Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2016117	01/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Crescent City Surgical Centre Diagnostics, Llc	3016 Galleria Drive, Metairie, 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 Recertification Survey was performed at Crescent City Surgical Centre , CLIA ID # 19D2016117 on January 14, 2020 through January 15, 2020. Crescent City Surgical Centre 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 moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant
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 Director failed to assess competency for two (2) of three (3) Technical Consultants per their policy. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed three (3) Technical Consultants. 2. Review of the laboratory's "Competency" policy revealed "Documented competency assessment is required for the personnel listed as Technical Consultant/Clinical Consultant on the 209 Form. This competency will be performed annually." 3. Review of personnel records revealed the laboratory did not perform competency assessments in 2019 for the duties of Technical Consultant for Technical Consultant 2 and Technical Consultant 3. 4. In interview on January 14, 2020, Technical 1 confirmed the Laboratory Director did not perform competency assessments for the identified Technical Consultants.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document the review of the performance evaluation for proficiency testing. Findings: 1. Review of the laboratory's "Proficiency Test" policy under "Survey Result Evaluation" section revealed "The Technical Consultant/Laboratory Manager is to perform the survey result evaluation review upon receipt of the result evaluation which includes any corrective action due to sample result failures. Final reviewed results will be approved and signed by the Laboratory Medical Director." 2. Review of the American Proficiency Institute (API) proficiency records for 2018 and 2019 revealed the laboratory did not have documentation of a performance evaluation by the Laboratory Director for the following two (2) events: a) 2019 Immunology /Immunohematology 2nd Event b) 2019 Hematology/Coagulation 2nd Event 3. In interview on January 6, 2020 at 11:30 am, Technical Consultant 1 confirmed the laboratory did not have documentation of the Laboratory Director evaluating the identified proficiency testing results.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform an assessment for Immunology proficiency test (PT) results that scored less than one hundred percent (100 %). Findings: 1. Review of the laboratory's 2019 American Proficiency Institute (API) PT results revealed the laboratory received the following "unacceptable" results: 2019 2nd Event: Sample IMP-06 for Haptoglobin, API grade: "unacceptable"-80% 2. Review of the laboratory's PT records revealed the laboratory did not perform assessments for the "unacceptable" by API PT results. 3. In interview on January 14, 2020 at 11:30, Technical Consultant 1 stated she did not remember doing any further action for the identified PT results.
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 have a complete policy and procedure manual. Refer to D5403. 2.

	The laboratory failed to have the Competency policy approved by the Laboratory Director. Refer to D5407. 3. The laboratory failed to ensure patient samples for arterial blood gases were analyzed within ten (10) minutes of collection per manufacturer requirements. Refer to D5411. 4. The laboratory failed to utilize normal donors for the Excyte Mini reference range studies. Refer to D5421 I. 5. The laboratory failed to utilize normal donors for the Roche Cobas reference range studies. Refer to D5421 II. 6. The laboratory failed to utilize normal donors for the Ortho Vitros 5600 reference range studies. Refer to D5421 III. 7. The laboratory failed to take corrective action when quality control (QC) samples were unacceptable for Chemistry testing. Refer to D5783. 8. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. 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 have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Erythrocyte Sedimentation Rate (ESR): Quality Control: to include but not limited to How to establish ranges for quality control material and/or verification 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. b) Quality Control: to include but not limited to how changes to established ranges are to be made, data used for establishment/reestablishment, correct means and ranges available to testing personnel, and acceptability criteria 2. In interview on January 6, 2020 at 1:10 pm, the laboratory's Compliance personnel confirmed the identified information was not included in the laboratory's 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 the Competency policy approved by the Laboratory Director. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory implemented their "Competency" policy on "4/15/19;" however, there was no documentation of the Laboratory Director approving and signing the policy. 2. In interview on January 15, 2020, Technical Consultant confirmed the Laboratory Director did not approve/sign the "Competency" policy.
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 record review and interview with personnel, the laboratory failed to ensure patient samples for arterial blood gases were analyzed within ten (10) minutes of collection per manufacturer requirements. Findings: 1. Review of the the i-Stat system manual under "Specimen Collection and Handling" revealed "For pH, blood gases, TCO2 and ionized calcium, test within 10 minutes of collection." 2. Review of patient test records for blood gases for 2019 revealed the following one (1) of two (2) patients was not analyzed within ten (10) minutes of collection: Patient 10006026: Collected: June 25, 2019 at 8:35 am, received at 8:59 am, tested at 9:50 am 3. In interview on January 15, 2020, Technical Consultant 1 confirmed the laboratory exceeded the manufacturer requirements for the identified patient.
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 utilize normal donors for the Excyte Mini reference range studies. Findings: 1. Observation by surveyor during the laboratory tour on January 14, 2020 revealed the laboratory utilizes the Excyte Mini for Erythrocyte Sedimentation Rate (ESR) testing. 2. Review of the laboratory's "Instrument Validation"policy under the "Reference Range (Normal Range)" section revealed the following: a) " The laboratory must verify that the manufacturer's reference intervals (reference range or

