Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0988376	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ecco Lab Group Co	8370 W Flagler St Ste 216, Miami, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A complaint survey for complaint number 2021014912, was conducted on 12/07/2021 to 12/16/2021 at Ecco Lab Group Co. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were not met: D5400-Analytic Systems
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 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. This CONDITION is not met as evidenced by: Based on record review and interview the Laboratory failed to report all SARS-CoV-2 antigen and antibody test results to the Department of Health (DOH) for 3,605 Patients reported. Findings Included: Review of Patient test results from one Account revealed that there were 2,069 SARS-CoV-2 antigen tests and 16 SARS-CoV-2 antibody tests ran from 01/01/2020 to 12/09/2021. Interview on 12/08/2021 at 4:10 PM the Assistant Administrator confirmed that the 2,085 test results were not reported to the DOH. He stated that no tests from this Account were reported to the DOH. Review of Patient SARS-CoV-2 antigen test results of Phlebotomists who work for the Laboratory revealed that there were 1,520 Phlebotomists tests that were not reported to the DOH. Interview on 12/08/21 at 4:20 PM the Assistant Administrator stated that the Phlebotomists have been getting tested weekly since 06/25/2020 and

	that there were 20 Phlebotomists. He confirmed that the results for the Phlebotomists were not reported to the DOH.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document collection time on 5 out of 5 Patient reports reviewed. Findings Included: Review of 5 Patient reports revealed Patient #1 collected on 09/10/21 with no collection time, Patient #2 collected on 09/10/21 with no collection time, Patient #3 collected on 12/07/21 with no collection time, Patient #4 collected on 09/10/21 with no collection time, and Patient #5 collected on 09/10/21 with no collection time. Review of Policy and Procedure (signed and reviewed by the Laboratory Director 01/28/21) did not list no collection time as a reason to reject a specimen. In the "Pre- To- Post Quality Assurance" policy, there is not instruction to monitor collection times. Interview on 12 /08/2021 at 4:30 PM the Molecular Supervisor confirmed that collection times are not documented on SARS-CoV-2 test specimens.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to perform a validation for the use of inactivation transport media (ITM) with ARIES SARS-CoV-2 Assay. The laboratory failed to complete a validation for COVID-19 patient samples shipped and tested outside of manufacturer required 2-8 Celsius (C) using CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. (See D5423)
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observations, record review, and interview the laboratory reported SARS-

	CoV-2 Patient test result (Patient #3) when the collection tube was expired and reported 388 Sensitivities on the Biomerieux Vitek 2 from 11/30/2021 to 12/08/2021 using expired Sodium Chloride. Findings Included: During a tour of the laboratory on 12/07/2021 at 10:13 AM Patient #3's SARS-CoV-2 specimen was observed in a rack in accessioning. The US Diagnostic Virus Sampling Tube (Lot#20206011) expired on 06/09/2021. Review of Patient #3 final report revealed that the specimen was ran and reported on 12/07/2021 at 2:17 PM even though the tube was expired. The Quality Assurance policy (signed by the Laboratory Director on 01/28/2021) did no address expired collection tubes and an expired collection tube was not on their reason for specimen rejection. Interview on 12/08/2021 at 5:00 PM the Molecular Supervisor confirmed that the collection tube was expired and confirmed that the test should not have been run if collected in an expired collection tube. During a tour of the storage area 6 bags of expired 0.45% Sodium Chloride Diluent (Lot# Q2002774) that expired on 08/01/2021 was observed. Interview on 12/07/2021 at 10:45 AM the Molecular Supervisor confirmed that the bags were expired and that they were used on the Biomerieux Vitek 2 in Microbiology that read sensitivities. Observations of the Biomerieux Vitek 2 on 12/07/2021 at 10:55 AM revealed that the expired Sodium Chloride was on the instrument. There was no date of when it was put in use on the instrument. Interview on 12/07/2021 at 10:55 AM the Microbiology technologist stated that he put it on the machine on 11/30/2021 and confirmed that there was no documentation of when it was put on the instrument. "Reagent and Solution Labeling Policy" signed by the Laboratory Director on 06/11/2020 states to "Review the expiration dates on reagents and solutions prior to use." The policy also states that "No reagent is to be used after its listed expiration date."
