Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0699040	05/16/2018
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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, instrument printouts, work sheets, and Proficiency Testing (PT) records and interview with Staff Number (#) 1 and #2 and the Laboratory Director (LD) on May 15, 2018 at approximately 11: 50 AM and on May 16, 2018 at approximately 2:00 PM, respectively, the laboratory failed to test PT samples for Magnesium and Calcium the same number of times as patient specimens for four (4) of the four (4) testing events reviewed (2017 MLE-M1,-M2, and M3; 2018 MLE- M1). The findings included: 1. Review of the laboratory's policies and procedures manual with a revision date of February 24, 2016 revealed instructions, to read "...MLE SAMPLES ONCE (WITH 5X STATISTICAL AVERAGING) UNLESS TECHNICAL DIFFICULTIES ARISE WHICH WOULD NECESSITATE DUPLICATE READING FOR NON MLE SAMPLES." 2. Review of worksheets and instrument printouts revealed that staff run MLE samples multiple times and reported the average as detailed below: (a) The staff run 2017 MLE-M1 samples on 2/8/17, 2/14/17, and two (2) times on 2/15/17. Although the staff repeated patient specimens along with the MLE samples on 2/8/17, the staff further repeated MLE samples on 2/14/17 and 2/15/17 and reported the average. (b) The staff run 2017 MLE-M2 samples on 5/17/17, 5/24/17 and 5/25/17. Although the staff repeated patient specimens along with the MLE samples on 5/17/17, the staff further repeated MLE samples on 5/24/17 and 5/25/17 and reported the average. (c) The staff run 2017 MLE-M3 samples on 9/13/17, and two (2) times on 9/27/17, and reported the average. (d) The staff run 2018 MLE-M1 samples two (2) times on 2/7/18, and once on 2/21/18 and reported the average. 3. Although the staff signed the attestation forms, indicating that MLE samples were tested the same as patient specimens, interview with the LD

	and Staff #1 and #2, confirmed that staff repeated MLE samples more times than patient specimens. Note: This deficiency is a repeat deficiency from the March 28, 2012 and April 2, 2014 re-certification surveys.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures and review of the laboratory's accuracy verification record and interview with the Laboratory Director (LD), on May 16, 2018 at approximately 2:00 PM, the laboratory failed to perform accuracy verification. There was no documented evidence of twice a year accuracy verification in 2017 for two (2) of the four (4) tests not listed in Subpart I, the Proficiency Testing Program for Non-waived Testing (Zinc and Copper). The findings included: 1. Review of the laboratory's policies and procedures with the revision date of April 30, 2018, revealed that the laboratory will send specimens for Zinc (Zn) and Copper (Cu) bi-annually to a reference laboratory for accuracy verification. 2. Although the LD stated that accuracy verification specimens were sent to a reference laboratory, in 2017, there was no documented evidence for verification.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of Medical Laboratory Evaluation (MLE), the Proficiency Test (PT) provider, reports and the review of the laboratory's quality assessment record and confirmation by interview with the Laboratory Director (LD) on May 15, 2018 at approximately 2:20 PM, the laboratory failed to investigate and take corrective action for unsatisfactory PT performance. The laboratory scored (0%) for Calcium for one (1) of the three (3) testing events in 2016 (Third Event in 2016). The findings included: 1. Review of the MLE report for the second testing event (MLE-M3) revealed that the laboratory's response for Calcium was unsatisfactory for five (5) of the five (5) challenges, resulting in 0% in the Center for Medicaid and Medicare Services (CMS) analyte score for Calcium. 2. Although the LD signed the MLE report, there was no evidence of an investigation and corrective action. 3. Interview with the LD confirmed the lack of investigation and corrective action. The staff were unaware of the need to investigate until surveyor brought it to their attention.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: A. Based on the review of the laboratory's policies and procedures and review of the laboratory's accuracy verification record and interview with the Laboratory Director (LD), on May 16, 2018 at approximately 2:00 PM, the laboratory's quality assessment for the general laboratory system failed to identify the laboratory's failure to perform accuracy verification in 2017 for two (2) of the four (4) tests not listed in Subpart I, the Proficiency Testing Program for Non-waived Testing (Zinc and Copper). Cross reference D5217. B. Based on the review of Medical Laboratory Evaluation (MLE), the Proficiency Test (PT) provider, reports and the review of the laboratory's quality assessment record and confirmation by interview with the Laboratory Director (LD) on May 15, 2018 at approximately 2:20 PM, the laboratory's quality assessment for the general laboratory system failed to identify the laboratory's failure to investigate and take corrective action for unsatisfactory PT performance for one (1) of the three (3) testing events in 2016 (Third Event in 2016). Cross reference D5221.
