Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 17D0047197	**(X3) Date Survey Completed** 09/14/2018
Name of Provider or Supplier Lincoln County Hospital	**Street Address, City, State** 624 North 2nd Street, Lincoln, KS	
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**
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and interview with Testing Personnel (TP) #2, the laboratory failed to examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. Findings Include: 1. Review of the laboratory's 2018 and 2017 API PT documentation found PT samples tested or examined in duplicate as follows: Chemistry - Core 2018 - 1st Testing Event Review of the laboratory's PT analyzer printouts found 25 out of 25 analytes for 5 out of 5 PT samples were analyzed in duplicate as follows: CH-01 Analyzed on 02/05/2018 at 1:22 PM and 3:20 PM. CH-02 Analyzed on 02/05/2018 at 1:23 PM and 3:20 PM. CH-03 Analyzed on 02/05/2018 at 1:23 PM and 3:20 PM. CH-04 Analyzed on 02/05/2018 at 1:24 PM and 3:21 PM. CH-05 Analyzed on 02/05/2018 at 1:24 PM and 3:21 PM. 2017 - 3rd Testing Event Review of the laboratory's PT analyzer printouts found 25 out of 25 analytes for 5 out of 5 PT samples were analyzed in duplicate as follows: CH-11 Analyzed on 09/08/2017 at 10:34 AM and 09/12/2017 at 9:50 AM. CH-12 Analyzed on 09/08/2017 at 10:35 AM and 09/12/2017 at 9:50 AM. CH-13 Analyzed on 09/08/2017 at 10:35 AM and 09/12/2017 at 9:50 AM. CH-14 Analyzed on 09/08/2017 at 10:35 AM and 09/12/2017

	at 9:51 AM. CH-15 Analyzed on 09/08/2017 at 10:36 AM and 09/12/2017 at 9:51 AM. 2017 - 2nd Testing Event Review of the laboratory's PT analyzer printouts found 25 out of 25 analytes for 5 out of 5 PT samples were analyzed in duplicate as follows: CH-06 Analyzed on 06/06/2017 at 1:16 PM (TP #2 name handwritten on top of printout) and 06/07/2017 at 9:05 AM (TP #3 name handwritten on top of printout). CH-07 Analyzed on 06/06/2017 at 1:16 PM and 06/07/2017 at 9:05 AM. CH-08 Analyzed on 06/06/2017 at 1:16 PM and 06/07/2017 at 9:06 AM. CH-09 Analyzed on 06/06/2017 at 1:17 PM and 06/07/2017 at 9:06 AM. CH-10 Analyzed on 06/06/2017 at 1:17 PM and 06/07/2017 at 9:06 AM. Hematology / Coagulation 2017 - 2nd Testing Event Review of the Blood Cell ID and Urine Sediment API PT sample pictures found 9 out of 9 pictures were assessed and responded to by two TP as follows: BCI-08 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. BCI-09 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. BCI-10 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. BCI-11 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. BCI-12 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. BCI-13 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. BCI-14 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. US-03 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. US-04 Two handwritten answers present with different handwriting. The first response written in black ink, the second response written in blue ink. 2. TP #2 stated the laboratory does not run all patient samples in duplicate. The interview occurred 09/14/2018 at 9:58 AM.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and interview with Testing Personnel (TP) #2 and 3, the laboratory failed to review and evaluate the results obtained on proficiency testing performed for analyte assigned a proficiency testing score that did not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part). Findings Include: 1. Review of the laboratory's 2018 and 2017 API PT documentation found API scored the following samples as "Not Graded": Hematology / Coagulation 2018 - 2nd Testing Event Blood Cell ID (Educational) BCI-13 Reported Result: Lymph, reactive (atyp, variant) Expected result: Blast **The laboratory's reported result failed to match the PT provider's expected result. The sample was not graded and no self-assessment or self-evaluation was present** BCI-14 APTT (sec) COA-07

