Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226364	04/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Chesterfield Pediatrics Pc	5955 Harbour Park Drive, Midlothian, 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 the Chesterfield Pediatrics on 04/04/23 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:
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a tour of the facility, record review and interviews, the lab failed to report twenty two (22) SARS-CoV-2 (COVID-19) positive test results for 90 of 90 testing dates from 01/01/23 up to date of survey on 04/03/23. Findings include: 1. A tour of the facility and interview with the primary testing personnel and technical consultant on 04/04/23 at 09:45 AM revealed the facility utilized one Quidel Sofia reader to perform to COVID-19 patient testing. During the same interview, the inspector requested to review a log sheet or mechanism in which the facility tracks COVID-19 testing and reporting of positive results to the State agency. The primary testing stated "We do not have log sheets and we report results directly into our electronic medical records. We have not been reporting positive results." Patient testing data was retrieved from the electronic medical records "Procedure code count by Plan" data

	query. 2. Twenty two (22) positive results were not reported as required during the period of review (90 testing dates). 3. The laboratory performed 342 COVID-19 tests during the period of review. 4. An exit interview with the primary testing personnel and technical consultant on 04/04/23 at approximately 11:45 AM 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 the review of manufacturer operator's manual, maintenance records, lack of documentation and interview, the lab failed to follow manufacturer's instructions of performing weekly maintenance for the Cell-Dyn Emerald hematology analyzer for 12 of 91 weeks from 07/01/21 up to date of survey on 04/04/23. Findings include: 1. Review of the Cell-Dyn Emerald operator's manual (Revision date March 2019) revealed the following statement, "Section 9, Weekly Maintenance, Bleach Cleaning-Bleach cleaning the system with a bleach solution is performed weekly and as needed if instrument use conditions cause frequent rejection of measured or quality control material out of range issues." 2. Review of the Cell-Dyn Emerald analyzer event log and daily logs for lab procedures that indicated performance of maintenance procedures from 07/01/21 up to date of survey on 04/04/23 revealed a lack of documentation of the performance of the weekly bleach cleaning procedures for the following weeks: August 23-27, 2021, September 27 - October 1, 2021, November 29- December 3, 2021, January 24-28, 2022, February 21-25, 2022, May 30- June 3, 2022, June 20-24, 2022, July 25-29, 2022, August 15-19, 2022, September 6-9, 2022, December 12-16, 2022 and December 26-30, 2022, Total of 12 weeks. 3. An exit interview with the testing personnel and technical consultant on 04/04/23 at 11:45 AM confirmed the findings.