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: Based on observation, record review and interview, the laboratory failed to perform a validation for the use of inactivation transport media (ITM) with ARIES SARS-CoV-2 Assay. The laboratory failed to complete a validation for COVID-19 patient samples shipped and tested outside of the manufacturer required guidelines of 2-8 Celsius (C) using CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. Findings Included: Review of ARIES SARS-CoV-2 Assay Package Insert stated "Materials Required but not Provided, Reagents for sample collection: Nasopharyngeal swab (NPS) (flocked or polyester swab) and Universal Transport Medium (UTM)." An observation of the sample collection area on 12/07/2021 at 11: 00 AM revealed only ITM tubes for COVID-19 testing. Review of Aries validation revealed no validation for ITM tubes testing on the Aries instrument. Review of CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

	Instructions for Use stated "Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens. Store specimens at 2-8C and ship overnight to CDC on ice pack. If a specimen is frozen at -70C or lower, ship overnight to CDC on dry ice. Specimens can be stored at 2-8C for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -70C or lower. Extracted nucleic acid should be stored at -70C or lower." Review of Stability Study for ITM COVID-19 samples revealed COVID-19 specimens were only tested for a stability study at 22 to 24 degrees C. Review of Molecular Room Temperature Logs revealed temperatures were below 22 degrees C for 227 out 280 days from January 2021 to December 2021. During an observation of the Molecular testing area on 12/07/2021 at 11:20 AM revealed COVID-19 ITM patient samples stored for 3 days on a metal storage shelf at room temperature. Review of COVID-19 Testing revealed 208,231 COVID-19 samples were tested by CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. 1,151 COVID-19 samples were tested by ARIES SARS-CoV-2 Assay Package Insert. During an interview on 12/08/2021 at 6:25 PM , the molecular supervisor confirmed that validation had not been completed for ARIES SARS-CoV-2 Assay and specimen stability for CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document corrective actions when the room, incubator, refrigerator, and freezer temperatures were not within the acceptable temperature ranges or recorded, and when the room humidity was not recorded from 01/02/2020 to 12/07/2021. Findings: 1. Review of the 2020 "Daily Temperature and Humidity Logs" for the Microbiology room and Polymerase Chain Reaction (PCR) room listed the acceptable ranges for the rooms as 18 to 25 degrees Celsius (C). The room temperatures for the microbiology room were out of range and no corrective action was documented for 3 of 356 days. 06/04/2020 temperature 26 degrees C 11/01/2020 temperature 26 degrees C 11/04/2020 temperature 26 degrees C The room temperatures for the PCR room were out of range and no corrective action was documented for 13 of 356 days. 01/12/2020 temperature 27 degrees C 01/14/2020 temperature 26 degrees C 02/16/2020 temperature 26 degrees C 02/17/2020 temperature 27 degrees C 02/18/2020 temperature 26 degrees C 03/07/2020 temperature 26 degrees C 05/29/2020 temperature 26 degrees C 05/31 /2020 temperature 26 degrees C 06/09/2020 temperature 26 degrees C 12/11/2020 temperature 26 degrees C 12/13/2020 temperature 48 degrees C 12/17/2020

