Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2138973	08/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Olol-North Baton Rouge Clinical Laboratory	5439 Airline Highway, Baton Rouge, 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/Initial Survey was conducted at OLOL-North Baton Rouge Clinical Laboratory-CLIA # 19D2138973 on August 20, 2018 through August 22, 2018. OLOL-North Baton Rouge Clinical Laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing moderatre complexity testing, Laboratory Director
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 observation, record review, and interview with personnel, the laboratory failed to ensure the quarterly blood bank alarm checks registered on the circular temperature charts for one (1) of three (3) quarters reviewed. Findings: 1. Observation by surveyor during laboratory tour on August 20, 2018 revealed the laboratory utilizes a Helmer refrigerator for storage of blood units for emergency release. 2. Review of the laboratory's policy and procedure manual for emergency release of blood products revealed the laboratory performs quarterly high/low alarm checks on the blood bank refrigerator. 3. Review of the 2018 blood bank circular temperature charts revealed the low alarm did not register on the circular chart for the following one (1) of three (3) quarters: 2nd Quarter: May 21, 2018 4. In interview on August 21, 2018 at 6:15 pm, Personnel 17 stated he did not see the low alarm spike on the temperature chart for the 2nd quarter.
D3033	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to maintain raw data for performance verification studies for the Architect instrument. Findings: 1. Review of the laboratory's performance verification studies for the Architect instrument revealed the laboratory performed method comparison (accuracy), precision, reference interval and reportable range (linearity) studies. 2. Further review of the performance verification studies revealed the laboratory did not have the raw data associated with the method comparison and reference interval studies. 3. In interview on August 21, 2018 at 4:25 pm, Personnel 18 stated the laboratory did not have the identified raw data. Personnel 18 stated she contacted the service technician who compiled the submitted data to see if they had a copy of the raw data files. 4. In interview on August 22, 2018, Personnel 18 stated the laboratory was unable to find the identified raw data.
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 record review and interview with personnel, the laboratory failed to follow written policies and procedures to assess competency for seventeen (17) of twenty one (21) Clinical Consultants and Technical Consultants reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following seventeen (17) personal were listed as Clinical Consultants and/or Technical Consultants: Personnel 2 Personnel 3 Personnel 4 Personnel 5 Personnel 6 Personnel 7 Personnel 8 Personnel 9 Personnel 10 Personnel 11 Personnel 12 Personnel 13 Personnel 14 Personnel 15 Personnel 19 Personnel 20 Personnel 21 2. Review of the laboratory's Technical Consultant Competency assessment form revealed the laboratory performs assessments upon hire and every two (2) years thereafter. 3. Review of personnel records for the fifteen (15) identified personnel revealed the competency assessments for the duties of Clinical Consultant and/or Technical Consultant were not performed. 4. In interview on August 20, 2018 at 10:46 am, Personnel 20 stated the Laboratory Director did not perform competency assessments for Technical Consultant duties for Respiratory. 5. In interview on August 20, 2018 at 11:30 am, Personnel 32 stated the main laboratory performs competency assessments for Technical Consultants upon hire and every two (2) years thereafter. In further interview, Personnel 32 stated the laboratory did not perform competency assessments for the Pathologists serving as Clinical Consultants and Technical Consultants. 6. In interview on August 20, 2018 at 12:12 pm, Personnel 21 stated the Laboratory Director did not perform a competency assessment for her duties as Technical Consultant.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure that patient blood samples for Coagulation were centrifuged according to manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on August 20, 2018 revealed the laboratory utilizes Greiner Bio-One Vacuette Sodium Citrate tubes for Coagulation test and a Hettich EBA 200 centrifuge. 2. Review of the Greiner Bio-One Vacuette package insert revealed the centrifugation recommendations for Coagulation tubes, Platelet Poor Plasma (PPP) samples, are "1500-2000 g for 10 minutes." 3. Review of the laboratory's "Annual QC-Coagulation Coagulation Centrifuge Packing Check-Platelet-Poor Plasma" form revealed the laboratory performed a platelet poor plasma check in November 2017 with the centrifuge set at 5693 RPM (2500 g). The laboratory collected three (3) sodium citrate tubes from the same person, spun one tube for three (3) minutes, one for five (5) minutes, and one for ten (10) minutes. The laboratory tested PT and platelet counts on all samples. 