Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0930808	03/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Crestview Clinical Laboratory, Llc	5 Holland, Ste 209, Irvine, CA	

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
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: On review of the deficiency cited it was noted that a transcription error occurred. This statement should be cited under D2109. Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) for 2018 and 2019 testing results and interview with the laboratory technical supervisor, it was determined that the laboratory failed to participate in the PT first event 2018 (Q1-2018) for Toxicology resulting in a score of zero. The findings included: a. The laboratory received a score of 0% for Q1-2018 in the subspecialty Toxicology. b. The technical supervisor (TS) affirmed 03/04/2020 at 15:00 that the proficiency testing records from AAB as well as patients reports from the year 2018 were not available for review due at the time of the survey (03/04/2020). c. The number of samples tested for lead during Q1-2018 time period is unknown.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.

	The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing policy SOP #CVDL.AN.215 the laboratory must document the handling, preparation, processing, examination, and each step in the testing, reporting, testing failures, and corrective action of results for all proficiency testing samples. The laboratory failed to maintain a copy of all records including; a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing, the attestation statement provided by the PT program signed by the analyst performing the tests and the laboratory director (LD), documentation that proficiency testing samples were tested in the same manner as patient specimens for a minimum of two years from the date of the proficiency testing event. Findings included: a. The laboratory was unable to produce the 2018 and 2019 proficiency testing attestation sheets with the testing personnel signatures and the laboratory director signatures., PT testing records, preventive maintenance, function checks, quality control, calibration and calibration verification, competency of staff, quality assurance, corrective action reports, and patient reports. b. The laboratory could not locate the proficiency testing worksheets, or the results review forms signed off by the laboratory director or designee. c. On March 4, 2020 at 15:00 the laboratory Technical Supervisor (TS) confirmed by interview these findings.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of CMS proficiency testing (PT) records (CMS CASPER Reports 96D entitled "CLIA Application and Survey Summary") for 2018 and 2019 results

	and interview with the technical supervisor (TS), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: a. The laboratory failed to achieve satisfactory proficiency testing performance in Routine Chemistry (D2087 & D2089, D2093 & D2096), Endocrinology (D2100 & 2104), Toxicology (D2011), General Immunology (D2081), Bacteriology (D2025), Syphilis Serology (D2071), Hematology (D2127), and ABO & D (Rho) typing (D2159). b. At the time of the survey 03/04/2020 15:00, documents including PT records, preventive maintenance, function checks, quality control, calibration and calibration verification, competency of staff, quality assurance, and patient reports were NOT available for review from 11/19/2017 to 09/25/19. c. The technical supervisor (TS) 03/04/2020 15: 00 affirmed that the laboratory did not have any documents for review from 11/19 /2017 to 09/25/19. d. According to the "Annual Test Volume of Test Performed" form LAB 167 submitted 09/16/2019, the laboratory tests approximately 75,120 samples annually.
D2025	BACTERIOLOGY CFR(s): 493.823(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) for 2018 and 2019 testing results and interview with the technical supervisor (TS); it was determined that the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program for the Bacteriology subspecialty for the PT third quarter event (Q3-2019) is unsatisfactory performance and results in a score of zero (0). The findings included: a. The American Association of Bioanalysts (AAB) proficiency reported to CMS for Q3-2019 an unsatisfactory score of 0% for Bacteriology for failure to submit results within the time frame specified by the program. b. The technical supervisor affirmed 03/04/2020 at 15:00 that the AAB proficiency testing records as well as patients reports from the year 2019 were not available for review. c. Based on the laboratory's annual test volume declaration Lab 167 submitted 04/04/2020 the laboratory analyzed and reported approximately 650 Bacteriology tests.
D2071	SYPHILIS SEROLOGY CFR(s): 493.835(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) for 2018 and 2019 results and interview with the technical supervisor (TS); it was determined that the laboratory failed to return PT results to the proficiency testing program within the time frame specified by the