temperature 28 degrees C 12/27/2020 temperature 28 degrees C 2. Review of the 2020 "Daily Temperature and Humidity Logs" for the Microbiology room and PCR room listed the acceptable ranges for the incubator #1 and #2 as 36.5 to 37.5 degrees C,. The incubator #1 temperatures were out of range and no corrective action was documented for 35 of 365 days. 01/02/2020 temperature 36.3 degrees C 01/06/2020 temperature 36.3 degrees C 01/13/2020 temperature 36.0 degrees C 01/18/2020 temperature 36.0 degrees C 02/04/2020 temperature 36.3 degrees C 02/09/2020 temperature 36.3 degrees C 02/10/2020 temperature 36.4 degrees C 02/12/2020 temperature 36.3 degrees C 02/13/2020 temperature 36.4 degrees C 02/18/2020 temperature 36.2 degrees C 02/20/2020 temperature 36.3 degrees C 02/25/2020 temperature 36.0 degrees C 02/26/2020 temperature 36.0 degrees C 03/02/2020 temperature 36.3 degrees C 03/10/2020 temperature 36.0 degrees C 03/13/2020 temperature 36.3 degrees C 03/16/2020 temperature 36.3 degrees C 03/17/2020 temperature 36.3 degrees C 04/03/2020 temperature 36.3 degrees C 04/04/2020 temperature 36.3 degrees C 04/10/2020 temperature 36.3 degrees C 04/19/2020 temperature 36.3 degrees C 04/21/2020 temperature 36.2 degrees C 04/23/2020 temperature 36.3 degrees C 05/02/2020 temperature 36.3 degrees C 05/03/2020 temperature 36.3 degrees C 05/06/2020 temperature 36.3 degrees C 05/08/2020 temperature 36.0 degrees C 05/12/2020 temperature 36.0 degrees C 05/23/2020 temperature 36.3 degrees C 06/06/2020 temperature 36.3 degrees C 06/21/2020 temperature 36.2 degrees C 09/22/2020 temperature 36.3 degrees C 09/23/2020 temperature 36.0 degrees C 10/06/2020 temperature 36.1 degrees C The incubator #2 temperatures were out of range and no corrective action was documented for 35 of 365 days. 01/03/2020 temperature 36.0 degrees C 01/15/2020 temperature 36.3 degrees C 01/18/2020 temperature 36.3 degrees C 01/27/2020 temperature 36.3 degrees C 01/28/2020 temperature 36.3 degrees C 01/29/2020 temperature 36.0 degrees C 02/01/2020 temperature 36.3 degrees C 02/02/2020 temperature 36.4 degrees C 02/07/2020 temperature 36.2 degrees C 02/08/2020 temperature 36.1 degrees C 02/14/2020 temperature 36.3 degrees C 03/06/2020 temperature 36.3 degrees C 03/09/2020 temperature 36.0 degrees C 03/12/2020 temperature 36.0 degrees C 03/17/2020 temperature 36.4 degrees C 04/24/2020 temperature 36.2 degrees C 04/25/2020 temperature 36.3 degrees C 04/27/2020 temperature 36.3 degrees C 05/15/2020 temperature 36.2 degrees C 05/19/2020 temperature 36.0 degrees C 05/20/2020 temperature 36.2 degrees C 05/21/2020 temperature 36.2 degrees C 05/22/2020 temperature 36.3 degrees C 05/28/2020 temperature 36.2 degrees C 06/29/2020 temperature 36.0 degrees C 07/07/2020 temperature 36.4 degrees C 07/09/2020 temperature 36.4 degrees C 07/20/2020 temperature 36.0 degrees C 07/30/2020 temperature 36.1 degrees C 07/31/2020 temperature 36.0 degrees C 08/01/2020 temperature 36.3 degrees C 08/02/2020 temperature 36.3 degrees C 09/17/2020 temperature 36.1 degrees C 10/05/2020 temperature 36.4 degrees C 12/20/2020 temperature 36.2 degrees C 3. Review of the 2020 "Daily Temperature and Humidity Logs" for the Microbiology room and PCR room listed the acceptable ranges for the freezer #1 and #2 as -20 to -30 degrees C. The freezer #1 temperatures were out of range and no corrective action was documented for 91 of 365 days. 04/01/2020 temperature 6 degrees C 04/02/2020 temperature 7 degrees C 04 /03/2020 temperature 6 degrees C 04/04/2020 temperature 4 degrees C 04/05/2020 temperature 5 degrees C 04/06/2020 temperature 3 degrees C 04/07/2020 temperature 2 degrees C 04/08/2020 temperature 4 degrees C 04/09/2020 temperature 4 degrees C 04/10/2020 temperature 5 degrees C 04/11/2020 temperature 4 degrees C 04/12/2020 temperature 4 degrees C 04/13/2020 temperature 5 degrees C 04/14/2020 temperature 6 degrees C 04/15/2020 temperature 6 degrees C 04/16/2020 temperature 6 degrees C 04/17/2020 temperature 7 degrees C 04/18/2020 temperature 7 degrees C 04/19/2020 temperature 6 degrees C 04/20/2020 temperature 6 degrees C 04/21/2020 temperature