4. Review of the user manual of the Hettich EBA 200 centrifuge revealed no specific settings by the manufacturer for centrifugation of tube types or testing. 5. In interview on August 20, 2018 at 9:35 am, Personnel 16 confirmed the laboratory utilizes the Hettich EBA 200 Centrifuge set at 5693 RPM (2500 g) for 5 minutes for coagulation samples.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. 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 within the analytic systems. Findings: 1. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. 2. 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. 3. The laboratory failed to have complete performance verification precision studies. Refer to D5421 I. 4. The laboratory failed to have complete verification studies for coagulation testing prior to patient testing. Refer to D5421 II. 5. The laboratory failed to perform quality control each day of patient testing for HIV

	testing. Refer to D5447 I. 6. The laboratory failed to perform quality control each day of patient testing for Chemistry testing. Refer to D5447 II. 7. The laboratory failed to perform positive and negative controls for Acetone testing for seventeen (17) of forty two (42) days reviewed. Refer to D5449. 8. The laboratory failed to establish to their own means and ranges for Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Refer to D5469. 9. The laboratory failed to perform quality control for two (2) of two (2) cerebrospinal fluid cell counts reviewed. Refer to D5543. 10. The laboratory's Quality Assurance monitors failed to identify and correct quality issues. Refer to D5793.
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 laboratory 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 complete policies for the following: a) 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 and in instrument, acceptability criteria, and how to address flags on quality control material. b) Reference range determination for Prothrombin/International Normalized Ratio (PT/INR) testing c) Back-up method if Respiratory analyzer becomes inoperable 2. In interview on August 21, 2018 at 9:00 am, Personnel 21 stated the laboratory did not have a policy to address flags that appear on quality control material for the Respiratory department. Personnel 21 stated the back-up method for the Respiratory analyzer listed in the policy/procedure manual was not in use as of yet.
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 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 August 20, 2018 revealed the laboratory utilizes the Stago Compact Max for the following analytes: Prothrombin Time (PT)/ International Normalized Ratio (INR), Partial Thromboplastin Time (PTT), Fibrinogen, and D-dimer. 2. In interview on August 20, 2018 at 9:35 am, Personnel 17 stated the laboratory's go-live date for patient testing was November 15, 2017. 3. Review of the laboratory's policy /procedure manual did not include guidelines for normal donors for mean PT. Additionally, the laboratory could not produce the manufacturer requirements of normal donors. 4. Review of the STA Neoplastine package insert under the Reference Interval section revealed the following: "Normal values vary from one laboratory to the next, depending on reagents, instrumentation and technique. So, each laboratory must determine its own expected values based on technique and instrumentation in use." 5. Review of the laboratory's performance verification studies revealed for Neoplastine Lot # 251427, the laboratory tested twenty one (21) donors with a calculated geometric mean of 12.8 seconds. However, the laboratory did not have documentation that donors utilized met normal donor requirements. 6. In interview on August 21, 2018 at 5:00 pm, Personnel 18 stated the laboratory tested twenty one (21) normal patients for PT. Personnel 18 further stated the normal samples used came from the main campus location. Personnel 18 stated the laboratory did not have written criteria for normal donors or document donors meeting any requirements. 7. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 1,039 PT/INR 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: I. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification precision studies. Findings: 1. Observation by surveyor during the laboratory tour on August 20, 2018 revealed the laboratory utilizes the following instruments and/or kits for laboratory testing: a) Two (2) Cell-Dyn Ruby instruments- Complete Blood Counts (CBC) testing b) Alere Leuko EZ-Vue- Lactoferrin Fecal c) Lifesign Status- Infectious Mononucleosis d) Clinitek Advantus- Urinalysis e) Cardinal Health HCG-Combo- Serum HCG 2. In interview on August 20, 2018 at 9:35 am, Personnel 17 stated the laboratory's go-live

