Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0358291	(X3) Date Survey Completed 10/25/2018
Name of Provider or Supplier Lutheran Hospital Of Indiana	**Street Address, City, State** 7950 West Jefferson Boulevard, Fort Wayne, IN	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain records documenting repeat testing of critical/panic values for one of one chemistry analyzer (Vista 1500) and one of twenty eight (patient #21) test reports reviewed for two years. Findings Include: 1) Review of policy titled, "Critical Values", approved by the laboratory director on 3/27/17, indicated any potassium level greater than 6.0 mmol/L (mmol/L=millimoles per liter) is considered "critical". The policy also indicated all critical values must be repeated. 2) Review of test report for patient #21 indicated a critical/panic value for potassium of "8.0 P mmol/L" (P=panic value). The test was performed on 8/16/17 at 0634 hrs on the Vista 1500 analyzer, serial number=SNDV3111321. A repeat test was not available for review. Annual test volume amount for potassium equals 10,541. 3) In interview on 10/23/18 at 12:40 pm, SP-5 confirmed panic values are repeated, but are purged out of their system approximately every six months.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue

	for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to retain one of twenty patients (patient #39) reviewed, histopathology slides and pathology specimen blocks for ten years. Findings include: 1. Review of policy/procedure titled "Retention Guidelines", effective date 06/14/2004, glass slide preparations and paraffin blocks for surgical pathology, will be maintained for ten years. 2. In interview on 10-24-18 at 11:33 AM, upon request for histopathology slides and pathology specimen blocks for patient #39 (testing date September 17, 2015), SP33 and SP34 indicated they could not be located.
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 document review and interview, the laboratory personnel failed to follow ten of ten Bacteriology procedures for ten of ten patients reviewed (patients #1-#10) with results in the specialty of Bacteriology. Finding(s) included: Body Fluid Culture Procedure 1. The policy, "Body Fluid Culture Procedure", reviewed by the laboratory director (LD) 11/10/17, read: "The specimen is stable for 1 hour at room temperature. Due to the difficulty in obtaining body fluids, specimens received after the 1 hour time will be accepted, but a disclaimer will be noted in the computer stating: specimen delayed in transport, therefore, results may be compromised. Inoculate blood agar plate (BAP) and chocolate (CHOC) with 2 or 3 drops of specimen. Incubate BAP and CHOC plates at 35-37 degrees Centigrade (C) in carbon dioxide (CO2) incubator. The plates are examined initially after 12-18 hours of incubation and negative plates are examined daily for 72 hours before discarding." 2. Review of patient #1's medical record (7/14/18), tested for body fluids, (total body fluid tests for 2017: 6134) revealed: a. The specimen was collected at 2:00 p.m. and received at 4:04 p.m. There was no disclaimer noted in the computer stating, "Specimen delayed in transport, therefore, results may be compromised." b. There was no documentation the specimen had been inoculated onto BAP or CHOC agar c. There was no documentation these plates had been incubated between 35-37 degrees C in a CO2 incubator d. There was no documentation the plates were examined between 12-18 hours of incubation. 3. In interview on 10/22/18 at 10:30 a.m., SP#3 acknowledged that the medical record for patient #1, including patient worksheet logs and patient final reports, did not contain documentation of a disclaimer statement, BAP or CHOC agar inoculation, incubation in a CO2 incubator and that there was no means of determining the plates had been initially examined between 12-18 hours of incubation. Blood Culture Procedure 1. The policy, "Blood Cultures", reviewed by the LD 11/19/17, in "Section IV. Positive Culture Work-Up" read: "Subculture aerobic bottle to one properly labeled 5% sheep blood and one chocolate agar plate. Subculture anaerobic bottles to two properly labeled 5% sheep blood and one chocolate agar plate. Incubate 5% sheep blood and the chocolate plate in the appropriate rack in the 35+/- CO2 incubator. Incubate one 5% sheep blood in an anaerobe bag or jar containing the appropriate anaerobic pouch

