Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315681	(X3) Date Survey Completed 06/23/2022
Name of Provider or Supplier Lexington Hospital Corporation	**Street Address, City, State** 200 West Church St, Lexington, TN	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, review of the laboratory's American Proficiency Institute (API) proficiency testing records, and interview with the laboratory supervisor, the laboratory failed to maintain enrollment in proficiency testing for performance of qualitative blood cultures in 2022. The findings include: 1. Observation of the laboratory on June 22, 2022 at 9 am revealed the BACT/Alert 3D in use for patient testing for blood cultures. 2. Review of patient test reports revealed a blood culture reported as positive on 02/25/22 for patient 115599 and a blood culture reported as negative on 06/18/22 for patient 130314. 3. Review of the laboratory's API proficiency testing records revealed no current enrollment for blood cultures. 4. Interview with the laboratory supervisor on June 22, 2022 at 5:15 pm confirmed the laboratory was performing blood cultures but was not currently enrolled in proficiency testing for blood cultures in 2022.
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:
Citation number one: Based on observation of the laboratory, review of validation studies and patient test reports, review of the laboratory procedure manual, document request, interview with the laboratory supervisor, and review of an email communication, the laboratory failed to follow its' own policy for assessing testing personnel competency for use of the new MedTox urine drug screen instrument in 2020 with approximately 1,593 patients reported since testing began. The findings include: 1. Observation of the laboratory on 06/22/22 revealed the MedTox instrument in use for patient testing for qualitative urine drug screen patient testing. 2. Review of validation studies and the first patient reported (104710) revealed patient testing for the new urine drug screen instrument began on 06/24/20. 3. Review of the laboratory's competency evaluation policy revealed that when test methods or instrumentation changes testing personnel will be re-evaluated for competency. 4. Request for training and competency assessments performed before the use of the MedTox instrument revealed no records were available for any of the testing personnel. 5. Interview with the laboratory supervisor on 06/23/22 at 12:50 pm confirmed the laboratory failed to follow the testing personnel competency assessment policy when it did not perform training or competency assessment for testing personnel when the new urine drug screen platform was implemented on 06/24/20. 6. Review of an email communication received on 06/24/22 from the laboratory supervisor revealed approximately 1,593 urine drug screen tests have been performed since patient testing began on 06/24/20.
Citation number two: Based on observation of the laboratory, review of the laboratory procedure manual, testing personnel competencies, and interview with the laboratory supervisor, the laboratory failed to follow the written procedure to include all six competency assessment elements each time competency was performed and failed to ensure the policy was in compliance with the regulations at Subpart M when it did not require competency assessments to be performed by personnel as defined in subpart M of the Clinical Laboratory Improvement Amendments (CLIA) regulations, i.e. the technical consultant, technical supervisor or general supervisor in 2020 and 2021. 1. Observation of the laboratory on 06/22/22 at 9 am revealed the following test systems in use for patient testing: Serology Section to include: Sophia-Waived Flu, Waived Strep, Moderate Respiratory Syntial Virus (RSV), Abbott ID Now-Waived SARS-COV-2, Cardinal Health waived urine pregnancy, moderate serum pregnancy, MedTox qualitative urine drug screen-moderately complex. Chemistry Section to include the Dimension EXL 200 for chemistry, toxicology, endocrinology - moderately complex and iStat for performance of Arterial blood gas, Basic Chemistry tests (sodium, potassium, chloride, glucose, creatinine, blood urea nitrogen, ionized calcium and total carbon dioxide-moderately complex, and troponin. Hematology Section to include the Diesse Minicube Erythrocyte Sedimentation Rate (ESR)-moderately complex, Sysmex XS 1000i for complete blood count and differential - moderately complex and Manual Differential-High complexity. Urinalysis section to include the Roche Cobas U411 Dipstick Urinalysis-moderately complex, Serum Ketone-qualitative-moderately complex, Microscope for wet prep and urine microscopics-moderately complex Coagulation Section to include: Sysmex Ca 660 for Prothrombin Time (PT), partial thromboplastin time (PTT), and D-Dimer- moderately complex. Microbiology section to include: BACT/Alert 3D for blood culture pathogen detection- moderately complex, Clostridium Difficile-moderate complexity, Fecal white blood cell--moderate, Beckman Coulter Hemocult for stool occult blood test-waived. Transfusion Medicine section to include ABO, Rh, Antibody Detection and

Compatibility testing (both moderate and high complexity) 2. Review of the laboratory's testing personnel competency assessment evaluation policy revealed that: "Six criteria are required to establish competency:A) Successful Performance of Quality Control, B) Direct Observation/Demonstrated Skill, C)Problem Solving / Troubleshooting, D) Proficiency / Blind Sample Testing, E) Maintenance, F) Recording / Reporting of Results." "Technical Staff will be evaluated by the Lab Supervisor or competent peer. If test methods or instrumentation changes, the laboratory staff will be re-evaluated to include skills in the areas of change." 3. Review of testing personnel competency assessments for the year 2020 and 2021 revealed the following: 2020 Competencies: Testing person #2-Competency for the Siemens EXL200 chemistry platform did not include all six elements, performed by a person other than the technical consultant. Competency assessment for the manual differential did not include all six required elements. Competency assessment for the microbiology section performed by a person other than the technical consultant /technical supervisor/general supervisor, competency assessment for gram stain, fecal white blood cell and clostridium difficile did not include all six required elements. Evaluation for blood bank testing performed by a person other than the technical consultant/technical supervisor/general supervisor. Competency assessment for the mono test did not include all six required elements. Competency for microscopic testing did not include all six elements as required in the procedure. Testing person #3-Competency for fecal white blood cell did not include all six elements. Testing person #4-Competency for fecal wbc and clostridium difficile did not include all six elements. Competency performed by a person other than the technical consultant /technical supervisor/general supervisor. Competency for the chemistry section performed by a person other than the technical consultant. Competency assessment for the coagulation section did not include all six required elements. Competency assessment for the blood bank section performed by a person other than the technical consultant/technical supervisor/general supervisor. Testing person #5-Competency for fecal white blood cell did not include all six elements, evaluation for blood bank testing done by a person other than the technical consultant/technical supervisor /general supervisor, evaluation for microbiology section done by a person other than the technical consultant/technical supervisor/general supervisor. Testing person #8--Competencies were not completed for the microbiology section and blood bank section of the laboratory. 