

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1083892	<b>(X3) Date Survey Completed</b>  02/05/2021
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Meditech	<b>Street Address, City, State</b>  98 Calle 2 Esquina 3 Barrio Mameyes 11, Rio Grande, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on COVID 19 worksheet serology test records reviewed from October 22, 2020 to February 5, 2021 and laboratory general supervisor interview on February 5, 2021 at 11:32 AM, it was found that the laboratory did not maintain original handwritten patient test reports for the COVID19 IgG / IgM rapid test (COVIBLOCK COVID 19 IgG / IgM Antibody test) from October 22, 2020 to February 5, 2021 and COVID 19 antigen test from December 10, 2020 to February 4, 2021. Refer to D3031.</p>
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:</p>

1. Based on COVID 19 test reports, Puerto Rico Department of Health (PRDOH) COVID 19 state reporting requirement and laboratory general supervisor interview on February 5, 2021 at 10:50 AM, it was determined that the laboratory did not follow the state COVID 19 tests reporting requirements. The findings include: a. The PRDOH requires that all COVID 19 test report must be informed, within 24 hours of the final report, to the Bio Portal platform. b. The laboratory used the COVIBLOCK - COVID 19 IgG / IgM for Antibody test kit and for antigen test the Clarity COVID 19 and the CareStart kits. c. The laboratory general supervisor stated on February 5, 2021 at 10:50 AM, that the laboratory adopted the PRDOH COVID 19 requirements as their written reporting instructions. d. The test report records showed 2,081 test SARS-CoV-Ig,IgG patient samples were reported from October 22, 2020 to February 5, 2021; 717 out of 2081 patient's reports were reported to the Bio Portal with more than 24 hours after the final test report. The laboratory did not report the SARS-CoV IgG / IgM patients results in the required frequency (24 hrs) by the Bio Portal: Date Date Patients tested reported reports (1). 10/22/2020 10/26/2020 64 reports (2). 10/28/2020 10/28/2020 25 reports (3). 11/02/2020 11/02/2020 36 reports (4). 11/06/2020 11/10/2020 83 reports (5). 11/13/2020 11/17/2020 112 reports (6). 11/20/2020 11/23/2020 90 reports (7). 12/14/2020 12/16/2020 36 reports (8). 01/04/2021 01/07/2021 33 reports (9). 11/25/2020 02/05/2021 30 reports (10). 12/01/2020 02/05/2021 40 reports (11). 12/04/2020 02/05/2021 37 reports (12). 12/05/2020 02/05/2021 19 reports (13). 12/11/2020 02/05/2021 2 reports (14). 12/16/2020 02/05/2021 38 reports (15). 12/18/2020 02/05/2021 2 reports (16). 12/23/2020 02/05/2021 7 reports (17). 01/07/2021 02/05/2021 1 report (18). 01/11/2021 02/05/2021 3 reports (19). 01/12/2021 02/05/2021 3 reports (20). 01/14/2021 02/05/2021 5 reports (21). 01/15/2021 02/05/2021 16 reports (22). 01/21/2021 02/05/2021 2 reports (23). 01/25/2021 02/05/2021 2 reports (24). 01/26/2021 02/05/2021 1 report (25). 01/27/2021 02/05/2021 9 reports (26). 01/28/2021 02/05/2021 19 reports (27). 01/29/2021 02/05/2021 1 report Total of reports greater than 24 hours: 717 reports e. The laboratory test records showed that 599 patients test were reported from December 10, 2020 to February 4, 2021; 73 out of 599 patient's reports were reported to the Bio Portal with more than 24 hours after the final test report. Date Date Patients tested reported reports (1). 01/04/2021 01/07/2021 17 reports (2). 12/02/2020 02/05/2021 1 report (3). 12/16/2020 02/05/2021 2 reports (4). 12/23/2020 02/05/2021 1 report (5). 01/07/2021 02/05/2021 1 report (6). 01/11/2021 02/05/2021 3 reports (7). 01/12/2021 02/05/2021 3 reports (8). 01/14/2021 02/05/2021 5 reports (9). 01/15/2021 02/05/2021 5 reports (10). 01/25/2021 02/05/2021 6 reports (11). 01/27/2021 02/05/2021 5 reports (12). 01/28/2021 02/05/2021 19 reports (13). 01/29/2021 02/05/2021 5 reports Total of reports greater than 24 hours: 73 reports. f. The laboratory general supervisor confirmed on February 5, 2021 at 10:50 AM, that the before mentioned tests were not reported within the 24 hours of the final test report.

