Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2074451	05/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Vista Clinical Diagnostics	3303 North Main Street Suite C, Danville, VA	

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	An announced CLIA Recertification survey was conducted at Vista Clinical Diagnostics on May 18-20, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Conditions: D5400 -42 C.F.R. 493-1250 Condition: Analytic Systems; D6076- 42 C.F.R. 493-1441 Condition: Laboratory Director. The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and an interview, the lab director or designee failed to sign seven of 12 PT attestation statements reviewed. Findings include: 1. Review of the American Proficiency Institute (API) chemistry PT records for four events in 2020 and eight events in 2021 revealed lack of documentation of the lab director or designee signature(s) on the attestation statements for the following events: 2020 Chemistry Core Event 3, 2020 Immunology/Immunohematology Event 3, 2021 Chemistry Core Event 1, 2021 Chemistry Miscellaneous Event 1, 2021 Immunology/Immunohematology Event 1 and Event 2, and 2021 Hematology/Coagulation Event 1. 2. An exit interview with the Laboratory Director, Chief Executive Director, Laboratory Manager, and Microbiology Technical Supervisor on May 20, 2022 at approximately 11:00 AM confirmed the above findings.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation and interviews, the lab failed to verify the accuracy of the parathyroid hormone (PTH) analyte twice a year in 2021. Findings include: 1. The laboratory utilizes American Proficiency Institute (API) PT for verification of accuracy of the PTH analyte, categorized as a non-regulated analyte. 2. API provides three events per calendar year for the PTH analyte. Review of the 2021 API PT results revealed the laboratory received the following scores: 2021 Routine Chemistry Event 1- 100% for PTH, 2021 Routine Chemistry Event 2- 50% for PTH and 2021 Routine Chemistry Event 3- 0% for PTH. On 05/19/22 at approximately 11:15 AM, the surveyor requested the laboratory manager/technical supervisor (TS) provide documentation of an alternative method(s) for verification of accuracy twice a year for the above-specified analyte in 2021. The documentation was not available for review. 3. An exit interview with the Laboratory Director, Chief Executive Director, Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings.
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 a tour, review of policies/procedures, maintenance/temperature records, calibration verification, analyzer operation guide, patient test logs, lack of documentation, and interviews, the laboratory failed to: 1. document monitoring of the microbiology molecular lab room temperature for fifteen (15) of the sixteen (16) months reviewed (January 2021 to the time of the inspection May 18-20, 2022) while reporting forty seven thousand sixty-eight (47,068) SARS-CoV-2 patient results- Refer to D5413 part A; 2. follow manufacturer instructions for storage of chemistry quality control (QC) and calibration materials- Refer to D5413 part B; 3. follow established policies for required preventative maintenance protocols for the microbiology molecular lab room's Thermo Fisher QuantStudio for 15 of 16 months reviewed (timeframe outlined above)- Refer to D5429 part A (*repeat deficiency); 4. follow the established policy of performing the manufacturer's preventative maintenance for the two Compact/STAGO coagulation analyzers- Refer to D5429 part B; 5. perform calibration validation studies twice annually per their policy for Tosoh G8 Glycohemoglobin assay while reporting twenty three thousand ninety (23,090) patient results in calendar year 2021- Refer to D5439; 6. follow the established policy of performing Prothrombin Time and Internal Normalized Ration