normal values) are appropriate for the laboratory's population. This may be accomplished by testing an appropriate number of 'normal' donor specimens to verify the manufacturer's claims for normal values." b) "Questionnaire: the Reference Study Questionnaire must be completed and signed prior to collecting the donor specimen. Certain conditions and/or medications will disqualify donors for participation in this study. E.g. if the patient is on thyroid or diabetes medication or has an underlying health issue. Refer to the manufacturer's guidelines to determine if conditions /medications would disqualify a potential donor." 3. Review of the laboratory's "Reference Study Questionnaire" revealed the following "Yes/No" questions: a) "Do you consider yourself to be healthy b) Have you recently been ill, When: c) Details of recent illness d) Are you taking any prescribed or over the counter medications e) Please list all medications f) Do you have a medical condition that requires ongoing treatment; if yes please describe" 4. Review of the "Reference Study Questionnaire" completed by donors revealed the following seven (7) donors did not meet the laboratory's "normal" requirements: Patient 4: Responded "Yes" to "Recently been ill" question Patient 7: Responded "Yes" to "Recently been ill" question Patient 9: Responded "Yes" to "Recently been ill, listed over the counter and prescribed medications, and responded "Yes" to "Having a medical condition that requires ongoing treatment" questions Patient 31: Responded "No" to "Do you consider yourself to be healthy" question Patient 40: Responded " Yes" to "Recently been ill", listed prescribed medications, and responded "Yes" to " Do you have a medical condition that requires ongoing treatment"questions Patient 41: Responded "Yes" to "Recently been ill" and "taking prescribed or over the counter medications" questions Patient 42: Responded "Yes" to " Recently been ill" and "taking prescribed or over the counter medications" questions; no response for "Do you have a medical condition that requires ongoing treatment" 5. In interview on January 14, 2020, the Technical Consultant 1 confirmed the laboratory utilized the identified donors for their reference range study. II. Based on observation, record review, and interview with personnel, the laboratory failed to utilize normal donors for the Roche Cobas reference range studies. Findings: 1. Observation by surveyor during the laboratory tour on January 14, 2020 revealed the laboratory utilizes the Roche Cobas for testing of the following Chemistry and Immunology analytes: FSH, LH, Progesterone, Prolactin, TSH, FT3, FT4, Estradiol, Testosterone, IGF-1, SHBG, hGH, PTH, C-Peptide, Cortisol, Cystatin Cm DHEA, Ferritin, Folate, Haptoglobin, Hemoglobin A!C, Insulin, Iron, UIBC, RF, Vitamin B12, Vitamin D, and Prealbumin. 2. . Review of the laboratory's "Instrument Validation"policy under the "Reference Range (Normal Range)" section revealed the following: a) " The laboratory must verify that the manufacturer's reference intervals (reference range or normal values) are appropriate for the laboratory's population. This may be accomplished by testing an appropriate number of 'normal' donor specimens to verify the manufacturer's claims for normal values." b) "Questionnaire: the Reference Study Questionnaire must be completed and signed prior to collecting the donor specimen. Certain conditions and/or medications will disqualify donors for participation in this study. E.g. if the patient is on thyroid or diabetes medication or has an underlying health issue. Refer to the manufacturer's guidelines to determine if conditions/medications would disqualify a potential donor." 3. Review of the laboratory's "Reference Study Questionnaire" revealed the following "Yes/No" questions: a) "Do you consider yourself to be healthy b) Have you recently been ill, When: c) Details of recent illness d) Are you taking any prescribed or over the counter medications e) Please list all medications f) Do you have a medical condition that requires ongoing treatment; if yes please describe" 4. Review of the "Reference Study Questionnaire" completed by donors revealed the following three (3) donors did not meet the laboratory's "normal" requirements: Corr 44: Responded "Yes" to "Recently been ill", listed over the counter and prescribed medications, and responded "Yes" to

