Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2081450	07/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Keystone Medical Urgent Care	1555 W Street Road, Warminster, PA	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Office Manager, the laboratory failed to establish and follow SARS-COVID-19 reporting policies from 08 /31/2021 to 07/26/2022. Findings Include: 1. On the day of survey, 07/26/2022 at 12: 02 pm, the laboratory could not provide procedures for reporting pateint SARS-COVID-19 antigen test results to the appropriate agencies. 2. The laboratory performed 649 SARS-COVID-19 antigen tests from 01/01/2022 to 02/28/2022. 3. The Office Manager confirmed the findings above on 07/26/2022 around 12:30 pm.
D1002	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 record review and interview with the Office Manager (OM), the laboratory failed to report SARS-Co-V-2 (COVID 19) test results as required for 59 of 59 days reviewed from January through February 2022. Findings include: 1. On the day of survey, 07/26/2022 at 12:02 pm, the laboratory was unable to provide documentation

	of reporting SARS-CoV 2 antigen test results to local/state agencies performed on the QuickVue SARS Antigen Test and the INDICAID COVID-19 Rapid Antigen Test kits for 649 of 649 patients tested from 01/01/2022 to 02/28/2022. 2. The Office Manager confirmed the findings above on 07/26/2022 around 12:30 pm.