	date for patient testing was November 15, 2017. 3. Review of the laboratory's performance verification studies revealed precision studies did not include day-to-day and operator variance. 4. In interview on August 20, 2018 at 4:00 pm, Personnel 18 stated the laboratory only performed simple precision for the Cell-Dyn Ruby instruments. Personnel 18 further stated the verification studies were performed prior to a laboratory inspection of main campus, where they learned that precision studies needed to include, day-to-day and operator variance. 5. In interview on August 22, 2018, Personnel 16 confirmed the laboratory did not include precision studies for Lactoferrin Fecal, Infectious Mononucleosis, Urinalysis and Serum HCG. 6. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs the following annual volumes: CBC-514, Urinalysis-5,312, Lactoferrin Fecal-twelve (12), Serum pregnancy tests-948, and Infectious Mononucleosis-thirty six (36). II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies for coagulation testing prior to patient testing. Findings: 1. Observation during laboratory tour on August 20, 2018 revealed the laboratory utilizes the Stago Compact Max for the following analytes: Prothrombin Time (PT)/ International Normalized Ratio (INR), Partial Thromboplastin Time (PTT), Fibrinogen, and D-dimer. 2. In interview on August 20, 2018 at 9:35 am, Personnel 17 stated the laboratory's go-live date for patient testing was November 15, 2017. 3. Review of the laboratory's performance verification studies revealed the laboratory did not perform the following studies: a) Reportable range studies for the following analytes: Prothrombin Time (PT)/ International Normalized Ratio (INR), Partial Thromboplastin Time (PTT), and Fibrinogen b) Verification of Reference ranges 4. In interview on August 21, 2018 at approximately 5:00 pm, Personnel 18 stated the laboratory utilizes the same reference ranges as main campus for PTT and Fibrinogen. Personnel 18 further stated the laboratory did not perform AMR (analytical measurement range) for Fibrinogen. Personnel 18 further stated she contacted the manufacturer who stated clot based tests did not require AMR. Personnel 18 stated the laboratory performed linearity for D-dimer. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs the following annual volumes: PT/INR-1039, PTT-904, , D-dimer- 247, and Fibrinogen- eight (8) .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on observation, record review, and interview with personnel, the laboratory failed to perform quality control each day of patient testing for HIV testing. Findings: 1. Observation by surveyor during laboratory tour on August 20, 2018 revealed the laboratory utilizes the Abbott Architect system for HIV testing. 2. In interview on August 21, 2018 at 2:29 pm, Personnel 16 stated patient testing on the Architect began on November 15, 2017. 3. Review of the "Laboratory Administration Manual: Laboratory's Quality Control Policy" revealed "QC should be performed as defined prior to beginning patient testing." 4. Review of the laboratory's quality control (QC) records for November 2017, December 2017, and July 2018 revealed the laboratory did not perform quality control prior to patient testing for the following date:

	November 16, 2017 5. Review of patient test records revealed the following four (4) patients were reported on November 16, 2017 without QC performance: Patient 23 Patient 24 Patient 25 Patient 26 6. In further interview on August 21, 2018 at 2:29 pm, Personnel 16 stated she was unsure of what happened on November 16, 2017. Personnel 16 stated the laboratory's Quality Assessment did not catch the identified date. II. Based on observation, record review, and interview with personnel, the laboratory failed to perform quality control each day of patient testing for Chemistry testing. Findings: 1. Observation by surveyor during laboratory tour on August 20, 2018 revealed the laboratory utilizes the Abbott Architect analyzer for Brain Natriuretic Peptide (BNP), CK-MB, Urine Drug Screens (UDS), and Troponin testing. 2. In interview on August 21, 2018 at 2:29 pm, Personnel 16 stated patient testing on the Architect began on November 15, 2017. 3. Review of the "Laboratory Administration Manual: Laboratory's Quality Control Policy" revealed "QC should be performed as defined prior to beginning patient testing." 4. Review of the laboratory's quality control (QC) records for November 2017, December 2017, and July 2018 revealed the laboratory did not perform quality control on November 16, 2017 for the following analytes prior to patient testing: BNP, Ecstasy, Benzodiazepine, and Troponin. 5. Review of patient test records revealed the following thirty nine (39) patients were reported on November 16, 2017 without QC performance: BNP: Patients 27- 35 Ecstasy and Benzodiazepine (UDS): Patients 36-42 Troponin: Patients 43-65 6. In further interview on August 21, 2018 at 2:29 pm, Personnel 16 stated she was unsure of what happened on November 16, 2017. Personnel 16 stated the laboratory's Quality Assessment did not catch the identified date.