	2018 - 1st Testing Event Blood Cell ID (Educational) BCI-06 BCI-07 Blood Cell Identification BCI-01 2017 - 2nd Testing Event Blood Cell ID (Educational) BCI-13 BCI-14 2017 - 1st Testing Event Blood Cell ID (Educational) BCI-06 BCI-07 Chemistry - Core 2017 - 1st Testing Event Triglycerides CH-01 Free Thyroxine CH-01 2. TP #2 and 3 stated the laboratory did not have documentation of a self-assessment or self-evaluation for the "Not Graded" samples listed above available for review. The interview Occurred 09/14/2018 at 10:49 AM.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's individualized quality control plan (IQCP), patient test reports, and Triage analyzer quality control (QC) documentation, the laboratory failed to ensure the individualized quality control plan (IQCP) was followed by testing personnel for the analytes CK-MB, troponin, D-Dimer, and myoglobin that are analyzed on the Alere Triage instrument. Findings Include: 1. Review of the laboratory's IQCP for the Alere Triage analyzer, signed and approved by the Laboratory Director (LD) on 01/27/2016, found the follow QC directions: Quality Control Policy (QCP) for the Alere Triage 5. Quality Control Plan Every 30 Days: - Perform two levels of external controls (Alere Triage Total 5 Control Levels 1 & 2) Alere Triage Quality Assessment Program The purpose of this Quality Assessment Program is to establish a review system for the ongoing monitoring of the effectiveness of the Individualized Quality Control Plan (IQCP) for testing on the Alere Triage analyzer. This will be accomplished by the Laboratory Director or designee performing and documenting the following monitors: Monthly: - Review of QC records ensuring external quality controls are performed and documented: -- Every 30 days; 2. Review of the laboratory's 2018 and 2017 QC documentation titled "Triage Meter Pro QC Sample Test Log Sheet" found external QC was not performed and documented for the following months: CK-MB, Myoglobin, and Troponin: June 2018 March 2018 November 2017 September 2017 March 2017 D-Dimer: July 2018 June 2018 April 2018 February 2018 November 2017 August 2017 June 2017 April 2017 February 2017 January 2017 **NOTE: All "Reviewed By:" lines on the QC logs were blank** 3. The Surveyor requested a report of patients analyzed for CK-MB, myoglobin, troponin, and D-Dimer in 2018 and 2017. Review of the documentation provided titled "Inventory Usage Report" and a second untitled report found patient samples were analyzed during the months external QC was not run as follows: CK-MB, Myoglobin, and Troponin June 2018 - 29 cardiac enzyme samples analyzed March 2018 - 25 cardiac enzyme samples analyzed November 2017 - 33 cardiac enzyme samples analyzed September 2017 - 18 cardiac enzyme samples analyzed March 2017 - 21 cardiac enzyme samples analyzed D-Dimer: July 2018 - 7 samples analyzed June 2018 - 8 samples analyzed April 2018 - 6 samples analyzed February 2018 - 6 samples analyzed November 2017 - 18 samples analyzed August 2017 - 6

samples analyzed June 2017 - 11 samples analyzed April 2017 - 5 samples analyzed February 2017 - 3 samples analyzed January 2017 - 2 samples analyzed Item 2 Based on review of the manufacturer's package insert instructions, the laboratory's policies and procedures, individualized quality control plan (IQCP) documentation, EPOC quality control (QC) logs, and interview with Testing Personnel (TP) #2 and Technical Consultant (TC) #3, the laboratory failed to ensure the EPOC test system controls were performed using the frequency specified by the manufacturer. Findings Include: 1. Review of the EPOC System Manual found the following directions: Section 9 - Quality Assurance 9.2 Recommended Quality Control for EPOC System B. Verification of Card Shipment From each lot in each shipment of cards, analyze at least two (2) levels of fluid controls in duplicate using any verified Reader(s). (For proper fluid handling, see 9.4 Aqueous Fluid Handling below). 2. Review of the laboratory's policy and procedure titled "Epoc Blood Analysis System For Use as a Blood Gas Analyzer and Lactic Acid and as a Back-Up for Primary Chemistry Analyzer" found the following directions: Quality Control From each lot in each shipment of cards, analyze at least two (2) levels of fluid controls in duplicate using any verified Reader. 