Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2074451	(X3) Date Survey Completed 09/24/2020
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 on-site survey was conducted at the Vista Clinical Diagnostics on September 22-24, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The surveyors began off-site record review of documentation from September 8-18, 2020. Specific deficiencies cited are as follows:
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the tour of the laboratory, lack of documentation, review of manufacturer's package insert(s) (PI) and interviews with the general supervisor (GS) and lab director (LD), the laboratory failed to label twelve (12) of 12 chemistry quality control (QC) materials with an open-vial date or revised expiration date according to the manufacturer's PI on September 23, 2020. Findings include: 1. A tour of the laboratory on September 23, 2020 at approximately 11:45 AM revealed storage of the chemistry QC materials in a double-door refrigerator in the chemistry and coagulation testing area. The following QC material vials were located in a tray within the refrigerator: BioRad Liquid Assayed Multiqual Premium Level 1 and 3 (lot numbers 86921 and 86923 exp 4/30/23), BioRad Liquicheck Immunology Control Level 1, 2 and 3 (lot numbers 68911, 68912 and 68913 exp 1/31/21), BioRad Lyphochek Therapeutic Drug Monitoring Control (TDM) Level 1 and 3 (lot numbers 57361 and 57363 exp 10/31/20), BioRad Liquichek Ethanol/Ammonia Control Level 1, 2 and 3 (lot numbers 54311, 54312 and 54313 exp 6/30/21) and, BioRad Liquichek Urine

	Chemistry Control Level 1 and 2 (lot numbers 68591 and 68592 exp 9/30/21). Total of 12 vials. All of the above-specified QC vials lacked documentation of a recorded open date or revised expiration date. In an interview with the GS at approximately 12:00 PM, the inspector inquired if QC material vials within the tray were currently in use and what dates the QC vials were opened. The GS stated, "yes, those vials in the tray are currently in use and the testing personnel are supposed to hand write the date opened on each vial following the typed sheet of open-vial stability for controls taped to the front of the refrigerator. I cannot tell you when those vials were opened at this time." 2. Review of the PI's for the above-specified QC materials revealed the following statements: BioRad Liquid Assayed Multiqual Premium Level 1 and 3 "Storage and Stability- Once opened and stored tightly capped at 2-8 degrees Celsius, this product will be stable as follows: all analytes 14 days. Except Alkaline Phosphatase, AST/SGOT, Bilirubin (Neonatal and Bilirubin (Total)- 9 days; Cholinesterase, Creatine Kinase (CK), Bilirubin (Direct), Triglycerides, Cholesterol (HDL) and Phosphorus- 7 days", BioRad Liquicheck Immunology Control Level 1, 2 and 3 "Storage and Stability- After reconstituting and stored tightly capped at 2-8 degrees Celsius, this product will be stable as follows: all analytes 30 days Except Beta-2- Microglobulin- 21 days and Rheumatoid Factor- 10 days.", BioRad Lyphochek Therapeutic Drug Monitoring Control (TDM) Level 1 and 3 "Storage and Stability- Once opened and stored tightly capped at 2-8 degrees Celsius, this product will be stable as follows: all analytes 30 days Except Caffeine- 10 days. ", BioRad Liquichek Ethanol/Ammonia Control Level 1, 2 and 3 "Storage and Stability- Once opened and stored tightly capped at 2-8 degrees Celsius, this product will be stable as follows: all analytes 20 day." and, BioRad Urine Chemistry Control Level 1 and 2 "Storage and Stability- Once opened and stored tightly capped at 2-8 degrees Celsius, this product will be stable as follows: all analytes 30." 3. An interview with the GS and the LD on September 23, 2020 at approximately 12:30 PM confirmed the 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 the review of performance verification records, lack of documentation and interviews with the general supervisor (GS) and lab director (LD), the laboratory failed to verify the reference range (normal range) for the Complete Blood Count (CBC) and Reticulocyte Count (Retic) performed on the two (2) Beckman Coulter DxH 800 hematology analyzers from April 11, 2019 and up to the date of survey on September 23, 2020. Findings include: 1. Review of the initial performance verification records for the Beckman Coulter DxH 800 hematology analyzers (serial numbers AZ06082 and AZ06083, installed on 2/28/19) revealed lack of documentation of the verification of reference ranges (normal range) for CBC and Retic testing. According to the Orchard-Harvest Laboratory Information System, the date of utilization for patient testing with the new instruments on 4/11/2020. The

