Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0193463	04/16/2019
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
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 Laboratory procedure manuals, testing personnel (TP) competency assessment documents and interview with general supervisor (GS) #1, the laboratory failed to establish a competency assessment policy to assess the competency of testing personnel of TP (6 of 6) who perform Microbiology, Chemistry, Hematology, Immunohematology, Immunology, Toxicology and Urinalysis testing and consultant competency (5 of 5) from 09/06/2017 to the date of survey. Findings include: 1. On the day of survey, 04/16/2019, the laboratory failed to provide a competency assessment policy to assess the competency of TP, technical consultants (TC), technical supervisors (TS) and for GS. 2. In 2018, TP #6 competency assessment was not assessed. 3. In 2018, TP #5 competency assessment document was missing points 1, 4, 5 and 6. 4. In 2018, TP #1- #4 competency assessment documents were missing points 5 and 6. 5. The laboratory could not provide documentation of competency assessed for 3 of 3 TC, 1 of 2 TS, and 5 of 5 GS. 6. In 2017 (09/06/2017 to 12/31/2019), approximately 8,000 specimen were analyzed. 7. In 2018, approximately 35,500 specimen were analyzed. 8. In 2019 (01/01 /2019 to 04/16/2019), approximately 19,500 specimen were analyzed. 9. The GS #1 confirmed the findings above on 04/16/2019 around 09:30 am.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the calibration verification records and interview with the general supervisor (GS) #1, the laboratory failed to perform calibration verification at least each 6 months on the Siemens Dimension ExL Chemistry analyzer for Hemoglobin A1C from 2018 to the date of survey. Findings include: 1. On the day of survey, 04/16 /2019, the GS could not provide documentation of calibration verification performed at least every 6 months on the Siemens Dimension ExL Chemistry analyzer for Hemoglobin A1C testing in 2018 to 2019. 2. The GS confirmed on 04/16/2019 around 11:15 am, that calibration verification was performed on 03/21/2018 and again on 02 /04/2019, but was not performed every 6 months. ***Repeat Deficiency***
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Bacteriology and Toxicology quality control (QC) records, and interview with general supervisor (GS) #1, the laboratory failed to perform a negative and positive control material each day of patient testing for Bio Rad Tox-See Urine drug analysis and Remel Xpect cdiff toxin A+B from 2017 to the date of survey. Findings Include: 1. On the day of survey, 04/16/2019, review of Bio Rad Tox-See Urine drug analysis and Remel Xpect cdiff toxin A+B QC records revealed the laboratory did not document a negative and positive control material each day of patient testing from 09/06/2017 to 04/16/2019. 2. In 2017 (09/06/2017 to 12/31/2017), 46 Bio Rad Tox-See Urine drug analysis and 23 Remel Xpect cdiff toxin A+B from were analyzed. 3. In 2018 (01/01/2018 to 12/31/2018), 127 Bio Rad Tox-See Urine drug analysis and 26 Remel Xpect cdiff toxin A+B from were analyzed. 4. In 2019 (01

	/01/2019 to 04/16/2019), 77 Bio Rad Tox-See Urine drug analysis and 9 Remel Xpect cdiff toxin A+B from were analyzed. 5. GS #1 confirmed on 04/16/2019 around 12:30 pm, that QC was performed on a each new lot, not each day of patient testing.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on Blood Bank record review and interview with the general supervisor (GS) #1, the laboratory failed to follow policy and monitor proper blood and blood product storage temperatures from September 2017 to April 2019. Findings Include: 1. The previous Plan of Correction signed by LD on 10/13/2017 D5555 #2 stated, "A log will be kept for documentation of testing blood bank alarm. This test is performed quarterly" and the fourth answer to the plan of correction stated, "Laboratory Manager will review charts quarterly." 2. On the day of survey, 04/16/2019, review of Blood Bank records revealed, the LD did not update and sign, the "Testing of Blood Bank Alarm policy" nor signed the quarterly reviews for Quality control testing performed on the blood bank alarm system. 3. From 09/06/2017 to 04/16/2019, 475 Blood Bank specimens were analyzed. 4. The GS #1 confirmed the findings above on 04/16/2019 around 09:40 am. ***Repeat Deficiency***
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 Quality Assurance procedure manual and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure quality assessment (QA) programs were established and maintained from 2017 to the day of survey. Findings Include: 1. On the day of survey, 04/16/2019, the GS #1 could not provide complete procedure and documentation of QA activities performed to assess the laboratory's pre-analytic, analytic and post analytic phases of testing from September of 2017 to March of 2019. 2. The laboratories QA policy was not signed by the LD and did not mention the frequency QA activities were performed. 3. The LD did not sign the American Association of Bioanalytics (AAB) 2018 Event #1 for Rheumatoid Factor Attestation form. 4. The LD did not sign all AAB attestation statements from 2017 to 2019. 5. The LD did not sign corrective actions for PT: a. 2018 1st Event, Non Chemistry, Analyte: PT/INR, Scored: 60 b. 2018 3rd Event, Non Chemistry, Analyte: Antibody ID, Scored: 40 6. The GS #1 provided QA activities on 04/16/2019 around 10:45 that reviewed the laboratories turn around time, but could not provide documentation of other QA activities.

D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the general supervisor (GS) #1, the laboratory failed to ensure that each individual performing High Complexity testing (1 of 6) is qualified. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for

	performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CLIA' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the general supervisor (GS) #1, the laboratory failed to ensure that each individual performing High Complexity testing (1 of 6) is qualified. Findings Include: 1. Testing personnel #6 obtained a Bachelors of Science in Communication Sciences & Disorders from Marywood University in Scranton, PA. 2. On the day of survey, 04/16/2019, review of TP #6's diploma and transcript revealed, the credentials do not meet the requirements of 493.1489(b) to perform high complexity level testing (manual differentials and immunohematology tests). 3. GS #1 confirmed the findings above on 04/16/2019 around 08:49 am.