Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473136	05/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hillcrest Hospital Claremore	1202 N Muskogee Pl, Claremore, OK	

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
D0000	The survey was performed on 05/07,08,09,10/18 The findings were reviewed with Regional Medical Laboratory support person, Regional Medical Laboratory executive director, testing person #9, testing person #11, director of quality, laboratory manager /technical consultant, human resource director, chief nursing officer/chief operating officer and chief executive officer of the hospital, during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1409; D6033: Technical Consultant 493.1201; D5002: Bacteriology 493.1441; D6076: High Complexity Laboratory Director
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager/technical consultant, the laboratory failed to ensure the requirements were met for the subspecialty of Bacteriology. Findings include: (1) The laboratory failed to have written policies and procedures for assessing employee competency. Refer to D5209; (2) The laboratory failed to check each batch of blood culture media for its ability to support growth. Refer to D5477.
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 a review of policies and procedures and interview with the laboratory manager/technical consultant, the laboratory failed to have written policies and procedures for assessing employee competency. Findings include: (1) On the first day of the survey, the surveyor reviewed the laboratory's policies and procedures. A policy that explained how employees were assessed for competency could not be located; (2) The surveyor asked the laboratory manager/technical consultant if a competency policy was available for review. The laboratory manager/technical consultant stated a policy had not been written. NOTE: For non-waived testing, the regulations require initial training, a semiannual evaluation during the first year, and an annual evaluation thereafter for each testing person for ensuring competency. The policy/procedure for evaluating competency must include, but is not limited to: *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing *Monitoring the recording and reporting of test results *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records *Direct observation of performance of instrument maintenance and function checks *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples *Assessment of problem solving skills
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with laboratory manager/technical consultant, the laboratory failed to follow the manufacturer's instructions for method verification between a current and new coagulation analyzer. Findings include: (1) On the first day of the survey, the laboratory manager/technical consultant stated to the surveyor that the laboratory began using the Sysmex CA-660 on 08/04/17 for the following: (a) D-dimer testing (2) On the third day of the survey, the surveyor reviewed the manufacturer's instructions for method verification that defined the relationship between a previous system (Sysmex CA 560) and a new system; (a) "Best results for method verification studies require a minimum of 40 patient samples (20 normal and 20 abnormal). Range should be from below to substantially above the expected reference range. Studies should be performed over several days." (3) The surveyor reviewed the method verification records and identified the laboratory only used 33 patients instead of 40 patients as required by the manufacturer; (4) The surveyor reviewed the records with the laboratory manager/technical consultant who stated 40 patients had not been used to perform the method verification.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager/technical consultant, the laboratory failed to ensure analyzers were stored as required by the manufacturer. Findings include: HEMATOLOGY DEPARTMENT (1) On the first day of the survey, the laboratory manager/technical consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex 1000i analyzer; (b) PT (Prothrombin Time)/INR (International Normalized Ratio), PTT (Partial Prothromboplastin Time) and D-Dimer testing was performed on the Sysmex CA-600 Series analyzer; (c) (ESR) Erythrocyte Sedimentation Rate testing was performed on the Excyte Mini Automated EST analyzer. (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzers. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory humidity records from January 2018 through March 2018 which verified the humidity readings were less than 30% for 3 of 3 months as follows: (a) January - 8 of 31 humidity readings were documented as less than 30% (days 1,2,3,4,5,16,17,18); (b) February 2018 - 1 of 28 humidity readings was documented as less than 30% (day 13); (c) March - 2 of 31 humidity readings were documented as less than 30% (days 8,14). (4) The surveyor reviewed the records with the laboratory manager/technical consultant who stated the humidity of the laboratory had been maintained below 30% as indicated above. PATHOLOGY DEPARTMENT (1) On the first day of the survey, the laboratory manager/technical consultant stated the following to the surveyor: (a) Frozen tissue samples were processed using the Thermo Scientific Cryostat Microm HM500. (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative maximum humidity of 60%; (3) The surveyor reviewed records from January 2018 through March 2018 which verified humidity readings were not documented. There was no evidence that the humidity of the laboratory had been monitored; (4) The surveyor asked the laboratory manager /technical consultant if the humidity in the Pathology department was being monitored. The laboratory manager/technical consultant stated it was not monitored.