3. Review of the laboratory's 2018 and 2017 QC and patient test logs titled "Lincoln County Hospital EPOC Log" found the following instances where a new lot of test cards were put into use but 2 levels of fluid controls were only analyzed 1 time: 09/10/2018 Lot: 0018166-30 Expiration Date: 11/30/2018 Controls level I and III were each analyzed one time. 08/01/2018 Lot: 00-1811-10 Expiration: 10/06/2018 Controls level I and III were each analyzed one time. 06/10/2018 Lot: 00-18108-30 Expiration: 10/03/2018 Controls level I and III were each analyzed one time with a bracket pointing to a handwritten note "New card 18108-30" Unknown Lot: 00-18031-10 Expiration: UNKNOWN On the test log containing testing dates from 04/01/2018 through 05/17/2018 this lot number was listed. No date indicating when the new lot was put into use was present. No controls run in duplicate were present on the test log. Unknown Lot: 100600-00 Expiration: 05/22/2018 On the test logs containing testing dates from 02/13/2018 through 03/31/2018 this lot number was listed. No date indicating when the new lot was put into use was present. No controls run in duplicate were present on the test logs. Unknown Lot: 00-17337-10 Expiration: UNKNOWN On the test log containing testing dates from 01/29/2018 through 02/12/2018 this lot number was listed. No date indicating when the new lot was put into use was present. No controls run in duplicate were present on the test log. Unknown Lot: 00-17251-10 Expiration: UNKNOWN On the test log containing testing dates from 11/30/2017 through 01/27/2018 this lot number was listed. No date indicating when the new lot was put into use was present. No controls run in duplicate were present on the test log. 09/13/2017 Lot: 00-17217-20 Expiration: UNKNOWN Controls level I and III were each analyzed one time. 08/04/2017 Lot: 00-17180-20 Expiration: UNKNOWN Controls level I and III were each analyzed one time. 06/08/2017 Lot: 00-17121-20 Expiration: UNKNOWN Controls level I and III were each analyzed one time on 06/09/2017. 05/21/2017 Lot: 00-17068-20 Expiration: 08/24/2017 Controls level I and III were each analyzed one time. Unknown Lot: 17403-30 Expiration: UNKNOWN On the test logs containing testing dates from 04/06/2017 through 05/13/2017 this lot number was listed. No date indicating when the new lot was put into use was present. No controls run in duplicate were present on the test logs. 4. TC #3 and TP #2 stated they were unaware of the requirement that external controls be run in duplicate for each new lot. The interview occurred 09/14/2018 at 2:30 PM. Item 3 Based on review of the laboratory's policies and procedures, patient and quality control (QC) test logs and records, and interview with Testing Personnel (TP) #2 and 3, the laboratory failed to perform control procedures using the number and frequency established by the laboratory for the EPOC test system. Findings Include: 1. Review of the laboratory's policy and procedure titled "Epoc Blood Analysis System For Use as a Blood Gas

	Analyzer and Lactic Acid and as a Back-Up for Primary Chemistry Analyzer" found the following directions: Quality Control ...QC will be performed every day of use. (2) levels of GAS-ISE are used for lactic acid and chemistries. For ABG's (2) levels of HCT must be performed along with the GAS-ISE. Review of the laboratory's policy titled "Quality Control Policy" found the following directions: Blood Gas (EPOC) Control Frequency: Quality Assurance On each day of patient testing, perform 2 levels ...For blood gas testing perform both levels of GAS-ISE metabolites and both levels of HCT controls. 