**D3031**

**RETENTION REQUIREMENTS**  
CFR(s): 493.1105(a)(3)

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 COVID 19 serology test quality control records reviewed from October 22, 2020 to February 5, 2021 and laboratory general supervisor interview on February 5, 2021 at 11:32 AM., it was found that the laboratory did not maintain the original

handwritten patient test reports for the COVID19 IgG / IgM rapid test (COVIBLOCK COVID 19 IgG / IgM Antibody test) from October 22, 2020 to February 5, 2021 not for COVID 19 antigen test from December 10, 2020 to February 4, 2021. The findings include: 1. The laboratory performed the COVID 19 IgG / IgM (COVIBLOCK COVID19 IgG / IgM Antibody Test) method and the COVID 19 antigen test (Clarity COVID 19 Antigen and CareStart COVID 19 Antigen rapid test). 2. The laboratory had a worksheet named: daily QC / PM / Patients (Pt). Results Documentation COVID 19, in which the following information must be documented by the testing personnel: date, room temperature, humidity, incubation, patient identification, patient full name, IgG / IgM patient test result, cassette internal control, QC external control and testing personnel initials. The laboratory general supervisor stated that all information must be documented in the worksheet to be later edited in the Laboratory Information System (LIS). 3. Review of serology test (COVID 19 IgG / IgM rapid test) worksheet from October 22, 2020 to February 5, 2021, showed that 1,201 out of 2,081 patient's test results were not documented. There was no evidence of the original test report, later edited in the LIS. 4. Review of COVID 19 Antigen test worksheet from December 10 to February 4, 2021, showed that 63 out of 176 patient's test results were not documented. There was no evidence of the original test report, later edited in the LIS. 5. The laboratory general supervisor confirmed on February 5, 2021 at 11:32 AM, that the laboratory did not document, at the required worksheet, those patient results.

**D5010**

**VIROLOGY**  
CFR(s): 493.1205

If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:  
Based on lack of written procedures for specimen storage, preservation and transportation, patient report and manufacturer's instructions review and laboratory general supervisor on February 5, 2021 at 11:55 AM, it was determined that the laboratory failed to ensure compliance with the preanalytic and analytic system requirements of Virology. Refer to D5311 (The laboratory did not establish and follow written policies for the specimen storage, preservation and transportation of COVID19 - RT - PCR (Polymerase Reaction Chain) test to reference laboratory). Refer to D5313 (The laboratory did not document the date and time of receive a COVID 19 - RT - PCR specimen). Refer to D5405 (The laboratory did not follow the manufacturer's instruction to document the cassette internal control).

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:  
 Based on review of the referral laboratory specimen collection kit instructions, laboratory freezer temperature records, written complainant allegations and laboratory general supervisor interview on February 5, 2021 at 10:17 AM, it was determined that the laboratory did not follow the referral laboratory instructions for Polymerase Chain Reaction (PCR) test specimen storage and preservation. The findings include: 1. The laboratory perform the sample collection for detection of COVID-19 - RT - PCR test since August 11, 2020 and the samples were referred to the LabCorp Laboratory, United States. 2. A complaint was received on January 17, 2021, the complainant alleged that a patient PCR sample was collected at an elderly living facility on December 15, 2020, after initially positive antigen test. However, the sample was finally referred to the referral laboratory on December 21, 2020 and the final test report was received on December 24, 2020, showing a negative PCR test. The patient died on December 17, 2020. 3. Review of the LabCorp COVID-19 - RT - PCR test (anterior nares) specimen collection kit showed that the referral laboratory was instructed to: "ship frozen at -20 C (preferred); refrigerated specimens acceptable (if received for testing within 72 hours of collection ); room temperature swabs acceptable (if received within 24 hours of collection)". 4. The laboratory freezer temperature log sheet (January 10, 2020 to December 29, 2020) was evaluated on February 5, 2021, showing that on 19 out of 19 days of December 2020, the laboratory recorded -18 C temperatures. 5. Review of the temperature records (specifically from December 15, 2020 to December 21, 2020), showed the following: e following records temperatures: Day Recorded Temperature 12/15/2020 -18 C 12/16 /2020 -18 C 12/17/2020 -18 C 12/18/2020 -18 C 12/19/2020 no done (laboratory close) 12/20/2021 no done (laboratory close) 12/21/2020 -18 C 6. The laboratory general supervisor stated on December 21, 2020, that the patient sample was referred to the referral laboratory 6 days after the sample collection and it was stored below the referral laboratory required storage temperature.

**D5313**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
 CFR(s): 493.1242(b)

The laboratory must document the date and time it receives a specimen.