or pack from anaerobic bottle. Place in the appropriate bin in the 35 +/- non-CO2 incubator. Gram stain the slide." 2. Review of patient #2 (10/03/18) medical record, tested for blood culture, (total blood culture tests for 2017: 27,414) revealed: a. There was no documentation the positive aerobic bottle had been subcultured to a 5% sheep blood and chocolate agar plate. b. There was no documentation the positive anaerobic bottle had been inoculated onto 5% sheep blood or a chocolate agar plate. c. There was no documentation a 5% sheep blood inoculated from the positive anaerobic bottle had been placed into an anaerobic bag or jar. d. There was no documentation the plates had then been placed in the non-CO2 incubator. 3. In interview on 10/22/18 at 11:20 a.m., SP#3 acknowledged that the medical record for patient #2 did not contain documentation of the following: the positive aerobic and anaerobic bottles were subcultured to 5% sheep blood and chocolate agar plates, a blood plate from the anaerobic bottle had been placed in an anaerobic bag or jar, and the plates had been placed in the non-CO2 incubator. Lower Respiratory Cultures 1. The policy, "Lower Respiratory Cultures, including Sputum, Tracheal, Bronchial Washing, Bronchial Alveolar Lavage (Including Quantitative BAL), and Lung Aspirate", reviewed by LD 11/10/17, read: "Plate specimens onto BAP, MAC (MacConkey), CHOC. Incubate all plates in CO2 at 35 degrees C. Examine all plates after 24 hours of incubation." 2. Review of patient #3's medical record (9/20/18), tested as a lower respiratory culture, (total lower respiratory culture tests for 2017: 2421) revealed: a. There was no documentation the specimen had been plated onto BAP, MAC or CHOC plates. b. There was no documentation the specimen had been incubated in a CO2 incubator at 35 degrees C. c. There was no indication that these plates had been examined after 24 hours of incubation. 3. In interview on 10/22/18 at 11:55 a.m., SP#3 acknowledged that the medical record for patient #2 did not contain documentation the specimen had been plated onto a BAP, MAC or CHOC plate, the plates were incubated in a CO2 incubator at 35 degrees C, and initially examined after 24 hours of incubation. Upper Respiratory Cultures 1. The policy, "Upper Respiratory Cultures including: Throat, Nose, Nasopharyngeal, Sinus, and Epiglottis", reviewed by LD 11/10/17, read: "For routine throats, nose and nasopharyngeal cultures a BAP and a CNA (Columbia Naladixic Acid) plate are set up. Incubate CNA anaerobically." 2. Review of patient #4's medical record (10/02/18), tested as a upper respiratory culture, (total upper respiratory culture tests for 2017: 2648) revealed: a. There was no documentation the specimen had been plated onto BAP or CNA plates. b. There was no documentation the CNA plate had been anaerobically incubated. 3. In interview on 10/22/18 at 12:30 p.m., SP#3 acknowledged that the medical record for patient #4 did not contain documentation the specimen had been plated onto a BAP or CNA plate or that the CNA plate had been incubated anaerobically. Urine Culture 1. The policy, "Urine Culture", reviewed by LD 11/10/17, read: "Inoculate the 5% Sheep Blood plate and the MacConkey plate for all urine cultures. Incubate aerobically in the CO2 incubator at 35 degrees C for 18 to 24 hours." 2. Review of patient #5's medical record (10/02/18), tested as a urine culture, (total urine culture tests for 2017: 23,024) revealed: There was no documentation the specimen had been inoculated onto a 5% Sheep Blood and a MacConkey plate and incubated in the CO2 incubator for 18 to 24 hours. 3. In interview on 10/22/18 at 1:30 p.m., SP#3 acknowledged that the medical record for patient #5 did not contain documentation that the specimen was plated onto a BAP or MacConkey plate and that the plates had been incubated aerobically in a CO2 incubator for between 18 to 24 hours. Urogenital Culture 1. The policy, "Urogenital Culture including GC, GC Culture only", reviewed by LD 11/10/17, read: "All specimens are inoculated to Thayer-Martin, Chocolate, Blood agar, CNA agar, and MAC. Incubate plates at 35-37 degrees C in CO2 overnight." 2. Review of patient #6's medical record (5/07/18), tested as a Urogenital culture, (total Urogenital culture tests for 2017: (324) revealed: a. There was no documentation the specimen had been

inoculated onto Thayer-Martin, Chocolate, Blood agar, CNA agar, and a MacConkey plate. b. There was no documentation the plates had been incubated at 35-37 degrees C in a CO2 incubator. 3. In interview on 10/22/18 at 2:30 p.m., SP#3 acknowledged that the medical record for patient #6 did not contain documentation the specimen had been inoculated onto a Thayer-Martin, Chocolate, Blood agar, CNA agar or MacConkey plate and that the plates had been incubated 35-37 degrees C. in a CO2 incubator overnight. Stool Culture 1. The policy, "Stool Culture", reviewed by LD 11 /10/16, read: "Inoculate a GN (gram negative) Broth for Shigatoxin testing. Place 50 uL (microliter) of unpreserved specimen, or 1175 uL of preserved specimen into an 8 ml (microliter) GN broth tube. Incubate with caps loose at 35-39 degrees C in ambient air for 16-24 hours. Place Campy plate in campy pouch bag and immediately add Campy gas generating sachet, a dampened 4 x 4 cotton gauze, and an extra 'buddy' plate (if only sealing one patient plate). Seal the bag and incubate at 42 degrees C. Campy plates are to be incubated 48 hours at 42 degrees before opening the bag. All other plates are incubated at 35-37 degrees C in the non-CO2 incubator." 