

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658052	(X3) Date Survey Completed 05/29/2019
Name of Provider or Supplier Laboratorio Clinico Canovanas	Street Address, City, State Calle Palmer # 8, Esq Calderon Mojica, Canovanas, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) testing records review (years 2017, 2018 and 2019) and laboratory directro interview on May 29, 2019 at 9:35 AM, it was determined that the laboratory failed to maintain a copy of all proficiency testing records during the year 2018. The findings include: 1. The PRPTP records were review from February 2017 to April 2019. 2. On May 29, 2019, the PRPTP records showed that the laboratory did not have the following proficiency testing records for the year 2018: a. Proficiency testing processing records: February 2018 and March 2018 events. b. PRPTP score results reports: February 2018, March 2018 and October 2018 events. c. Copy attestation statement: February 2018, March 2018 and April 2018. 3. The laboratory director confirmed on May 29, 2019 at 9:35 AM, that those proficiency testing records were not available in the laboratory.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on lack of endocrinology, special chemistry and routine chemistry quality control records(year 2018)) and laboratory director interview on May 29, 2019 at 11:30 AM, it was determined that the laboratory failed to retain the quality control records of the year 2018 for the endocrinology, special chemistry and routine chemistry tests. The findings include: 1. The laboratory did not have available the endocrinology and special chemistry quality control records from January 1, 2018 to May 29, 2018, Refer to D 5405 (1). 2. The laboratory did not not have available the Levy-Jennings records of the routine chemistry test from January 1, 2018 to December 31, 2018. Refer to D 5481. 3. The laboratory director confirmed on May 29, 2019 at 11:30 AM, that those quality control records were not available. This deficiency was cited on May 23, 2017.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) testing records review (years 2017, 2018 and 2019) and laboratory director interview on May 29, 2019 at 9:35 AM, it was determined that the laboratory failed to retain all proficiency testing records for at least 2 years. The findings include: 1. The PRPTP records were review from February 2017 to April 2019. 2. The laboratory did not maintain all the proficiency testing records for the year 2018. Refer to D 2015. 3. The laboratory director confirmed on May 29, 2019 at 9:35 AM, that those proficiency testing records were not available in the laboratory. This deficiency was cited on May 23, 2017

D5020

ENDOCRINOLOGY

CFR(s): 493.1212

If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on lack of preventive maintenance records for the Access 2 system, lack of Access 2 system endocrinology and special chemistry quality control records (January 1, 2018 to May 29, 2018), Access 2 manufacturer's instructions, patients reports records review and laboratory director interview on May 29, 2019 at 11:30 AM, it was determined that the laboratory failed to meet the analytic system requirements for the following tests: T 3 uptake (T 3), Thyroxine (T4), Thyroid stimulating hormone (TSH) and Prostatic specific antigen (PSA) from January 1, 2018 to May 29, 2019. Refer to D 5405(1) (The laboratory failed to follow written instructions for quality

control procedures of the Access 2 system). . Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance of the Access 2 system). This deficiency was cited on May 23, 2017.

D5024

HEMATOLOGY
CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on manufacturer's instructions, hematology quality control records (years 2018 and 2019) review and interview with the laboratory director on May 29, 2019 at 1:00 PM, it was determined that the laboratory failed to meet the analytic system requirements for Hematology specialty (CBC) tests from February 15, 2019 to December 26, 2018. Refer to D 5405 (2) (The laboratory failed to follow quality control procedures when 150 out of 150 patients specimens were processed and reported for complete cell count (CBC) from February 15, 2019 to December 26, 2018 by the Coulter Act 5 diff system). This deficiency was cited on 05/23/2017.