This STANDARD is not met as evidenced by:  
 Based on lack of laboratory written procedures related to date and time of the specimen collection documentation, LabCorp patient test report, complaint review and laboratory general supervisor interview on February 5, 2021 at 11:26 AM, it was determined that the laboratory failed to document the date and time sample collection. The findings include: 1. The laboratory perform the sample collection for detection of COVID 19 - RT - PCR test and the samples are referred to LabCorp, United States. 2. On January 17, 2021, a complaint related to a delay in a PCR sample report was received. 3. During the interview on February 5, 2021 at 11:26 AM, the laboratory general supervisor stated that the referred sample was collected on December 15, 2020 at elderly living facility. She also stated that the sample was stored at the laboratory until December 21, 2020, when the complainant requested the final test report. 4. On December 21, 2020, after several request of the daughter's patient (complainant) , the sample was referred to LabCorp reference laboratory in United States. 5. Review of the LabCorp patient report, showed the following information: sample collection date: December 21, 2020; date received at Lab Corp - December 22, 2020 date entered on December 22, 2020 and date report on December 24, 2020. 6. The laboratory general supervisor confirmed on February 5, 2021 at 11:26 AM, that

the sample for COVID 19 - RT - PCR was sent to LabCorp reference laboratory on December 21, 2020 at 2:25 PM, 6 days after the sample collection. The laboratory supervisor also stated that the sample collection date was recorded as December 21, 2020, instead of December 15, 2020. 7. The laboratory did not have written instructions related to samples collection dates documentation.

**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 COVID 19 serology test quality control, manufacturer's instructions review and laboratory general supervisor interview on February 5, 2021 at 10:17 AM, it was determined that the laboratory failed to follow the manufacturer's instruction to document the COVID 19 cassette internal control , from October 22, 2020 to February 5, 2021. The findings include: (A). The laboratory performed COVID-19 IgG / IgM rapid tests (COVIBLOCK COVID19 IgG/IgM rapid test cassette). (B). The manufacturer instructed the laboratory to document the internal cassette procedural control (C). The procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred. (C). Review of the COVID 19 IgG / IgM patient's workbook , from October 22, to February 5, 2021, showed that the laboratory did not document the cassette internal procedural control on the following days: a. 10/22/2020 (12 of 18 patients) b. 10/23/2020 (29 of 29 patients) c. 10/26/2020 (24 of 24 patients) d. 10/27/2020 (17 of 17 patients) e. 10/28/2020 (10 of 10 patients) f. 10/29/2020 (16 of 16 patients) g. 10/30/2020 (28 of 28 patients) h. 11/02/2020 (28 of 28 patients) i. 11/04/2020 (34 of 34 patients) j. 11/05/2020 (30 of 30 patients) k. 11/06/2020 (37 of 37 patients) l. 11/09/2020 (38 of 38 patients) m. 11/11/2020 (9 of 9 patients) n. 11/12/2020 (56 of 56 patients) o. 11/13/2020 (24 of 24 patients) p. 11/16/2020 (44 of 44 patients) q. 11/17/2020 (12 of 12 patients) r. 11/18/2020 (42 of 42 patients) s. 11/19/2020 (9 of 9 patients) t. 11/20/2020 (36 of 36 patients) u. 11/23/2020 (28 of 28 patients) w. 11/24/2020 (25 out of 25 patients) x. 11/25/2020 (15 out of 15 patients) y. 11/30/2020 (27 of 27 patients) z. 12/01/2020 (15 of 15 patients) aa. 12/02/2020 (32 of 32 patients) bb. 12/03/2020 (33 of 33 patients) cc. 12/04/2020 (31 of 31 patients) dd. 12/09/2020 (11 of 11 patients) ee. 12/10/2020 (42 of 42 patients) ff. 12/11/2020 (9 of 9 patients) gg. 12/14/2020 (29 of 29 patients) hh. 12/15/2020 (38 of 38 patients) ii. 12/16/2020 (13 of 13 patients) jj. 12/17/2020 (15 of 15 patients) kk. 12/18/2020 (39 of 39 patients) ll. 12/21/2020 (22 of 22 patients) mm. 12/22/2020 (18 of 18 patients) nn. 12/23/2020 (9 of 9 patients) pp. 12/28/2020 (14 of 14 patients) qq. 12/29/2020 (15 of 15 patients) rr. 01/04/2021 (12 of 12 patients) ss. 01/07/2021 (17 of 17 patients) tt. 01/08/2021 (18 of 18 patients) uu. 01/11/2021 (11 of 11 patients) ww. 01/12/2021 (15 of 15 patients) The laboratory processed, from October 22, 2020 to February 5, 2021, a total of 1,201 patient tests. (3). The laboratory general supervisor confirmed on February 5, 2021 at 10:17 AM, that the laboratory did not document the cassette internal control those days. 2. Based on COVID 19 antigen test quality control, manufacturer's instructions review and laboratory general supervisor interview on February 5, 2021 at 10:17 AM, it was determined that the laboratory failed to follow the manufacturer's instructions, related to internal procedural control,

