

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0667819	(X3) Date Survey Completed 11/13/2019
Name of Provider or Supplier Pr Clinical Reference Laboratory	Street Address, City, State Jose J Acosta 46, Vega Baja, PR	
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
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on C. Diff Quik Check Complete quality control records (year 2019) review and interview with the laboratory supervisor at 10:10 AM on November 13, 2019, the laboratory failed to comply with the analytic system requirements for the detection of the Clostridium difficile Glutamate Dehydrogenase Antigen test. Refer to D 5449 (1) (The laboratory did not include each day of testing a negative and a positive control material when 103 out of 103 patients specimens were tested and reported for the detection of Clostridium difficile Dehydrogenase Antigen from January 1, 2019 to November 12, 2019 by Alere C. Diff Quik Check Complete method).</p>
D5014	<p>GENERAL IMMUNOLOGY CFR(s): 493.1208</p> <p>If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: 1. Based on Mycoplasma IGM quality control records (year 2019) review and interview with the laboratory supervisor at 9:20 AM on November 13, 2019, the laboratory failed to comply with the analytic system requirements for the detection of the qualitative Mycoplasma IgM tests. Refer to D 5449 (2) (The laboratory did not</p>

include each day of testing a negative and a positive control materials when 576 out of 576 patients specimens were tested and reported for qualitative Mycoplasma IgM tests from May 15, 2019 to November 11, 2019 by the Immuno Card Mycoplasma method). 11586 2. Based on lack of performance verification procedures and Anti - HCV manufacturer's insert (ADVIA Centaur XP system) review on November 13, 2019 at 10:54 AM, it was determined that the laboratory failed to meet the requirement for Anti-HCV tests. Refer to D 5423 - The laboratory did not establish the performance characteristic of the Anti-HCV test prior to use it with infants and children samples. 15869 3. Based on Immuno Concepts ANA HEP-2000 manufacturer's instructions, antinuclear antibody (ANA) quantitative testing records (years 2018 and 2019), procedures manual for ANA quantitative tests, verification of performance specification records's of Immuno Concepts ANA HEP-2000 and interview with the laboratory director, the testing personnel #2 and the general supervisor on November 13, 2019 at 12:05 PM, it was determined that the laboratory failed to meet the requirements of the General Immunology (ANA quantitative tests). Refer to D 5405 (The laboratory failed to perform the 1:40 initial dilution and failed to perform dilutions above 1:320). Refer to D5421 (The laboratory failed to complete the evaluation of the performance specification of the ANA tests).

D5405

PROCEDURE MANUAL

CFR(s): 493.1251(c)

Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

1. Based on Immuno Concepts ANA HEP-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative patient's testing records (year 2018 and 2019), laboratory general immunology procedures manual review and interview with the laboratory director on November 13, 2019 at 12:10 PM, it was determined that the laboratory failed to follow, both the manufacturer's instructions and its own written procedures, when 42769 out of 42769 patients specimens were processed and reported for ANA quantitative tests from January 2018 to November 14, 2019. The findings include: a. The laboratory performed the ANA quantitative tests by Immuno Concepts ANA HEP-2000 method. b. Both, the Immuno Concepts ANA HEP-2000 manufacturer's instructions, as well as the procedures manual, instructed the laboratory to perform an initial patient's serum dilution of of 1:40. c. Review of the antinuclear antibody (ANA) quantitative patient's testing records (year 2018 and 2019) showed that the laboratory performed an initial serum dilutions of 1:80 instead of 1:40. d. The laboratory performed initial dilutions of 1:80 to 42769 out of 42769 patients specimens from January 2018 to November 14, 2019. e. The laboratory director stated, that the kit vendor instructed them to perform an initial dilution of 1: 80. 2. Based on Immuno Concepts ANA HEP-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative patient's testing records (year 2018 and 2019), laboratory general immunology procedures manual review and interview with the testing personnel # 2 on November 13, 2019 at 1:00 PM, it was determined that the laboratory failed to follow, both the manufacturer's instructions and its own written procedures, regarding the use of the phosphate-buffered saline powder control (PBS) The findings include: a. The Immuno Concepts ANA HEP-2000 manufacturer's instructions, as well as the procedures manual, instructed the laboratory to include a

