Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2154327	09/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gulf States Diagnostics-Acadia, Llc	1305 Crowlwy Rayne Hwy, 2nd Floor, Crowley, 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 CERTIFICATION SURVEY was performed at Provecta Diagnostics - Acadia - LA2229819 on May 8, 2018 through May 11, 2018. Provecta Diagnostics - Acadia was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1240 CONDITION: Preanalytic 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
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 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 system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. The laboratory failed to ensure patient samples received from outside facilities are processed according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable test results for seven (7) of seven (7) patients reviewed. . Refer to D5311. 2. The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 3. The laboratory's Quality Assurance (QA) system failed to monitor, assess, and correct problems identified with the Pre-analytic system. Refer to D5391.

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 patient samples received from outside facilities are processed according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable test results for seven (7) of seven (7) patients reviewed. Findings: 1. Observation by surveyors on May 8, 2018 revealed the laboratory maintained the following analyzers for patient testing: Sysmex XP 300 Hematology Analyzer for Complete Blood Cell count (CBC) includes White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count (PLT), and Automated Differential. VITROS 5600 Chemistry Analyzer for: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (Amy), Apolipoprotein A (ApoA), Apolipoprotein B (ApoB), Aspartate Aminotransferase (AST), Beta Human Chorionic Gonadotropin (BHCG), Total Bilirubin (TBil), Direct Bilirubin (DBil), Blood Urea Nitrogen (BUN), Cortisol (Cort) Creatinine (Creat), Chloride (CL), Calcium (CA), Carbon Dioxide (CO2), Estradiol (E2), Follicle Stimulating Hormone (FSH), Glucose (Glu), Growth Hormone (GH), Hemoglobin A1C (HgbA1C), Homocysteine (Homo), Insulin, Leutinizing Hormone (LH), Osteocalcin (Osteo) Potassium (K), Progesterone (Prog), Prolactin (Prol), Sodium (NA), Total Protein (TP), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Prealbumin (Palb), Rheumatoid Factor (RF), Testosterone (Test). Thyroid Hormone Binding Capacity (THBC),Triglyceride (Trig), Triiodothyronine Uptake (T3U), Free Triiodothyronine (FT3), Total Thyroxine (T4), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Lipase (Lip), Magnesium (Mg), Phosphorous (Phos), Prostate Specific Antigen (PSA), C Reactive Protein (CRP), Iron (Fe)
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Observation by surveyors on May 8, 2018 revealed the laboratory maintained the following analyzers for patient testing: Sysmex XP 300 Hematology Analyzer for Complete Blood Cell count (CBC) includes White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count