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 a review of records, policy and procedures, and interview with the laboratory manager/technical consultant, the laboratory failed to verify the reportable range for a new test method. Findings include: (1) At the beginning of the survey, the laboratory manager/technical consultant stated to the surveyor the Excyte Mini-ESR analyzer was approved to perform ESR (Erythrocyte Sedimentation Rate) testing on 10 /31/17; (2) The surveyor then reviewed the installation records for the analyzer. The records indicated the laboratory had verified a reportable range of 2-74 mm/hr, however, they were utilizing the manufacturer's AMR (Analytical Measurement Range) of 1-140 mm/hr as the reportable range for ESR testing, as reflected in the laboratory policy and procedure; (3) The surveyor asked the laboratory manager /technical consultant if there was additional documentation to prove the reportable range had been verified beyond 2-74 mm/hr. The laboratory manager/technical consultant stated the reportable range had not been verified beyond 2-74 mm/hr.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager/technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: BECKMAN COULTER AU 480 (1) At the beginning of the survey, the laboratory manager/technical consultant stated the following to the surveyor: (a) *CMP, Ammonia, Amylase, Cholesterol, Creatine Kinase, HDL (High Density Lipoprotein), Triglycerides, Ethyl Alcohol, Iron, Lactate, Lipase, Magnesium, Uric Acid, UIBC (Urine Iron Binding Capacity), Acetaminophen, Carbamazepine, Direct Bilirubin, Gentamicin, Phenytoin, Salicylic Acid, Vancomycin and Valproic Acid testing were performed on the Beckman Coulter AU 480 analyzer, denoted as Righty; (b) *CMP, Ammonia, Amylase, Cholesterol, Creatine Kinase, HDL (High Density Lipoprotein), Triglycerides, Ethyl Alcohol, Iron, Lactate, Lipase, Magnesium, Uric Acid, UIBC (Urine Iron Binding Capacity), Acetaminophen, Carbamazepine, Direct Bilirubin, Gentamicin, Phenytoin, Salicylic Acid, Vancomycin,Valproic Acid,*Urine Drug Screen, CSF (Cerebral Spinal Fluid) Glucose, CSF Total Protein testing were performed on the Beckman Coulter AU 480 analyzer, denoted as Lefty; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Weekly (i) Clean the Sample Probe and Mix Bars (ii) Perform a W2 (iii) Perform a Photocal (iv) Clean the Pre-dilution Bottle (v) Enhanced Cleaning of the ISE Electrode Line (3) The surveyor then reviewed maintenance records for both analyzers for 16 months (January 2017 through April 2018). The following weekly maintenance had not performed as follows: (a) Righty (i) Perform a W2, Perform a Photocal, Clean the Pre-dilution Bottle not documented as performed between: (aa) 09/04/17 and 09/16/17 (ii) Perform an Enhanced Cleaning of the ISE Electrode Line not documented as performed between: (aa) 02/20/17 and 03 /06/17 (bb) 05/31/17 and 06/12/17 (cc) 06/12/17 and 06/25/17 (dd) 08/07/17 and 08/20 /17 (ee) 08/20/17 and 09/04/17 (ff) 09/04/17 and 09/16/17 (b) Lefty (i) Perform a W2,

Perform a Photocal, Clean the Pre-dilution Bottle not documented as performed between: (aa) 09/05/17 and 09/17/17 (ii) Perform an Enhanced Cleaning of the ISE Electrode Line not documented as performed between: (aa) 01/27/17 and 02/08/17 (bb) 08/07/17 and 08/20/17 (4) The surveyor reviewed the records with the laboratory manager/technical consultant, who stated the maintenance had not been documented as performed as required. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein *UDS - Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine, Ecstasy, Methadone, Opiate, Phencyclidine BECKMAN COULTER ACCESS 2 (1) At the beginning of the survey, the laboratory manager/technical consultant stated the following to the surveyor: (a) BNP (B-Type Natriuretic Peptide), Beta HCG (Human Chorionic Gonadatropin), CKMB, Troponin I and TSH (Thyroid Stimulating Hormone) testing were performed on the Beckman Coulter Access 2 analyzer. (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Weekly - System Check Results (i) Washed RLU/%CV (ii) Substrate RLU /%CV (iii) Unwashed RLU/%CV (iv) Wash Efficiency PPM (v) Substrate Ratio (vi) Substrate: Washed Ratio (b) Weekly - Maintenance (i) Clean Instrument Exterior (ii) Inspect Liquid Waste Bottle (iii) Check Waste Filter Bottle (iv) Inspect/Clean Primary Probe (v) Replace/Clean Aspirate Probes (vi) Run Daily Maintenance (vii) Run System Check (3) The surveyor then reviewed maintenance records for the analyzers for 16 months (January 2017 through April 2018). The following was identified: (a) Weekly - System Check Results had not been documented as performed between: (i) 07/17/17 and 08/03/17 (ii) 08/20/17 and 09/01/17 (b) Weekly - Maintenance had not documented as performed between: (i) 08/20/17 and 09/01/17 (4) The surveyor reviewed the records with the laboratory manager/technical consultant, who stated the maintenance had not been documented as performed as required. SYSMEX XS 1000i (1) At the beginning of the survey, the laboratory manager/technical consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing were performed on the Sysmex XS 1000i analyzer. (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Weekly (i) Power Down IPU (ii) Perform Rinse (1,2000 cycles) (3) The surveyor then reviewed maintenance records for the analyzer for 16 months (January 2017 through April 2018). The following was identified: (a) Weekly - System Check Results had not been documented as performed between: (i) 05/11/17 and 05/25/17 (4) The surveyor reviewed the records with the laboratory manager/technical consultant, who stated the maintenance had not been documented as performed as required. SIEMENS CLINITEK ADVANTUS (1) At the beginning of the survey, the laboratory manager/technical consultant stated the following to the surveyor: (a) Routine Urinalysis testing was performed on the Clinitek Advantus analyzer. (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for daily maintenance were as follows: (a) Daily (i) Clean Push Bar (ii) Clean Fixed Platform (iii) Clean Moving Table (iv) Clean Strip Holddown Plate (v) Clean Display Screen (3) The surveyor then reviewed maintenance records for the analyzers for 16 months (January 2017 through April 2018). The following was identified: (a) Daily maintenance had not been documented as performed between: (i) 12/09/17 and 12/11 /17 (ii) 12/24/17 and 12/26/17 (iii) 01/20/18 and 01/22/18 (iv) 02/16/18 and 02/18/18 (4) The surveyor reviewed the records with the laboratory manager/technical consultant, who stated the maintenance had not been documented as performed as

	required. NOTE: D5429 was cited on the recertification survey performed on 04/12, 13,14/16
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 a review of records and interview with the laboratory manager/technical consultant, the laboratory failed to perform a negative and positive control each day of patient Serum HCG (Human Chorionic Gonadotropin) screen testing. Findings include: SERUM QUALITATIVE PREGNANCY TEST (1) On the first day of the survey, the laboratory manager/technical consultant stated to the surveyor the laboratory performed HCG screen testing using the Quidel HCG Combo test kit (a non-waived test kit); (2) On the second day of the survey, the surveyor reviewed records of patient testing from June 2017 through March 2018 and identified the following during 1 of the 10 months: (a) Negative and positive quality control testing had not been perform for 1 day of the review period: (a) Testing performed on 05/10 /17 (3) The surveyor reviewed the records with the laboratory manager/technical consultant, who believed the control testing had been performed, but