	(PT/INR) and Activated Prothrombin Time (PTT) QC materials every eight hours- Refer to D5545 (*repeat deficiency); and 7. follow their approved individualized quality control plan (IQCP) for twice annual analyzer comparison of polymerase chain reaction (PCR) amplification microbiology test panel results- Refer to D5775.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A. Based on a tour, review of policies and available temperature records, lack of documentation, patient test logs, and interviews, the laboratory failed to document monitoring of the microbiology molecular lab room temperature for fifteen (15) of the sixteen (16) months reviewed (January 2021 to the time of the inspection May 18-20, 2022) while reporting forty seven thousand sixty-eight (47,068) SARS-CoV-2 patient results. Findings include: 1. During a tour of the laboratory on 5/18/22 at approximately 10:00 AM, the inspectors noted high complexity real time (RT) Lyra Direct Polymerase Chain Reaction (PCR) assays were being utilized for SARS-CoV-2 testing on Thermo Fisher QuantStudio 7 Pro in the facility's single use room designated as the "microbiology molecular SARS-CoV-2 room". 2. Review of the laboratory's RT PCR Lyra Direct QuantStudio procedures revealed instructions outlined under Assay Procedure: "Run the procedures at controlled room temperatures of 20 C - 25 C." 3. Review of the laboratory's available temperature logs revealed no documentation of monitoring the microbiology molecular SARS-CoV-2 room. The inspectors requested to review the room temperature records for the timeframe of January 2021 to 5/19/22. The microbiology technical supervisor (TS) provided a view of the laboratory's Media Lab electronic temperature records for the the time of 4/26 /22 to 5/19/22. The microbiology TS stated on 5/19/22 at approximately 1:00 PM: "We started monitoring the temperature in this area a few weeks ago on April 26, 2022. We were not monitoring the room temperature prior." 4. Review of the laboratory's patient test logs for the timeframe of January 2021 to 4/25/22 revealed 47,068 SARS-CoV-2 patient results were reported while not verifying adherence to the established procedure's room temperature requirements. 5. An exit interview with the Laboratory Director, Chief Executive Director, Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings. B. Based on tour of the lab, manufacturer package inserts, freezer temperature records, policy and procedure (P&P), and interviews, the laboratory failed to follow manufacturer instructions for storage of chemistry quality control (QC) materials for 142 of 211 days reviewed in 2021 and 2022. Findings include: 1. Tour of the lab 05/18/22 at approximately 10 AM, the surveyor observed a stand-alone freezer in the chemistry testing area. The freezer contained BioRad Liquid Assay Multiqual (levels 1&3), BioRad Liquicheck Immunology (levels 1, 2 & 3), BioRad Liquicheck Specialty Immunoassay (levels 1&2) QC materials and Applied Biosystems 96-well 2 mL Spectral Calibration plates. 2. Review of the manufacturer package inserts revealed the following temperature storage requirements: BioRad

	Liquid Assay Multiqual (level 1&3)- store frozen at -20 to -70 degrees Celsius, BioRad Liquicheck Immunology (levels 1, 2 & 3)- store frozen at -20 to -70 degrees Celsius, BioRad Liquicheck Specialty Immunoassay (level 1&2)- store frozen at -20 to -70 degrees Celsius, and Applied Biosystems 96-well 2 mL Spectral Calibration plates- store frozen at -20 degrees Celsius or colder. 3. Random selection of months and days of freezer temperature records (recorded in the Orchard Harvest laboratory information system) revealed the following: February 2021- 21 days recorded as warmer than -20 degrees Celsius, April 2021- 8 days recorded as warmer than -20 degrees Celsius, June 2021- 8 days recorded as warmer than -20 degrees Celsius, August 2021- 18 days recorded as warmer than -20 degrees Celsius, December 2021- 30 days recorded as warmer than -20 degrees Celsius, January 2022- 27 days recorded as warmer than -20 degrees Celsius, and April 2022- 30 days recorded as warmer than -20 degrees Celsius. Total 142 of 211 days reviewed. 4. Review of P&P revealed a policy (D-10-120 Temp Monitoring and Thermometer Calibration) that stated, "Reagent/specimen freezers must by less than or equal to -20 to -10 degrees Celsius depending on if reagents or specimens are stored in them." 5. The laboratory manager /technical supervisor (TS) acknowledged the storage of the aforementioned materials in the freezer and recorded temperatures during an interview on 05/19/22 at approximately 1535. 6. An exit interview with the Laboratory Director, Chief Executive Director, Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings.