2021 competency assessments Testing person #2-Competency for the serology section did not all six required elements. Competency for the urinalysis section did not include all six required elements. Competency for the microbiology section did not include all six elements for any of the tests. Competency for the chemistry section did not include all six required elements. Competency for the coagulation section did not include all six elements. Competency for hematology section did not include all six elements. Competency for the blood bank section did not include all six elements. Testing person #3-Competency for the coagulation section did not include all six required elements. Competency for the hematology section did not include all six required elements for any of the test systems, Competency for the urinalysis section did not clearly define how competency was assessed for any of the test systems. Competency for the microbiology section did not include all six required elements for any of the test systems. Competency for the serology section did not include all six required elements for any of the test systems. Competency for the chemistry section did not include all six required elements. Transfusion medicine section did not include all six required elements. Testing person #4-Competency for the microbiology section did not include all six elements for any of the test systems. Competency for the serology section did not include all six elements for any of the test systems. competency for the hematology section did not include all six elements for any of the test systems. Competency for the urinalysis

	section did not include all six elements for any of the test systems. Competency for the coagulation section did not include all six required elements for any of the test systems. Competency for the transfusion medicine section did not include all six required elements. Competency for the chemistry section did not include all six required elements for any of the test systems. Testing person #5-- Competency for the serology section did not define how competency was assessed. Competency for the microbiology section did not define how competency was assessed. Competency for the hematology section did not define how competency was assessed. Urinalysis section did not define how competency was assessed. Competency for the transfusion services section did not define how competency was assessed. Competency for the coagulation section did not define how competency was assessed. Competency for the chemistry section did not define how competency was assessed. Testing person #6--Coagulation section--Did not include all six required elements. Microbiology section-Did not include all six required elements for any of the test systems. Serology section did not include all six elements for nay of the test systems. Urinalysis section did not include all six elements for any of the test systems. Hematology section did not include all six elements for any of the test systems. Transfusion services section-did not include all six required elements for any of the test systems. Chemistry section did not include all six required elements for any of the test systems. Testing person #8--Urinalysis section- Competency did not include all six elements for any of the test systems and competency was not performed by the technical consultant. Competency for the serology section did not include all six required elements for the pregnancy test, the Sophia flu, strep and RSV, the MedTox urine drug screen instrument, the Abbott ID now SARS-COV 2 test, and the Mono test. Competency for the chemistry section did not include how competency was assessed and it was not performed by the technical consultant. Competency for the hematology section did not include all six elements for any of the test systems in use and it was not performed by the technical consultant/technical supervisor/general supervisor. Competency for th microbiology section did not include all six elements as required by the procedure and was not performed by the technical consultant. Competency for the coagulation section did not include all six elements for either test system and was not performed by the technical consultant. Transfusion services section competency was not performed using all six elements and was not performed by the technical consultant/technical supervisor /general supervisor. Testing person #9-Competency for the serology section of the lab did not define how competency was assessed. Competency for the Broche Cobias U 411, and Microscopic procedures did not define how competency was assessed. Serum acetone competency did not include the six required elements. Competency for the hematology did not define how competency was assessed for the Sysmex XS1000iC, the Streck ESR, and the manual differential competency did not include all six elements. Competency for the chemistry section did not include the six required elements. Testing person #11- Serology competency did not include all six elements for any of the test systems. Urinalysis section did not include all six elements for any of the test systems. Microbiology section did not include all six elements for any of the test systems. Hematology section did not include all six elements for any of the test systems. Chemistry section-did not include all six elements for any of the test systems. Coagulation section competency did not include all six required elements. Transfusion services section did not include all six required elements. 3. Interview with the laboratory supervisor on 06/23/20 at 4:45 pm confirmed the laboratory failed to follow the established testing personnel policies and failed to ensure its' current policy was in compliance with the regulations when it did not require competency to be performed by the personnel defined in subpart M of the CLIA regulations.