2. Review of patient #7's medical record (7/24/18), tested as a Stool culture, (total Stool culture tests for 2017: 1908) revealed, there was no documentation for the following: a. The specimen had been inoculated into a GN Broth tube. b. Incubated with its cap loose between 35-39 degrees C. in ambient air for 16-24 hours. c. The Campy plate had been placed in a campy pouch bag, a gas generating sachet added with gauze and that the bag had been sealed and incubated at 42 degrees C. d. The Campy plate had been incubated 48 hours at 42 degree prior to opening the bag. e. All other plates were incubated at 35-37 degrees C in a non-CO2 incubator. 3. In interview on 10/23/18 at 9: 00 a.m., SP#3 acknowledged that the medical record for patient #7 did not contain documentation the specimen had been inoculated into GN broth, incubated for 16-24 hours, that the Campy plate had been placed in a campy pouch bag and incubated 48 hours at 42 degrees, and that all the other plates had been incubated in a non-CO2 incubator. Anaerobic Culture 1. The policy, "Anaerobic Culture", reviewed by LD 11 /10/17, read: "The specimens for anaerobic culture should be plated in pre-reduced ANA II (anaerobic blood agar) and KV (Karromycin Vancomycin) by rolling transport swab over one-sixth of the media and streaking for isolation. The plates should be incubated at 35-37 degrees C for at least 48 hours in the anaerobic jars or bags before examining. Incubate the Choc plate overnight in CO2." 2. Review of patient #8's medical record (10/17/18), tested as an anaerobic culture, (total anaerobic culture tests for 2017: 4929) revealed: a. There was no documentation the specimen had been plated in a pre-reduced ANA II or CV media and that the plates were incubated at 35-37 degrees C for least 48 hours in anaerobic jars or bags. b. There was no documentation the chocolate plate had been incubated overnight in a CO2 incubator. 3. In interview on 10/23/18 at 10:10 a.m., SP#3 acknowledged that the medical record for patient #8 did not contain documentation the specimen had been plated in a pre-reduced ANA II or CV media, placed in an incubator for at least 48 hours in anaerobic jars or bags or that the chocolate plate had been incubated overnight in a CO2 incubator. Wound Tissue Culture 1. The policy, "Wound Tissue Culture", reviewed by LD 11/10/17, read: "Incubate BAP, CNA, MacConkey, and CHOC plates at 35-37 degrees C in CO2 incubator. If an anaerobic culture is also desired, anaerobic plates should be set up in an anaerobic environment following similar inoculation procedure. The plates are examined initially after 12-18 hours of incubation." 2. Review of patient #9's medical record (10/04/18), tested as a wound tissue culture, (total wound tissue culture tests for 2017: 6133) revealed there was no documentation the specimen had been inoculated onto a BAP, CNA, MacConkey and CHOC plates and incubated in a CO2 incubator. 3. In interview on 10/23/18 at 10:10 a.m., SP#3 acknowledged that the medical record for patient #9 did not contain documentation the specimen had been inoculated onto a BAP, CNA, MacConkey or

	CHOC plates and placed in a CO2 incubator. Fungus Culture 1. The policy, "Fungus Culture", reviewed 11/06/17, read: "For fungus culture setup, consult the microbiology setup guide located near the setup bench. Setup Guide MHI: Brain Heart Infusion Agar SAB: Sabouraud Dexrose Agar SAB Dex (Emmmons) with Chloramphenicol CAND: CHROMagar Candida Plates are placed in the non-CO2 fungus incubator at 30 degrees C with the agar side down. Fungus cultures are to be evaluated weekly. 2. Review of patient #10's medical record (8/10/18), tested as a fungal culture, (total fungal culture tests for 2017: 2687) revealed: a. There was no documentation the specimen had been incubated onto a MHI, SAB, SAB Dex, or CAND b. There was no documentation to indicate these plates were placed in a non-CO2 fungus incubator at 30 degrees C and evaluated weekly. 3. In interview on 10/23 /18 at 11:30 a.m., SP#3 acknowledged that the medical record for patient #10 did not contain documentation the specimen had been inoculated onto MHI, SAB, SAB Dex, or CAND and that these plates had been placed in a non-CO2 fungus incubator at 30 degrees C and evaluated weekly.