7 degrees C 04/22/2020 temperature 5 degrees C 04/23/2020 temperature 7 degrees C 04/24/2020 temperature 4 degrees C 04/25/2020 temperature 4 degrees C 04/26/2020 temperature 2 degrees C 04/27/2020 temperature 2 degrees C 04/28/2020 temperature 4 degrees C 04/29/2020 temperature 5 degrees C 04/30/2020 temperature 2 degrees C 05/01/2020 temperature 4 degrees C 05/02/2020 temperature 5 degrees C 05/03/2020 temperature 6 degrees C 05/04/2020 temperature 5 degrees C 05/05/2020 temperature 6 degrees C 05/06/2020 temperature 7 degrees C 05/07/2020 temperature 6 degrees C 05/08/2020 temperature 4 degrees C 05/09/2020 temperature 5 degrees C 05/10/2020 temperature 2 degrees C 05/11/2020 temperature 6 degrees C 05/12/2020 temperature 5 degrees C 05/13/2020 temperature 5 degrees C 05/14/2020 temperature 5 degrees C 05/15/2020 temperature 6 degrees C 05/16/2020 temperature 6 degrees C 05/17/2020 temperature 7 degrees C 05/18/2020 temperature 7 degrees C 05/19/2020 temperature 6 degrees C 05/20/2020 temperature 4 degrees C 05/21/2020 temperature 4 degrees C 05/22/2020 temperature 5 degrees C 05/23/2020 temperature 6 degrees C 05/24/2020 temperature 4 degrees C 05/25/2020 temperature 5 degrees C 05/26/2020 temperature 6 degrees C 05/27/2020 temperature 3 degrees C 05/28/2020 temperature 3 degrees C 05/29/2020 temperature 3 degrees C 05/30/2020 temperature 2 degrees C 05/31/2020 temperature 2 degrees C 06/01/2020 temperature 6 degrees C 06/02/2020 temperature 6 degrees C 06/03/2020 temperature 6 degrees C 06/04/2020 temperature 6 degrees C 06/05/2020 temperature 7 degrees C 06/06/2020 temperature 5 degrees C 06/07/2020 temperature 4 degrees C 06/08/2020 temperature 3 degrees C 06/09/2020 temperature 4 degrees C 06/10/2020 temperature 2 degrees C 06/11/2020 temperature 2 degrees C 06/12/2020 temperature 8 degrees C 06/13/2020 temperature 2 degrees C 06/14/2020 temperature 4 degrees C 06/15/2020 temperature 8 degrees C 06/16/2020 temperature 5 degrees C 06/17/2020 temperature 4 degrees C 06/18/2020 temperature 3 degrees C 06/19/2020 temperature 2 degrees C 06/20/2020 temperature 2 degrees C 06/21/2020 temperature 4 degrees C 06/22/2020 temperature 3 degrees C 06/23/2020 temperature 3 degrees C 06/24/2020 temperature 2 degrees C 06/25/2020 temperature 4 degrees C 06/26/2020 temperature 4 degrees C 06/27/2020 temperature 5 degrees C 06/28/2020 temperature 3 degrees C 06/29/2020 temperature 3 degrees C 06/30/2020 temperature 3 degrees C The freezer #2 temperatures were out of range and no corrective action was documented for 91 of 365 days. 04/01/2020 temperature 4 degrees C 04/02/2020 temperature 3 degrees C 04/03/2020 temperature 4 degrees C 04/04/2020 temperature 2 degrees C 04/05/2020 temperature 4 degrees C 04/06/2020 temperature 4 degrees C 04/07/2020 temperature 5 degrees C 04/08/2020 temperature 5 degrees C 04/09/2020 temperature 4 degrees C 04/10/2020 temperature 4 degrees C 04/11/2020 temperature 3 degrees C 04/12/2020 temperature 2 degrees C 04/13/2020 temperature 2 degrees C 04/14/2020 temperature 4 degrees C 04/15/2020 temperature 6 degrees C 04/16/2020 temperature 6 degrees C 04/17/2020 temperature 