Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2135248	04/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Anchor Health Initiative	30 Myano Ln, Ste 16, Stamford, CT	

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	Unannounced visits on March 23 and 28, 2022 by representatives of the Facilities Licensing and Investigation Section of the Department of Public Health for the purposes of conducting a complaint investigation, ACTS Reference Number CT# 31736, at the Anchor Health Initiative testing locations at 30 Myano Lane, Stamford, CT 06902 and 2200 Whitney Avenue, Suite 290, Hamden, CT 06518 operating under the multisite CLIA # 07D2135248 Certificate of Waiver, to determine compliance with 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Deficiencies were cited as a result of this survey. These deficient practices resulted in the finding of Immediate Jeopardy. The likelihood of serious adverse outcome due to the laboratory failing to ensure HIV and Urinalysis Testing were being performed according to the manufacturer's instructions can result in inaccurate test results and affect the diagnosis and treatment of patients. The Compliance and Privacy Officer and the HIV Prevention & Treatment Program Medical Director (HIVMD) were made aware of the findings of Immediate Jeopardy on April 1, 2022 at 12:30 PM. The Compliance and Privacy Officer was emailed the Immediate Jeopardy Template on April 1, 2022 at 1:03 PM for 493.15 and 493.1771 and 493. 1775 (b)1. At the time of notification of the Immediate Jeopardy, the HIVMD stated the laboratory paused laboratory testing. The laboratory submitted a written 'Action Plan to Remove the Immediacy' on April 1, 2022 at 9:16 PM. The plan included immediately pausing all lab services except for PAP Smear, swabs for STI screening, and urine pregnancy (for Depo-Provera only), keeping a specific track for these tests. The laboratory removed all expired implements in the laboratories, performed onsite review by compliance and management, ran control test for all CLIA tests and provided training competencies with a control test for each employee.
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:
A. Based on observations at the time of the survey, review of the OraQuick Advance Rapid HIV-1/2 Antibody Test and the Alere Determine HIV-1/2 Ag/Ab Combo kits instructions for use, and confirmed by interviews with the Head Registered Nurse (RN) and the Compliance and Privacy Officer (CPO), the laboratory failed to follow the manufacturer's instructions for performing HIV testing at the Stamford multisite location. Findings Include: 1. Surveyor observation on 3/23/2022 at 10:00 AM of the contents of the Stamford laboratory cabinet revealed: a. OraQuick Advance Rapid HIV-1/2 Antibody Test kit, lot #0006672847, Expired 11/30/2021, opened and in use. b. Alere Determine HIV-1/2 Ag/Ab Combo, lot # 110834, Expired 11-28-2020, box was empty. 2. Record review on 3/23/2022 of the OraQuick ADVANCE Rapid HIV-1 /2 Antibody Test Package Insert revealed: a. Header: "Read this package insert completely before using this product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results." b. External Quality Control (QC): "CLIA Waived Laboratories: Run the Kit Controls under the following circumstances: Each new operator prior to performing testing on patient specimens, When opening a new test kit lot, Whenever a new shipment of test kits is received, If the temperature of the test kit storage area falls outside of 2C- 27C (35 80F), If the temperature of the testing area falls outside of 15C- 37C (59- 99F), and At periodic intervals as dictated by the user facility." c. Restrictions: "Sale of the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test is restricted to clinical laboratories. - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met; and - where there is assurance that operators will receive and use the instructional materials. The OraQuick ADVANCE rapid HIV-1/2 Antibody Test is approved for use only by an agent of a clinical laboratory." d. Handling Precautions: "Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing." 3. Record review on 3/23/2022 of the Laboratory's 'Lab Policy' binder revealed: At-Home HIV Test Procedure: Testing Specimen Section, # 5 "You must take a picture of your results after 20 minutes and send to us via MyChart or text at 475-214-3308. Please include your full name and DOB if sending via text message." 4. Interview with a representative from OraSure Technologies Inc. technical support for the OraQuick Advance Rapid HIV-1/2 Antibody Test on 3/29/2022 at 3:15 PM stated "Quality Control requirements are the same for waived as well as the moderate complexity specimen types." 