2. The surveyor requested a list of patient testing performed in 2018 and 2017. Review of the untitled test list, the laboratory's QC and patient test log titled "Lincoln County Hospital EPOC log", and electronic final test reports found the following: 03/09/2017 A patient was tested for arterial blood gas that was resulted at 6: 12 PM. No QC documentation was present on the laboratory's QC and patient log. 04 /16/2017 A patient sample was analyzed for arterial blood gas and was resulted at 1: 26 PM. No QC documentation was present on the laboratory's QC and patient log. 06 /05/2017 A patient's sample was analyzed for arterial blood gas and was resulted at 12: 05 PM. No QC documentation was present on the laboratory's QC and patient log. 08 /05/2017 A patient's sample was analyzed for arterial blood gas and was resulted at 4: 50 PM. No QC documentation was present on the laboratory's QC and patient log. 09 /27/2017 A patient's sample was analyzed for arterial blood gas and was resulted at 2: 58 PM. No QC documentation was present on the laboratory's QC and patient log. 11 /14/2017 A patient's sample was analyzed for arterial blood gas and was resulted at 5: 28 PM. No QC documentation was present on the laboratory's QC and patient log. 02 /07/2018 A patient's sample was analyzed for arterial blood gas and was resulted at 8: 20 AM. No QC documentation was present on the laboratory's QC and patient log. No performance of QC or patient sample was present in the instrument printout records provided by TP #3. 03/04/2018 Two patients' samples were analyzed for arterial blood and were resulted at 10:33 AM and 1:13 PM. No QC documentation was present on the laboratory's QC and patient log. No performance of QC was present in the instrument printout records provided by TP #3. 06/19/2018 A patient's sample was analyzed for arterial blood gas and was result at 12:37 PM. No QC documentation was present on the laboratory's QC and patient log. QC was performed on 06/19/2018 at 1:12 PM, according to the instrument printout records provided by TP #3, after the patient's test results were reported. 3. TP #3 stated the laboratory performed external QC on the EPOC analyzer every 24 hours, which does not always end up being on the same day that a patient's test is performed. TP #3 also stated the laboratory ceased using the QC and patient log titled "Lincoln County Hospital EPOC Log" in July 2018 for patient test results. The interview occurred 09/14/2018 at 2:32 PM.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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 review of the laboratory's coagulation quality control (QC) records, patient test lists, and interview with Testing Personnel (TP) #1, the laboratory failed to ensure results of control materials must meet the laboratory's criteria for acceptability before reporting patient test results. Findings Include: 1. The Surveyor requested a report of patients analyzed coagulation tests in 2018 and 2017. Review of the untitled documentation and the laboratory's coagulation QC documentation found patient

	samples were analyzed when QC results did not meet criteria for acceptability as follows: 01/05/2017 "Coagulation Quality Control" January 2017 PT QC results for level QC01 and QC03 were marked with asterisks indicating the results were out-of-range. No documentation of repeat testing for levels QC 01 and 03 were present on the instrument printout. 2 patients' samples were analyzed for PT/INR. 05/03/2017 "Coagulation Quality Control" May 2017 aPTT QC results for level QC03 was marked with an asterisk indicating the result was out-of-range. No documentation of repeat testing for level QC 03 was present on the instrument printout. 2 patients' samples were analyzed for PTT. 02/06/2018 "Coagulation Quality Control" February 2018 PT QC results for level QC03 was marked with an asterisk indicating the result was out-of-range. No documentation of repeat testing for level QC 03 was present on the instrument printout. 1 patient's sample was analyzed for PT/INR. 02/09/2018 "Coagulation Quality Control" February 2018 PT QC results for level QC03 was marked with an asterisk indicating the result was out-of-range. No documentation of repeat testing for levels QC 03 was present on the instrument printout. 5 patients' samples were analyzed for PT. 02/28/2018 "Coagulation Quality Control" February 2018 PT QC results for level QC03 was marked with an asterisk indicating the result was out-of-range. No documentation of repeat testing for levels QC 03 was present on the instrument printout. 2 patients' samples were analyzed for PT. 2. TP #1 confirmed the QC results listed above were out of the laboratory's established criteria for acceptability but stated there were just a little bit out-of-range. The interview occurred 09/14/2018 at 3:25 PM.