5 degrees C 04/18/2020 temperature 5 degrees C 04/19/2020 temperature 7 degrees C 04/20/2020 temperature 6 degrees C 04/21/2020 temperature 7 degrees C 04/22/2020 temperature 5 degrees C 04/23/2020 temperature 8 degrees C 04/24/2020 temperature 4 degrees C 04/25/2020 temperature 3 degrees C 04/26/2020 temperature 2 degrees C 04/27/2020 temperature 4 degrees C 04/28/2020 temperature 3 degrees C 04/29/2020 temperature 2 degrees C 04/30/2020 temperature 3 degrees C 05/01/2020 temperature 5 degrees C 05/02/2020 temperature 7 degrees C 05/03/2020 temperature 8 degrees C 05/04/2020 temperature 6 degrees C 05/05/2020 temperature 6 degrees C 05/06/2020 temperature 8 degrees C 05/07/2020 temperature 5 degrees C 05/08/2020 temperature 3 degrees C 05/09/2020 temperature 4 degrees C 05/10/2020 temperature 4 degrees C 05/11/2020 temperature 5 degrees C 05/12/2020 temperature 4 degrees C 05/13/2020 temperature 3 degrees C 05/14/2020 temperature 3 degrees C 05/15/2020 temperature 4 degrees C 05/16/2020 temperature 5 degrees C 05/17/2020 temperature 4 degrees C 05/18/2020 temperature 3 degrees C 05/19/2020 temperature 2 degrees C 05/20/2020 temperature 2 degrees C 05/21/2020

temperature 4 degrees C 05/22/2020 temperature 5 degrees C 05/23/2020 temperature 3 degrees C 05/24/2020 temperature 3 degrees C 05/25/2020 temperature 2 degrees C 05/26/2020 temperature 2 degrees C 05/27/2020 temperature 4 degrees C 05/28/2020 temperature 4 degrees C 05/29/2020 temperature 4 degrees C 05/30/2020 temperature 2 degrees C 05/31/2020 temperature 4 degrees C 06/01/2020 temperature 4 degrees C 06/02/2020 temperature 4 degrees C 06/03/2020 temperature 4 degrees C 06/04/2020 temperature 4 degrees C 06/05/2020 temperature 3 degrees C 06/06/2020 temperature 5 degrees C 06/07/2020 temperature 4 degrees C 06/08/2020 temperature 3 degrees C 06/09/2020 temperature 6 degrees C 06/10/2020 temperature 2 degrees C 06/11/2020 temperature 4 degrees C 06/12/2020 temperature 2 degrees C 06/13/2020 temperature 5 degrees C 06/14/2020 temperature 6 degrees C 06/15/2020 temperature 4 degrees C 06/16/2020 temperature 8 degrees C 06/17/2020 temperature 7 degrees C 06/18/2020 temperature 4 degrees C 06/19/2020 temperature 3 degrees C 06/20/2020 temperature 2 degrees C 06/21/2020 temperature 4 degrees C 06/22/2020 temperature 7 degrees C 06/23/2020 temperature 7 degrees C 06/24/2020 temperature 4 degrees C 06/25/2020 temperature 4 degrees C 06/26/2020 temperature 5 degrees C 06/27/2020 temperature 7 degrees C 06/28/2020 temperature 5 degrees C 06/29/2020 temperature 6 degrees C 06/30/2020 temperature 3 degrees C 4. Review of the 2021 "Daily Temperature and Humidity Logs (Microbiology) listed the acceptable ranges for Room Temp #6 as 20 to 25 degrees C, Room Temp #7 as 18-25 degrees C, and Room Temp #8 as 20 to 25 degrees C. The Room Temp #6 temperatures were out of range or not recorded, and no corrective action was documented for 24 of 342 days. 02/21/2021 no temperature was recorded 04/27/2021 temperature 19 degrees C 05/16/2021 temperature 19 degrees C 05/17/2021 temperature 19 degrees C 05/18/2021 temperature 19 degrees C 06/24/2021 temperature 26 degrees C 06/25/2021 temperature 26 degrees C 06/27/2021 temperature 26 degrees C 06/29/2021 temperature 26 degrees C 07/02/2021 temperature 26 degrees C 07/06/2021 temperature 26 degrees C 07/07/2021 temperature 26 degrees C 07/08/2021 temperature 27 degrees C 07/09/2021 temperature 27 degrees C 07/10/2021 temperature 28 degrees C 07/11/2021 temperature 26 degrees C 07/12/2021 temperature 26 degrees C 07/16/2021 temperature 