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 observation, review of the laboratory's policies and procedures manual and confirmation by interview with Staff Number (#)1 on May 16, 2018 at approximately 11:15 AM, and interview with the Laboratory Director (LD) on May 16, 2018 at approximately 2:00 PM, the laboratory failed to ensure that all reagents and chemicals that are in use are labeled with expiration dates. The findings included: 1. The laboratory failed to develop a mechanism for assigning an expiration date for stock chemicals that had no expiration dates assigned by the manufacturer. During tour of the laboratory, the following sampled chemicals were observed without expiration dates: (a) Sodium Chloride (5988-500 gram) Lot # 5LBJ1540 manufactured by SIGMA ALDRICH. According to the Product Specification sheet, the product has a 6-year Retest period. There was no expiration date on the bottle. Note: According to the manufacturer "The Recommended Retest date is the end of a period of time during which the batch is expected to remain within established specifications if stored under Sigma-Aldrich's defined conditions." (b) Urea (U5128-500 gram) Lot # 5LBH9709V manufactured by SIGMA ALDRICH. According to the Product Specification sheet, the product has a 5-year Retest period. There was no expiration date on the bottle. (c) Sucrose (S5016-1 Kilogram) Lot #SLBK500TV manufactured by SIGMA ALDRICH. According to the Product Specification sheet, the product has a 5-year Retest period. There was no expiration date on the bottle. (d) Lanthanum (III) Chloride, heptahydrate (26072-500 gram) Lot #MKBJ8694 and Bromothymol Blue Lot # MKV0915V manufactured by SIGMA ALDRICH. There were no expiration dates on the bottles. The product specification sheets for Lanthanum (III) Chloride and Bromothymol Blue did not reveal a retest or expiration dates. However, according to a document entitled "Product Dating Information Statement" by the manufacturer, if there is No Retest or Expiration Date, the recommendation is to handle per defined conditions as printed in the product literature and website product descriptions. The

	manufacturer further suggests using products with no expiration or re-test date within five (5) years of opening. Note: The Lanthanum (III) Chloride bottle had an opening date of 8/6/2014 and no expiration date. The bottle for Bromothymol Blue had no opening or expiration date. 2. The laboratory failed to develop a mechanism for labeling working solutions with expiration date. During tour of the laboratory, the following sampled chemicals were observed without expiration date: (a) 1 Molar (M) Sucrose made 1/18/18 no expiration date. (b) 5 M Sodium Chloride (NaCL) made 4/5 /17. No expiration date. According to Staff #1 the date the solution was made may have changed but the label on the container was not updated to reflect the new date. (c) 8 M Urea made 4/5/17 no expiration date. According to Staff #1 the date the solution was made may have changed but the label on the container was not updated to reflect the new date. 3. Review of the laboratory's procedure failed to provide evidence of expiration date for all the chemicals in use (stock and working reagents). Review of test procedure for the individual assay revealed inconsistent information regarding the stability of the working reagents for example, According to the laboratory's assay protocol for Carbonic Anhydrase I, II, and VI, the Barbital Buffer and Barbital buffer with Bromothymol Blue could be stored at 2-8 Degrees centigrade (C) for no longer than six months. However, review of the assay protocol for Magnesium and Calcium did not provide specific instruction for the stability of the reagents used for the assay such as, the 5% Lanthanum Chloride. 4. Interview with Staff #1 and the LD confirmed the lack of protocol for labeling reagents with expiration dates.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of CDU-5000 IEC centrifuge manufacturer's instruction, and the review of the laboratory's policies and procedures manual, and interview with Staff Number (#1) on May 15, 2018 at approximately 3:00 PM, and interview with the Laboratory Director (LD) on May 16, 2018 at approximately 2:00 PM, the laboratory failed to develop a protocol for maintaining one (1) of the two (2) centrifuges (old centrifuge- CDU-5000 IEC). The findings included: 1. Review of the manufacturer's instruction for CDU-5000 IEC centrifuge revealed periodic and scheduled maintenance depending on the model. 