PBS control with each slide. b. The Immuno Concepts ANA HEP-2000 manufacturer's instructions, as well as the procedures manual showed the following: "The PBS control is used to observe non-specific staining by the enzyme antibody reagent, and should not exhibit blue staining. If the control do not appear as described, the test is invalid and should be repeated". c. Review of the antinuclear antibody (ANA) quantitative patient's testing records (year 2018 and 2019) showed that the laboratory did not include the PBS control when 42769 out of 42769 patients specimens were processed from January 2018 to November 14, 2019. d. The testing personnel #2 stated that the PBS control was not included when patient's samples were processed for ANA tests. 3. Based on Immuno Concepts ANA HEP-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative patient's testing records (year 2018 and 2019), laboratory general immunology procedures manual review and interview with the testing personnel #2 and the technical supervisor on November 13, 2019 at 1:00 PM, it was determined that the laboratory failed to follow, both the manufacturer's instructions and its written procedures, regarding the semi-quantitative titrating when patients specimens were processed and reported for ANA semi-quantitative tests. The findings include: a. The Immuno Concepts ANA HEP-2000 manufacturer's instructions, as well as the procedures manual, instructed the laboratory to perform two-fold dilutions staining at the 1:40 titer through 1:2560 titer. The instructions also included that the titer results should be reported as the last serial dilution in which a clearly discernible staining is seen. The appearance of a clearly defined nuclear pattern is a key factor to consider in the determination of the titer end point. b. Review of the antinuclear antibody (ANA) quantitative patient's testing records (year 2018 and 2019) showed that the laboratory only performed the following dilutions in order to determine the titer end point : 1:80, 1:160 and 1:320. No dilution beyond the 1:320 were performed even in those patient's reported as positive 1:320. c. Review at random of the patient's testing records showed the following: July 17, 2018 - nine (9) patient's samples with two-fold dilutions three (3) of them reported as positive 1:320 July 18, 2018 - seven (7) patient's samples with two-fold dilutions three (3) of them reported as positive 1:320 July 20, 2018 - ten (10) patient's samples with two-fold dilutions three (3) of them reported as positive 1:320 July 30, 2018 - twenty four (24) patient's samples with two-fold dilutions sixteen (16) of them reported as positive 1:320 October 8, 2018 - twelve (12) patient's samples with two-fold dilutions one (1) of them reported as positive 1:320 October 18, 2018 - ten (10) patient's samples with two-fold dilutions one (1) of them reported as positive 1:320 October 26, 2018 - seven (7) patient's samples with two-fold dilutions five (5) of them reported as positive 1:320 November 1, 2018 - eleven (11) patient's samples with two-fold dilutions three (3) of them reported as positive 1:320 November 16, 2018- seventeen (17) patient's samples with two-fold dilutions two (2) of them reported as positive 1:320 November 21, 2018 -eighteen (18) patient's samples with two-fold dilutions five (5) of them reported as positive 1:320 November 28, 2018- eleven (11) patient's samples with two-fold dilutions four (4) of them reported as positive 1:320 November 29, 2018 -nineteen (19) patient's samples with two-fold dilutions four (4) of them reported as positive 1:320 March 14, 2019 -fourteen (14) patient's samples with two-fold dilutions three (3) of them reported as positive 1:320 March 15, 2019-Twenty (20) patient's samples with two-fold dilutions one (1) of them reported as positive 1:320 March 21, 2019-eleven (11) patient's samples with two-fold dilutions four (4) of them reported as positive 1:320 March 29, 2019-nine (9) patient's samples with two-fold dilutions three (3) of them reported as positive 1:320 June 24, 2019- twenty three (23) patient's samples with two-fold dilutions ten (10) of them reported as positive 1:320 June 26, 2019- nineteen (19) patient's samples with two-fold dilutions eight (8) of them reported as positive 1:320 June 28, 2019- eight (8) patient's samples with two-fold dilutions one (1) of them reported as positive 1:320