had not been documented. IMMUNOHEMATOLOGY (1) On the first day of the survey, the laboratory manager/technical consultant stated to the surveyor the laboratory performed ABO/Rh and Antibody Screen testing using the Ortho MTS Gel System. (2) On the fourth day of the survey, the surveyor reviewed records of patient testing from January 2017 through May 2017 and identified the following during 3 of the 5 months: (a) Negative and positive quality control testing had not been perform for 3 days of the review period: (i) Testing performed on 02/24/17 (ii) Testing performed on 04/01/17 (iii) Testing performed on 05/12/17 (3) The surveyor reviewed the records with the laboratory manager/technical consultant, who believed the control testing had been performed, but had not been documented.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant, the laboratory failed to check each batch of blood culture media for its ability to support growth. Findings include: (1) At the beginning of the survey, the

	laboratory manager/technical consultant stated the following to the surveyor: (a) Automated microbial detection was performed using the bioMerieux BackT/Alert 3D system; (b) A gram stain was performed and reported on any positive growth; (c) Culture workup sent to the reference laboratory. (2) On the third day of the survey, the surveyor asked the laboratory manager/technical consultant if quality control (QC) checks (the ability to support growth or no growth) were performed on each batch of blood culture media, received into the laboratory from March 2018 through May 2018. The laboratory manager/technical consultant stated QC testing had not been performed. The surveyor then asked the laboratory manager/technical consultant if an IQCP (Individualized Quality Control Plan) had been developed for each type of blood culture media used in the laboratory. The supervisor stated an IQCP had not been developed. Therefore, the surveyor determined QC checks must be performed on each batch of blood culture media received, as appropriate; (4) Examples of patient testing using the media were: (a) Blood Culture Media: (i) Patient #1 - Verified on 03 /07/18 (ii) Patient #2 - Verified on 03/09/18 (iii) Patient #3 - Verified on 03/11/18 (iv) Patient #4 - Verified on 03/13/18 (v) Patient #5 - Verified on 03/16/18 (vi) Patient #6 - Verified on 03/21/18 (vii) Patient #7 - Verified on 03/29/18 (viii) Patient #8 - Verified on 04/01/18 (ix) Patient #9 - Verified on 04/03/18 (x) Patient #10 - Verified on 04/05/18 (xi) Patient #11 - Verified on 04/08/18 (xii) Patient #12 - Verified on 04 /16/18 (xiii) Patient #13 - Verified on 04/18/18 (xiv) Patient #14 - Verified on 04/24 /18 (xv) Patient #15 - Verified on 04/30/18 (xvi) Patient #16 - Verified on 05/06/18 (xvii) Patient #17 - Verified on 05/07/18 (xviii) Patient #18 - Verified on 05/08/18 (xix) Patient #19 - Verified on 05/08/18
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 a review of patient test reports and interview with the laboratory manager /technical consultant, the laboratory failed to ensure patient test reports included the name of the laboratory. Findings include: (1) On the fourth day of the survey, the surveyor reviewed 2 patient test reports as follows: (a) Report #1 - ABO/Rh and Antibody Screen testing was performed with the results reported on 04/01/18; (b) Report #2 - Cord Blood testing was performed with the results reported on 02/24/18. (2) The surveyor identified that the name of the laboratory on the reports was "Hillcrest Hospital Claremore", which did not match the name on the CLIA certificate. The name on the CLIA certificate was "Regional Medical Lab-Hillcrest Hospital Claremore"; (3) The surveyor reviewed the reports with the laboratory manager/technical consultant, who stated the name on the reports did not match the name on the CLIA certificate.