	"Having a medical condition that requires ongoing treatment" questions Corr 53: Responded "No" to "Do you consider yourself healthy", listed over the counter and prescribed medications, and no response to " Do you have a medical condition that requires ongoing treatment" Corr 57: Responded "Yes" to "Recently been ill" and listed over the counter and prescribed medications 5. In interview on January 14, 2020, the Technical Consultant 1 confirmed the laboratory utilized the identified donors for their reference range study. III. Based on observation, record review, and interview with personnel, the laboratory failed to utilize normal donors for the Ortho Vitros 5600 reference range studies. Findings: 1. Observation by surveyor during the laboratory tour on January 14, 2020 revealed the laboratory utilizes the Ortho Vitros 5600 for testing of the following Chemistry analytes: BUN, Creatinine, Sodium, Potassium, Chloride, CO2, Calcium, ALT, AST, Alkaline Phosphatase, Albumin, Total Bilirubin, Direct Bilirubin, Total Protein, Glucose, direct HDL, direct LDL, Cholesterol, Triglycerides, Amylase, Lipase, Magnesium, Phosphorus, PSA, and Uric Acid. 2. . Review of the laboratory's "Instrument Validation"policy under the "Reference Range (Normal Range)" section revealed the following: a) " The laboratory must verify that the manufacturer's reference intervals (reference range or normal values) are appropriate for the laboratory's population. This may be accomplished by testing an appropriate number of 'normal' donor specimens to verify the manufacturer's claims for normal values." b) "Questionnaire: the Reference Study Questionnaire must be completed and signed prior to collecting the donor specimen. Certain conditions and/or medications will disqualify donors for participation in this study. E.g. if the patient is on thyroid or diabetes medication or has an underlying health issue. Refer to the manufacturer's guidelines to determine if conditions /medications would disqualify a potential donor." 3. Review of the laboratory's "Reference Study Questionnaire" revealed the following "Yes/No" questions: a) "Do you consider yourself to be healthy b) Have you recently been ill, When: c) Details of recent illness d) Are you taking any prescribed or over the counter medications e) Please list all medications f) Do you have a medical condition that requires ongoing treatment; if yes please describe" 4. Review of the "Reference Study Questionnaire" completed by donors revealed the following one (1) donor did not meet the laboratory's "normal" requirements: Corr 11: Responded "Yes" to "Recently been ill" and listed over the counter and prescribed medications 5. In interview on January 14, 2020, the Technical Consultant 1 confirmed the laboratory utilized the identified donors for their reference range study.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to take corrective action when quality control (QC) samples were unacceptable for Chemistry testing. Findings: 1. Observation by surveyor during laboratory tour on January 14, 2020 revealed the laboratory utilizes the following controls for Chemistry