	surveyor requested to review the documentation of the verification of the reference ranges for the aforementioned analytes and analyzers prior to testing patients on 4/11/20. The documentation was not available for review. 2. An interview with the GS and LD on September 23, 2020 at approximately 12:30 PM confirmed the 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 a review of policies and procedures, laboratory tour, equipment calibration records, interviews, manufacturer's user guide, and lack of documentation, the laboratory failed to perform six (6) month maintenance for two (2) fixed volume single channel pipettes utilized for microbiology testing in calendar year 2019 and up to the date of the onsite survey, 09/23/20. Findings include: 1. A review of the laboratory's online policy manual revealed a quality assurance (QA) pipette policy (titled: QA 18 Pipette Calibration). The policy wording was for thermometer calibrations. The inspector requested to review the pipette maintenance policy. The written policy was not available for review upon request. 2. During a tour of the microbiology laboratory on 09/23/20, at approximately 1:45 PM, the inspector noted 2 MLA pipettes (MLA 25 ul Serial Number (SN) 802730 and 100 ul SN 931678) in the testing area. The pipettes were sticker labeled "calibration due 8/2020". The inspector inquired how the pipette calibration protocols are followed. The technical supervisor (TS) stated, "Our general supervisor handles sending the pipettes out for calibrations every six months". During the tour, inspector asked a testing personnel to describe how each of the 2 observed pipettes were utilized in the laboratory. The testing personnel stated at approximately 2:15 PM, "They are for the Rapidec Carba NP test for carbapenemase detection. We use them for reagent and specimen preparation. Per the procedure, we use the 100 ul to place the suspension medium into the kit wells and after incubation, we use the 25ul to make dilutions before the next incubation." 3. Review of the laboratory's microbiology pipette calibration records from September 2018 to the date of the onsite tour 09/23/20 revealed the following pipette calibration documentation performed by an outside vendor (Altman Scientific): MLA SN 802730: Calibrated and verified on 6/19/19 and 02/1/20. The inspector requested documentation of calibration in December 2019 and August 2020; no documentation was available for review. MLA SN 931678: Calibrated and verified on 11/18/18, 7/15/19 and 02/1/2020. The inspector requested documentation of calibration in May 2019 and August 2020; no documentation was available for review. The general supervisor (GS) stated at approximately 4:00 PM, "We try to ensure that pipettes are calibrated and in proper working order every 6 months. The pipettes are shipped to Altman Scientific with a calibration request form. I emailed our Altman tech on 9/15/20 but have not sent the micro pipettes in yet." 4. Review of MLA Pipette user guide revealed manufacturer's instructions for calibration/maintenance: "necessary at six month intervals". 5. In an exit interview with the GS and TS on 9/24/20 at 11:00 AM the above findings were confirmed.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the general supervisor (GS) and technical consultant (TC), the TC failed to ensure that one (1) of eight (8) TP had training and competency assessment prior to performing patient testing for new automated urinalysis analyzer from July 1, 2020 and up to the date of survey on September 23, 2020. Findings include: 1. Review of CLIA CMS-209 form revealed that the lab director performs the duties of TC and TP A performs urinalysis testing (See attached TP Code Sheet). 2. Review of TP A records revealed the lack of documentation of training and competency assessment for the new Iris iQ Elite 200 urinalysis analyzer (serial number C15969 and installed 4/20/20) prior to performing patient testing on July 1, 2020. 3. Interview with the TC and GS on September 23, 2020 at approximately 12:30 PM confirmed the above-listed findings.