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: *REPEAT DEFICIENCY for lack of maintenance documentation by the laboratory* A. Based on a review of policies/procedures, available maintenance records, lack of documentation, and interviews, the laboratory failed to follow established policies for required preventative maintenance protocols for the microbiology molecular lab room's Thermo Fisher QuantStudio 7 Pro for fifteen (15) of the sixteen (16) months reviewed (timeframe: January 2021 to the time of the inspection May 18-20, 2022). Findings include: 1. Review of the laboratory's Standard Operating Procedures revealed a Quality Assessment Plan that stated under Section XIV Quality Control Assessment: "Preventative maintenance is performed according to manufacturer's recommendations for all instruments and equipment." 2. Review of the laboratory's SARS-CoV-2 Thermo Fisher QuantStudio 7 Pro procedures and maintenance guidelines revealed the following required maintenance protocols (outlined under "Quality Assurance Schedule QuantStudio Real-Time PCR System"): Weekly - check disk space, archive or back up files and instrument settings, power off/on the computer, clean surface of instrument; Monthly - perform a background calibration, run disk cleanup and disk defragmentation, perform instrument self test; Semi-annually - perform a ROI calibration, perform a background calibration, perform a dye calibration, perform a normalization calibration. 3. Review of the laboratory's available microbiology maintenance log records revealed lack of documentation for the above required maintenance tasks in calendar year 2021 and up to the date of the survey request on 5/19/22. The inspectors requested to review documentation for the maintenance. The microbiology technical supervisor (TS) stated on 5/19/22 at

	approximately 3 PM: "We initiated recording the maintenance a few weeks ago after receiving an email from our lab director to do so. We started recording the maintenance into Media Lab on 4/26/22." 4. An exit interview with the Laboratory Director, Chief Executive Director, Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings. B. Based on a tour of the lab, policy and procedures (P&P), manufacturer guidelines, maintenance records, and interviews, the lab failed to follow the established policy of performing the manufacturer's preventative maintenance for the two Compact/STAGO coagulation analyzers for eight of 12 months reviewed. Dates of record review 01/01 /21 up to 12/31/21. Findings include: 1. During a tour of the lab on 05/18/22 at approximately 10 AM, the surveyor observed two coagulation analyzers: Sysmex CS-2500 and Sysmex CA-600. An interview with the technical supervisor (TS) during the tour revealed the Sysmex analyzers were new as of January 2022 and that the lab discontinued the use of the previous two Comact/STAGO coagulation analyzers as of January 2022. 2. Review of the P&P revealed a Quality Assessment Plan that stated under Section XIV Quality Control Assessment, "Preventative maintenance is performed according to manufacturer's recommendations for all instruments and equipment." 3. Review of the Comact/STAGO user's guide revealed the following maintenance guidelines: Weekly- clean air filters, clean product and sample drawers, clean the measurement plate and suction tip, check the Peltier reservoir, clean washing well, and perform needle purge. Monthly- Replace the syringe Teflon tip and O-ring. 4. Review of maintenance records recorded in the Orchard Harvest laboratory information system (LIS) for the two Comact/STAGO coagulation analyzers (serial numbers 311A499 and 311A500) revealed lack of documentation of the weekly and monthly maintenance from 01/01/21 up to 09/13/21. 5. An exit interview with the Laboratory Director, Chief Executive Director, Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings.
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 a tour, review of calibration verification records, procedures, analyzer operations guide, patient test logs, lack of documentation, and interviews, the laboratory failed to perform calibration validation studies twice annually per their policy for Glycohemoglobin (HbA1c) while reporting twenty three thousand ninety (23,090) patient results in calendar year 2021. Findings include: 1. During a tour of the laboratory on 5/18/22 at approximately 10:00 AM, the inspectors noted a Tosoh G8 HPLC analyzer (serial number 10517206R) in use for patient HbA1c measurements. 2. Review of the laboratory's available chemistry calibration verification documentation revealed no calibration verification records for the Tosoh G8 HbA1c assay for calendar year 2021 and up to the date of the survey. The inspector requested to review documentation of HbA1c assay calibration verification studies performed in calendar year 2021 and year to date 2022. No documentation was available for review. 