2. Review of the laboratory's policies and procedure manual failed to provide evidence of a maintenance protocol for CDU-5000 IEC centrifuge. 3. Interview with Staff #1 revealed that the staff use the centrifuge routinely to spin blood. Further interview revealed that an authorized person performed maintenance on the centrifuge on July 29, 2015. 4. Interview with the LD revealed that the laboratory no longer has a contract with a manufacturer representative or an authorized person.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, instrument printouts, work sheets, and Proficiency Testing (PT) records and interview with Staff Number (#) 1 and #2 and the Laboratory Director (LD) on May 15, 2018 at approximately 11: 50 AM and on May 16, 2018 at approximately 2:00 PM, respectively, the LD failed to ensure that the staff tested PT samples for Magnesium and Calcium the same number of times as patient specimens for four (4) of the four (4) testing events reviewed (2017 MLE-M1,-M2, and M3; 2018 MLE- M1). Cross reference D2010.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of Medical Laboratory Evaluation (MLE), the Proficiency Test (PT) provider, reports and the review of the laboratory's quality assessment record and confirmation by interview with the Laboratory Director (LD) on May 15, 2018 at approximately 2:20 PM, the LD failed to ensure that the 0% score for Calcium had been investigated and corrective action taken for one (1) of the three (3) testing events in 2016. (Third Event in 2016). Cross reference D5221.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A. Based on the review of the laboratory's policies and procedures and review of the laboratory's accuracy verification record and interview with the Laboratory Director (LD), on May 16, 2018 at approximately 2:00 PM, the LD failed to ensure laboratory's quality assessment for the general laboratory system identified the laboratory's failure to perform accuracy verification in 2017 for two (2) of the four (4) tests not listed in Subpart I, the Proficiency Testing Program for Non-waived Testing (Zinc and Copper). Cross reference D5291-A. B. Based on the review of Medical Laboratory Evaluation (MLE), the Proficiency Test (PT) provider, reports and the review of the laboratory's quality assessment record and confirmation by interview with the Laboratory Director (LD) on May 15, 2018 at approximately 2:20 PM, the LD failed to ensure that the laboratory's quality assessment for the general laboratory system identified the laboratory's failure to investigate and take corrective action for unsatisfactory PT performance for one (1) of the three (3) testing events in 2016 (Third Event in 2016). Cross reference D5291-B. This is a repeat citation from 4/2 /2014 and 2/17/2016 re-certification surveys.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)

	The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: A. Based on observation, review of the laboratory's policies and procedures manual and confirmation by interview with Staff Number (#)1 on May 16, 2018 at approximately 11:15 AM and interview with the Laboratory Director (LD) on May 16, 2018 at approximately 2:00 PM, the LD failed to ensure that the laboratory had a protocol to ensure that all reagents and chemicals that are in use are labeled with expiration dates. Cross reference D5415. B. Based on the review of CDU-5000 IEC centrifuge manufacturer's instruction, and the review of the laboratory's policies and procedures manual, and interview with Staff Number (#1) on May 15, 2018 at approximately 3:00 PM, and interview with the Laboratory Director (LD) on May 16, 2018 at approximately 2:00 PM, the LD failed to ensure that a maintenance protocol had been developed for one (1) of the two (2) centrifuges (old centrifuge- CDU-5000 IEC). Cross reference D5429. This is a repeat citation from 4/2/2014 re-certification survey.