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 observation, record review, and interview with personnel, the laboratory failed to perform positive and negative controls for Acetone testing for seventeen (17) of forty two (42) days reviewed. Findings: 1. Observation by surveyor during laboratory tour on August 20, 2018 revealed the laboratory performs serum Acetone testing utilizing K-check tablets. 2. Review of the laboratory's "Serum K-check QC Log" revealed the "Quality control is to be done with each new lot/shipment and each day of patient testing." 3. Review of the "Laboratory Administration Manual: Laboratory's Quality Control Policy" revealed "QC should be performed as defined prior to beginning patient testing." 4. Review of quality control and patient logs from March 5, 2018 through August 20, 2018 revealed the laboratory reported twenty (20) patient results without performance of positive and negative controls on the following seventeen (17) dates: March 24, 2018: Patient 1 March 27, 2018: Patient 2 and Patient 3 April 20, 2018: Patient 4 April 22, 2018: Patient 5 April 23, 2018: Patient 6 May 15, 2018: Patient 7 May 21, 2018: Patient 8 and Patient 9 June 1, 2018: Patient 10 June 3, 2018: Patient 11 June 9, 2018: Patient 12 June 13, 2018: Patient 13 June 16, 2018: Patient 14 June 22, 2018: Patient 15 June 30, 2018: Patient 16 July 13, 2018: Patient

	17 July 15, 2018: Patient 18 August 6, 2018: Patient 19 August 12, 2018: Patient 20 5. In interview on August 22, 2018 at 10:16 am, Personnel 16 stated quality control was not performed for the identified dates.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Findings: 1. Observation by surveyor during laboratory tour on August 20, 2018 revealed the laboratory utilizes the Stago Compact Max for Prothrombin Time (PT)/International Normalized Ratio (INR) testing with STA Coag Controls. 2. In interview on August 21, 2018 at 5:50 pm, Personnel 16 stated the laboratory establishes its own quality control means and ranges for coagulation testing. 3. Review of the manufacturer's package insert for the STA Coag Controls under "Performance Characteristics" revealed "The control values for each of the parameters may vary from one lot another, but are clearly indicated for each lot." 4. Review of the laboratory's 2018 "Corrective Action and Troubleshooting Log" for the Stago Compact revealed the following: a) "7/6: PT Abn consistently out of established ranged high. Reset to package insert range of 31-46. Monitor to establish new means and ranges. (Values have been within insert range, outside of established range for approx. 2 wks. Techs had to rerun several times to get w/in established range + Bias observed)" b) "8/19: Adjusted range for PT Abn using data points from 7/6/18 to 8/19/18" 5. In further interview on August 21, 2018, Personnel 16 stated from July 6, 2018 through August 19, 2018 the labooratory used the manufacturers' abnormal quality control ranges until a new one could be established. 6. Review of the laboratory's quality control records revealed the laboratory utilized STA Coag Controls, Lot # 251601.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform quality control for two (2) of two (2) cerebrospinal fluid cell counts reviewed. Findings: 1. Review of the laboratory's Quality Control (QC) policy revealed for cerebrospinal fluid (CSF) cell counts quality control is performed every eight (8) hours in duplicate. 2. Review of the "Laboratory Administration Manual: Laboratory's Quality Control Policy" revealed "QC should be performed as defined prior to beginning patient testing." 3. Review of the laboratory's quality control records and patient logs from February 2018 through August 20, 2018 revealed the laboratory performed a total of two (2) patients for CSF testing. The laboratory did not document the performance of quality control for the following two (2) patients: April 22, 2018: Patient 21 July 15, 2018: Patient 22 4. In interview on August 22, 2018 at 9:58 am, Personnel 16 stated for the identified dates and patients QC was not performed for CSF testing.
