Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0699040	03/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Taste & Smell Clinic,The	5125 Macarthur Blvd #20, Washington, DC	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not report results of chemistry proficiency testing in the same manner as patient specimens. Findings: 1. The laboratory performs proficiency testing for calcium and magnesium. If the quality control is unacceptable during the testing of proficiency test samples, the laboratory will retest the specimens and average the test results of the failed test run and the results obtained from the repeated test run instead of reporting the test results from the repeated test run, and documenting that the test was repeated because the quality control failed for the first test run; and 2. This was confirmed during interview with staff during the afternoon of the day of survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency

	testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not document each activity performed by testing staff for chemistry proficiency testing. Findings: 1. Both staff members were documented on the attestation records for all three proficiency test events of 2019; and 2. During interview on the afternoon of the day of survey, analyst 1 stated that she or the other analyst may prepare the specimen for testing, but the other analyst may operate the analyzer. The attestation did not identify who prepared the specimen for testing and who operated the analyzer.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with testing personnel, the laboratory did not have written procedures for all areas of the laboratory when performing chemistry testing. Findings: 1. The laboratory performs chemistry testing using red blood cells, urine, saliva, and plasma collected from patients. 2. The specimens are ran on a spectrophotometer to measure for zinc, copper, magnesium, and calcium that may be present in patient samples. 3. The laboratory did not have procedures for storing patient red blood cells, urine, saliva, and plasma samples for up to a month after testing in the refrigerator and used for quality control and preparing standards. 4. The "Pooled sample preparation procedure for performing standards and quality control" did not include "red blood cells" as one of the sources that can be pooled for quality control and preparing standards. 5. The laboratory used a zinc stock solution when preparing standards for performing chemistry testing. 6. The stock solution expired September 2020 and the standard was prepared on 9/29/20.

	7. The testing person stated that once the standard is prepared from the stock solution it is good for up to one year. 8. The laboratory did not write procedures nor performed an analysis of the expired standards to ensure actual and reliable patient testing. 9. And did not write procedures for using the standard beyond the expiration date.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory did not have all reagents needed to prepare the Bromothymol blue solution when performing chemistry testing. Findings: 1. The laboratory did not have Barbituric acid to bring down the PH of the Bromothymol blue solution when the PH was above 8.30. 2. The laboratory prepares a Bromothymol blue solution that is used for performing patient testing. 3. The PH of the solution is checked after preparation and should have a PH of 8.20. 4. If the PH is high, above 8.20, Barbituric acid is used to bring the PH down to the required test limit. 5. The testing person confirmed that Barbituric acid was not available in the lab.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing personnel, the laboratory did not maintain storage requirements for all reagents used when performing chemistry testing. Findings: 1. The laboratory prepared a stock solution from carbonic anhydrase that is used for zinc testing. 2. The carbonic anhydrase was opened in the year 2013 and states on the container to be stored between 2-8 degrees Celsius. 3. The laboratory stored the carbonic anhydrase in a freezer between -6 to -10 degrees Celsius. 4. The testing personnel confirmed that the carbonic anhydrase stock solution was not stored at the correct temperature.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)

	Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory did not ensure that reagents were not used beyond the expiration date and had required storage information on the container. Findings: 1. The laboratory uses a prepared Barbital Buffer solution when performing chemistry testing. 2. The solution was prepared four months ago and did not have an expiration date on the bottle nor storage requirements. 3. The testing person stated that the prepared buffer solution can be stored refrigerated up to six months. 4. The testing person confirmed the Barbital Buffer solution did not have an expiration date on the bottle nor storage requirements.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory did not ensure that reagents were not used beyond the expiration date. Findings: 1. The laboratory used a zinc stock solution when preparing standards for performing chemistry testing. 2. The stock solution expired September 2020 and the standard was prepared on 9/29/20 and still being used at the time of the survey. 3. The testing person stated that once the standard is prepared from the stock solution it is good for up to one year. 4. The laboratory did not perform an analysis of the expired standard and did not write procedures for using the standard beyond the expiration date. 5. The testing person confirmed that the stock solution expired September 2020.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory director did not evaluate proficiency testing conducted by split sampling to determine if the results obtained by the laboratory were in agreement with the results obtained form the laboratory that performed the split sample testing,, for zinc and copper analysis. This split sampling is to check the accuracy of the laboratory test results; Findings: 1. The laboratory split samples with another laboratory for copper and zinc to check

	agreement; The laboratory records for this split sampling did not show a statistical review comparing the lab's results with the other lab's results and using criteria established by the lab to determine if they are in agreement or if the laboratory results did not agree; 3. There was no documentation that the director reviewed the split sampling results and the lab did not document if the results of each test were acceptable or not acceptable; 4. This was confirmed with laboratory staff during interview of lab staff performed the afternoon of the day of survey.