5. Record review on 3/23/2022 of the Stamford Quality Control (QC) records revealed, lack of external QC documentation for the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test kit. 6. Record review on 3/23/2022 of the laboratory's CLIA Binder containing the Package Inserts available for testing personnel use revealed, the manual did not contain a package insert or instructions for use for the Alere Determine HIV-1/2 Ag /Ab. 7. Staff interview with the Laboratory's Head RN on 3/23/2022 at 10:52 AM revealed: a. The OraQuick HIV-1/2 Antibody test is used at both the Stamford and Hamden locations. b. "The OraQuick HIV-1/2 Antibody testing cartridges, along with a lancet for blood collection and directions for use were being mailed to patient's homes. Patients perform the test, take a picture of the cassette and either attach it to 'MyChart' or text it to the Clinic. The cassette is then read by an RN or provider." c. The OraQuick HIV-1/2 Antibody test kit was used as opposed to one that is FDA approved for home use because the home use test kits are expensive. d. "The laboratory stopped recording the lot number and expiration date of the HIV kits used when the Head RN took over the HIV Prep program in October 2020." e. "The laboratory does not have documentation for external QC for the OraQuick HIV-1/2

Antibody test kit." f. The Alere HIV kit is used for onsite testing only and the laboratory does not document anywhere the test method used for any given HIV patient result performed onsite. 8. Staff interview with the CPO on 3/23/2022 at 11:00 AM confirmed: a. The laboratory does not have documented training for 5 of 5 Stamford testing personnel (TP) performing HIV patient testing. b. The laboratory does not have the package insert or instructions for use for the Alere Determine HIV-1 /2 Ag/Ab test kit. c. Both the OraQuick HIV-1/2 Antibody test kit and the Alere Determine HIV-1/2 Ag/Ab Combo were expired. B. Based on observations at the time of the survey, review of the OraQuick Advance Rapid HIV-1/2 Antibody Test, and the McKesson Consult 10SG Urine Reagent Strips Instructions for use, and confirmed by staff interviews, the laboratory failed to follow the manufacturer's instructions for performing HIV and Urinalysis testing at the Hamden multisite location. Findings include: 1. Surveyor observation on 3/28/2022 at 12:25 PM of the Hamden laboratory's 10SG Urine Reagent Strips in use revealed: a. The canister was labeled with 3/25/2022 and initials. b. Updated expiration date was not documented on the canister. 2. Record review on 3/28/2022 of the 'McKesson Consult 10SG Urine Reagent Strips Parameter User Manual', Storage and Stability section revealed, "Once the canister is opened, the remaining strips are stable for up to 3 months". 3. Staff interview on 3/28/2022 at 12:30 PM with the CPO confirmed, the laboratory did not label the 10SG Urine Reagent Strips canister with the updated expiration date after opening. 4. Record review on 3/23/2022 of the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test Package Insert revealed: a. Header: "Read this package insert completely before using this product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results." b. External Quality Control (QC): "CLIA Waived Laboratories: Run the Kit Controls under the following circumstances: Each new operator prior to performing testing on patient specimens, When opening a new test kit lot, Whenever a new shipment of lest kits is received, If the temperature of the test kit storage area falls outside of 2C- 27C (35 80F), If the temperature of the testing area falls outside of 15C- 37C (59- 99F), and At periodic intervals as dictated by the user facility." c. Restrictions: "Sale of the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test Is restricted to clinical laboratories. - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met; and - where there is assurance that operators will receive and use the instructional materials. The OraQuick ADVANCE rapid HIV-1/2 Antibody Test Is approved for use only by an agent of a clinical laboratory." 5. Interview with a representative from OraSure Technologies Inc. technical support for the OraQuick Advance Rapid HIV-1/2 Antibody Test on 3/29/2022 at 3:15 PM stated "QC requirements are the same for waived as well as the moderate complexity specimen types." 6. Record review on 3/28/2022 of the Hamden QC records revealed, lack of external QC documentation for the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test kit. 7. Staff interview with the Stamford Laboratory's Head RN on 3/23/2022 at 10:52 AM revealed: a. The OraQuick HIV-1/2 Antibody test is used at both the Stamford and Hamden locations. b. "The OraQuick HIV-1/2 Antibody testing cartridges, along with a lancet for blood collection and directions for use were being mailed to patient's homes. Patients perform the test, take a picture of the cassette and either attach it to 'MyChart' or text it to the Clinic. The cassette is then read by an RN or provider." c. The OraQuick HIV-1/2 Antibody test kit was used as opposed to one that is FDA approved for home use because the home use test kits are expensive. d. "The laboratory stopped recording the lot number and expiration date of the HIV kits used when the Head RN took over the HIV Prep program in October 2020." e. "The laboratory does not have documentation for external QC for the OraQuick HIV-1/2 Antibody test kit." f. The Alere HIV kit is used for onsite testing only and the