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 a review of records and interview with the laboratory manager/technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individuals who performed the duties and responsibilities of the technical consultant, met the qualifications. 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 a review of records and interview with the laboratory manager/technical consultant, the technical consultant failed to ensure the individuals who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings

	include: (1) On the first day of the survey, the surveyor reviewed records for testing persons performing moderate complexity testing in 2016, 2017 and 2018. The records verified the evaluations had been performed by individuals who did not meet the regulatory qualification requirements of the technical consultant: (a) Bleeding Time - 9 of 9 testing persons (i) Laboratory manager/technical consultant (aa) The 05/26/16 annual evaluation had been performed by testing person #11 (this person had earned an associate degree) (bb) The 05/19/17 annual evaluation had been performed by testing person #11 (ii) Testing Person #1 (aa) The 05/06/16 semi-annual evaluation had been performed by testing person #11 (bb) The 04/10/17 annual evaluation had been performed by testing person #11 (iii) Testing Person #2 (aa) The 03/01/18 semi-annual evaluation had been performed by testing person #5 (this person had earned a high school diploma) (iv) Testing Person #3 (aa) The 05/23/16 annual evaluation had been performed by testing person #12 (this person had earned an associate degree) (bb) The 04/13/17 annual evaluation had been performed by testing person #9 (this person had earned an associate degree) (v) Testing Person #4 (aa) The 03/09/18 annual evaluation had been performed by testing person #6 (this person had earned a high school degree) (vi) Testing Person #6 (aa) The 04/13/17 annual evaluation had been performed by testing person #11 (vii) Testing Person #11 (aa) The 05/06/16 annual evaluation had been performed by previous testing person #1 (this person had earned an associate degree) (bb) The 04/17/17 annual evaluation had been performed by previous testing person #2 (this person had earned an associate degree) (viii) Testing Person #12 (aa) The 05/03/16 semi-annual evaluation had been performed by testing person #11 (bb) The 04/18/17 annual evaluation had been performed by previous testing person #2 (ix) Testing Person #17 (aa) The 05/22/16 annual evaluation had been performed by previous testing person #3 (this person had earned an associate degree) (bb) The 05/26/17 annual evaluation had been performed by previous testing person #4 (this person had earned an associate degree) (b) Moderate Complexity Testing (i.e. Routine Chemistry performed on the Beckman Coulter AU480, Microscopic Urinalysis, Wet Prep Analysis, CBC (Complete Blood Count) performed on the Sysmex XS1000i) - 4 of 4 testing persons (i) Testing Person #1 (aa) The 05/03/16 annual evaluation had been performed by testing person #11 (this person had earned an associate degree) (bb) The 04/07/17 annual evaluation had been performed by testing person #11 (ii) Testing Person #11 (aa) The 05/03/16 annual evaluation had been performed by pervious testing person #1 (this person had earned an associate degree) (bb) The 04/17/17 annual evaluation had been performed by previous testing person #2 (this person had earned an associate degree) (iii) Testing Person #12 (aa) The 05/03/16 annual evaluation had been performed by testing person #11 (bb) The 04/18/17 annual evaluation had been performed by previous testing person #2 (iv) Testing Person #17 (aa) The 05/16/16 annual evaluation had been performed by previous testing person #3 (this person had earned an associate degree) (bb) The 05/26/17 annual evaluation had been performed by previous testing person #4 (this person had earned an associate degree) (2) The surveyor explained to the laboratory manager/technical consultant that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures and interview with laboratory manager/technical consultant, the laboratory director failed to provide overall management and direction for high complexity testing. Findings include: (1) The laboratory director failed to ensure that quality control programs were established and maintained. Refer to D6093; (2) The laboratory director failed to ensure policies and procedures were established for monitoring the competency of testing persons. Refer to D6103.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 a review of records and interview with the laboratory manager/technical consultant, the laboratory director failed to ensure that quality control programs were established and maintained. Findings include: (1) The laboratory director failed to ensure each batch of blood culture media was checked for its ability to support growth. Refer to D5477.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, and interview with the laboratory manager/technical consultant, the laboratory director failed to ensure policies and procedures were established for monitoring the competency of testing persons. Findings include: (1) The laboratory director failed to ensure the laboratory had written policies and procedures for assessing employee competency. Refer to D5209.