October 8, 2019 -Twenty six (26) patient's samples with two-fold dilutions eight (8) of them reported as positive 1:320 October 25, 2019 -twenty one (21) patient's samples with two-fold dilutions five (5) of them reported as positive 1:320 October 30, 2019- fourteen (14) patient's samples with two-fold dilutions seven (7) of them reported as positive 1:320 November 1, 2019 -fourteen (14) patient's samples with two-fold dilutions two (2) of them reported as positive 1:320 November 7, 2019- fifteen (19) patient's samples with two-fold dilutions five (5) of them reported as positive 1:320 November 16, 2019 -eleven (11) patient's samples with two-fold dilutions two(2) of them reported as positive 1:320 d. The testing personnel # 2 stated that the laboratory did not performed dilutions neither reported patient's samples above 1:320. e. The laboratory technical supervisor also stated on November 13, 2019 at 3:00 PM that they did not perform any dilutions above 1:320. f. Due the increased concentration of SAA/ RO antigen in the overexpressing cells, the laboratory may missed the staining of these cells in very high titers.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

1. Based on ADVIA Centaur XP Anti-HCV package insert, ADVIA Centaur XP instrument verification of performance specifications, patients samples test report from January 1, 2018 to November 12, 2019 review and interview with the testing personnel # 2 on November 13, 2019 at 10:54 AM, it was found that the laboratory did not establish the performance specifications for infants and children populations. The findings include: a. The laboratory processed the Anti-HCV tests by the ADVIA Centaur XP system. b. The Anti-HCV package insert (10629875_EN Rev. T, 2013-02) intended use section showed the following: Assay performance characteristic has not been established for population of immunocompromised, immunosuppressed, infants, children, or adolescent patients. The user is responsible for establishing their own assay performance characteristics in these populations. c. During the interview on November 13, 2019 at 10:54 AM, the testing personnel # 2 stated that they performed Anti-HCV tests for infants and children. d. The initial instrument verification procedures for ADVIA Centaur XP system was reviewed. The laboratory did not included infants nor children patient's samples. e. Review patient's samples test report from January 1, 2018 to August 31, 2019 showed that a 81 out of 7,788 patient's samples were tested for Anti-HCV were from infants and children.
2. Based on Immuno Concepts ANA HEp-2000 performance specification verification records, manufacturer's instruction review and interview with the laboratory technical supervisor interview on November 13, 2019 at 2:00 PM, it was determined that the laboratory failed to complete the verification of the performance specification of the ANA quantitative tests. The findings include: a. The Immuno Concepts ANA HEp-

2000 manufacturer instructed the laboratory to dilute patient sample with an initial dilution of 1:40 and then two-fold dilutions: 1:40, 1:80, 1:160, 1:320, 1:640, 1:1280 to 1:2560. b. The laboratory used the AFT 2000 instrument to perform the ANA serial dilutions and detect the end titer. c. On November 13, 2019 at 2:00 PM, the verification of the performance specification records showed that the laboratory only verify the performance specifications of the 1:80, 1:160 and 1:320 titers . d. The laboratory technical supervisor stated that the data in the verification of the performance specification documents effectively showed that the high dilution verified was up to 1:320. e. The laboratory modified the manufacturer's instructions by only performing dilutions beginning in 1:80 and as high as 1:320, thus missing the possibility of identifying distinct nuclear pattern that are visible only at high dilutions over 1:320.

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:

1. Based on manufacturer's written procedures, Cobas 6000 preventive maintenance records review (year 2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 9:30 A.M., it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Cobas 6000 systems. The findings include: a. The laboratory uses the Cobas 6000 system (module A, B, C) to perform endocrinology and special tests. b. The manufacturer's written procedures established that the laboratory must document and perform the daily, weekly, monthly and every six months preventive maintenance. c. Review of preventive maintenance records from January 2019 to November 13, 2019, showed that the laboratory did not perform nor document the monthly preventive maintenance (clean sampling unit filter and inspect/ clean the DI water tank and every six months preventive maintenance (clean inlet water filter) since January 2019. d. The laboratory processed and reported 600,000 approximately endocrinology and special chemistry patient tests since January 2019. e. The laboratory director confirmed on November 13, 2019 at 2:30 P. M. that the laboratory failed to follow written instructions for the preventive maintenance of Cobas 6000 systems. 2. Based on manufacturer's written procedures, Cobas 601 preventive maintenance records review (year 2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 9:30 A.M., it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Cobas 601 systems. The findings include: a. The laboratory uses the Cobas 601 system (module A, B, C) to perform endocrinology and special tests. b. The manufacturer's written procedures established that the laboratory must document and perform the daily, weekly, monthly, every 3 months and every 6 months preventive maintenance. c. Review of preventive maintenance records from January 2019 to November 13, 2019, showed that the laboratory did not perform nor document every 3 months the preventive maintenance (replace the pinch valve tubing) and every six months preventive maintenance (replace pipette seals) since January 2019. d. The laboratory processed and reported 600,000 approximately endocrinology and special chemistry patient tests since January 2019. e. The laboratory director confirmed on November 13, 2019 at 2:30 P.M. that the laboratory failed to follow written instructions for the preventive maintenance of Cobas 601 systems. 3. Based on