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's coagulation quality control (QC) records, patient test lists, and interview with Testing Personnel (TP) #1 and 3, the laboratory failed to include two levels of control material each 8 hours of operation for the nonmanual coagulation test systems. Findings Include: 1. The Surveyor requested a report of patients analyzed coagulation tests in 2018 and 2017. Review of the untitled documentation and the laboratory's coagulation QC documentation found patient samples were analyzed when 2 levels of quality control had not been performed as follows: 05/31/2017 "Coagulation Quality Control" May 2017 PT and aPTT No QC results for 05/31/2017 were listed on the instrument printout. 1 patient sample was analyzed for PT/INR. 11/21/2017 "Coagulation Quality Control" November 2017 PT and aPTT No QC results for 11/21/2017 were listed on the instrument printout. 1 patient sample was analyzed for PT/INR and PTT. 02/08/2018 "Coagulation Quality Control" February 2018 PT and aPTT QC results for level QC01 was listed for 02/08 /2018. No QC results for level QC03 02/08/2018 were listed on the instrument printouts. 5 patients' samples were analyzed for PT/INR. 2. TP #1 and 3 confirmed the dates listed above did not have QC documentation present on the reports. The interview occurred 09/14/2018 at 3:24 PM.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality assessment (QA) policy and procedure and QA documentation, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings Include: 1. Review of the laboratory's QA policy and procedure titled "Quality Assessment Plan" found the follow directions: Analytic Systems - Control policies; Review of quality control results identifies inaccuracies and any shifts/trends in test systems prior to reporting patient results. Mechanisms of Review: - Quality control policies are effective to produce a high degree of confidence in patient test results and lab director/supervisory reviews are conducted routinely. Post Analytic Systems QA review of the Post-Analytic System includes assessing all processes relating to test reports: - Laboratory information systems (LIS): -- information received at the final destination was the same data sent by the laboratory Proficiency Testing Performance Mechanism of Review: - Results not formally evaluated or scored by the PT provider are evaluated by the laboratory. Personnel Assessment QA review of personnel will assist in verifying that hiring, training, and continuing education processes are appropriate and ensure that laboratory personnel are qualified by education and experience according to CLIA requirements and are competent to perform all tasks assigned to them. Mechanism of Review: Verify that there is documentation of the following on file: - Competency assessments (at 6 & 12 months for new hires). 2. Review of the laboratory's 2017 and 2018 QA documentation found: 2018 Monthly Review by "Laboratory Director" January API 01/23/2018 Chem, Hemat, Coag 2nd and 3rd events QC 01/23/2018 Hemat 9/17 - 1/18 Chem 7/17 - 11/17 Coag 10&11/17 February QC 02/13/2018 Coag 1/18 Hemat 11/18 & 12/20 March API BLANK QC BLANK April API 04/04/2018 Chem 1st Event QC Coag 2/18, 3/18 Chem 2/19, 3/18 May QC Coag 4/18 Hemat 2/18, 3/18, 4/18 Glyco 2/18 June API BLANK QC BLANK July 07/13/2018 Chem Mis Hemat 1st Event QC 07/13/2018 Coag 5/18, 6/18 Hemat 4/18, 5/18, 6/18 Chem 5/18 August API BLANK QC BLANK Chemistry Quality Assessment Monitors 2018 QC performed at appropriate intervals (blood gas) "Yes" was documented for all months January through August Coagulation Quality Assessment Monitors 2018 QC performed at appropriate intervals "8 hrs" was documented for all months January through August Monthly review of QC results verify that all are w/in acceptable ranges "Yes" was documented for all months January through August 2017 Monthly Review by "Laboratory Director" January API 01/10/2017 2016 Hemat Coag 1st event QC 01/10/2017 Coag February QC N/A March API 03/28/2017 Chem Group 2 3rd event QC 03/28/2017 Coag, Chem, Hemat April API N/A