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 observation, document review and staff interview, the laboratory failed to verify the precision of one of one immunohematology analyzer prior to reporting patient test results. Findings include: 1. On 10-22-2018 at 11:08 AM, during tour of the immunohematology department in the laboratory an Ortho Vision immunohematology analyzer was observed to be in use. 2. Review of performance specifications for the Ortho Vision immunohematology analyzer, signed by the laboratory director on 7-27-2018, indicated the laboratory did not perform precision. 3. Review of patient records indicated the following patients had ABO/Rh testing on the Ortho Vision: Patient Date Time _____ 40 9-7-2018 1053 42 9-18-2018 1940 44 10-1-2018 1139 55 10-24-2018 1304 56 9-15-2018 0352 57 9-16-2018 0627 58 9-21-2018 1209 59 9-26-2018 0941 60 9-27-2018 1612 61 9-27-2018 2042 62 9-28-2018 0055 63 9-28-2018 0259 64 9-29-2018 2332 65 9-30-2018 1533 66 9-30-2018 1925 67 9-25-2018 2328 4. In interview on 10-22-2018 at 11:08 AM, SP15 indicated the laboratory began using the Ortho Vision immunohematology analyzer for patient testing on August 10, 2018. 5. In interview on 10-23-2018 at 10:10 AM, SP26 indicated the performance specifications for the Ortho Vision immunohematology analyzer only included a comparison study with the Ortho ProVue analyzer. SP26 further indicated all testing for the comparison study was performed on the same date, none of the testing was duplicated, the testing was not performed during multiple shifts, and there were two operators who performed the comparison study. SP 26 also indicated the laboratory was performing ABO/Rh testing and antibody screens on the Ortho Vision immunohematology analyzer. 6. In interview on 10-23-2018 at 10:40 AM, SP23 indicated the laboratory had 17 testing personnel in the immunohematology department, operating the Ortho Vision

	immunohematology analyzer. On 10-25-2018 at 10:32 AM, SP23 further indicated the laboratory had performed approximately 1890 patient tests on the Ortho Vision immunohematology analyzer between August 10, 2018 and October 22, 2018.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to verify and support running monthly external quality controls for four of four iStat assays/cartridges reviewed. Findings Include: 1) Review of the Individualized Quality Control Plan (IQCP) Risk Assessment for the following iStat assays did not include data demonstrating that the stability of the test system, as it is used in the laboratory, supports the running of quality control monthly; Sodium (Chem 8+cartridge), PT /INR, HcG, PCO2. (PT/INR=Prothrombin Time/International Normalized Ratio, HcG=Human Chorionic Gonadotropin, PCO2=Carbon Dioxide Partial Pressure). 2) Medical record review indicated the following patients had Sodium (Chem 8+cartridge), PT/INR, HcG, and PCO2 testing performed with controls being run monthly and having no verification data to support this frequency in their IQCP: a. PT#31/10-20-17/Sodium=143 mmol/L b. PT#32/8-26-18/Sodium=143 mmol/L c. PT#35/4-10-17/PT/INR=13.6 seconds d. PT#36/10-2-18/PT/INR=11.2 seconds e. PT#33/6-26-17/HcG=less than 5 IU/L (International Units per Liter) f. PT#34/8-9-18 /HcG=less than 5 IU/L g. PT#37/7-11-17/PCO2=48.2 mm/Hg (millimeters per mercury) h. PT#38/5-3-18/PCO2=44.6 mm/Hg Annual test volume amounts for the above assays at the time of survey equals 4841. 3) In interview on 10/23/18 at 1:50 pm, SP-14 confirmed the above patients had testing performed on the iStat analyzers with controls run monthly and did not have performance specification verification data to support a frequency other than two different levels of quality control being run every day of patient testing.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to follow their policy regarding calibration frequency procedures for one of one urine microscopic analyzer