3. Review of the laboratory's procedures revealed a policy (titled: Calibration Verification, #D-10-100) that stated, "Calibration verification is intended to confirm that the calibration setting continues to provide accurate results over the reportable range of the test system. It requires a minimum of three specimens (low, mid-point, high). These specimens need to have known values and should be tested in the manner as patients. Perform calibration verification six months on every instrument where the test is calibrated with 2 or less calibrators". A schedule for laboratory studies quality assurance form is checked on a monthly basis to ensure that the calibration verification studies are performed every 6 months". 4. Review of the manufacturer's Tosoh G8 operator's guide revealed a two-point calibration. The inspectors requested to review the quality assurance form for HbA1c mentioned in the policy outlined above. No record was available for review. 5. Review of the laboratory's patient test logs revealed 23,090 HbA1c patient results were resulted from the Tosoh G8 in calendar year 2021. 6. An exit interview with the Laboratory Director, Chief Executive Director, Laboratory Manager, and Microbiology Technical Supervisor on May 20, 2022 at approximately 11:00 AM confirmed the above findings.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a tour of the lab, the review of CLIA Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116), policy and procedures (P&P), quality control (QC) records, daily patient testing log, and interviews, the lab failed to follow the established policy of performing Prothrombin Time and Internal Normalized Ration (PT/INR) and Activated Prothrombin Time (PTT) QC materials every eight hours for 48 days of 365 days reviewed. Dates of record review 05/18/21 up to 05/18/22. Finding include: 1. During a tour of the lab on 05/18/22 at approximately 10 AM, the surveyor observed two coagulation analyzers, Sysmex CS-2500 and Sysmex CA-600. An interview with the technical supervisor during the tour revealed the Sysmex analyzers were new as of January 2022 and that the lab discontinued the use of the previous two Comact/STAGO coagulation analyzers as of January 2022. 2. Review of CMS-116 form revealed hours of operation as 7 AM-

	2300 (total of 17 hours). An interview with the laboratory manager/technical supervisor (TS) on 05/19/22 at 10:43 AM revealed the lab assays patient samples for PT/INR and PTT analytes after hours of operation (>2300) as needed. They stated, "We do run patients for coag testing on third shift as needed. We perform QC on first and second shift but not currently on third shift." 3. Review of the P&P revealed a Quality Management System policy (D-10-010) that defined frequency of performing QC procedures for the coagulation analyzers as every 8 hours. 4. Review of daily QC records for the two Comact/STAGO coagulation analyzers from 05/18/21 up to 01/24 /22 and the two Sysmex coagulation analyzers from 01/24/22 up to 05/18/22 revealed lack of documentation of the performance of PT/INR and PTT QC materials from midnight (2300) up to 7 AM for 48 of 356 days reviewed. 5. Review of the daily patient testing report accessed from the Orchard Harvest laboratory information system (LIS) revealed 153 patients assayed and reported during the hours of midnight (2300) up to 7 AM on the 48 days lacking QC from 05/18/21 up to 05/18/22. 6. An exit interview with the Laboratory Director, Chief Executive Director, Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies/procedures, quality assurance (QA) records, lack of documentation, and interviews, the laboratory failed to follow their approved individualized quality control plan (IQCP) for twice annual analyzer comparison of polymerase chain reaction (PCR) amplification microbiology test panel results performed on two (2) Becton Dickinson BD Max instruments in calendar year 2021. Findings include: 1. During a laboratory tour on 5/18/22 at approximately 10 AM, the inspectors noted 2 BD Max analyzer's in use for PCR amplification testing for C. difficile toxin (Cdiff), Enteric Bacteria Panel (Salmonella, Campylobacter jejuni and coli, Shigella, Enteroinvasive E. coli, Shiga Toxin), Enteric Parasite Panel (Giardia lamblia, Cryptosporidium, Entamoeba histolytica) and SARS-CoV-2 real-time (RT) PCR. 2. Review of the laboratory's policies/procedures revealed a QA IQCP (approved/dated 12/8/20) to evaluate every six months a comparison of PCR testing resulted on the 2 BD Max Instruments: Serial Number (SN) CT0853 and SN CT1766. 3. Review of the laboratory's QA records from January 2021 through the second day of the survey on 5/19/22 revealed two BD Max instrument comparison studies were documented (dated/approved on 10/4/21, 4/1/22). The inspectors requested to review additional BD Max instrument comparison studies for Cdiff, Enteric Bacteria Panel, Enteric Parasite Panel, and SARS-CoV-2 RT PCR performed in calendar year 2021. No additional records for calendar year 2021 were available for review. The microbiology technical supervisor (TS) stated on 5/19/22 at approximately 1:00 PM, "I started here in September of 2021 and the previous supervisor notified me that the instrument comparison studies had not been performed yet for the year due to lack of staffing. She informed me of this on her last day here." 4. An exit interview with the Laboratory Director, Chief Executive Director,

	Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings.