	program for the Syphilis Serology subspecialty for the third quarter event (Q3-2019) testing is unsatisfactory performance and results in a score of zero (0). The findings included: a. The American Association of Bioanalysts (AAB) proficiency reported to CMS for Q3-2019 an unsatisfactory score of 0% for Syphilis Serology for failure to submit results within the time frame specified by the program. b. The technical supervisor affirmed 03/04/2020 at 15:00 that the AAB proficiency testing records as well as patients reports from the year 2019 were not available for review. c. The number of samples tested for Syphilis Serology during the Q3-2019 time period is unknown.
D2081	GENERAL IMMUNOLOGY CFR(s): 493.837(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) for 2018 and 2019 testing results and interview with the technical supervisor (TS); it was determined that the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame for results for General Immunology subspecialty for the third quarter event (Q3-2019) specified by the program is unsatisfactory performance and results in a score of zero (0). The findings included: a. The American Association of Bioanalysts (AAB) proficiency reported to CMS for Q3-2019 an unsatisfactory score of 0% for General Immunology including ANA, ASO, Infectious mononucleosis, RA/RF, and Rubella failure to submit results within the time frame specified by the program. b. The technical supervisor affirmed 03/04/2020 at 15:00 that the AAB proficiency testing records as well as patients reports from the year 2019 were not available for review at the time of the survey. c. Based on the laboratory's annual test volume declaration Lab 167 submitted 09/16/2019 the laboratory analyzed and reported approximately 350 General Immunology tests.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) for 2018 and 2019 testing results and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the PT second test event 2018 (Q2-2018) and third event 2018 (Q3-2018) for following analytes: albumin, ALT (SGPT), total cholesterol, glucose (non-waived), sodium, and BUN The findings included: a. Q2-2018, CMS 96D report indicated unsatisfactory proficiency testing scores 40% for albumin analyte. b. Q3-2018, CMS 96D PT summary report indicated unsatisfactory proficiency testing scores: ALT (SGPT) = 60%, albumin = 60%, total cholesterol = 40%, glucose (non-waived) = 40%, sodium

	40%, and BUN 60%. a. The technical supervisor affirmed 03/04/2020 at 15:00 that the proficiency testing records from AAB as well as patients reports from the year 2018 were not available for review at the time of the survey. b. Based on the laboratory's annual test volume declaration Lab 167 submitted 09/16/2019 the laboratory analyzed and reported approximately 30,000 Routine Chemistry tests.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) for 2018 and 2019 testing results and interview with the laboratory technical supervisor; it was determined that the laboratory failed to participate in the proficiency testing event for Routine Chemistry first event (Q1-2018) for multiple analytes resulting in a score of zero. The findings included: a. The laboratory received a score of 0% for Q1-2018 for Routine Chemistry for ALT (SGPT), albumin, alkaline phosphatase, amylase, AST (SGOT), total bilirubin, total calcium, chloride, total cholesterol, HDL, total CK, creatinine, glucose (non-waived), total iron, LDH, magnesium, potassium, sodium, total protein, triglycerides, BUN, and uric acid analytes. b. The technical supervisor affirmed(03/04/2020 at 15:00 that the proficiency testing records from AAB as well as preventive maintenance, function checks, quality control, calibration and calibration verification, competency of staff, quality assurance, and patient reports were from the year 2018 were not available for review at the time of the survey. c. Based on the laboratory's annual test volume declaration Lab 167 submitted 09/16/2019 the laboratory analyzed and reported approximately 30,000 Routine Chemistry tests which included the multiple analytes listed above in item a.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) report 96D (CLIA Application and Survey Summary) for 2019 testing results and interview with the technical supervisor; it was determined that the laboratory failed to return PT results for Routine Chemistry subspecialty for the third quarter PT event (Q3-2019) to the proficiency testing program within the time frame specified by the program is

