Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2110804	02/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Vista Medical Center North Arlington	5335 Langston Blvd, Arlington, 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 initial survey was conducted at Vista Medical Center-North Arlington on February 21, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The inspector noted the laboratory performs SARS-CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. Specific deficiencies cited are as follows and include the following Condition under 42 CFR part 493 CLIA Regulation: D6063 - 42 C.F.R. 493.1421 Condition: Testing Personnel.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's policy and procedures, reagent records, quality control (QC) records, lack of documentation, patient test records and interview, the laboratory failed to follow their established policy to perform external QC materials with each shipment/lot number of each assay or, at minimum, monthly for two (2) of five (5) months reviewed from October 11, 2022 until the date of the survey on February 21, 2023. The findings include: 1. A tour of the lab on February 21, 2023 at approximately 9:30 AM revealed the laboratory performs SARS CoV-2 (COVID-19), Influenza A and B, Respiratory Syncitial Virus testing utilizing the Xpert Xpress CoV-2/Flu/RSV plus cartridges on the Cepheid GeneXpert Xpress System. 2. Review of the laboratory's policies and procedures revealed an Individualized Quality Control Plan (IQCP) approved by the laboratory director on June 18, 2022. The IQCP stated, "Quality Control for Cepheid GeneXpert

	assays will consist of documenting acceptable results for 2 levels of external controls for each shipment/lot of each assay or, at minimum, monthly." 3. Review of reagent records from October 11, 2022 until the date of the survey on February 21, 2023 revealed the laboratory received a shipment of the Xpert Xpress CoV-2/Flu/RSV plus cartridges (reagent lot number 01908 exp 06/25/2023) on October 11, 2022. The laboratory received no additional shipments as of the date of the survey. External QC was performed for the shipment of Xpert Xpress CoV-2/Flu/RSV plus cartridges on October 11, 2022. 4. Review of QC and patient records for the GeneXpert Xpress system from October 11, 2022 until the date of the survey on February 21, 2023 revealed a lack of documentation of external QC materials for the Xpert Xpress CoV-2 /Flu/RSV plus cartridges for November 2022 and December 2022. Review of patient test records revealed one patient was tested on 11/27/2022 utilizing the Xpert Xpress CoV-2/Flu/RSV plus cartridges. The surveyor requested to review documentation of the external QC for the Xpress CoV-2/Flu/RSV plus cartridges for November 2022 and December 2022. The laboratory provided no documentation for review. 5. In an exit interview with the technical consultant on February 21, 2023, at approximately 1: 00 PM, the above findings were confirmed.
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: A. Based on a laboratory tour, review of the laboratory's maintenance logs, policies and procedures, manufacturer's operator guide, lack of documentation and interviews, the laboratory failed to provide documentation of the daily and monthly maintenance performed on the Horiba ABX Micros 60 hematology analyzer for six months from September 1, 2022 until the date of the survey on February 21, 2023. The findings include: 1. During a tour of the laboratory on February 21, 2023 at approximately 9:30 AM, the surveyor noted the laboratory utilizes the Horiba ABX Micros 60 Hematology analyzer (serial number 111CS99917) to perform Complete Blood Counts (CBC). 2. Review of the laboratory's maintenance logs from September 1, 2022 until the date of the survey on February 21, 2023 revealed a lack of documentation of the completed maintenance logs from September 1, 2022 until February 21, 2023. The surveyor requested to review the monthly maintenance logs for September 2002 to February 2023. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures revealed the following statement: "Horiba Micros 60: Maintenance: Daily-Check Reagent levels; Check Waste level-empty if needed; Perform Start-up Cycle and verify acceptable; Run control and verify acceptable; Perform Shut-down Cycle at end of day; Document with initials on Maintenance Chart for Horiba Micros 60; Weekly-to help insure reliability of analyzer and results generated; Perform concentrated cleaning; Perform Backflush of system; and Document with initials on Maintenance Chart for Horiba Micros 60." 4. Review of the manufacturer operator's guide revealed maintenance procedures to include performing daily start-up and shutdown, check reagent levels, check waste level and monthly performance of concentrated cleaning procedures. 5. In an exit interview with the technical consultant on February 21, 2023, at approximately 1:00 PM, the above findings were confirmed. B. Based on a laboratory tour, review of the laboratory's maintenance logs, policies and procedures,

	manufacturer's operator guide, lack of documentation and interviews, the laboratory failed to provide documentation of the weekly and quarterly maintenance performed on the Cepheid GeneXpert Xpress System from from September 1, 2022 until the date of the survey on February 21, 2023. The findings include: 1. During a tour of the laboratory on February 21, 2023 at approximately 9:30 AM, the surveyor noted the laboratory utilizes the Cepheid GeneXpert Xpress System (serial number (845270) to perform SARS CoV-2 (COVID-19), Influenza A and B, and Respiratory Syncitial Virus testing. 2. Review of the Cepheid GeneXpert manufacturer's operator guide revealed the following maintenance procedures: Weekly-power down the GeneXpert instrument and computer; Quarterly-Clean plunger rod, cartridge bays, and instrument surfaces. 3. Review of the Cepheid GeneXpert's maintenance logs from September 1, 2022 until the date of the survey on February 21, 2023 revealed the following weeks lacked documentation of the weekly maintenance: November 2022 - 2 of 4 weeks; December 2022 - 2 of 4 weeks; January 2023 - 2 of 4 weeks; February 2023 - 2 of 3 weeks. The surveyor requested to review documentation of the weekly maintenance for the above listed months. The laboratory provided no documentation for review. 4. Review of the Cepheid GeneXpert's maintenance logs from September 1, 2022 until the date of the survey on February 21, 2023 revealed quarterly maintenance was performed during installation on July 20, 2022 and again on January 30, 2023. The surveyor requested to review additional documentation of the quarterly maintenance. The laboratory provided no documentation for review. 5. In an exit interview with the technical consultant on February 21, 2023, at approximately 1:00 PM, the above findings were confirmed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available testing personnel records, lack of documentation, and interview, the laboratory failed to provide documentation of education qualifications for two of five laboratory testing personnel performing non-waived testing on the Horiba ABX Micros 60 Hematology analyzer and the Cepheid GeneXpert Xpress analyzer from September 1, 2022 to the date of the survey on February 21, 2023. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of

	Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and interview, the laboratory failed to retain documentation of education qualifications for two of five testing personnel (TP) from September 1, 2023 to the date of the inspection on February 21, 2023. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed that the Lab Director (LD) identified five TP as qualified to perform moderate complexity Complete Blood Count (CBC) and Food and Drug Administration (FDA) Emergency Use Authorized (EUA) Cepheid GenExpert Express Real-Time Polymerase Chain Reaction (RT-PCR) COVID-19 patient testing. 2. Review of the available laboratory personnel records of TP A and TP B for evaluation of education documentation revealed a lack of documentation of TP A and TP B's education. TP A and TP B's personnel record indicated initial training and patient testing began September 2022. The surveyor requested to review education documentation for TP A and TP B. The laboratory provided no education documentation to review. (See attached Personnel Code Sheet.) 3. In an exit interview with the technical consultant on February 21, 2023 at approximately 1:00 PM, the above findings were confirmed.