

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2183223	(X3) Date Survey Completed 02/22/2023
Name of Provider or Supplier Hopkins Medical Association Llc	Street Address, City, State 460 Front Street, Richlands, 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	<p>An announced CLIA Initial survey was conducted at the Hopkins Medical Association on 02/22/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The laboratory is in compliance with the applicable Conditions and Standards under 42 CFR part 493-CLIA Regulations.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a tour of the facility, record review and interviews, the lab failed to report four SARS-CoV-2 (COVID-19) positive test results for 13 of 13 testing dates from 06/01/22 up to date of survey on 02/22/23. Findings include: 1. A tour of the facility and interview with the testing personnel (TP) on 02/22/23 at 12:45 PM revealed the facility had one BD Veritor reader that was utilized to perform to COVID-19 patient testing, located in a cabinet. The TP stated that they are not currently performing COVID-19 testing with the BD Veritor test kits and reader because they had no kits at this time. During the same interview, the inspector requested to review a log sheet or mechanism in which the facility tracks COVID-19 testing and reporting positive results to the State agency. The TP provided a daily testing log book that indicated</p>

patients and types of waived testing performed. The TP stated, "I have not been reporting positive results." 2. Four positive results were not reported as required during the period of review (13 testing dates). 3. The laboratory performed 13 COVID-19 tests during the period of review. 4. An exit interview with the TP and general supervisor on 02/22/23 at approximately 1400 confirmed the findings.