26 degrees C 07/19/2021 temperature 26 degrees C 07/25/2021 temperature 26 degrees C 07/26/2021 temperature 26 degrees C 07/27/2021 temperature 26 degrees C 08/10/2021 temperature 26 degrees C 08/11/2021 temperature 27 degrees C 08/12/2021 temperature 27 degrees C The Room Temp #7 temperatures were not recorded and no corrective action was documented for 3 of 342 days. 02/21/2021 no temperature was recorded 07/01/2021 no temperature was recorded 07/31/2021 no temperature was recorded The Room Temp #8 temperatures were out of range or not recorded, and no corrective action was documented for 30 of 342 days. 02/20/2021 no temperature was recorded 02/21/2021 no temperature was recorded 05/29/2021 no temperature was recorded 05/30/2021 no temperature was recorded 05/31/2021 no temperature was recorded 07/02/2021 temperature 27 degrees C 07/05/2021 temperature 27 degrees C 07/06/2021 temperature 27 degrees C 07/07/2021 temperature 26 degrees C 07/08/2021 temperature 27 degrees C 07/19/2021 temperature 28 degrees C 07/10/2021 temperature 26 degrees C 07/11/2021 temperature 29 degrees C 07/12/2021 temperature 29 degrees C 07/14/2021 temperature 30 degrees C 07/15/2021 temperature 29 degrees C 07/16/2021 temperature 27 degrees C 07/17/2021 temperature 27 degrees C 07/18/2021 temperature 28 degrees C 07/19/2021 temperature 29 degrees C 07/20/2021 temperature 29 degrees C 07/21/2021 temperature 27 degrees C 07/22/2021 temperature 26 degrees C 07/25/2021 temperature 26 degrees C 07/26/2021 temperature 26 degrees C 07/27/2021 temperature 26 degrees C 07/26/2021 temperature 26 degrees C 07/27/2021 temperature 26 degrees C 08/26/2021 temperature 26.8 degrees C 08/27/2021 temperature 26.8 degrees C 5. Review of the

2021 "Daily Temperature and Humidity Logs (Microbiology) listed the acceptable ranges for incubator #1, #2 and #3 as 37 degrees C Plus/Minus 2 degrees. The incubator #1, #2, and #3 temperatures were not recorded and no corrective action was documented for 02/21/2021. 6. Review of the 2021 "Daily Temperature and Humidity Logs (Microbiology) listed the acceptable ranges for refrigerator #6 as 2 to 8 degrees C. The refrigerator #4 and refrigerator #5 temperatures were not recorded and no corrective action was documented for 02/21/2021. The refrigerator #6 temperatures were out of range or not recorded, and no corrective action was documented for 11 of 342 days. 02/21/2021 no temperature was recorded 09/03/2021 temperature 0 degrees C 09/04/2021 temperature 2 degrees C 09/05/2021 temperature -1 degrees C 09/06 /2021 temperature -1 degrees C 09/07/2021 temperature -1 degrees C 09/08/2021 no temperature was recorded 09/09/2021 temperature -4 degrees C 09/10/2021 temperature 1 degrees C 09/11/2021 temperature 1 degrees C 09/20/2021 temperature 1 degrees C 7. Review of the 2021 "Daily Temperature and Humidity Logs (Microbiology) listed the acceptable ranges for incubator as 37 degrees C plus/minus 2 degrees C. The incubator #1, #2, and #3 temperatures were not recorded, and no corrective action was documented for 02/21/2021. 8. Review of the 2021 "Daily Temperature and Humidity Logs (Microbiology) listed the acceptable ranges for freezers #3 as -10 to -20 degrees C. The log did not list the acceptable ranges for freezers #4. The freezer #3 and #4 temperatures were not recorded, and no corrective action was documented for 02/21/2021. 