

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2074451	(X3) Date Survey Completed 02/16/2024
Name of Provider or Supplier Vista Clinical Diagnostics	Street Address, City, State 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 February 13-15, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The inspection included a follow up interview with the laboratory manager on 2/16/24. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D6076 -42 CFR. 493.1441 Laboratory Director.
D2026	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain documentation of corrective/remedial action for one of one unsatisfactory Microbiology/Bacteriology Wound Culture PT event reviewed (review timeframe of June 2022 to the date of the inspection February 13-15, 2024). Findings include: 1. Review of the laboratory's American Proficiency Institute (API) microbiology PT documentation (2022 Event 2, 2023 Event 1, 2), a total of three events, revealed that the laboratory received unsatisfactory performance for 2022 Microbiology/Bacteriology Event 2. The laboratory received a 0% score for Wound Culture-Anaerobic. 2. The inspector observed that the laboratory manager wrote on the API Performance Review and Corrective Action form, "corrective action documentation is attached". The inspector requested to review the corrective action</p>

for the unsatisfactory performance outlined above. No records were available for review. The microbiology technical supervisor (TS) stated on 2/14/24 at 11 AM, "I cannot find the corrective action. I recall that the wound culture was repeated and testing personnel were retrained but I cannot find the documentation." 3. An exit interview with laboratory manager, TS, and laboratory director on 02/15/24 at 11:00 AM confirmed the above findings.

D3011

FACILITIES
CFR(s): 493.1101(d)

Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

This STANDARD is not met as evidenced by:

A. Based on observations, review of policy and procedures (P&P), and an interview, the laboratory failed to ensure testing personnel (TP) followed the established "Infection Control" P&P for wearing gloves while processing two of two patient samples on dates of survey on 02/13/24 - 2/15/24. Findings include: 1. The inspector observed TP #1 processing patient #1 culture media sample for shipment to a reference laboratory on 02/13/24 at 1500, and TP #2 processing patient #2 culture media sample for manual kit test procedures and assessment of growth on 02/14/24 at 1335. Both observations revealed the TP were not wearing gloves during the processes. See Personnel Code Sheet. 2. Review of the P&P revealed the following statement, "Infection Control/Microbiology Department- Personal Protective Equipment- Wear gloves (e.g. latex free or vinyl) when handling specimen." Observation of the door leading into the microbiology department on 02/14/24 at 1330 revealed a posted sign with the following statement, "Personal Infection control practices- (5) Lab coats and gloves must be worn at all times when handling specimens or working in clinical areas." 3. An exit interview with laboratory manager, technical supervisor, laboratory director on 02/15/24 at 11:00 AM confirmed the above findings. B. Based on a review of policies, tour, maintenance logs, and interviews, the laboratory failed to document inspection/testing/flushing for two (2) of six (6) safety stations and failed to record a review by the Chemical Hygiene Officer per their policy from September 2023 to the dates of the inspection on February 13-15, 2024. Findings include: 1. Review of the General Laboratory Policy binders revealed a "Chemical Hygiene Plan" that stated "eyewash fountains are inspected, tested, and flushed weekly. Safety showers are inspected, tested, and flushed weekly. Records are maintained and reviewed by the Chemical Hygiene Officer. All eyewash stations containing bottles of eyewash solution are inspected monthly." 2. Tour of the specimen processing area, main core laboratory, and microbiology laboratory revealed the following 6 safety eye wash/shower stations: Processing 1 Eyewash Bottle Station (two eyewash solution bottles), Processing 2 Eyewash Bottle Station (two eyewash solution bottles), Main Lab Urinalysis Eyewash Bottle Station (two eyewash solution bottles), Main Lab Chemistry/Coagulation Section Safety Shower, Main Lab Chemistry/Coagulation Section Eyewash Sink Fountain, Microbiology Eyewash Bottle Station (two eyewash solution bottles). 3. Review of available safety maintenance logs for calendar year 2023 up to 2/13/24 revealed one log sheet labeled "eyewash bottle station" with dates of inspection recorded for each month in 2023 and up to 2/13/24. The inspector inquired regarding additional logs for each of the four eyewash bottle safety stations outlined above (a total of eight bottles). The laboratory manager stated on 2/13/24 at 3:00 PM, "I used one log to indicate that I checked all of

