram stain from swab" and "read gram stain". - The Collection, transport, and handling specimens under respiratory tract cultures state:"Sputum gram stains showing greater than 10 epithelial cells per low field is commented as a poor specimen". 2. On the day of survey, 10/27/2021, the laboratory could not provide documentation of gram stains performed from 10/27/2019 to 10/27/2021 . 3. The laboratory performed the following number of tests: - sputum cultures: From 10/27/2019 to 12/31/2019: 6. From 01/01/2020 to 12/31/2020: 22. From 01/01/2021 to 10/27/2021: 16. - wound cultures: From 10/27/2019 to 12/31/2019: 31. From 01/01/2020 to 12/31/2020: 98. From 01/01/2021 to 10/27/2021: 116. 4. The GS#1 confirmed the findings above on 10 /27/2021 at 09:15 a.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with general supervisor (GS) #1 and #2, the laboratory failed to establish a collection policy for the SARS-CoV-2 testing performed from 2020 to the day of survey. Findings Include: 1. On the day of survey, 10/27/2021, the laboratory could not provide a SARS-CoV-2 collection policy for tests collected from 2020 to 10/27/2021. 2. GS #1 and #2 confirmed the findings above on 10/27/2021 around 11:00 am.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with the general supervisor (GS) #1, the laboratory failed to have the Biomerieux Biofire procedure signed and dated by the current laboratory director (LD) from September of 2020 to the day of survey. Findings include: 1. On the day of survey, 10/27/2021, a review of laboratory procedures revealed, the Biofire procedure was not signed by the LD. 2. The GS #1 confirmed the finding above on 10/27/2021 around 12:50 pm.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 the Biofire analyzer validation records and interview with the General Supervisor (GS) #1, the laboratory failed to establish criteria for acceptable performance specifications for the respiratory viral panel and the gastro-intestinal (GI) panel validations from 09/15/2020 to 10/27/2021. Findings Include: 1. On the day of survey 10/27/2021, review of the Biofire analyzer validation records revealed, the validation performed on 09/15/2020 for the respiratory viral panel and on 09/28/2020 for the GI panel did not include criteria for acceptable precision and accuracy. 2. The

	laboratory performed the following number of tests. - Respiratory viral panel: From 09 /15/2020 to 12/31/2020: 827. From 01/01/2021 to 10/27/2021: 1903. - GI Panel: From 09/15/2020 to 12/31/2020: 8. From 01/01/2021 to 10/27/2021: 30. 3. The GS#1 confirmed the findings above on 10/27/2021 around 10:35 a.m.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must 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 observation of the laboratory and interview with the general supervisor (GS) #1, the laboratory failed to establish a maintenance policy to assess the maintenance /function for 3 of 3 thermometers in use in the laboratory from 2019 to the day of survey. Findings Include: 1. On the day of survey, 10/27/2021, the surveyor observed the following 3 of 3 thermometers in use to monitor room temperatures and refrigerator temperatures in the laboratory: - Temp Chex Strex Laboratories thermometer used to monitor the mini table top refrigerator. - Taylor Handy Temp. thermometer used to monitor the laboratory room temperature . - Fisher Scientific ERTCO refrigerator thermometer used to monitor the laboratory floor refrigerator. 2. The laboratory could not provide a thermometer maintenance policy or maintenance records for the thermometers above. 3. The GS #1 confirmed the findings above on 10 /27/2021 around 12:00 pm.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the general supervisor (GS) #1 and #2, the laboratory failed to include two control materials of different concentrations for D-dimer tests performed on the Quidel Triage Meter at least once each day for patient testing from 2020 to the date of survey. Findings include: 1. On the day of survey, 10/27/2021, review of QC records revealed, the laboratory did not perform two levels of control materials of different concentrations, each day of use for D-dimer tests performed on the Quidel Triage Meter from 10/27 /2019 to 10/27/2021. 2. In 2019 (10/27/2019 to 12/31/2019) - 19 D-dimer tests were performed. 3. In 2020 (01/01/2020 to 12/31/2020) - 170 D-dimer tests were performed. 4. In 2021 (01/01/2021 to 10/27/2021). - 99 D-dimer tests were performed. 5. GS #1 and #2 confirmed the finding above on 10/27/2021 around 12:50 pm.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the general supervisor (GS) #1, the laboratory failed to test the Sure-Vue Select Staph ID latex slide agglutination test for negative and positive reactivity each day of patient testing and document lot numbers and expiration dates for the Wright-Giemsa Stain QC in use from 10/27/2019 to the date of survey. Finding Include: 1. On the day of survey, 10/27/2021, the laboratory could not provide QC records for the Sure-Vue Select Staph ID latex slide agglutination test performed each day of patient testing from 10/27/2019 to the day of survey. 2. Review of the wright-giemsa stain QC records revealed, the daily QC logs did not state the lot numbers and expiration dates of stains in use. 3. The GS#1 confirmed the findings above on 10/27/2021 around 11:15 a.m.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the General Supervisor (GS) #1, the laboratory failed to check and document each batch or shipment of MacConkey (MAC) agar media for its ability to select or inhibit specific organisms and/or produce a biochemical response for 13 of 13 new batches from 01/01/2021 to the date of survey. Findings include: 1. On the day of survey, 10/27/2021, review of the media QC log revealed, the laboratory failed to document 13 of 13 new batches of MAC agar media for its ability to select or inhibit specific organisms and/or produce a biochemical response from 01/01/2021 to the day of survey. 2. The GS#1 confirmed the finding above on 10/27/2021 at 08:45 a.m.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

	This STANDARD is not met as evidenced by: Based on the review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with general supervisor (GS) #1, the laboratory director failed ensure all proficiency testing reports received, were reviewed to identify any problems that require corrective actions in 2019, 2020 and 2021. Findings Include: 1. On the day of survey, 10/27/2021, the laboratory could not provide correction action plans documented for the following AAB PT events: - 2019 AAB PT Event #3 - Rubella score of 80%. - 2019 AAB PT Event #3 - Antibody Identification score of 0%. - 2020 AAB PT Event #1 - ALT score of 80%. - 2021 AAB PT Event #1 - Sodium score of 80%. - 2021 AAB PT Event #1 - Uric Acid score of 80%. - 2021 AAB PT Event #1 - Antibody Detection score of 80%. 2. The GS#1 confirmed the findings above at 10/27/2021 around 9:15 am.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory procedures, lack of documentation and interview with general supervisor (GS) #1, the laboratory director (LD), failed to ensure quality assessment (QA) programs were established and maintained to assure the quality of laboratory services provided from 10/27/2019 to the day of survey. Findings include: 1. On the date of survey, 10/27/2021, the laboratory could not provide a QA policy. 2. The laboratory could not provide QA records assessing the laboratories pre-analytical, analytical and post-analytical assessment of the laboratory from 10/27/2019 to 10/27 /2021. 3. The GS #1 confirmed the findings above on 10/27/2021 around 10:00 am.