Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2165644	06/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Harm Reduction Coalition	350 Albemarle Avenue Sw, Roanoke, 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 unannounced, on-site CLIA complaint survey was conducted at Virginia Harm Reduction Coalition on June 4, 2020; and an off-site complaint survey conducted on May 26, 2020 to June 16, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: A. Based on document review and interviews, the laboratory performed high complexity testing for three hundred fifty-five (355) patients utilizing the Aytu Bioscience COVID-19 IgG/IgM Rapid Test Cassette Test not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from April 3, 2020 to May 23, 2020. The findings include: 1. Review of the laboratory's invoices from AYTU Bioscience, INC revealed the following purchases:

twenty (20) boxes of "Covid 19 IgG/IgM Test-Box of 25" on April 3, 2020; and fifty (50) "Covid-19 Test Kits" on April 9, 2020. 2. Review of the Instructions for Use (IFU) for the Aytu BioScience COVID-19 IgG/IgM Rapid Test Cassette test revealed the statement, "This test has not been reviewed by the FDA." 3. Review of the laboratory's CMS ASPEN WEB-116 revealed the laboratory possesses a CLIA Certificate of Waiver, CLIA # 49D2165644. 4. On June 2, 2020, a review of the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) "In Vitro Diagnostics EUA" website revealed no listing for an EUA granted for the Aytu BioScience COVID-19 IgG/IgM Rapid Test Cassette test (manufactured by Zhejiang Orient Gene Biotech Co., Ltd). Review of the "FDA FAQs on Testing for SARS-CoV-2" website revealed the following: "Manufacturers that have notified FDA that they have validated and intend to distribute serology tests as set forth in Section IV.D: Manufacturer and Test-Zhejiang Orient Gene Biotech, Co. Ltd COVID-19 IgG/IgM Rapid Test Cassette; Authorization Status-Not FDA authorized; Settings for use-H; Settings for use include the following: H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests..." 5. Review of patient test logs revealed the laboratory tested 355 patients using Aytu BioScience COVID-19 IgG /IgM Rapid Test Cassette test from April 3, 2020 to May 23, 2020. 6. In an exit interview on June 16, 2020 at approximately 1:30 PM, the Lab Director (LD) confirmed the above findings. B. Based on document review and interviews, the laboratory performed high complexity testing for three hundred forty-four (344) patients utilizing the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) Test not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from April 3, 2020 to May 15, 2020. The findings include: 1. Review of the laboratory's invoices from RayBiotech revealed the purchase of one hundred thirty-three (133) "Coronavirus (COVID-19) IgM Rapid Test Kit Rapid Covid-19 Test Kit for finger prick samples; 20 strips" on April 1, 2020. 2. Review of the IFU for the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) test revealed the statement, "This test has not been reviewed by the FDA." 3. Review of the laboratory's CMS ASPEN WEB-116 revealed the laboratory possesses a CLIA Certificate of Waiver, CLIA # 49D2165644. 4. On June 2, 2020, a review of the "FDA EUA In Vitro Diagnostics EUA" website revealed no listing for an EUA granted for the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) test. Review of the "FDA FAQs on Testing for SARS-CoV-2" website revealed the following: "Manufacturers that have notified FDA that they have validated and intend to distribute serology tests as set forth in Section IV.D: Manufacturer and Test- RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) Test; Authorization Status-Not FDA authorized; Settings for use-H; Settings for use include the following: H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests..." 5. Review of patient test logs revealed the laboratory tested 344 patients using the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) test between April 3, 2020 and May 15, 2020. 6. In an exit interview on June 16, 2020 at approximately 1:30 PM, the LD confirmed the above findings. C. Based on document review and interviews, the laboratory performed high complexity testing for three hundred seventeen (317) patients utilizing the RayBiotech Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method) Test not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from April 3, 2020 to May 15, 2020. The findings include: 1. Review of the laboratory's invoices from RayBiotech revealed the

	purchase of forty-four (44) "Coronavirus (COVID-19) IgG Rapid Test Kit Rapid Covid-19 Test Kit for finger prick samples; 20 strips" on April 1, 2020. 2. Review of the IFU for the RayBiotech Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method) test revealed the statement, "This test has not been reviewed by the FDA." 3. Review of the laboratory's CMS ASPEN WEB-116 revealed the laboratory possesses a CLIA Certificate of Waiver, CLIA # 49D2165644 . 4. On June 2, 2020, a review of the "FDA EUA In Vitro Diagnostics EUA" website revealed no listing for an EUA granted for the RayBiotech Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method) test. Review of the "FDA FAQs on Testing for SARS-CoV-2" website revealed the following: "Manufacturers that have notified FDA that they have validated and intend to distribute serology tests as set forth in Section IV.D: Manufacturer and Test-RayBiotech Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method) Test; Authorization Status-Not FDA authorized; Settings for use-H; Settings for use include the following: H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests..." 5. Review of patient test logs revealed the laboratory tested 317 patients using the RayBiotech Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method) test between April 3, 2020 and May 15, 2020. 6. In an exit interview on June 16, 2020 at approximately 1:30 PM, the LD confirmed the above findings.
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 patient logs, lack of temperature and humidity logs, manufacturer's instruction for use (IFU) and interviews, the laboratory failed to follow manufacturer's IFUs for the storage of four testing kits used for patient testing while at mobile testing sites from April 3, 2020 to May 23, 2020. Findings include: 1. A review of patient test logs revealed the following kits used and number of patients tested from April 3, 2020 to May 23, 2020: Aytu Bioscience COVID-19 IgG/IgM Rapid Test Cassette Test - 355 patients; RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) Test - 344 patients; RayBiotech Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method) Test - 317 patients; and OraQuick HCV (Hepatitis C Virus) Rapid Antibody Test - 22 patients. 2. A review of the IFUs for above listed kits revealed, kits should be stored "...in a cool and dry place at 2-30 degrees Celsius." 3. In an interview on June 5, 2020 at approximately 1:40 PM, the Lab Director (LD) stated, "We do not monitor the mobile unit temperature." The surveyor requested mobile unit temperature and humidity logs from April 3, 2020 to May 23, 2020. The laboratory provided no documentation of the temperature and humidity logs. 4. In an exit interview on June 16, 2020 at approximately 1:30 PM, the LD confirmed the above findings.