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 Assurance monitors failed to identify and correct quality issues. Findings: 1. Review of the laboratory's "Laboratory Administration Manual" revealed the following monitors: a) Quality Control b) Outreach Registration Accuracy c) Positive Blood Gram Stain Notification TAT for inpatients and outpatients d) Positive Blood Culture Notification TAT for inpatients and outpatients e) Sterlie Body Site Critical Value Notification TAT f) Inpatient Blood Culture Contamination g) Blood Culture Volume Monitoring h) Venipuncture Patient/Specimen Identification i) Barcode Scanner Compliance j) Re-stick TAT k) Stat Turnaround Time l) Critical Value Reporting m) Cell Safe Temperature Monitoring for blood and blood products n) Crossmatch to Transfusion Ratio o) Rejected Blood Bank Specimens p) Wrong Blood in Tube Samples r) POCT Glucose reagent Monitoring s) Blood Component Wastage t) Blood Donor/Distribution 2. Review of the laboratory's policy and procedure manual, quality control records, and patient test records did not identify the following issues: a) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. b) 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. c) The laboratory failed to have complete performance verification precision studies. Refer to D5421 I. d) The laboratory failed to have complete verification studies for coagulation testing prior to patient testing. Refer to D5421 II. e) The laboratory failed to perform quality control each day of patient testing for HIV testing. Refer to D5447 I. f) The laboratory failed to perform quality control each day of patient testing for Chemistry testing. Refer to D5447 II. g) The laboratory failed to perform positive and negative controls for Acetone testing for seventeen (17) of forty two (42) days reviewed. Refer to D5449. h) The laboratory failed to establish to their own means and ranges for Quality Control (QC) material

	utilized for Prothrombin Time (PT) testing. Refer to D5469. i) The laboratory failed to perform quality control for two (2) of two (2) cerebrospinal fluid cell counts reviewed. Refer to D5543.
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 laboratory personnel performed testing as required. Refer to D6014. 3. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
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 laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421 I and D5421 II.
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 laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure that patient blood samples for Coagulation were centrifuged according to manufacturer requirements. Refer to D5311. 2. 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.
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 the quality control was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform quality control each day of patient testing for HIV testing. Refer to D5447 I. 2. The laboratory failed to perform quality control each day of patient testing for Chemistry testing. Refer to D5447 II. 3. The laboratory failed to perform positive and negative controls for Acetone testing for seventeen (17) of forty two (42) days reviewed. Refer to D5449. 4. The laboratory failed to establish to their own means and ranges for Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Refer to D5469. 5. The laboratory failed to perform quality control for two (2) of two (2) cerebrospinal fluid cell counts reviewed. Refer to D5543.
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 were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or

	continuing education to improve skills. Findings: 1. The laboratory failed to follow written policies and procedures to assess competency for seventeen (17) of twenty one (21) Clinical Consultants and Technical Consultants reviewed. Refer to D5209. 2. The Technical Consultants failed to ensure the procedures to assess personnel competency were complete. Refer to D6046.
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 responsible for any aspect of the testing process. Refer to D5403.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure performance specification verification studies were complete. Refer to D5421 I and D5421 II.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform quality control each day of patient testing for HIV testing. Refer to D5447 I. 2. The laboratory failed to perform quality control each day of patient testing for Chemistry testing. Refer to D5447 II. 3. The laboratory failed to perform positive and negative controls for Acetone testing for seventeen (17) of forty two (42) days reviewed . Refer to

	D5449. 4. The laboratory failed to establish to their own means and ranges for Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Refer to D5469. 5. The laboratory failed to perform quality control for two (2) of two (2) cerebrospinal fluid cell counts reviewed. Refer to D5543.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to ensure the procedures to assess personnel competency were complete. Findings: 1. Review of the Respiratory department's policy and procedure manual revealed the laboratory utilizes a competency assessment form that includes at a minimum the six (6) competency assessment criteria required by CLIA. 2. Review of the Respiratory department's personnel records revealed the laboratory did not have documentation of initial orientation and/or semi-annual competency assessments performance at the North Baton Rouge location for the following eight (8) of thirteen (13) personnel reviewed: Personnel 23 Personnel 24 Personnel 25 Personnel 26 Personnel 27 Personnel 29 Personnel 30: semi-annual competency assessment due June 2018 Personnel 31 3. In interview on August 20, 2018 at 10:46 am, Personnel 21 stated for PRN employees the laboratory did not perform competency assessments at the North Baton Rouge campus site. Personnel 21 further stated prior to their recent accreditation organization's inspection, the laboratory thought it was acceptable to use the PRN employees' competency assessments from the main campus location. 4. In further interview on August 20, 2018 at 10:46 am, Personnel 21 stated the laboratory did not perform the semi-annual competency assessment for Personnel 30.