Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0979467	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Avala	67252 Industry Lane, Covington, LA	

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	A Validation Survey was performed at Avala, CLIA ID # 19D0979467 on February 3, 2020 through February 4, 2020. Avala was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1215 CONDITION: Hematology 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a current contract with The Blood Center. Findings: 1. In interview on February 3, 2020 at 9:47 am,Technical Consultant 2 stated the laboratory transfuses blood only. Technical Consultant 2 further stated the laboratory receives the blood from The Blood Center of New Orleans, who performs the type and screen. 2. Review of the laboratory's "Addendum to Agreement For Provision of Compatibility Testing Services" for The Blood Center revealed the following: "The Blood Center is extending its original agreement terms through December 31, 2019." 3. In interview on February 4, 2020 at 1:45 pm, Technical Consultant 2 stated she was unaware the contract with The Blood Center had expired.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains

	blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure continuous temperature monitoring of the blood bank refrigerator. Findings: 1. Review of the 2018 and 2019 circular temperature charts for the blood bank refrigerators revealed the temperature was not recorded for the following four (4) dates: Refrigerator 1: January 2, 2018 from 12:00 am to 8:00am January 8, 2018 from 8:00 am to 12:00am May 29, 2018 from 12:00 am to 7:00 am June 4, 2018 from 8:30 am to June 5, 2018 at 12:00am Refrigerator 2: January 2, 2018 from 12:00 am to 8: 00am January 8, 2018 from 8:00 am to 12:00am May 29, 2018 from 12:00 am to 7:00 am June 4, 2018 from 8:30 am to June 5, 2018 at 12:00am 2. In interview on February 4, 2020 at 8:57 am, Technical Consultant 2 stated the gaps on the circular temperature charts were due to the chart removed late due to the weekend. Technical Consultant 2 confirmed the laboratory did not document cause of the gaps for the identified dates.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing for the specialty of Hematology. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to follow their procedure for Complete Blood Count (CBC) flags. Refer to D5401 II. 3. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 4. The laboratory failed to have procedure for Complete Blood Counts (CBC) signed by the Laboratory Director. Refer to D5407. 5. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer to D5411 II. 6. The laboratory failed to have complete reference range studies for Coagulation testing. Refer to D5421.
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: I. Based on record review and interview with personnel, the laboratory failed to establish complete procedures for testing personnel competency assessments. Findings: 1. Review of the laboratory's "Laboratory Competencies/Inservices" policy

	revealed the laboratory did not include the frequency (initial training, semi-annual, and annual assessments thereafter). 2. Further review of the "Laboratory Competencies /Inservices" policy and assessment forms revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. In interview on February 3, 2020 at 10:00 am, the Technical Consultant stated she plans on updating the competency forms. The Technical Consultant 2 confirmed the laboratory's competency assessment policy did not include the identified information. II. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for Technical Consultant were complete. Findings: 1. Review of the laboratory's " Laboratory Competencies/Inservices" policy revealed the laboratory did not include competency assessment criteria and frequency of performance for personnel serving as the Technical Consultant. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the Laboratory Director and Technical Consultant 2 serve as Technical Consultants. 3. Review of personnel records for Technical Consultant 2 revealed the Laboratory Director did not perform a competency assessment for her duties as Technical Consultant. 4. In interview on February 3, 2020 at 9:47 am, Technical Consultant 2 confirmed the Laboratory Director did not perform a competency assessment for her duties as Technical Consultant.
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: I. Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's electronic policy and procedure manual revealed the following procedures were not included: a) Flag Policy for Complete Blood Counts (CBC) b) Manual INR calculation including frequency 2. In interview on February 3, 2020 at 12:51 pm, Technical Consultant 2 stated the flag policy for CBC's was not included in the laboratory's policy manual . Technical Consultant 2 confirmed the laboratory's electronic manual did not include the identified policies. II. Based on record review and interview with personnel, the laboratory failed to follow their procedure for Complete Blood Count (CBC) flags. Findings: 1. Review of the laboratory's "Sysmex XNL 430 Procedure" revealed the following: a)"Review results in IPU to determine whether repeat or reflex testing is required b) "There are different methods for handling samples with platelet clumping or 'platelet satellitism'. These methods include vortexing of the original sample and reanalyzing or adding amikacin to the