	(PLT), and Automated Differential. VITROS 5600 Chemistry Analyzer for: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (Amy), Apolipoprotein A (ApoA), Apolipoprotein B (ApoB), Aspartate Aminotransferase (AST), Beta Human Chorionic Gonadotropin (BHCG), Total Bilirubin (TBil), Direct Bilirubin (DBil), Blood Urea Nitrogen (BUN), Cortisol (Cort) Creatinine (Creat), Chloride (CL), Calcium (CA), Carbon Dioxide (CO2), Estradiol (E2), Follicle Stimulating Hormone (FSH), Glucose (Glu), Growth Hormone (GH), Hemoglobin A1C (HgbA1C), Homocysteine (Homo), Insulin, Leutinizing Hormone (LH), Osteocalcin (Osteo) Potassium (K), Progesterone (Prog), Prolactin (Prol), Sodium (NA), Total Protein (TP), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Prealbumin (Palb), Rheumatoid Factor (RF), Testosterone (Test). Thyroid Hormone Binding Capacity (THBC),Triglyceride (Trig), Triiodothyronine Uptake (T3U), Free Triiodothyronine (FT3), Total Thyroxine (T4), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Lipase (Lip), Magnesium (Mg), Phosphorous (Phos), Prostate Specific Antigen (PSA), C Reactive Protein (CRP), Iron (Fe), Total Iron Binding Capacity (TIBC), Ferritin (Fer), Fo
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems, identified with the preanalytic system for Routine Chemistry. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic system as follows: a) The laboratory failed to ensure patient samples received from outside facilities are processed according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable test results for seven (7) of seven (7) patients reviewed. . Refer to D5311. b) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. Interview with personnel 1 confirmed the above findings.
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 demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the VITROS 5600 Integrated Analyzer. Findings: 1. Observation by surveyor on May 8, 2018 revealed the laboratory maintained the VITROS 5600 Integrated Analyzer for patient testing for: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (Amy), Apolipoprotein A (ApoA), Apolipoprotein B (ApoB), Aspartate Aminotransferase (AST), Beta Human Chorionic Gonadotropin (BHCG), Total Bilirubin (TBil), Direct Bilirubin (DBil), Blood Urea Nitrogen (BUN), Cortisol (Cort) Creatinine (Creat), Chloride (CL), Calcium (CA), Carbon Dioxide (CO2), Estradiol (E2), Follicle Stimulating Hormone (FSH), Glucose (Glu), Growth Hormone (GH), Hemoglobin A1C (HgbA1C), Homocysteine (Homo), Insulin, Leutinizing Hormone (LH), Osteocalcin (Osteo) Potassium (K), Progesterone (Prog), Prolactin (Prol), Sodium (NA), Total Protein (TP), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Prealbumin (Palb), Rheumatoid Factor (RF), Testosterone (Test). Thyroid Hormone Binding Capacity (THBC),Triglyceride (Trig), Triiodothyronine Uptake (T3U), Free Triiodothyronine (FT3), Total Thyroxine (T4), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Lipase (Lip), Magnesium (Mg), Phosphorous (Phos), Prostate Specific Antigen (PSA), C Reactive Protein (CRP), Iron (Fe), Total Iron Binding Capacity (TIBC), Ferritin (Fer), Folate (Fol), Vitamin B12 (B12), Vitamin D (VitD), and Uric Acid (Uric). 2. Review of the Laboratory's Policy and Procedure Manual revealed a "Instrument Implementation" policy and procedure that was effective December 2016. The Instrument Implementation policy revea
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (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 in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the VITROS 5600 Integrated Analyzer. Refer to D5421 I. b) The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the SYSMEX XP 300 Hematology Analyzer. Refer to D5421 II. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that would correct the issues cited above. 3. Interview with personnel 1 on May 11, 2018 confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review, the laboratory failed to include the correct address of the laboratory location where testing was performed on test reports for seven (7) of seven (7) patients reviewed. Findings: 1. Review of Patient Test Reports revealed the address of the laboratory as 1301 Crowley Rayne HWY Crowley, LA 70526. The correct address of the laboratory is 1305 Crowley Rayne HWY Crowley, LA 70526. 2. Review of random selection of Patient Test Reports from April 19, 2018 through May 9, 2018 revealed the laboratory failed to include the correct address of the laboratory on patient final test reports for the following seven (7) patients: Patient 1 was collected on April 19, 2018 at 14:30 PM for CBC, CMP, Amy, HgbA1C, ApoA, ApoB, Cort, C-pep, CRP, DBil, E2, Ferr, Fol, FSH, FT3, FT4, Homo, Insulin, Fe, TIBC, LH, Lipase, Chol, Trig, HDL, LDL, Mg, Phos, Palb, Prog, Prol, RF, TSH, T4, T3U, Uric, B12 and VitD. Patient 2 was collected on April 23, 2018 at 10:30 AM for CBC, CMP, Amy, HgbA1C, ApoA, ApoB, Cort, C-pep, CRP, DBil, E2, Ferr, Fol, FSH, FT3, FT4, Homo, Insulin, Fe, TIBC, LH, Lipase, Chol, Trig, HDL, LDL, Mg, Phos, Palb, Prog, Prol, RF, TSH, T4, T3U, Uric, B12 and VitD. Patient 3 was collected on April 27, 2018 at 8:11 AM for CBC, CMP, Amy, HgbA1C, ApoA, ApoB, Cort, C-pep, CRP, DBil, E2, Ferr, Fol, FSH, FT3, FT4, Homo, Insulin, Fe, TIBC, LH, Lipase, Chol, Trig, HDL, LDL, Mg, Phos, Palb, Prog, Prol, RF, TSH, T4, T3U, Uric, B12 and VitD. Patient 4 was collected on April 30, 2018 at 9:00 AM for CBC, CMP, Amy, HgbA1C, ApoA, ApoB, Cort, C-pep, CRP, DBil, E2, Ferr, Fol, FSH, FT3, FT4, Homo, Insulin, Fe, TIBC, LH, Lipase, Chol, Trig, HDL, LDL, Mg, Phos, Palb, Prog, Prol, RF, TSH, T4, T3U, Uric, B12 and VitD. Patient 5 was collected on April 30, 2018 at 10:35 AM for CBC, CMP, Amy,
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 verification procedures are performed to determine accuracy, precision, reportable and reference ranges for five (5) of five (5) new pieces of equipment and for establishing Quality Control performance specifications for the Biomerieux Biofire Filmarray AnalyzerRefer to D 6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D 6021. 4.