manufacturer's written procedures, Cobas 501 preventive maintenance records review (year 2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 9:45 A.M., it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Cobas 501 systems. The findings include: a. The laboratory uses the Cobas 501 system (module A, B, C) to perform routine chemistry tests. b. The manufacturer's written procedures established that the laboratory must document and perform the daily, weekly, monthly, every 2 months, quarterly and every 6 months preventive maintenance. c. Review of preventive maintenance records from January 2019 to November 13, 2019, showed that the laboratory did not perform nor document the quarterly preventive maintenance (replace ISE pinch valve tubing , ISE slipper tubing and clean the ultrasonic mixers) since January 2019. d. The laboratory processed and reported 69,000 approximately routine chemistry patient samples since January 2019. e. The laboratory director confirmed on November 13, 2019 at 2:30 P.M. that the laboratory failed to follow written instructions for the preventive maintenance of Cobas 501 systems.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on routine chemistry calibration verifications records reviewed (year 2018-2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 10:00 A.M., it was determined that the laboratory failed to perform at least every six months the calibration verification procedures for the routine chemistry tests (Inorganic phosphorus urine and blood urea nitrogen urine) processed by the Cobas 501 system. The findings include: a. The laboratory uses a Cobas 501 system for routine chemistry tests. b. Review of routine chemistry calibration verification records from January 2018 to November 13, 2019, showed that the laboratory did not perform the calibration verification procedures for urine chemistry tests tests (Inorganic phosphorus urine and blood urea nitrogen urine) in October 2018. c. The laboratory

director confirmed on November 13, 2019 at 2:30 P.M. that the laboratory did not perform at least six months the calibration verification procedures for these urine chemistry tests perform by the Cobas 501 system

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

1. Based on C. Diff Quik Check Complete quality control records (year 2019) review and interview with the laboratory supervisor on at 10:10 AM on November 13, 2019, it was determined that the laboratory failed to include each day of testing a negative and a positive control material when 103 out of 103 patients specimens were tested and reported for the detection of Clostridium difficile Dehydrogenase Antigen from January 1, 2019 to November 12, 2019 by Alere C. Diff Quik Check Complete method. The findings include : a. The laboratory used the Alere C. Diff Quik Check Complete method (moderated complexity) for the detection of Clostridium difficile Dehydrogenase Antigen in fecal patients specimens. b. On November 13, 2019 at 10:10 AM , the C. Diff Quik Check Complete quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials when patients specimens were processed from January 1, 2019 to November 12, 2019. c. The laboratory includes the negative and the positive control materials when it placed in routine use the following lots numbers of the C. Diff Quik Check Complete reagents kit: lot 8239670 on February 11, 2019, lot 8448749 on March 26, 2019, lot 8982272 on August 14, 2019 and lot 9231300 on October 21, 2019. d. The general supervisor confirmed on November 13, 2019 at 10:10 AM, that the laboratory did not include the negative and the positive control materials each day of testing, instead the laboratory includes a negative and a positive control materials when it places in routine use every new lot or new shipping of the C. Diff Quik Check Complete Kit. e. The laboratory tested and reported 103 out of 103 patients fecal specimens for the detection of Clostridium difficile Dehydrogenase Antigen from January 1, 2019 to November 12, 2019 by Alere C. Diff Quik Check Complete method. 2. Based on Mycoplasma IGM quality control records (year 2019) review and interview with the laboratory supervisor at 9:20 AM on November 13, 2019, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 576 out of 576 patients specimens were tested and reported for qualitative Mycoplasma IgM tests from May 15, 2019 to November 11, 2019 by the Immuno Card Mycoplasma method. The findings include : a. On November 13, 2019 at 9:20 AM, the Mycoplasma IGM quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials from from May 15, 2019 to November 11, 2019. b. The laboratory includes the negative and the positive control materials when it placed in routine use the following lots numbers of the Immuno Card Mycoplasma reagents kit: lot 709030L051 on May 30, 2019, lot 709030L052 on July 2, 2019, lot 709030L046 on July 16, 2019, lot 709030L052 on August 24, 2019, lot 709030L064 on October 1, 2019, lot 709030L065 on October 16, 2019, lot 709030L070 on October 22, 2019 and lot 709030L073 on November 5, 2019. c. The general supervisor confirmed on