	original sample and reanalyzing. Laboratories should define and validate the method (s) used by their facility." 2. Review of the laboratory's "Flags and Rule Comments" for "PLT Flags" revealed the following: a) "Remix and rerun sample, report if no flag b) If flag is still present , check specimen for clots and redraw if indicated c) If not clot present and results are consistent with history, result final" 3. Review of random selection of patients with CBC testing in October 2019 revealed the following patient was not retested: October 17, 2019: Patient 10059562 : Instrument Flags: "# 75 : Make smear and scan PLT IP Message: PLT Clumps?" 4. In interview on February 3, 2020, Technical Consultant 2 confirmed the laboratory did not repeat the identified patient with the platelet flag.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not include detailed instructions for the following: a) Step-by-step detailed instructions for procedure performance of Platelet Poor Plasma Study b) Quality Control: to include but not limited to: Establishment of means and ranges of quality control material; who is to monitor and how changes are to be made, data used for establishment/reestablishment, correct means and ranges available to testing personnel, acceptability criteria, frequency, and how to address flags on quality control material c) Corrective Action to take for quality control failures to include, but not limited to, specific actions to be taken, when patient assessment is necessary and how to assess such patients. d) Reference range determination for Prothrombin /International Normalized Ratio (PT/INR) testing, to include detailed instructions, donor requirements, and frequency 2. In interview on February 3, 2020 at 12:51 pm, Technical Consultant 2 confirmed the laboratory's electronic manual did not include the identified policies.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have procedure for Complete Blood Counts (CBC) signed by the Laboratory Director. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy/procedure addressing CBC flags. 2. Technical Consultant 2 gave surveyor on February 3, 2020 at 12:51 pm the "Flags and Rule Comments" procedure. 3. Review of the "Flags and Rule Comments" procedure revealed no documentation of the Laboratory Director's approval/signature. 4. In interview on February 3, 2020 at 12:51 pm, Technical Consultant 2 stated the identified procedure was not included in the laboratory's policy manual . Technical Consultant 2 confirmed the Laboratory Director did not sign the identified procedure for CBC flags.
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: I. Based on observation, record review, and interview with personnel, the laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Findings 1. Observation by surveyor during laboratory tour on February 3, 2020 at 9:10 am revealed the laboratory utilizes the following BacT/ALERT blood culture bottles: BacT/ Alert FN Plus, Lot # 4053876, Lot # 4053984 BacT/Alert FA Plus, Lot # 4053976, Lot # 4054362 BacT/ Alert PF Plus, Lot # 4053262 2. Review of the BacT/ALERT package insert revealed "Prior to use, visually inspect all BacT/ALERT bottles for evidence of damage or contamination. A bottle should not be used if any evidence of leakage is notes. Do not use a bottle which contains media exhibiting turbidity, excess gas pressure, or a yellow sensor; these are signs of possible contamination." 3. In interview on February 3, 2020 at 9:15 am, Technical Consultant 2 stated an area hospital supplies the laboratory with the blood culture bottles. Technical Consultant 2 further stated the laboratory does not document visual inspection of the blood culture bottles. II. Based on observation, record review, and interview with personnel, the laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Findings: 1. Observation by surveyor during laboratory tour on February 3, 2020 at 9:10 am revealed the laboratory utilizes the Sysmex CA 600 series for Prothrombin Time (PT)/ International Normalized Ratio (INR) and Partial Thromboplastin Time (PTT). 2. Review of the laboratory's policy/procedure manual did not include guidelines for normal donors for mean PT. 3. Review of the "Siemens Healthcare Diagnostics Sysmex CA-600 Series System Reference Interval" revealed the following donor requirements: a)"Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients) b) Donors