from December 10, 2020 to February 4, 2021. The findings include: (1). The laboratory performed COVID-19 antigen (Clarity COVID 19 Antigen and CareStart COVID 19 Antigen) tests. (2). Review of the patient's workbook, from December 10, 2020 to February 4, 2021, showed that the laboratory did not document the internal control on the following days: a. 12/14/2020 (4 of 4 patients) b. 12/15/2020 (3 of 3 patients) c. 12/21/2020 (8 of 8 patients) d. 12/22/2020 (12 of 12 patients) e. 12/28 /2020 (8 of 8 patients) f. 12/29/2020 (3 of 3 patients) g. 01/04/2021 (6 of 6 patients) h. 01/07/2021 (9 of 9 patients) The total of patients processed from December 10, 2020 to February 4, 2021: 176 tests performed. (3). The laboratory general supervisor confirmed on February 5, 2021 at 10:17 AM, that the laboratory did not documented the internal control those days.

**D5800**

**POSTANALYTIC SYSTEMS**  
CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on COVID 19 quality control records review and laboratory general supervisor interview on February 5, 2021 at 11:35 AM, it was found that the laboratory failed to ensure compliance with the postanalytic system requirements of patient test results. Refer to D5803 (1) (The laboratory did not document the patient's test results in the COVID 19 IgG / IgM rapid test daily quality control from October 22, 2020 to February 5, 2021). Refer to D5803 (2) (The laboratory did not document the patient's test results in the COVID 19 antigen test daily quality control from December 10, 2020 to February 4, 2021).

**D5803**

**TEST REPORT**  
CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:  
1. Based on Covid 19 daily quality control, patient's results workbook review and laboratory general supervisor interview on February 5, 2021 at 10:12 AM, it was determined that the laboratory failed to document the patient's test results in the COVID 19 IgG / IgM rapid test daily workbook , from from October 22, 2020 to February 5, 2021. The finding includes: (1). The laboratory performed COVID-19 IgG / IgM rapid tests (COVIBLOCK COVID19 IgG/IgM rapid test cassette). (2). The laboratory general supervisor stated on February 5, 2021 at 10:12AM, that the laboratory had a workbook to document the patient results, and later the test results were edited to the laboratory information system (LIS). (3). Review of the patient's workbook, from October 22, to February 5, 2021, showed that the laboratory did not document the patient's tests results on the following days: a. 10/22 / 2020 (12 of 18 patients) b. 10/23/2020 (29 of 29 patients) c. 10/26/2020 (24 of 24 patients) d. 10/27