	unsatisfactory performance and results in a score of zero (0). The findings included: a. The American Association of Bioanalysts (AAB) proficiency reported to CMS for Q3-2019 an unsatisfactory score of 0% for Routine Chemistry [ALT (SGPT), albumin, alkaline phosphatase, amylase, AST (SGOT), total bilirubin, total calcium, chloride, total cholesterol, HDL, total CK, creatinine, glucose (non-waived), total iron, LDH, magnesium, potassium, sodium, total protein, triglycerides, BUN, and uric acid] failure to submit results within the time frame specified by the program. b. The technical supervisor affirmed(03/04/2020 at 15:00 that the AAB proficiency testing records as well as patients reports from the year 2019 were not available for review at the time of the survey. c. Based on the laboratory's annual test volume declaration Lab 167 submitted 09/16/2019 the laboratory analyzed and reported approximately 30,000 Routine Chemistry tests which included the multiple analytes listed above (a).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CMS CASPER proficiency testing (PT) records report 0155D (Individual Laboratory Profile) for 2019, and 2020 testing results, it was determined that laboratory failed to achieve satisfactory performance for the same analyte total iron (TFE) in two consecutive events, which constitutes subsequently unsuccessful performance. The findings included: a. Total Iron (TFE) Q2-2019 Q1-2020 20% 60% b. Based on the laboratory's annual test volume declaration Lab 167 submitted 09/16 /2019 the laboratory analyzed and reported approximately 30,000 Routine Chemistry tests which included total iron.
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) for 2018 testing results and interview with the laboratory technical supervisor, it was determined that the laboratory failed to participate in the PT event for Endocrinology for the first event of 2018 (Q1-2018) resulting in a score of zero. The findings included: a. The laboratory received a score of 0% in the subspecialty Endocrinology for the following analytes: Free T4, HCG, T3 uptake, triiodothyronine, TSH and T4. b. The technical supervisor (TS) affirmed 03

	/04/2020 at 15:00 that the proficiency testing records from American Association of Bioanalyst (AAB) as well as preventive maintenance, function checks, quality control, calibration and calibration verification, competency of staff, quality assurance, and patient reports were not available for review for the year 2018.
D2104	ENDOCRINOLOGY CFR(s): 493.843(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) from 2018 to 2019 proficiency testing results and interview with the technical supervisor (TS); it was determined that the laboratory failed to return PT results for Endocrinology subspecialty for the third quarter event (Q3-2019) to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of zero (0) The findings included: a. The American Association of Bioanalysts (AAB) proficiency reported to CMS for Q3-2019 an unsatisfactory score of 0% for (endocrinology) Free T4, HCG, T3 uptake, triiodothyronine, TSH and T4 failure to submit results within the time frame specified by the program. b. The technical supervisor affirmed 03/04/2020 at 15: 00 that the AAB proficiency testing records from the year 2019 were not available for review. c. Based on the laboratory's annual test volume declaration Lab 167 submitted 09/16/2019 the laboratory analyzed and reported approximately 25,000 tests which included Free T4, HCG, T3 uptake, triiodothyronine, TSH and T4.
D2109	TOXICOLOGY CFR(s): 493.845(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 96D (CLIA Application and Survey Summary) for 2018 and 2019 testing results and interview with the laboratory technical supervisor, it was determined that the laboratory failed to participate in the PT first event 2018 (Q1-2018) for Toxicology resulting in a score of zero. The findings included: a. The laboratory received a score of 0% for Q1-2018 in the subspecialty Toxicology. b. The technical supervisor (TS) affirmed 03/04/2020 at 15:00 that the proficiency testing records from AAB as well as patients reports from the year 2018 were not available for review due at the time of the survey (03/04 /2020). c. The number of samples tested for lead during Q1-2018 time period is unknown.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a