	The Laboratory Director failed to ensure that all personnel have the appropriate education and experience to accurately report patient test results. Refer to D6029. 5. The Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. 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 observations, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for two (2) of two (2) new analyzers. Findings: 1. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the VITROS 5600 Integrated Analyzer. Refer to D5421 I. 2. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the SYSMEX XP 300 Hematolgy Analyzer. Refer to 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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure patient samples received from outside facilities are processed according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable test results for seven (7) of seven (7) patients reviewed. . Refer to D5311. 2. The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 3. The laboratory failed to include the correct address of the laboratory location where testing was performed on test reports for seven (7) of seven (7) patients reviewed. Refer to D5805.
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 laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic and analytic system as follows: a) The laboratory failed to ensure patient samples received from outside facilities are processed according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable test results for seven (7) of seven (7) patients reviewed. . Refer to D5311. b) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. c) The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the VITROS 5600 Integrated Analyzer. Refer to D5421 I. d) The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the SYSMEX XP 300 Hematology Analyzer. Refer to D5421 II. e) The laboratory failed to include the correct address of the laboratory location where testing was performed on test reports for seven (7) of seven (7) patients reviewed. Refer to D5805. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited
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 review of laboratory personnel records and interview with laboratory personnel, the Laboratory Director failed to ensure the Technical Consultant maintained documentation of at least one (1) year of laboratory training or experience in General Immunology, Routine Chemistry, Endocrinology and Hematology. Refer to D6035.

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 provide written job descriptions for all Laboratory Personnel. Findings: 1. Review of FORM 209 provided to the surveyor on May 8, 2018 revealed the laboratory failed to have written job descriptions for the following personnel: a) Laboratory Director a) Clinical Consultant c) Technical Consultant d) Testing Personnel 2. Interview with Personnel 1 on May 11, 2018 confirmed the laboratory failed to have written job descriptions for all Laboratory Personnel.
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 meet the qualifications and provide technical oversight of the laboratory. Findings: 1. The Technical Consultant failed to meet the qualifications for a Technical Consultant of moderate complexity testing. Refer to D6035. 2. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D6036.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory

	training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to meet the qualifications for a Technical Consultant of moderate complexity testing. Findings: 1. Review of Personnel records for the Technical Consultant revealed the laboratory failed to maintain documentation of at least one (1) year laboratory experience in each specialty/subspecialty that the Technical Consultant has oversight. 2. Interview with Personnel 1 on May 10, 2018 confirmed the laboratory failed to maintain documentation of laboratory training or experience in non-waived testing to qualify as the Technical Consultant.
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 observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the FORM CMS 209 submitted to the surveyor on May 8, 2018 revealed that personnel 1 fulfilled the duties for Technical Consultant. 2. Observation, record review and interview with personnel revealed the Technical Consultant failed to address the following problems identified in the laboratory: a) The laboratory failed to ensure patient samples received from outside facilities are processed according to the manufacturer for ensuring the integrity of patient samples for accurate and reliable test results for seven (7) of seven (7) patients reviewed. . Refer to D5311. b) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. c) The laboratory failed to

	demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the VITROS 5600 Integrated Analyzer. Refer to D5421 I. d) The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the SYSMEX XP 300 Hematology Analyzer. Refer to D5421 II. e) The laboratory failed to include the correct address of the laboratory location where testing was performed on test reports for seven (7) of seven (7) patients reviewed. Refer to D5805. 3. Interview with the Technical Consultant on May 11, 2018 confirmed he failed to identify the deficiency cited above.