	reviewed (Sysmex UF-1000i, Serial number=13034). Findings Include: 1) Review of policy titled, "AUTOMATED MICROSCOPIC URINALYSIS ON THE SYSMEX UF-1000i," approved by the laboratory director on 11/14/17, read on page 15 under section "Calibration," "Initial calibration is performed during installation and verified bi-annually during preventive maintenance (PM) by the Sysmex Field Service Representative (FSR)..." 2) Review of Sysmex Field Service report for 2017 titled, "Maintenance Protocol System on page 8 under section 12, read "...Perform Sensitivities, Total Count and Conductivity Calibration..." and check marked on the form as "OK." The report indicated a completion date of 10/27/17 with no other service dates indicated for 2017. 3) Record review indicated patient #29 had a urine microscopic performed on the Sysmex UF-1000i (serial #13034) on 8/17/17. Annual test volume amount for urine microscopics equals 7,177. 4) In interview on 10/24/18 at 2:50 pm, SP-5 confirmed only one calibration was performed on the Sysmex UF-1000i (serial #13034) in 2017 and that they failed to follow their policy for biannual frequency.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interview, three of three individuals reviewed, who were performing competency on employees performing moderate complex testing, failed to qualify as a technical consultant. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii)

	Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on document review and interview, three of three individuals reviewed, who were performing competencies on employees performing moderately complex testing, failed to qualify as a technical consultant. Findings include: 1. Review of policy /procedure titled: "Competency Assessment," policy number unknown, last reviewed and signed by the laboratory director on 3-27-2017, read: "Direct observation assessment will be conducted by associates deemed expert. Expert is defined by the following...Associate Degree in Lab Science with at least at least twenty-four (24) semester hours of medical technology courses..." 2. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 10-23-2018, indicated SP51, SP52, SP53, SP55, SP56, SP57, and SP58 were testing personnel perfoming moderately complex testing. 3. Review of personnel records indicated the following: a. SP56 had an "Associated of Applied Science" in "Nursing Technology" and had performed the "Direct Observation of Patient Test" and assessed the "Test Performance" on 9-7-2018 for the competency for SP55. b. SP57 had an "Associate of Science in Nursing" and had performed the "Direct Observation of Patient Test" and had assessed the "Test Performance" on 8-26-2018 for the competency for SP51. c. SP58 had an "Associate of Science in Nursing" had performed the "Direct Observation of Patient Test" and had assessed the Test Performance" on 10-18-2018 for the competency for SP52. SP58 had also performed the assessment of "Problem Solving Skills" on 10-17-2018 for the competency for SP52. SP58 performed the "Direct Observation of Patient Test" and assessed the "Test Performance" and "Problem Solving Skills" on 10-3-218 for the competency for SP53. 4. In interview on 10-24-2018 at 12:30 PM, SP14 acknowledged SP56, SP57, and SP58 had associate degrees and had performed part of the competency assessments for the above mentioned testing personnel.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to specify, in

	writing, the responsibilities and duties of four of four testing personnel reviewed performing moderately complex point of care testing. Findings include: 1. Review of personnel records indicated the following: a. The laboratory director's responsibilities did not include specifying, in writing, the responsibilities and duties of each testing personnel. b. SP51, Registered Nurse (RN), SP52 (RN), SP53 (RN), and SP55 (RN) did not have duties and responsibilities specified in writing by the laboratory director to perform moderately complex point of care testing. 2. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 10-23-2018, indicated SP51, SP52, SP53, and SP55 were testing personnel performing moderately complex testing. 3. Review of patient records indicated the following: a. SP52 performed a moderately complex protime (PT) and an international normalized ratio (INR) test, using the Abbott "I-STAT" analyzer, on patient 99 (6-21-2018) and patient 100 (10-5-2018). b. SP55 performed moderately complex arterial blood gasses (ABG), using the Abbott "I-STAT" analyzer, on patient 101 (10-24-2018) and patient 102 (10-23-2018). 4. In interview on 10-24-2018 at 10:10 AM, SP5 indicated there were not written duties and responsibilities for RN's performing moderately complex point of care testing. SP5 further indicated there were approximately 600 RN's performing moderately complex point of care testing on the I-STAT analyzer.