QC N/A May QC N/A June API 06/07/2017 Chem core 1st event Hemat Coag 1st event QC 06/07/2017 Coag Hemat Chem July 07/05/2017 Chem Mis 1st Event QC 07/05/2017 Chem, Hemat, Immunology, Coag August API Chem core 2nd Event QC Coag Hemat September QC Chem Hemat Coag October 10/23/2017 Hem/Coag 2nd Event QC 10/23/2017 Hemat, Coag November API N/A QC N/A December API N/A QC N/A Chemistry Quality Assessment Monitors 2017 QC performed at appropriate intervals (blood gas) "Yes" was documented for all months January through December Coagulation Quality Assessment Monitors 2017 QC performed at appropriate intervals "8 hrs" was documented for all months January

	through August Monthly review of QC results verify that all are w/in acceptable ranges "Yes" was documented for all months January through December 3. The laboratory's QA policies and reviews were found to be ineffective: The laboratory failed to examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. (Refer to D2006) The laboratory failed to review and evaluate the results obtained on proficiency testing performed for analyte assigned a proficiency testing score that did not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part). (Refer to D5215) The laboratory failed to ensure the individualized quality control plan (IQCP) was followed by testing personnel for the analytes CK-MB, troponin, D-Dimer, and myoglobin that are analyzed on the Alere Triage instrument. (Refer to D5445, Item 1) The laboratory failed to ensure the EPOC test system controls were performed using the frequency specified by the manufacturer. (Refer to D5445, Item 2) The laboratory failed to perform control procedures using the number and frequency established by the laboratory for the EPOC test system. (Refer to D5445, Item 3) The laboratory failed to include two levels of control material each 8 hours of operation for the nonmanual coagulation test systems. (Refer to D5545) The laboratory failed to ensure results of control materials must meet the laboratory's criteria for acceptability before reporting patient test results. (Refer to D5481) The laboratory failed to have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. (Refer to D5801) The Technical Consultants (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. (Refer to D6053) The Technical Consultants (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually after the first year the individual tests patient specimens. (Refer to D6054)
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's urine microscopic test records and electronic final test reports, the laboratory failed to have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. Findings Include: 1. Review of the laboratory's urine microscopic test records found the following results documented: 08/20/2018 @ 4:53 PM >20 RBC 7 - 9 WBC 08/19/2018 @ 7:59 AM WBC Rare Ep Cell 0 - 2 07/10 /2018 @ 1:26 PM Occ WBC 2 - 3 Ep Cells 07/04/2018 @ 9:?9 PM 2 - 3 WBC 2 - 4 Ep Cells 07/04/2018 @ 9:29 PM 4 - 6 Ep Cells 06/22/2018 @ 12:13 PM 5 - 7 Sq Ep

	Cells Rare RBC/WBC 05/21/2018 @ 11:14 AM TNTC WBC 8 - 10 RBC Bacteria 03 /07/2018 @ 9:17 AM 2-4 (sediment not identified) Few Sq Ep Cells 2. Review of the laboratory's electronic final test reports found the following results documented: 08/20 /2018 @ 4:51 PM WBC 5 - 10/hpf RBC >20/hpf Bacteria Rare/hpf The result of rare bacteria was not present on the test record. The result of 7 - 9 WBC on the test record does not match the result of 5 - 10 WBC on the final test report. 08/19/2018 @ 7:57 AM WBC 0 - 1/hpf Squamous Epi 0 - 2 The result of rare WBC on the test record does not match the result of 0 - 1 WBC on the final test report. 07/10/2018 @ 1:39 PM WBC 0 - 1/hpf Squamous Epi 0 - 2/hpf The result of 2 - 3 epithelial cells on the test record does not match the result of 0 - 2 epithelial cells on the final test report. 07 /04/2018 @ 9:21 PM WBC 0 - 1/hpf Squamous Epi 0 - 2/hpf The result of 2 - 3 WBC on the test record does not match the result of 0 - 1 WBC on the final test report. The result of 2 - 4 epithelial cells on the test record does not match the 0 - 2 epithelial cells on the final test report. 