	testing: BioRad Multiqual Levels 1 and 3, BioRad Lyphochek Immunoassay Plus 1 and 2, BioRad Liquichek Speciality Immuno 1, 2 and 3, and BioRad Liquichek Diabetes Level 1 and 2. 2. Review of the laboratory's "Quality Control" policy under "Corrective Action" section revealed the following: "When a QC analysis is found to be outside established limits, a systematic effort should be made to resolve the problem. The following steps should be followed for this purpose: i) Perform QC analysis again using the same control material ii) If QC falls in an "out of control" situation again, either repour/reconstitute the QC material or open a new vial of QC material (depending on the quantity remaining in the vial) iii) Calibrate the analyte and /or change reagent. If the test values are still unacceptable, call tech support. Once QC is in range, repeat 3 patients until the last incoming QC incorporating different times of the shift(s). iv) All failed QC is to be recorded on the QC Corrective Action Log v) If patient repeats are necessary lab manager must be notified. Pathologist will make clinical determination if patients were affected." 3. During review of QC records for December 2019 and October 2019 for Chemistry and Immunology tests performed on the Ortho Vitros and Roche Cobas, the surveyor was unable to determine acceptability of QC ranges for October 1, 2019 through October 27, 2019. 4. In interview on January 15, 2020, Technical Consultant 1 stated she was having a difficult time providing documentation of the ranges in use for October 2019 due to range adjustments. 5. Review of QC records for October 28, 2019 through October 31, 2019 revealed the laboratory did not take corrective actions for glucose for the following dates: October 28, 2019: BioRad Mutiqual Level 1: Reported QC result: 56.1, Flag: +3s October 29, 2019: BioRad Multiqual Level 1: Reported QC result: 55.4, Flag: +3s October 30, 2019: BioRad Multiqual Level 1: Reported QC result: 56.9, Flag +3s 6. Review of the patient logs for the identified dates revealed the following patients were reported without corrective action: a) October 28, 2019: total of thirteen (13) patients Patient 10010383 Patient 10010380 Patient 10010378 Patient 10010366 Patient 10010365 Patient 10010364 b) October 29, 2019: total of thirteen (13) patients Patient 10010405 Patient 10010406 Patient 10010407 Patient 10010408 Patient 10010413 Patient 10010414 c) October 30, 2019: total of ten (10) patients Patient 10010426 Patient 10010442 Patient 10010440 Patient 10010439 Patient 10010456 Patient 10010458 7. In interview on January 15, 2020, Technical Consultant 1 confirmed the identified dates had unacceptable QC and patients reported without corrective action.
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. Review of the laboratory's "Quality Assessment" policy revealed the following: "Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical funactioins and all locations/sites where testing is performed. The laboratory will monitor the corrective action(s) taken have prvented recurrence of the original problem. All documents listed on the Overall Month-End QC/QA Review document are gathered

	for review by the Lab Manager/Technical Consultant and presented to the (pahtologist) Lab Director." 2. Observation during laboratory tour and review of the laboratory's policy and procedure manual, quality control records, and patient test records revealed the laboratory's monitors did not identify the following issues: a) The laboratory failed to have a complete policy and procedure manual. Refer to D5403. b) The laboratory failed to have the Competency policy approved by the Laboratory Director. Refer to D5407. c) The laboratory failed to ensure patient samples for arterial blood gases were analyzed within ten (10) minutes of collection per manufacturer requirements. Refer to D5411. d) The laboratory failed to utilize normal donors for the Excyte Mini reference range studies. Refer to D5421 I. e) The laboratory failed to utilize normal donors for the Roche Cobas reference range studies. Refer to D5421 II. f) The laboratory failed to utilize normal donors for the Ortho Vitros 5600 reference range studies. Refer to D5421 III. g) The laboratory failed to take corrective action when quality control (QC) samples were unacceptable for Chemistry testing. Refer to D5783.
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 delegate, in writing, the responsibilities of Technical Consultant for two (2) of three (3) Technical Consultants reviewed. Refer to D6005. 2. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 3. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 4. The Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6018. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 6. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D6024. 7. 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.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

	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 for two (2) of three (3) Technical Consultants reviewed. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed three (3) Technical Consultants. 2. Review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating tasks and responsibilities to Technical Consultant 2 and Technical Consultant 3. 3. In interview on January 14, 2020 at 10:24 am, Technical Consultant 1 confirmed the laboratory did not have documentation of Technical Consultant responsibilities delegated by the Laboratory Directory for Technical Consultant 2 and Technical Consultant 3.
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. Findings: 1. The laboratory failed to utilize normal donors for the Excyte Mini reference range studies. Refer to D5421 I. 2. The laboratory failed to utilize normal donors for the Roche Cobas reference range studies. Refer to D5421 II. 3. The laboratory failed to utilize normal donors for the Ortho Vitros 5600 reference range studies. Refer to D5421 III.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5411.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5211.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. 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 and to identify failures as they occur. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D5783.
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 D5407.
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 observation, record review, and interview with personnel, the Technical Consultants failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultants failed to ensure performance verification reference range studies were complete. Refer to D6040. 3. The Technical Consultants failed to ensure the quality control program was established to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultants failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6043.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5411.
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 verification reference range studies were

	complete. Findings: 1. The laboratory failed to utilize normal donors for the Excyte Mini reference range studies. Refer to D5421 I. 2. The laboratory failed to utilize normal donors for the Roche Cobas reference range studies. Refer to D5421 II. 3. The laboratory failed to utilize normal donors for the Ortho Vitros 5600 reference range studies. Refer to D5421 III.
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 record review and interview with personnel, the Technical Consultants failed to ensure the quality control program was established to assure the quality of laboratory testing. Refer to D5401.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.