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 lack of endocrinology and special chemistry quality control records (January 1, 2018 to May 29, 2018), manufacturer's instructions, patients reports records review and laboratory director interview on May 29, 2019 at 11:30 AM, it was determined that the laboratory failed to follow manufacturer instructions when the laboratory processed and reported the following patients specimens by the Access 2 system from January 1, 2018 to May 29, 2018: 793 patients specimens for T 3 uptake (T 3), 785 patients specimens for Thyroxine (T4), 2714 patients specimens for Thyroid stimulating hormone (TSH) and 470 patients specimens for Prostatic specific antigen (PSA) by the Access 2 system. The findings include: a. The laboratory processed and reported patients specimens for T 3, T4, TSH and PSA by the Access 2 system. b. The manufacturer instructed the laboratory to run two levels of control each day of testing. c. On May 29, 2019 at 11:30 AM, the laboratory did not have available the quality control records for the T 3, T4, TSH and PSA tests from January 1, 2018 to May 29, 2018. d. The laboratory director confirmed on May 29, 2019 at 11:30 AM, that the quality control procedures for this period were not available. He stated that the laboratory performed the quality control procedures but the record were not available. e. The laboratory processed and reported the following patients specimens by the Access 2 system from January 1, 2018 to May 29, 2018: 793 patients specimens for T3 , 785 patients specimens for T4, 2714 patients specimens for TSH and 470 patients specimens for PSA. This deficiency was cited on 05/23/2017. 2. Based on manufacturer's instructions, hematology quality control records (years 2018

and 2019) review and interview with the laboratory director on May 29, 2019 at 1:00 PM, it was determined that the laboratory failed to follow quality control procedures when 150 out of 150 patients specimens were processed and reported for complete cell count (CBC) from February 15, 2019 to December 26, 2018 by the Coulter Act 5 diff system. The findings includes: a. The laboratory processed and reported the CBC patients specimens by the Coulter Act 5 diff system. b. The manufacturer instructed the laboratory to include the three levels of CBC control material each day of testing . c. The hematology quality control records showed that the laboratory did not include the three levels of CBC control material when the following 150 patients specimens were processed and reported for CBC: from February 15, 2018 to February 26, 2019 the laboratory reported 119 patients specimens for CBC and no records of three levels of control material were available for those dates; on April 7, 2019 the laboratory reported 15 patients specimens for CBC and no records of three levels of control material were available for this date; on April 10, 2019 the laboratory reported 1 patient specimen for CBC and no records of three levels of control material were available for this date; on June 21, 2018 the laboratory reported 2 patients specimens for CBC and no records of the high nor the normal level of control materials were available for this date and on December 26, 2018 13 patients specimens were reported and no records for the low level control material was available for this date. d. The laboratory director stated on May 29, 2019 at 11:30 AM, that the laboratory performed the quality control procedures but the quality control records for those dates were not available. This deficiency was cited on 05/23/2017.

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 manufacturer's instructions, lack of preventive maintenance records for the Access 2 system and interview with the laboratory director on May 29, 2019 at 12:10 PM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of the Access 2 system when it processed and reported the following patients specimens from January 1, 2018 to May 29, 2019: 2,518 patients specimens for T 3, 2,432 patients specimens for T4, 18,612 patients specimens for TSH and 1,371 patients specimens for PSA. The findings include: 1. The Access manufacturer instructed the laboratory to perform the daily and weekly preventive maintenance procedures. 2. On May 29, 2019 at 12:10 PM, the laboratory did not have available the daily and weekly preventive maintenance log of the Access 2 system from January 1, 2018 to May 29, 2019. 3. The laboratory director confirmed on May 29, 2019 at 12:10 PM, that the laboratory did not document the preventive maintenance log of the Access 2 system from January 1, 2018 to May 29, 2019. He stated, that the laboratory only maintained in record the print out of the Access temperatures verification. 4. The laboratory processed and reported the following patients specimens from January 1, 2018 to May 29, 2019: 2,518 patients specimens for T 3, 2,432 patients specimens for T4, 18,612 patients specimens for TSH and 1,371 patients specimens for PSA.

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 calibration verification records reviewed and laboratory director interview on May 29, 2019 at 10:50 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for glucose and lipid panel tests when it processed and reported 96 patients specimens for glucose tests and 1,788 patients specimens for lipid panel tests by the Hitachi 914 system from February 2, 2019 to May 29, 2019. The findings include: 1. The laboratory processed and reported the glucose and the lipids panel tests by the Hitachi 914 system. 2. On May 29, 2019 at 10:50 AM, the calibration verification records of the Hitachi 914 system showed that the laboratory did not perform at least every 6 months the calibration verification of the glucose and the lipids panel tests. The laboratory performed the calibration verification of those tests on August 1, 2018 and not performed the calibration verification procedures as scheduled in February 2019. 3. The laboratory director confirmed on May 29, 2019 at 10:50 AM, that the laboratory did not perform at least every 6 months the calibration verification for the glucose and the lipids panel tests. He stated that the laboratory performed the calibration verification procedures for those tests on August 1, 2018. 4. The laboratory processed and reported 96 patients specimens for glucose tests and 1,788 patients specimens for lipids panel tests from February 2, 2019 to May 29, 2019.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of routine chemistry quality control Levy-Jennings records (year 2018) and laboratory director interview on May 29, 2019 at 10:45 AM, it was determined