	should not take any medication, including aspirin c) A minimum of 20 donors with a reasonably even distribution of males and females should be included. d) Donors should span the adult age range (NOTE: A separate range should be established for pediatric populations." 4. In interview on February 3, 2020 at 11:32 am, Technical Consultant 2 stated the laboratory began patient testing on the Sysmex CA 600 series on October 29, 2019. 5. Review of the laboratory's performance verification studies for PT revealed the laboratory did not have documentation the 120 donors utilized met normal donor requirements. 6. In interview on February 3, 2020 at 11:35 am, Technical Consultant 2 confirmed the laboratory did not have a policy for reference interval establishment and verification of new lots of thromboplastin. Technical Consultant 2 stated the laboratory did not maintain donor information. Technical Consultant 2 confirmed the laboratory did not have documentation of donor questionnaires or criteria for "normal" donors. 7. Review of the laboratory's test menu revealed the laboratory performs 248 PT/INR tests annually.
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, record review, and interview with personnel, the laboratory failed to have complete reference range studies for Coagulation testing. Findings: 1. Observation by surveyor during laboratory tour on February 3, 2020 at 9:10 am revealed the laboratory utilizes the Sysmex CA 600 series for Prothrombin Time (PT)/ International Normalized Ratio (INR) and Partial Thromboplastin Time (PTT). 2. In interview on February 3, 2020 at 11:32 am, Technical Consultant 2 stated the laboratory began patient testing on the Sysmex CA 600 series on October 29, 2019. 3. Review of the "Siemens Healthcare Diagnostics Sysmex CA-600 Series System Reference Interval" revealed the following donor requirements: a)"Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients) b) Donors should not take any medication, including aspirin c) A minimum of 20 donors with a reasonably even distribution of males and females should be included. d) Donors should span the adult age range (NOTE: A separate range should be established for pediatric populations." 4. Review of the laboratory's Coagulation (PT/ INR and PTT) validation studies for reference range revealed the laboratory did not include documentation "normal" donors were utilized. The laboratory did not maintain donor questionnaires. 5. In interview on February 3, 2020 at 11: 35 am, Technical Consultant 2 stated the laboratory did not maintain donor information. Technical Consultant 2 confirmed the laboratory did not have documentation of donor questionnaires or criteria for "normal" donors. 6. Review of the laboratory's test menu revealed the laboratory performs 248 PT/ INR and 231 PTT tests annually.
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: I. Based on record review and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Findings: 1. In interview on February 3, 2020, Technical Consultant 2 stated external controls for the i-Stat are tested each new lot, shipment and monthly. 2. Review of the laboratory's IQCP documents on February 3, 2020 revealed the laboratory had quality control records to support the stability of the system for 10 days. 3. Review of the laboratory's IQCP documents revealed the laboratory did not include the following: a) In-house data to support the reduction in frequency of external QC to monthly b) Frequency of Quality Assessment Plan 4. In interview on February 4, 2020 at 12:45 pm, Technical Consultant 2 confirmed the laboratory had ten days of QC data for their IQCP. 5. Review of the laboratory's test menu revealed the laboratory performs twenty one (21) blood gas tests annually. II. Based on observation, record review and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for methicillin-resistant Staphylococcus aureus (MRSA) and methicillin susceptible Staphylococcus aureus (MSSA) testing. Findings: 1. Observation by surveyor on February 4, 2020 revealed the laboratory utilizes the Cepheid Gene Xpert for testing of MRSA and MSSA. 2. In interview on February 3, 2020 at 10:50 am, Technical Consultant 2 stated three (3) levels of external controls are tested each new lot /shipment and every thirty (30) days. 3. Review of the laboratory's IQCP documents on revealed the laboratory did not include the following: a) In-house data to support the reduction in frequency of external QC to monthly b) frequency of Quality Assessment Plan 4. In interview on February 3, 2020, Technical Consultant 2 confirmed the laboratory did not have data to support the reduction of frequency of external QC. 5. Review of the laboratory's test menu revealed the laboratory performs 600 MRSA and 600 MSSA tests annually.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic

	system. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to follow their procedure for Complete Blood Count (CBC) flags. Refer to D5401 II. 3. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 4. The laboratory failed to have procedure for Complete Blood Counts (CBC) signed by the Laboratory Director. Refer to D5407. 5. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 6. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer to D5411 II. 7. The laboratory failed to have complete reference range studies for Coagulation testing. Refer to D5421. 8. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445 I. 9. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for methicillin-resistant Staphylococcus aureus (MRSA) and methicillin susceptible Staphylococcus aureus (MSSA) testing. Refer to D5445 II.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met education requirements. Refer to D6029. 6. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031. 8. The Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant. Refer to D6032.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are

	adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to ensure continuous temperature monitoring of the blood bank refrigerator. Refer to D3021. 2. The laboratory failed to follow their procedure for Complete Blood Count (CBC) flags. Refer to D5401 II. 3. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 4. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer to D5411 II.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5445 I and D5445 II.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met education requirements. Refer to D6065.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209 I and D5209 II.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 3. The laboratory failed to have procedure for Complete Blood Counts (CBC) signed by the Laboratory Director. Refer to D5407.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the Laboratory Director and Technical Consultant 2 served as served as Technical Consultants. 2. Review of personnel records for Technical Consultant 2 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant. 3. In interview on February 3, 2020 at 9: 47 am, Technical Consultant 2 confirmed the laboratory did not have documentation of her Technical Consultant responsibilities delegated by the Laboratory Director.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide

	documentation to ensure all testing personnel met education requirements. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure one (1) of six (6) respiratory personnel met the educational qualifications for performing moderate complexity testing. Findings: 1. Review of personnel records on February 3, 2020 revealed the laboratory did not maintain documentation of at least a High School Diploma or equivalent for the following personnel: Respiratory Testing Personnel 6 2. In interview on February 3, 2020 at 10:30 am, Technical Consultant 2 stated the laboratory stated Respiratory Testing Personnel 6 was unable to provide a copy of her education. Technical Consultant 2 confirmed the laboratory did not have documentation of education for the identified personnel.