Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0677292	11/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Environmental Health Center - Dallas	399 Melrose Dr, Richardson, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the CMS-155 proficiency testing report, American Proficiency Institute records, and interview with facility personnel, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the American Proficiency Institute for 1 of 3 events in 2018. The findings included: 1. Based on review of the CMS-155 proficiency testing report, American Proficiency Institute sent the following scores to CMS for the third event of 2018 (three events per year): Routine Chemistry - 0 percent potential Hydrogen (PH) Blood Gas - 0 percent Partial Pressure Oxygen (pO2) - 0 percent Partial Pressure Carbon Dioxide (pCO2) - 0 percent 2. Based on review of American Proficiency Institute

	records, the laboratory was without a laboratory director from August 16, 2018 through September 28, 2018. The American Proficiency Institute samples were received on August 28, 2018 and the Testing Person analyzed the specimens on August 31, 2018. 3. In an interview at 13:42 hours on 11/05/2018 in the laboratory, Testing Person 1 stated the laboratory was unable to submit results to the proficiency testing program within the time frame specified by the program due to the gap in laboratory directorship. The laboratory self-graded the 3 event of 2018 on October 11, 2018 and had 5 of 5 acceptable scores.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS Form 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of competency assessments on 1 of 1 technical supervisor. 1. A review of the laboratory's submitted CMS Form 209 (signed by the laboratory director on 11/05/2018) revealed the laboratory identified 1 technical supervisor for high complexity testing. 2. A review of the laboratory's personnel records for the technical supervisor revealed the laboratory did not have documentation of assessing the competency for 2016 and 2017. The laboratory was asked to provide documentation of performing the competency assessments as required. No documentation was provided. 3. An interview with testing person 1 as listed on Form CMS 209 on 11/05/2018 1445 hours in the office revealed the laboratory did not perform competency assessments on the technical supervisor. This confirmed the findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records, review of the manufacturer's instructions for the CVC 123 Calibration Verification Controls, and staff interview, it was revealed the failed to have documentation of performing corrective actions when the results of calibration verification failed. The findings were: 1. A review of the laboratory's calibration verification records for pO2 testing performed on the IRMA Trupoint blood gas analyzer performed on February 23, 2018 revealed the average of the 3 replicates for Level 2 was outside the manufacturer's acceptable range. Level 2 Run 1 133.6 Run 2 71.3 Run 3 65.6 Average: 90.2 Accept.

	Range 56.1 - 76.1 2. Further review of the calibration records revealed the laboratory removed the 133.6 value from the calculations and recalculated the average. The new average was 68.5 which fell into the acceptable range. 3. A review of the manufacturer's instructions for the CVC 123 Calibration Verification Controls (REF CVC 123) revealed the manufacturer required that a minimum of 3 replicates be used for the calculations, thus the laboratory could not remove a value and recalculate. 4. The laboratory was asked to provide documentation of performing corrective actions for the failed calibration verification. No documentation was provided. 5. An interview with testing personnel number 1 on 11-05-2018 at 1530 hours in the hallway revealed no corrective actions was performed. She stated the upper value was removed and the the average recalculated. This confirmed the findings.