the eyewash bottle stations. We do not have a separate log for each station's eyewash solutions". 4. The inspector noted that the Main Lab Chemistry/Coagulation safety logs had no documentation during the timeframe of September 2023 to the date of the tour on 2/13/24 for the safety shower and fountain sink eyewash. The inspector inquired regarding the missing safety checks. TP #3 stated on 2/14/24 at 2:00 PM, "That sink eyewash fountain and safety shower was always checked by our former PCR lab tech who is no longer working here." See Personnel Code Sheet. 5. The inspector noted that none of the safety maintenance logs were reviewed by the Chemical Hygiene Officer (identified as TP # 4) per the laboratory's policy. See Personnel Code Sheet. 6. An exit interview with laboratory manager, technical supervisor, and laboratory director on 02/15/24 at 11:00 AM confirmed the above findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on a review of instrument performance verification records, lack of documentation, test logs, and interviews, the laboratory director (LD) failed to document an evaluation/verification of the accuracy for two (2) of 2 Roche Cobas chemistry systems prior to reporting two hundred fifty-eight thousand seventy-seven (258,077) patient results from July 24, 2023 up to the dates of the inspection, February 13-15, 2024. Findings include: 1. Review of the laboratory's instrument validation records revealed the following two Cobas Pro chemistry analyzer systems (included Core, c503, ISE, and e801 analyzers) installed by a Roche field service technical specialist in calendar year 2023: Cobas Pro Serial Number (SN) 22A5-06 (labeled as Pro #1), and Cobas Pro SN 22F6-04 (labeled as Pro #2). 2. The inspector noted that the installation reports, outlined above, lacked a LD assessment of accuracy evaluation/verification for the following forty-two (42) onboard analytes: Calcium Chloride Cholesterol, Total Cholesterol, HDL Cholesterol, LDL Creatine Phosphokinase Carbon Dioxide Creatinine C-Reactive Protein (Highly Sensitive) Glucose Iron, Total Magnesium Potassium Prealbumin Sodium Total Protein Triglycerides Unsaturated Iron Binding Capacity Uric Acid NT-Pro BNP (B Type Natriuretic Peptide) Prostate Specific Antigen Parathyroid Hormone Thyroxine Free Thyroxine Thyroxine Uptake Thyroid Stimulating Hormone Vitamin B12 Urine Microalbumin Urine Creatinine Carbamazepine Digoxin Gentamicin Keppra Lithium Phenobarbital Phenytoin Theophylline Tobramycin Valproic Acid Vancomycin Ferritin Folate The inspector requested to review documentation that the LD validated the Roche manufacturer's specified accuracy for both installations prior to patient testing for the 42 analytes outlined above. No documentation was available for review. 3. Review of the two new analyzers' test logs revealed that the laboratory had reported the following number of patient analyte results up to the dates of the survey on 2/13/24 - 2/15/24: One hundred sixty-five thousand seven hundred ten (165,710) on Cobas Pro # 1 after go live on 7/24/23; Ninety-two thousand three hundred sixty-

seven (92,367) on Cobas Pro # 2 after go live on 09/22/23; A total of 258,077 patient results with no record of LD's assessment of accuracy evaluation/verification. 4. An exit interview with laboratory manager, technical supervisor, and laboratory director on 02/15/24 at 11:00 AM, and a follow up interview with the laboratory manager on 2/16/24 at 10 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:
Based on review of procedures, tour, manufacturer's user manual, maintenance records, lack of documentation, and interviews, the laboratory failed to perform /document periodic maintenance for one (1) of 1 chemistry ultra low temperature freezer per their policy and manufacturer's guidelines for nineteen (19) of 19 months as noted during the inspection on February 13-15, 2024. Findings include: 1. Review of the laboratory's procedures revealed a Standard Operating Procedure-Quality Assessment Plan that stated, "Preventative maintenance is performed according to manufacturer's recommendations for all instruments and equipment." 2. During a tour on 2/13/24 at 11 AM, the inspector noted a ThermoFisher Scientific TSX Series Ultra Low Freezer (Serial Number 1120178001200720) located in a supply storage area utilized for storing the core chemistry laboratory's Biorad quality controls (Liquicheck Immunology, Multi-Qual Premium, and Specialty) with a storage requirement -20 C to -70 C. The inspector noted an ice buildup of approximately 2 inches on the freezer shelving. 3. Review of the ThermoFisher Scientific manufacturer's user manual revealed the following Ultra Low Freezer maintenance protocols: "Clean the condenser at least every six months, clean the condenser filters every two or three months, defrost the freezer once per year or whenever the ice buildup exceeds 3/8 inches". The inspector inquired regarding defrosting protocols for the ultra low temperature freezer outlined above. Core lab testing personnel (TP #4) stated on 2/13/24 at 12 PM, "We do not defrost that freezer." 4. The inspector requested to review maintenance documentation as outlined above. No maintenance records were available for review. 5. An exit interview with laboratory manager, technical supervisor, and laboratory director on 02/15/24 at 11:00 AM confirmed the 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 review of procedures, quality assurance (QA) records, lack of documentation, and interviews, the laboratory failed to document a comparison evaluation of the two (2) methodologies utilized for patient white blood cell (WBC)