9. Review of the 2021 "Daily Temperature and Humidity Logs (Microbiology) listed the acceptable ranges for the humidity as 30 to 90% (percent). The humidity for room #6 and #7 not recorded, and no corrective action was documented for 02/21/2021. The humidity for room #8 not recorded, and no corrective action was documented for 5 of 342 days. 02/20/2021 no humidity was recorded 02/21/2021 no humidity was recorded 05/29/2021 no humidity was recorded 05/30/2021 no humidity was recorded 05/31/2021 no humidity was recorded 10. Review of the 2021 "Daily Temperature and Humidity Logs" for the PCR room listed the acceptable ranges for the room #9 of 18 to 25 degrees C, room #10 and #11 of 20 to 25 degrees C. The room temperatures for the PCR room #9 were out of range and no corrective action was documented for 7 of 342 days. 07/01/2021 temperature 16 degrees C 07/07/2021 temperature 17 degrees C 07/08/2021 temperature 17 degrees C 07/09/2021 temperature 17 degrees C 07/10/2021 temperature 16 degrees C 07/13 /2021 temperature 17 degrees C 07/14/2021 temperature 16 degrees C The room temperatures for the PCR room #10 were out of range and no corrective action was documented for 64 of 341 days. 02/02/2021 temperature 19 degrees C 02/03/2021 temperature 19 degrees C 02/04/2021 temperature 19 degrees C 05/03/2021 temperature 19 degrees C 05/05/2021 temperature 18 degrees C 05/07/2021 temperature 18 degrees C 05/10/2021 temperature 19 degrees C 05/11/2021 temperature 19 degrees C 05/12/2021 temperature 19 degrees C 05/13/2021 temperature 18 degrees C 05/14/2021 temperature 19 degrees C 05/15/2021 temperature 19 degrees C 05/16/2021 temperature 19 degrees C 05/18/2021 temperature 18 degrees C 05/20/2021 temperature 18 degrees C 05/21/2021 temperature 19 degrees C 05/31/2021 temperature 19 degrees C 06/02/2021 temperature 19 degrees C 06/03/2021 temperature 18 degrees C 06/05/2021 temperature 19 degrees C 06/06/2021 temperature 18 degrees C 06/07/2021 temperature 18 degrees C 06/08/2021 temperature 19 degrees C 06/09/2021 temperature 19 degrees C 06/10/2021 temperature 19 degrees C 06/11/2021 temperature 19 degrees C 06/12/2021 temperature 18 degrees C 06/13/2021 temperature 19 degrees C 06/14/2021 temperature 18 degrees C 06/15/2021 temperature 19 degrees C 06/18/2021 temperature 19 degrees C 06/19/2021 temperature 19 degrees C 06/20/2021 temperature 18 degrees C 06/21/2021 temperature 19 degrees C 06/22/2021 temperature 19 degrees C 06/23/2021

	temperature 19 degrees C 06/24/2021 temperature 19 degrees C 06/25/2021 temperature 18 degrees C 06/26/2021 temperature 17 degrees C 06/27/2021 temperature 17 degrees C 06/28/2021 temperature 17 degrees C 06/29/2021 temperature 18 degrees C 06/30/2021 temperature 17 degrees C 06/02/2021 temperature 19 degrees C 07/01/2021 temperature 17 degrees C 07/02/2021 temperature 17 degrees C 07/03/2021 temperature 17 degrees C 07/05/2021 temperature 17 degrees C 07/06/2021 temperature 17 degrees C 07/07/2021 temperature 17 degrees C 07/08/2021 temperature 17 degrees C 07/09/2021 temperature 17 degrees C 07/10/2021 temperature 16 degrees C 07/11/2021 temperature 17 degrees C 07/12/2021 temperature 17 degrees C 07/13/2021 temperature 17 degrees C 07/14/2021 temperature 19 degrees C 07/18/2021 temperature 19 degrees C 07/19/2021 temperature 19 degrees C 07/25/2021 temperature 19 degrees C 07/26/2021 temperature 19 degrees C 07/27/2021 temperature 19 degrees C 08/27/2021 temperature 19 degrees C 08/29/2021 temperature 19 degrees C The room temperatures for the PCR room #11 were out of range and no corrective action was documented for 14 of 341 days. 01/31/2021 temperature 27 degrees C 06/19/2021 temperature 19 degrees C 11/05/2021 temperature 19 degrees C 11/16/2021 temperature 19 degrees C 