/2020 (17 of 17 patients) e. 10/28/2020 (10 of 10 patients) f. 10/29/2020 (16 of 16 patients) g. 10/30/2020 (28 of 28 patients) h. 11/02/2020 (28 of 28 patients) i. 11/04/2020 (34 of 34 patients) j. 11/05/2020 (30 of 30 patients) k. 11/06/2020 (37 of 37 patients) l. 11/09/2020 (38 of 38 patients) m. 11/11/2020 (9 of 9 patients) n. 11/12/2020 (56 of 56 patients) o. 11/13/2020 (24 of 24 patients) p. 11/16/2020 (44 of 44 patients) q. 11/17/2020 (12 of 12 patients) r. 11/18/2020 (42 of 42 patients) s. 11/19/2020 (9 of 9 patients) t. 11/20/2020 (36 of 36 patients) u. 11/23/2020 (28 of 28 patients) w. 11/24/2020 (25 out of 25 patients) x. 11/25/2020 (15 out of 15 patients) y. 11/30/2020 (27 of 27 patients) z. 12/01/2020 (15 of 15 patients) aa. 12/02/2020 (32 of 32 patients) bb. 12/03/2020 (33 of 33 patients) cc. 12/04/2020 (31 of 31 patients) dd. 12/09/2020 (11 of 11 patients) ee. 12/10/2020 (42 of 42 patients) ff. 12/11/2020 (9 of 9 patients) gg. 12/14/2020 (29 of 29 patients) hh. 12/15/2020 (38 of 38 patients) ii. 12/16/2020 (13 of 13 patients) jj. 12/17/2020 (15 of 15 patients) kk. 12/18/2020 (39 of 39 patients) ll. 12/21/2020 (22 of 22 patients) mm. 12/22/2020 (18 of 18 patients) nn. 12/23/2020 (9 of 9 patients) pp. 12/28/2020 (14 of 14 patients) qq. 12/29/2020 (15 of 15 patients) rr. 01/04/2021 (12 of 12 patients) ss. 01/07/2021 (17 of 17 patients) tt. 01/08/2021 (18 of 18 patients) uu. 01/11/2021 (11 of 11 patients) ww. 01/12/2021 (15 of 15 patients) The total of patients processed from October 22, 2020 to February 5, 2021: 1, 201 tests performed. (4). The laboratory general supervisor confirmed on February 5, 2021 at 10:17 AM, that the laboratory did not document the patient's results on the workbook on those days. 2. Based on Covid 19 daily quality control / patient's workbook review and laboratory general supervisor interview on February 5, 2021 at 10:17 AM, it was determined that the laboratory failed to document the patient's test results in the COVID 19 antigen test daily quality control /patient workbook , from December 10, 2020 to February 4, 2021. The findings include: (A). The laboratory performed COVID-19 antigen (Clarity COVID 19 Antigen and CareStart COVID 19 Antigen) tests. (B). The laboratory general supervisor stated on February 5, 2021 at 10:12AM, that the laboratory had a workbook to document the patient results, and later the test results were edited to the laboratory information system (LIS). (C). Review of the patient's workbook, from December 10, 2020 to February 4, 2021, showed that the laboratory did not document the patient's tests results on the following days: a. 12/14/2020 (4 of 4 patients) b. 12/15/2020 (3 of 3 patients) c. 12/21/2020 (8 of 8 patients) d. 12/22/2020 (12 of 12 patients) e. 12/28/2020 (8 of 8 patients) f. 12/29/2020 (3 of 3 patients) g. 01/04/2021 (6 of 6 patients) h. 01/07/2021 (9 of 9 patients) The total of patients processed from December 10, 2020 to February 4, 2021: 176 tests performed. (D). The laboratory general supervisor confirmed on February 5, 2021 at 10:17 AM, that the laboratory did not document the patient's results on the workbook on those days. (E) There no evidence of the initially documented patient results that was later edited to the LIS

**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 COVID 19 rapid test serology quality control from October 22, 2020 to February 5, 2021, manufacturer's instructions, patients report review and laboratory general supervisor interview on February 5, 2021 at 11:35 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure

compliance with the quality control and storage, preservation and transportation for samples collection for COVID 19 PCR and sent to reference laboratory. Refer to D5010 (The laboratory failed to ensure compliance with the preanalytic and analytic system requirements of Virology). Refer to D5800 (The laboratory failed to ensure compliance with the postanalytic system requirements of patient test results).

**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 COVID 19 serology test quality control from October 22, 2020 to February 5, 2021 records, manufacturer's instructions review and laboratory general supervisor interview on February 5, 2021 at 11:42 AM, it was determined that the laboratory director did not assure the specimen storage, preservation and transportation test of the PCR (Polymerase Recation Chain) samples referred to the LabCorp reference laboratory, not assure the quality control procedures of the COVID 19 antibody or antigen tests. The findings include: 1. Refer to D5311 (The laboratory did not establish and follow written polices for the specimen storage, preservation and transportation of COVID19 - RT - PCR (Polymerase Reaction Chain) test to reference laboratory). 2. Refer to D5313 (The laboratory did not document the date and time of receive a COVID 19 - RT - PCR specimen). 3. Refer to D5405 (The laboratory did not follow the manufacturer's instruction to document the cassette internal control).

**D6117**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on COVID19 serology quality control (IgG/IgM rapid test and antigen rapid test) from October 22, 2020 to February 5, 2021, manufacturer's instructions review and laboratory general supervisor interview on February 5, 2021 at 11:40 AM, it was determined that the technical supervisor did not ensure procedures the quality control for COVID 19 IgG / IgM rapid test and COVID 19 Antigen rapid test were followed by the testing personnel from October 22, 2020 to February 5, 2021. The findings include: 1. Refer to D5311 (The laboratory did not establish and follow written polices for the specimen storage, preservation and transportation of COVID19 - RT - PCR (Polymerase Reaction Chain) test to reference laboratory). 2. Refer to D5313 (The laboratory did not document the date and time of receive a COVID 19 - RT - PCR specimen). 3. Refer to D5405 (The laboratory did not follow the manufacturer's instruction to document the cassette internal control).