	score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) report 96D (CLIA Application and Survey Summary) for 2018 and 2019 testing results and interview with the technical supervisor (TS); it was determined that the laboratory failed to return proficiency testing results for Hematology for the third quarter event (Q3-2019) to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of zero (0). The findings included: a. The American Association of Bioanalysts (AAB) proficiency reported to CMS for Q3-2019 an unsatisfactory score of 0% for Cell ID or WBC Diff, RBC, HCT (non-waived), Hemoglobin (non-waived), WBC, and platelets failure to submit results within the time frame specified by the program. b. The technical supervisor affirmed 03/04/2020 at 15:00 that the AAB proficiency testing records from the year 2019 were not available for review. c. Based on the laboratory's annual test volume declaration Lab 167 09/16/2019 the laboratory analyzed and reported approximately 18,000 Hematology tests.
D2159	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) report 96D (CLIA Application and Survey Summary) testing results and interview with the technical supervisor (TS); it was determined that the laboratory failed to return proficiency testing results for ABO Group and D(RHO) typing for the third quarter event (Q3-2019) to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of zero (0). The findings included: a. The American Association of Bioanalysts (AAB) proficiency reported to CMS for Q3-2019 an unsatisfactory score of 0% for ABO grouping and Rh typing failure to submit results within the time frame specified by the program. b. The technical supervisor affirmed 03/04/2020 at 15:00 that the AAB proficiency testing records from the year 2019 were not available for review. c. The number of samples tested for ABO grouping and Rh typing during the Q3-2019 time period is unknown.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyors' observation, examination of laboratory reagents, patient test reports covering the period from September 1, 2019 to March 3, 2020, and interview with the laboratory Technical Supervisor (TS), it was determined that the laboratory

	failed to not use reagents when they have exceeded their expiration date. The findings included: a. On the day of inspection, 03/04/2020 at approximately15:00, the examiners found the following Bacteriology reagents currently being used beyond its expiration date [Amoxicillin/clavulanic acid (Co-Amoxiclav), Clindamycin (Cleocin), Sulfamethoxazole (TMP/MX)]: Reagent Lot # Exp. Date Mfrs./QC org. Spot Indole 430860 10/05/19 Hardy Co-Amoxiclav 6027957 08/31/17 BBL Cleocin 4183850 07 /31/19 BBL Ceftriaxone 6109515 04/30/19 BBL TMP/MX 6307960 12/31/19 BBL Tetracycline 3247450 09/30/16 BBL McFarland Std. N/A 11/22/18 Hardy S. aureus " 11/16 ATCC E. coli " 02/17 ATCC P. aeruginosa " 04/17 ATCC E. faecalis " 10/16 ATCC b. The technical superior affirmed on 03/04/2020 using the reagents listed in (a) beyond its expiration date. c. For three (3) out of three (3) patient records of bacteriological cultures that were randomly sampled during the testing period from 09 /01/2019 and 03/01/2019, the laboratory tested and reported patient samples using expired reagents. d. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 650 Bacteriology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the laboratory's Maintenance procedure SOP# CVDL.QA.613, lack of documentation, and interview with the laboratory Technical Supervisors (TS), it was determined that the laboratory failed to perform, and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory equipment. The findings included: a. The laboratory's standard operating procedure (SOP) Maintenance under Quality Assessment section indicates that annual maintenance and equipment service according to manufacturer's requirements be performed on microscope, heat block(s), water bath(s), and incubator (s). The same policy also indicates that thermometers, centrifuges, and pipettes be calibrated annually. b. The Technical supervisor confirmed 03/04/2020 at 15:00 that the laboratory failed to follow manufacturer's instruction for maintenance and calibration of the designated laboratory equipment indicated in the SOP. c. According to the annual test volume declared by the laboratory, the laboratory performs 75,120 tests.
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 review of the laboratory's final patient reports and interview with the technical supervisor (TS), for nineteen (19) out of nineteen (19) patient reports reviewed covering periods from 09/26/2020 to 01/27/2020, it was determined that the laboratory failed to indicate the correct name of the facility where the tests were performed. The findings included: a. Review of the patients' final test results did not indicate the correct name of the facility where the tests were performed. b. For nineteen (19) out of nineteen (19) randomly chosen patient reports reviewed covering period from 09/26/2020 to 01/27/2020; the final reports sent to the submitters did not indicate the correct name of the laboratory where the tests were performed. c. The TS affirmed 03/04/2020 at 15:00 that the patient test reports did not indicate the correct name of the laboratory where the test were performed.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory documents reporting prostate specific antigen (PSA test results, and interview with the Technical Supervisor (TS); it was determined that the laboratory failed to state that the results were obtained using the ST AIA-PACK PA test system to aid in interpreting PSA test results. Findings included: a. The manufacturer's instructions for the ST AIA-PACK PA PSA test states: "The concentration of PSA in a given specimen may vary with devises from different manufacturers. Values obtained with different assay methods cannot be used interchangeably. It is mandatory that results reported by the laboratory to the physician include the identity of the assay used." b. The TS affirmed 03/04 /2018 15:00 (survey date) the laboratory's failure to identify ST AIA-PACK PA on the laboratory reports as the test system used to obtain PSA results. c. Based on the reported estimated annual tests volumes, the laboratory reported approximately 35,000 chemistry results, including PSA.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review and the lack of records for at least two years of proficiency testing for multiple analytes for the years 2018 and 2019 (D2015), the use of expired reagents (D5417), lack of maintenance and repair information of laboratory equipment