11/20/2021 temperature 19 degrees C 11/22/2021 temperature 19 degrees C 11/25/2021 temperature 19 degrees C 11/27/2021 temperature 19 degrees C 11/29/2021 temperature 19 degrees C 11/30/2021 temperature 19 degrees C 11/01/2021 temperature 19 degrees C 11/03/2021 temperature 19 degrees C 11/04/2021 temperature 19 degrees C 11/05/2021 temperature 19 degrees C 11. Review of the 2021 "Daily Temperature and Humidity Logs" for the PCR rooms listed the acceptable ranges for the freezer #5 and #8 as -18 to -24 degrees C, freezer #6 as -29 to -34 degrees C, and freezer #7 as -67 to -72 degrees C. The freezer #5 temperatures were out of range and no corrective action was documented for 5 of 341 days. 01/15 /2021 temperature -25 degrees C 01/18/2021 temperature -25 degrees C 11/16/2021 temperature -25 degrees C 11/17/2021 temperature -26 degrees C 11/25/2021 temperature -26 degrees C The freezer #6 temperatures were out of range and no corrective action was documented for 5 of 341 days. 01/23/2021 temperature -37 degrees C 12/03/2021 temperature -26 degrees C 12/04/2021 temperature -27 degrees C 12/05/2021 temperature -26 degrees C 12/07/2021 temperature -28 degrees C The freezer #7 temperatures were out of range and no corrective action was documented for 6 of 341 days. 01/31/2021 temperature -75 degrees C 02/28/2021 temperature -73 degrees C 11/01/2021 temperature -72.3 degrees C 11/19/2021 temperature -72.2 degrees C 11/29/2021 temperature -72.9 degrees C 11/30/2021 temperature -72.6 degrees C The freezer #8 temperatures were out of range and no corrective action was documented for 5 of 341 days. 12/02/2021 temperature -26 degrees C 12/03/2021 temperature -30 degrees C 12/04/2021 temperature -26 degrees C 12/05/2021 temperature -27 degrees C 12/06/2021 temperature -26 degrees C On 12/08/2021 at 6: 02 PM, the Laboratory Supervisor acknowledge there were no corrective actions
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor failed to do 6

	months competency for 1 Testing Personnel (TP) out of 12 TP in 2020, failed to sign initial and six month competency for 1 TP in 2020 and for 1 TP in 2021. Findings Include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 12/07/2021 revealed the following: a) There were 2 TS (A and B). TS A oversaw Chemistry Area and TS B, was in charge of Microbiology, Diagnostic Immunology and Hematology Areas, TS B is also the GS. b) There were 12 TP: A, B, C, D, E, F, G, H, I J, K and L. c) Employee records review revealed that the TS failed to : - To do the six-month competency evaluation for TP J in 2020. - To sign the initial and six-month evaluation for TP L in 2020. -To sign initial and six-month evaluation for TP H in 2021. During an interview on 12/08/2021 at 06:25 PM with TS, he confirmed that he failed to do the competency six-month assessment for TP J in 2020 and failed to sign the competencies listed above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor failed to sign annual competency for 1 Testing Personnel (TP) out of 12 TP in 2020. Findings Include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 12/07/2021 revealed the following: a) There were 2 TS (A and B). TS A oversaw Chemistry Area and TS B, was in charge of Microbiology, Diagnostic Immunology and Hematology Areas, TS B is also the GS. b) There were 12 TP: A, B, C, D, E, F, G, H, I J, K and L. c) Employee records review revealed that the TS failed to: - To sign the annual competency for TP F in 2020. During an interview on 12/08/2021 at 06:30 PM with TS, he confirmed that he failed to sign competence listed above.