Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2233526	09/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Grassroots Crisis Intervention Center	8990 Old Annapolis Rd Ste A, Columbia, MD	

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 the instructions for use (IFU) for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) test kits and interview with the testing person (TP) and operation manager (OM), the laboratory failed to follow the manufacturers' instructions for performing SARS-CoV-2 rapid antigen testing. Findings: 1. The "Warnings and Precautions" section of the IFU for the QuickVue SARS Antigen Test states "Do not use the kit contents beyond the expiration date printed on the outside of the box." The "Warnings and Precautions" section of the IFU for QuickVue At-Home OTC COVID-19 Test states "Do not use the QuickVue At-Home COVID-19 Test Kit after its expiration date." This standard also apply's to the urine toxicology test kits being used in the laboratory. The TP stated that the laboratory does not maintain documentation of the lot numbers and expiration dates of the kits used, therefore, the laboratory cannot verify that the kits were not used past the expiration date. 2. During the survey on 09/13/2022 at 1:25 PM, the OM confirmed that the laboratory was not keeping a record of the lot numbers and expiration dates of the CLIA waived kits being used in the laboratory.
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 review of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) product inserts, and interview with the operation manager (OM), the laboratory failed to report SARS-CoV-2 test results to the Maryland Department of Health (MDH). Findings: 1. The instructions for use (IFU) for the QuickVue At-Home OTC COVID-19 Test states "All prescribing healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC." 2. The IFU for the QuickVue SARS Antigen Test states "Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. During the survey on 09/13/22 at 1:25 PM, the OM confirmed that they have been licensed to perform waived SARS-CoV-2 testing for about a year and that they did not know that they were to report positive or negative SARS-CoV-2 test results to the MDH and/or local health authority. The laboratory failed to ensure that SARS-CoV-2 results were reported to the local health authority as required by the IFU of the two kits being used at the laboratory.