	laboratory does not document anywhere the test method used for any given HIV patient result performed onsite. 8. Staff interview with the CPO on 3/23/2022 at 11:00 AM confirmed, the laboratory does not have documented training for 8 of 8 Hamden testing personnel performing HIV patient testing.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on observations at the time of the survey, lack of Quality Control (QC) and testing personnel (TP) training records, review of the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test, the Alere Determine HIV-1/2 Ag/Ab Combo kit, and the McKesson Consult 10SG Urine Reagent Strips Instructions For Use and confirmed by interview with the Head RN (Stamford) and the Compliance and Privacy Officer (CPO) (Stamford and Hamden), both the Stamford and the Hamden laboratory locations are performing testing in a manner that constitutes an imminent and serious risk to public health (Refer to D8103, D8201).
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, record review, lack of documentation and staff interview, the laboratory failed to provide all the information and data necessary to assess compliance with the federal CLIA requirements for certificate of waiver laboratories. Findings include: 1. Record review on 3/29/2022 of an excel spreadsheet, 'All Point of Care (POC) Tests' attached to an email received on 3/28/2022 at 5:25 PM including Stamford and Hamden locations revealed: a. 28 of the 73 patients listed on the spreadsheet were HIV POC tests. b. 28 of 28 HIV POC tests lacked

	documentation as to the test method/kit used, the lot number and expiration date of the kit or the testing location (onsite or at home). 2. Record review on 3/31/2022 of an email received on 3/31/2022 at 7:03 AM from the CPO of the Stamford (2) and Hamden (2) Laboratory's patient charts containing HIV results revealed: a. Lack of documentation of the HIV test method/kit used. b. Lack of documentation of the lot number and expiration date of the HIV kit used. c. Two of two Stamford patients and One of two Hamden patients lacked documentation as to where the test was performed (home or in the laboratory). 3. Record review on 4/4/2022 of an email received on 4/1/2022 at 3:10 PM from the CPO containing nine attachments of eight patient HIV test records performed by the patients at home revealed: a. Five of the Eight patients did not have a picture of the test cassette as part of their medical record. b. Three of Three HIV test cassette pictures lacked patient identifiers. 4. Record review on 4/1/2022 of an email received on 4/1/2022 at 2:20 PM from the CPO revealed, "We had 12 home kits from the 28 HIV POC test in the list, we have three pictures and the rest are TE documentations." 5. Surveyor observation on 3/23/2022 at 12:02 PM of the Stamford Laboratory's hand washing sink revealed an unlabeled container of yellow liquid. 6. Staff interview with the Head RN on 3/23/2022 at 12:02 PM with reference to #5 above revealed: a. "The liquid in the container is urine." b. "It is unlabeled, but only 1 patient was seen today, so I know who the specimen belongs to." 7. Surveyor observation on 3/28/2022 at 12:25 PM of the Hamden laboratory testing area revealed one of three yellow liquid samples in the sink was unlabeled. 8. Staff interview on 3/28/2022 at 12:25 PM with Medical Assistant #1 with reference to #7 above stated, "I am not sure if the specimens in the sink have been processed or not. I am not sure who the unlabeled specimen in the sink belongs to." 9. Staff interview with the CPO on 3/28/2022 at 12:30 PM confirmed the specimen referenced in #7 above was unlabeled.
D8201	INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b) (b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. This STANDARD is not met as evidenced by: Based on observations at the time of the survey, review of the OraQuick Advance Rapid HIV-1/2 Antibody Test instructions for use, and confirmed by interview with the Head RN and the Compliance and Privacy Officer (CPO), the laboratory failed to follow the manufacturer's instructions for performing HIV testing at the Stamford and Hamden multisite locations by allowing at home testing. (Refer to D1001)