Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1045138	03/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Monarch Molecular, Old Dominion University	4111 Monarch Way Room 3104, Norfolk, 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 Monarch Molecular, Old Dominion University on March 30-31, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of the laboratory's equipment maintenance /calibration records, lack of documentation, and interviews, the laboratory failed to document performance of every six month maintenance protocols for twenty-four (24) of 24 pipettes utilized for patient molecular SARS-COV-2 (COVID-19) and respiratory pathogen panel testing according to their policy during a twenty (20) month review timeframe (July 2021 to the date of the inspection, March 30, 2023). Findings include: 1. During a tour of the laboratory on 3/30/23 at approximately 10:30 AM, the inspector noted the following pipettes in the molecular specimen preparation area -listed by by Serial Number (SN) and manufacturer: RU02091 ThermoFisher 1000 ul SU03021 ThermoFisher 100 ul RU08359 ThermoFisher 20ul RU08374 ThermoFisher 2 ul 046460J Eppendorf 300 ul 046449J Eppendorf 300 ul 1152466J

	Eppendorf 10 ul QU43032 ThermoFisher 1000 ul RU00987 ThermoFisher 1000 ul SU02961 ThermoFisher 1000 ul RU00937 ThermoFisher 200 ul RU09728 ThermoFisher 200 ul RU02036 ThermoFisher 100 ul QU42258 ThermoFisher 100 ul RU01097 ThermoFisher 20 ul RU09628 ThermoFisher 20 ul SU02991 ThermoFisher 10 ul QU42333 ThermoFisher 10 ul RU09678 ThermoFisher 2 ul RU00872 ThermoFisher 2 ul RU09578 ThermoFisher 1000 ul RU07034 ThermoFisher 1000 ul RU08339 ThermoFisher 200 ul RU02056 ThermoFisher 10 ul The inspector inquired regarding the pipettes' use and pipette calibration protocols. The Technical Supervisor (TS)/General Supervisor (GS) described the pipette uses were for reagent, quality control, and specimen preparation for COVID-19 and respiratory viral sample assays on the Biofire Diagnostics, Roche 6800, and Diasorin Molecular analyzers. The TS /GS and lead testing personnel stated on 3/30/23 at approximately 10:45 AM "We have Precision Calibration Services come in every six months to calibrate our pipettes. The calibration records are not stored here in the lab but are in my office and we can get them out for you to review." 2. Review of the laboratory's equipment calibration records from July 2021 to the date of the recertification inspection on 3/30 /2 revealed pipette calibration for the 24 pipettes outlined above was performed by outside vendor, Precision Calibration Services, on 12/13/21 (with note by vendor "next calibration is due 06/2022") and on 09/16/22. 3. The inspector requested to review additional pipette calibration records during the 20 months of review. The lead testing personnel stated on 3/30/23 at approximately 12:45, "We may not have had the pipettes calibrated in June 2022 as planned but had them come in September last year." The TS/GS stated on 3/30/23 at approximately 12:45 PM, "I can reach out to the rep at Precision Calibration to find out if he has additional records." No additional records were available for review. 4. A follow up exit interview with the TS/GS on 3 /31/23 at approximately 1:30 PM confirmed the above findings.