that the laboratory failed to run and evaluated the two levels of control materials when 4397 patients specimens for lipid panel were processed and reported from February 2018 to October 2018 by the Hitachi 914 system. The findings include: 1. The laboratory processed the lipid panel by the Hitachi 914 system. 2. On May 29, 2019 at 10:45 AM, the laboratory did not have available the routine chemistry quality control Levy-Jennings records for the year 2018. 3. The laboratory director confirmed on May 29, 2019 at 10:45 AM, that the laboratory the laboratory processed and reported 4397 patients specimens for lipid panel , but the routine chemistry quality control Levy-Jennings records were not available.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

Based on lack of endocrinology, special chemistry and routine chemistry quality control records(year 2018), lack of all the proficiency testing records for the year 2018, lack of preventive maintenance records for the Access 2 system, lack of Access 2 system endocrinology and special chemistry quality control records (January 1, 2018 to May 29, 2018), Access 2 manufacturer's instructions, Coulter Act 5 diff system manufacturer's instructions, hematology quality control records (years 2018 and 2019), lack of routine chemistry quality control Levy-Jennings records (year 2018), calibration verification records of routine chemistry tests, patients reports records, personnel file review and laboratory director interview on May 29, 2019 at 1: 40 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory records retention, proficiency testing records, analytical system requirements, clinical consultant qualification requirement and testing personnel training. The findings include: 1. Refer to D 6079 (The laboratory director did not comply with the laboratory's records retention requirements). 2. Refer to D 6091 (The laboratory director did not comply with the proficiency testing records). 3. Refer to D 6093 (The laboratory director did not comply with the analytical systems requirements). 4. Refer to D 6101 (The laboratory director did not comply with the Clinical Consultant requirements for his qualification). 5. Refer to D 6102 (The laboratory director did not comply with testing personnel training). This deficiency was cited on May 23, 2017.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on lack of endocrinology, special chemistry and routine chemistry quality control records(year 2018), lack of all the proficiency testing records for the year 2018 and laboratory director interview on May 29, 2019 at 11:30 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory's records retention requirements. Refer to D 3031 (Proficiency Testing Program records retention). Refer to D 3037 (Quality Control records retention).

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 Puerto Rico Proficiency Testing Program (PRPTP) testing records review (years 2017, 2018 and 2019) and laboratory director interview on May 29, 2019 at 9:35 AM, it was determined that the laboratory failed to ensure that all the proficiency testing reports were testing reports received are reviewed The finding includes: 1. Refer to D 2015 (The laboratory failed to maintain a copy of all proficiency testing records during the year 2018).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on lack of preventive maintenance records for the Access 2 system, lack of Access 2 system endocrinology and special chemistry quality control records (January 1, 2018 to May 29, 2018), Access 2 manufacturer's instructions, Coulter Act 5 diff system manufacturer's instructions, hematology quality control records (years 2018 and 2019), lack of routine chemistry quality control Levy-Jennings records (year 2018), calibration verification records of routine chemistry tests, patients reports records review and laboratory director interview on May 29, 2019 at 11:30 AM, it was determined that the laboratory director failed to comply with the analytic system requirements from January 1, 2018 to May 29, 2019. The findings include: 1. Refer to D D 5020 (The laboratory director failed to ensure that the laboratory meet with the analytic system requirements for the following tests: T 3 uptake, T4, TSH and PSA from January 1, 2018 to May 29, 2019). 2. Refer to D 5424 (The laboratory director failed to ensure that the laboratory meet the analytic system requirements for CBC tests from February 15, 2019 to December 26, 2018). 3. Refer to D 5429 (The laboratory director failed to ensure that the laboratory follow the written instructions for the preventive maintenance of the Access 2 system). 4. Refer to D 5439 (The laboratory director failed to ensure that laboratory perform at least every six months

the calibration verification procedures for glucose and lipid panel tests). 5. Refer to D 5481 (The laboratory director failed to ensure that the laboratory run and evaluate the two levels of routine chemistry control materials). This deficiency was cited on May 23, 2017.