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 a tour of the lab, the review of CLIA Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116), Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), policy and procedures (P&P), quality control (QC) records, daily patient testing log, laboratory personnel files, quality assessment policy, lack of documentation, and interviews, the laboratory director (LD) failed to ensure: 1. the established policy of performing Prothrombin Time and Internal Normalized Ration (PT/INR) and Activated Prothrombin Time (PTT) QC materials every eight hours of patient testing- Refer to D6093. 2. the laboratory adhered to established QA policies- Refer to D6094. 3. a semi-annual competency evaluation was performed for a newly assigned primary testing personnel responsible for the high complexity SARS-CoV-2 Thermo Fisher QuantStudio 7 Pro assay- Refer to D6102 part A. 4. a technical supervisor (TS) competency evaluation was performed for a newly assigned personnel responsible for the technical supervision of the facility's microbiology department- Refer to D6102 part B.
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 a tour of the lab, the review of CLIA Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116), policy and procedures (P&P), quality control (QC) records, daily patient testing log, and interviews, the lab director failed to ensure the established policy of performing Prothrombin Time and Internal Normalized Ration (PT/INR) and Activated Prothrombin Time (PTT) QC materials every eight hours of patient testing for 48 days of 365 days reviewed. Refer to D 5545.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 a tour, review of maintenance records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, quality assessment policy, quality assurance (QA) records, lack of documentation, and interviews, the laboratory director failed to ensure the laboratory adhered to established QA policies of oversight of scheduled instrument preventative maintenance, twice annual comparison of analyzer test results, and personnel competency documentation in calendar year 2021. Cross reference D5429*REPEAT DEFICIENCY*, D5775, D6102.
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: A. Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, quality assessment policy, lack of documentation, and interviews, the laboratory director (LD) failed ensure that the semi-annual competency evaluation was performed for a newly assigned primary testing personnel responsible for the high complexity SARS-CoV-2 Thermo Fisher QuantStudio 7 Pro assay procedures and platform maintenance in calendar year 2021. Findings include: 1. Review of the CMS 209 form with the laboratory manager, during an entrance interview on 5/18/22 at approximately 11:00 AM, revealed that during a period in calendar year 2021 the LD also performed the duties of technical supervisor (TS) during a staffing shortage. The review of CMS 209 also revealed that the LD identified one (1) primary testing personnel (TP A) as responsible for performing SARS-CoV-2 Thermo Fisher QuantStudio 7 Pro procedures and maintenance from January 2021 up to the survey of 5/18/22-5/20/22. (See Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed that TP A had an initial training for the high complexity SARS-CoV-2 QuantStudio protocols in January 2021. The inspectors requested to review a semi-annual competency assessment documentation for TP A. No records were available for review. 3. Review of the laboratory's Standard Operating Procedures revealed a policy (titled: Quality Assessment Plan, #F-10-0101) that stated under Section VII Personnel Assessment: "All employees are evaluated twice within the first year. The first employee competency must occur before the employee is allowed to report patient results. The second assessment is at six month evaluation." 4. An exit interview with the LD, Chief Executive Director, Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings. B. Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the laboratory director (LD) failed ensure that a technical supervisor (TS) competency evaluation was performed for a newly assigned personnel responsible for the technical supervision of the facility's microbiology department in calendar year 2021 and up to the date of the survey May 18-19, 2022. Findings include: 1. Review of the CMS 209 form with the laboratory manager, during an entrance interview on 5/18/22 at approximately 11:00 AM, revealed that during a period in calendar year 2021 the LD also performed the duties of technical supervisor during a staffing shortage. The

	review of the CMS 209 also revealed that the LD identified one (1) personnel (TP B) as responsible for technical supervision of the microbiology laboratory services from September 2021 to the date of the entrance on 5/18/22. (See Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed that TP B had an initial training for employee orientation and microbiology laboratory testing personnel checklist in September of 2021. The inspectors requested to review a competency assessment documentation for TP B for the role of microbiology TS. No record was available for review. 3. An exit interview with the LD, Chief Executive Director, Laboratory Manager, and Microbiology TS on May 20, 2022 at approximately 11:00 AM confirmed the above findings.