November 13, 2019 at 9:20 AM, that the laboratory did not include the negative and the positive control materials each day of testing, instead the laboratory includes a negative and a positive control materials when it places in routine use every new lot or new shipping of the Immuno Card Mycoplasma reagents Kit. d. The laboratory tested and reported 576 out of 576 patients specimens for qualitative Mycoplasma IgM tests from May 15, 2019 to November 11, 2019 by the Immuno Card Mycoplasma method.

D5543

HEMATOLOGY
CFR(s): 493.1269(a)(d)

(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on sperm count testing records review and general supervisor interview on November 13, 2019 at 9:30 AM, it was determined that the laboratory failed to test in duplicate 80 out of 80 patients sperm cells specimens for manual counts performed from January 08, 2019 to October 08, 2019 by the the hemocytometer . The findings included: 1. The laboratory performed manual sperm cell count by the hemocytometer. 2. On November 13, 2019 at 9:30 AM, the sperm count testing records showed that the laboratory did not tested in duplicate 80 out of 80 patients sperm cells specimens for manual counts from January 08, 2019 to October 08, 2019 by the hemocytometer. 3. The general supervisor stated on November 13, 2019 at 9:30 AM, that the laboratory tested in duplicate those specimens but recorded the final sperm cell count result.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on bacteriology quality control records review from January 2, 2018 to November 13, 2019 and laboratory testing personnel # 3 interview on November 13, 2019 at 9:46 AM, it was determined that the laboratory failed to follow the established written policies to evaluate twice a year the relationship of microorganisms identification results processed by the Walk Away 96 plus system versus Auto Scan 4 system (back up). The findings include: 1. The bacteriology quality control records were reviewed from January 2, 2019 to November 13, 2019. 2. The laboratory performed microorganisms identification tests by the Walk Away 96 plus SI and Auto Scan 4 systems. 3. The laboratory did not performed the scheduled evaluation (June and December)of each year. Review of records showed that the last evaluation was performed in June 2019. 4. The laboratory testing personnel # 3 stated on November 13, 2019 at 9:46 AM, that the laboratory did not perform the twice a year evaluation.

<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on laboratory ANA tests records and interview with the technical supervisor and the testing personnel on November 13, 2019, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory ANA quality control requirements. Refer to D 6093, D6086 and D6087.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on the verification of the performance specification of the Immuno Concept ANA HEp 2000 tests and interview with the technical supervisor on November 13, 2019, it was determined that the laboratory director did not assure that the procedures performed to evaluate the performance of the ANA test were the adequate ones. Refer to D5423.</p>
<p>D6087</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on review of ANA testing records on November 13, 2019 at 2:00 PM , it was determined that the laboratory director did not ensure that the testing personnel, who performed Immuno Concept ANA HEp 2000 tests, followed the established quality control program and test procedure. The finding includes: a. The testing personnel did not include a PBS buffer, did not perform the initial 1:40 dilution and did not performed two-fold dilutions above 1:320. Refer to D6177.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by:</p>