D6101

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Based on personnel file review and laboratory director interview on May 29, 2019 at 1:40 PM, it was determined that the laboratory director failed to ensure that the Clinical Consultant comply with the requirements for his qualification. Refer to D 6134 (The Clinical Consultant failed to comply with the requirements for the Clinical Consultant qualification).

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must 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 personnel file review and laboratory director interview on May 29, 2019 at 1:40 PM, it was determined that the laboratory director failed to ensure that the new testing personnel, prior to testing patients' specimens have the appropriate training. The findings include: 1. On May 29, 2019 at 1:40 PM, the personnel file showed that the laboratory hired a new testing personnel in July, 2018. This testing personnel processed and reported patients specimens in the following areas: hematology, urinalysis, routine chemistry, endocrinology and syphilis serology since July 2018. However, the personnel file records did not include the testing personnel documented training for those tests. 2. The laboratory director stated on May 29, 2019 at 1:40 PM, that the testing personnel training for the hematology, urinalysis, routine chemistry, endocrinology and syphilis serology tests were not available on the laboratory. 3. Refer to D 6168 (The personnel failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system from January 1, 2018 to May 29, 2019).

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 personnel file review and laboratory director interview on May 29, 2019 at 1:40 PM, it was determined that the Clinical Consultant failed to comply with the requirements for the Clinical Consultant qualification. Refer to D 6135 (The personnel file of the Clinical Consultant did not include the current Registry Certificate from the Office of Regulation and Certification of Health Professionals, Commonwealth of Puerto Rico Department of Health).

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 personnel file review and laboratory director interview on May 29, 2019 at 1:40 PM, it was determined that the clinical consultant failed to comply with the requirements for the Clinical Consultant qualification position. The findings include:
1. On May 29, 2019 at 1:40 PM, the personnel file of the Clinical Consultant did not include the current Registry Certificate from the Office of Regulation and Certification of Health Professionals, Commonwealth of Puerto Rico Department of Health. 2. The laboratory director confirmed on May 29, 2019 at 1:40 PM, that the Clinical Consultant personnel file did not include the required current Registry Certificate.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on lack of preventive maintenance records for the Access 2 system, lack of Access 2 system endocrinology and special chemistry quality control records (January 1, 2018 to May 29, 2018), Access 2 manufacturer's instructions, Coulter Act 5 diff system manufacturer's instructions, hematology quality control records (years 2018 and 2019), lack of routine chemistry quality control Levy-Jennings records (year 2018), calibration verification records of routine chemistry tests, patients reports records review and laboratory director interview on May 29, 2019 at 11:30 AM, it was determined that the testing personnel failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system from January 1, 2018 to May 29, 2019. Refer to D 6177. (The testing personnel failed to follow quality control procedures).

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:

Based on lack of preventive maintenance records for the Access 2 system, lack of Access 2 system endocrinology and special chemistry quality control records (January 1, 2018 to May 29, 2018), Access 2 manufacturer's instructions, Coulter Act 5 diff system manufacturer's instructions, hematology quality control records (years 2018 and 2019), lack of routine chemistry quality control Levy-Jennings records (year 2018), calibration verification records of routine chemistry tests, patients reports records review and laboratory director interview on May 29, 2019 at 11:30 AM, it was determined that the testing personnel failed to follow quality controls procedures from January 1, 2018 to May 29, 2019. The findings include: 1. Refer to D 5405(1) (The laboratory failed to follow written instructions for quality control procedures of the Access 2 system). 2. Refer to D 5405 (2) (The laboratory failed to follow quality control procedures when 150 out of 150 patients specimens were processed and reported for complete cell count (CBC) from February 15, 2019 to December 26, 2018 by the Coulter Act 5 diff system). 3. Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance of the Access 2 system). 4. Refer to D 5439 (The laboratory failed to perform at least every 6 months the calibration verification procedures for glucose and lipid panel tests). 5. D 5481 (The laboratory failed to run and evaluated the two levels of control materials when 4397 patients specimens for lipid panel were processed and reported from February 2018 to October 2018 by the Hitachi 914 system).