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: Based on review of the laboratory manual, review of new test method validations and patient test records, interview with the laboratory supervisor, and email communication with the laboratory supervisor, the laboratory failed to follow its' own policy for performing reference range studies when new test methods were implemented in 2021 for the Iron, Iron Binding Capacity, Troponin (High-Sensitivity), and whole blood glucose analytes with patient testing performed. The findings include: 1. Review of the laboratory procedure titled "Testing Performance Verification" revealed that each new test method would be evaluated for reference range using 20 patients samples. The procedure also included a "New Testing Checklist" to be used when a new test is implemented. 2. Review of new test methods validation and patient test records revealed the following: Iron/Iron Binding Capacity implemented for patient testing on 07/27/21 (patient 129203), no reference range study performed. Troponin High Sensitivity implemented for patient testing on 10/21 /21 (patient 55669), reference range study did not include 20 patients. Whole Blood Glucose implemented for patient testing on 12/01/21 (patient 111710). 3. Interview with the laboratory supervisor on 06/23/22 at 12:50 pm confirmed the laboratory failed to follow the new test method verification procedure in 2021 for the Iron, Iron Binding Capacity, Troponin High Sensitivity method, and the whole blood glucose analytes. 4. Review of an email communication from the laboratory supervisor on 06 /24/22 regarding the number of tests performed since each test was implemented revealed the following: 471 iron tests 385 iron binding capacity tests 1,182 troponin tests 4,620 whole blood glucose
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, Complete Blood Count (CBC) quality control (QC) records, and interviews with the laboratory supervisor, the laboratory failed to have a process in place to identify the person performing CBC QC from 01/01/20 to the date of the survey on 06/23/22. The findings include: 1. Observation of the laboratory on 06/22/22 at 9 am revealed the Sysmex XS 1000i in use for patient CBC testing. 2. Review of patient number 300383 revealed testing performed for CBC on 03/09/22. 3. Review of laboratory quality control records revealed the identity of the person who performed the quality control on 03/09/22 could not be determined. Further review determined the identity of the

	person who performed CBC QC had not been documented from 01/01/20 to the date of survey on 06/23/22. 4. Interview with the laboratory supervisor on 06/23/22 at 4:45 pm confirmed the laboratory did not have a process in place to identify the person who performed CBC quality control testing on 03/09/22. She further confirmed during a phone interview on 06/29/22 at 9:30 am that there was no process in place to determine the identity of the person who performed CBC quality control from 01/01 /20 to the date of the survey on 06/23/22.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of iStat Arterial Blood Gas (ABG) instrument printouts, final patient test reports and interview with the laboratory supervisor, the final patient test report failed to include units of measure for partial pressure of Carbon Dioxide (pCO2) and partial pressure of Oxygen (pO2) for patient 2878 reported on 05/27/21. The findings include: 1. Observation of the laboratory on 06/22/22 at 9 am revealed the Abbott iStat instrument in use for performing arterial blood gas testing. 2. Review of iStat ABG instrument printouts revealed pCO2 and pO2 units of measure are in mmHg. 3. Review of the final patient test report for patient 2878 reported on 05/27/21 revealed no units of measure were present for pCO2 and pO2. 4. Interview with the laboratory supervisor on 06/23/22 at 4:45 pm confirmed the final patient test failed to include units of measure for pCO2 and pO2 for patient 2878 reported on 05/27/21.