	(D5429), reporting PSA test results not following test manufacturer's directions (D5809), and review of the laboratory's policy, procedure for staff competency (5209); it was determined that the laboratory director (LD) failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on the survey findings, the Laboratory Director (LD) is herein cited for deficient practice in providing overall administration to ensure proficiency testing results are returned within the timeframes established by the proficiency testing program. Findings included: a. The laboratory missed the deadline for reporting the proficiency results for the third event of 2019 (Q3-2019) for bacteriology, syphilis serology, general immunology, routine chemistry, endocrinology and hematology. b. The laboratory failed to follow policies and procedures on mechanisms to ensure that results are reported by the stated deadlines. See 2025, D2071, D2081, D2093, D2104, and D2157.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing policy SOP #CVDL.AN.215, lack of evaluation of proficiency testing performance records, lack of corrective action records and documentation, and interview with the technical supervisor, the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. The findings include: See D2089, D2100, D2011, D2087, D205, D2071, D2081, D2093, D2096, D2104 and D2159
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: Based on the lack of laboratory personnel competency evaluation, the lack of laboratory written policies and procedures for assessing individual performances, and interview with the technical supervisor; the Laboratory Director (LD) failed to ensure that policies and procedures are established and followed 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. The findings included: See D6127.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 the review of personnel training and competency assessments documentation on March 4, 2020 (Survey date), the technical supervisor (TS) failed to evaluate the competency of all testing personnel and assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. The findings included: See D6127.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of lack of the personnel competency evaluation records and interview with the Technical Supervisor (TS), it was determined the laboratory failed to follow its written policies and procedures to assess its employees' competencies. The findings included: a. There were no complete records of personnel competency evaluation records for 2018 and 2019 available at the time of survey. b. The TS affirmed(03/04/2020 at 15:00 that no personnel competency records were available at the time of survey.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.

	This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory consultant was not met. Based on interview with the technical consultant the current laboratory director does not possess the required qualifications to be a clinical consultant. The findings included: See D 6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on the laboratory director qualifications and interview with the technical supervisor (TS) it was determined that the laboratory director does not meet the requirements as stated in 493.1455 "Clinical consultant qualification" to qualify to be the laboratory's clinical consultant. The findings included: a. The current laboratory director (LD) holds and earned a doctorate in a chemical, physical, biological, or clinical laboratory science from an accredited institution; therefore, qualified for laboratory director license title as Clinical Laboratory Bioanalyst. b. The LD does not possess any of the medical degrees as stated in 493.1443 to be qualified as clinical consultant. c. The TS confirmed on 03/04/2020 15:00 (survey date) that the LD does not hold a medical degree to meet the required qualifications to be the laboratory's clinical consultant.