differential determinations twice annually during the twenty months reviewed (review timeframe: June 2022 to dates of the inspection February 13-15, 2024). *REPEAT DEFICIENCY Findings include: 1. Review of the procedures revealed the following 2 procedures for the determination of WBC differential counts: Beckman Coulter DxH Complete Blood Count with automated White Blood Cell Differential, and Manual Differential and Smear Review. 2. Review of the laboratory's Standard Operating Procedure-Quality Assessment Plan revealed the following protocol: Parallel Comparison - "comparison studies will be done on all analytes or tests performed on different instruments or performed by different methodologies and will be reviewed by the technical supervisor and division manager. The comparison studies are performed twice annually." 3. Review of the laboratory's QA documentation from June 2022 and year to dates of the inspection revealed no WBC differential test result comparison studies for the 2 methods outlined above. The inspector inquired regarding the parallel comparison studies. The laboratory manager stated on 2/14/24 at 9:30 AM, " It is a requirement to evaluate data to verify comparability of results performed using different methodologies. I have retained the manual differential reports and plan to perform an evaluation but have not completed at this date." 4. An exit interview with laboratory manager, technical supervisor, and laboratory director on 02/15/24 at 11:00 AM confirmed the 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 review of policies/procedures, proficiency testing (PT) records, quality assessment logs, observations/tour, maintenance records, lack of documentation, and interviews, the laboratory director failed to ensure: 1. quality assurance PT corrective actions were followed for the 2022 Microbiology/Bacteriology Event 2 unsatisfactory performance for anaerobic wound culture testing - CROSS REFERENCE D6092; 2. quality assurance corrective action for the lack of twice annual comparison evaluation of two methodologies utilized for white blood cell differential determinations - CROSS REFERENCE D6094 A; 3. laboratory adhered to quality assessment policies for Infection Control (glove wearing), Engineering Controls (safety station checks), and Standard Operating Procedures (scheduled equipment maintenance) - CROSS REFERENCE D6094 B.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on a review of procedures, microbiology proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the quality assurance protocols for PT corrective action were followed for one (1) unsatisfactory PT event, 2022 Microbiology/Bacteriology Event 2. Findings include:

1. Review of the laboratory's Standard Operating Procedure-Quality Assessment Plan revealed PT protocol statements, "In the event that PT performance indicates unsatisfactory responses for analyst and/or speciality/subspecialty, the Missed Analyte Investigation section of the Proficiency Testing Performance Report (Appendix QAP-22 and QAP-23) must be completed by the supervisor within ten working days. Copies must be submitted to the Quality Management and the laboratory director for review". 2. Review of the laboratory's American Proficiency Institute (API) microbiology PT documentation from June 2022 to the date of the inspection revealed that the laboratory received unsatisfactory performance for 2022 Microbiology /Bacteriology Event 2. The laboratory received a 0% score for Wound Culture-Anaerobic. 3. The inspector requested to review the Proficiency Testing Performance Report per the quality assessment plan outlined above for the API 2022 Microbiology /Bacteriology Event 2. The inspector inquired regarding twice annual accuracy verification for Anaerobic Wound Cultures in calendar year 2022 based on the unsatisfactory PT results on one of two events in 2022. The requested records were not available for review. 4. An exit interview with laboratory manager, technical supervisor, and LD on 02/15/24 at 11:00 AM confirmed the findings.

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:

A. Based on review of procedures, quality assurance (QA) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the laboratory adhered to QA corrective action protocols when twice annual comparison evaluation of white blood cell (WBC) differential methodologies were not documented for twenty (20) of 20 months reviewed (review timeframe: June 2022 to dates of the inspection February 13-15, 2024). Findings include: 1. Review of the laboratory's Standard Operating Procedure-Quality Assessment Plan revealed the following protocols: Parallel Comparison - "comparison studies will be done on all analytes or tests performed on different instruments or performed by different methodologies and will be reviewed by the technical supervisor and division manager. The comparison studies are performed twice annually." Remedial Actions - "when QA established timeframes cannot be met, remedial actions will be reviewed monthly by the technical supervisors and include review of effectiveness of corrective actions taken" 2. Review of the laboratory procedures revealed the following 2 procedures for determination of WBC differential counts: "Beckman Coulter DxH Complete Blood Count with automated White Blood Cell Differential" and "Manual Differential and Smear Review". 3. Review of the laboratory's monthly QA documentation from June 2022 and year to date 2024 revealed no WBC differential test result comparison studies for the 2 methods outlined above. The inspector requested to review twice annual comparison studies during the 20 month review timeframe. No records were available. No corrective action documentation was provided for the lack of method comparison evaluations. 4. An exit interview with laboratory manager, technical supervisor, and LD on 02/15/24 at 11:00 AM confirmed the findings. B. Based on observations/tour, review of policy and procedures, maintenance records, quality assessment policy, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the laboratory adhered to quality assessment policies for: 1.

"Infection Control" - wearing gloves while processing patient samples on the dates of survey on 02/13/24-2/15/24 - Cross Reference D3011A; 2. "Engineering Controls"- inspection/testing/flushing for two (2) of six (6) safety stations - Cross Reference D3011B; 3. "Standard Operating Procedure"- oversight of scheduled equipment preventative maintenance - Cross Reference D5429.