07/04/2018 @ 9:19 PM WBC 1 - 3/hpf Squamous Epi 3 - 6 /hpf The result of 1 - 3 WBC was not present on the test record. 06/22/2018 @ 12:16 PM WBC 0 - 1/hpf RBC 1 - 3/hpf Squamous Epi 3 - 6/hpf The result of 5 - 7 epithelial cells on the test record does not match the 3 - 6 epithelial cells on the final test report. The result of rare WBC/RBC on the test record does not match the 0 - 1 WBCs and 1 - 3 RBCs on the final test report. 05/21/2018 @ 11:26 AM WBC TNTC RBC 5 - 10/hpf Squamous Epi 0 - 2/hpf Bacteria 3+/hpf The result of bacteria on the test record does not match the result of 3+ bacteria on the final test report. The result of 0 - 2 epithelial cells on the final test report was not on the test record. 03/07/2018 @ 8:24 AM WBC 1 - 3/hpf Squamous Epi 0 - 2/hpf The result of 1 - 3 WBC does not appear on the test record. The result of few epithelial cells on the test record does not match the result of 0 - 2 epithelial cells on the final test report.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of documentation of education, Form CMS-209 Laboratory Personnel Report (CLIA), the laboratory's competency assessment documentation, and interview with Testing Personnel (TP) #2, the Technical Consultants (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings Include: 1. TP #2 stated that TP #3 and #4 were new TP since the previous survey. The following start dates were provided: TP #3: May 2016 TP #4: September 2016 The interview occurred 09/14/2018 at 8:14 AM. 2. Review of the Form CMS-209, signed by the Laboratory Director (LD) on 09/11/2018, found three individuals certified by the LD to fulfil the role of technical consultant (TC). TP #2 was not certified by the LD to fulfil the role of TC. 3. Review of the laboratory's 2018, 2017, and 2016 competency assessment documentation found the new TP had their competency assessed as follows: TP #3: 10/04/2017 May 2016 (1 year) NONE 10 /01/2016 (6 month)** 05/01/2016 (Initial) **competency assessment performed and documented by TP #2 who does not qualify as a TC. No documentation of a 6 month competency assessment, performed by a qualified TC, was found. No documentation of a one year competency assessment was found. TP #4: 10/01/2017 (1 year) March 2017 (6 month) NONE 09/06/2016 (Initial)** **competency assessment performed

	and documented by TP #2 who does not qualify as a TC. No documentation of a 6 month competency assessment was found. No documentation of an initial competency assessment, performed by a qualified TC, was found. 4. TP #2 stated that TC #2 and TP #2 take turns assessing employee competency. The interview occurred 09/14/2018 at 8:58 AM. 5. Review of the provided documentation of education for TP #2 found a diploma in medical assisting, dated February 26, 1976, from the Brown Mackie College. No Bachelor's or Master's degree in a science or Medical Degree was provided for TP #2.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of documentation of education, Form CMS-209 Laboratory Personnel Report (CLIA), the laboratory's competency assessment documentation, and interview with Testing Personnel (TP) #2, the Technical Consultants (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually after the first year the individual tests patient specimens. Findings Include: 1. Review of the Form CMS-209, signed by the Laboratory Director (LD) on 09/11/2018, found three individuals certified by the LD to fulfil the role of technical consultant (TC). TP #2 was not certified by the LD to fulfil the role of TC. 2. Review of the laboratory's 2018, 2017, and 2016 competency assessment documentation found TP had their competency assessed as follows: TP #1: 11/07/2017 10/21/2016** **competency assessment performed and documented by TP #2 who does not qualify as a TC. TP #2: 10/04/2017 10/01/2016 3. TP #2 stated that TC #2 and TP #2 take turns assessing employee competency. The interview occurred 09/14/2018 at 8:58 AM. 5. Review of the provided documentation of education for TP #2 found a diploma in medical assisting, dated February 26, 1976, from the Brown Mackie College. No Bachelor's or Master's degree in a science or Medical Degree was provided for TP #2.