1. Based on C. Diff Quik Check Complete quality control records (year 2019) review, Mycoplasma IGM quality control records (year 2019) review and interview with the laboratory supervisor on at 10:10 AM on November 13, 2019, the laboratory director failed to comply with the analytic system requirements. Refer to D 5449 (1). Refer to D 5449 (2). 2. Based on manufacturer's written procedures, Cobas systems preventive maintenance records review (year 2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 9:30 A.M., it was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D5429 3. Based on routine chemistry calibration verifications records reviewed (year 2018-2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 10:00 A.M., it was determined that the laboratory director failed to comply with the routine chemistry analytic system requirements. Refer to D5439. 11586 5. Based on ADVIA Centaur XP Anti-HCV package insert, ADVIA Centaur XP instrument verification of performance specifications, patients samples test report from January 1, 2018 to November 12, 2019 review and interview with the testing personnel # 2 on November 13, 2019 at 10:54 AM, it was found that the laboratory director failed to ensure compliance with he requirement for analytic system (did not establish the performance specifications for infants and children populations). The finding includes: 1. The laboratory did not establish the performance specifications for infants and children population. Refer to D5423. 15869 4. Based on ANA control records review and interview with the laboratory testing personnel # 2 on November 13, 2019, it was determined that the laboratory director did not make sure that control procedures were followed when the testing personnel performed ANA test using the Immuno Concepts HEp 2000 reagent kit. Refer to D6177.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and 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:
1. Based on lack of records, review of the Anti-HCV package insert and interview with the laboratory testing personnel # 2 on November 13, 2019 at 10:54 AM, it was found that the technical supervisor did not establish the performance specifications of the Anti-HCV test for infants and children prior to use it. The findings include: a. The Anti-HCV package insert instructed the laboratory to establish their own assay performance characteristics for infants and children populations. b. The technical supervisor did not establish the assay performance characteristics before use it with the mentioned population. 2. Based on ANA test performance specification verification procedures on November 13, 2019 at 2:00 PM, it was found that the technical supervisor failed to demonstrate that the nuclear pattern, at its chosen end point titer of 1:320, did not appear at the higher dilution of 1:2560 titer. Refer to D5423. (The laboratory did not verify dilutions above 1:320).

D6144

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

1. Based on C. Diff Quik Check Complete quality control records (year 2019) review, Mycoplasma IGM quality control records (year 2019), sperm count testing records review and interview with the laboratory supervisor on at 10:10 AM on November 13, 2019, the general supervisor failed to comply with the analytic system requirements. Refer to D 5449 (1). Refer to D 5449 (2). Refer to D 5543. 2. Based on manufacturer's written procedures, Cobas systems preventive maintenance records review (year 2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 9:30 A. M., it was determined that the laboratory general supervisor failed to to comply with the analytic system requirements. Refer to D5429 3. Based on routine chemistry calibration verifications records reviewed (year 2018-2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 10:00 A.M., it was determined that the laboratory general supervisor failed to to comply with the analytic system requirements. Refer to D5439.

D6177

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

1. Based on C. Diff Quik Check Complete quality control records (year 2019) review, Mycoplasma IGM quality control records (year 2019), sperm count testing records review and interview with the laboratory supervisor on at 10:10 AM on November 13, 2019, the testing personnel failed to follow quality control procedures. Refer to D 5449 (1). Refer to D 5449 (2). Refer to D 5543. 2. Based on manufacturer's written procedures, Cobas systems preventive maintenance records review (year 2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 9:30 A.M., it was determined that the laboratory testing personnel failed to follow written instructions for the preventive maintenance of Cobas systems. Refer to D5429 3. Based on routine chemistry calibration verifications records reviewed (year 2018-2019) and laboratory testing personnel # 2 interview on November 13, 2019 at 10:00 A.M., it was determined that the laboratory testing personnel failed to perform at least every six months the calibration verification procedures for the urine chemistry tests (Inorganic phosphorus urine and blood urea nitrogen urine) processed by the Cobas 501 system. Refer to D5439. 11586 Based on ADVIA Centaur XP Anti-HCV package insert, ADVIA Centaur XP instrument verification of performance specifications, patients samples test report from January 1, 2018 to November 12, 2019 review and interview with the testing personnel # 2 on November 13, 2019 at 10:54 AM, it was found that the testing personnel did not establish the performance specifications for infants and children populations. Refer to D5423. 15869 Based on review of ANA test testing records and interview with the testing personnel #2, it was determined that the testing personnel did not follow the manufacturer's instructions nor the laboratory written procedures when they performed ANA tests. The findings include: a. The testing personnel did not performed the initial serum 1:40 dilution as instructed by the manufacturer and as established in the laboratory procedure manual. b. The testing personnel did not performed dilutions above 1:320 when the ANA tests initial patient results showed a positive dilution of 1:80. c. The testing personnel did not include the PBS control with each patient slide. Refer to D5405