Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0968273	11/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dc Dfs Public Health Laboratory	401 E Street Sw, 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
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: Based on record review and interview, the laboratory failed to follow written procedures for an ongoing mechanism to monitor, assess, and correct problems identified in regards to an unsuccessful proficiency testing event for blood metals. 1. The laboratory's procedure "DOM08 - Procedures for Quality Preventive Action" states under 5.2 Part A: Situation/Condition: 5.2.1. Part A of a Q-PAR describes the background of the situation/ potential nonconformity. This will include all information regarding the event, parties involved (If a Situation/Condition occur within an ISO Unit, list the names of individuals involved), the frequency of occurrence, possible impacts, and any immediate actions taken to address the potential nonconformity. 5.2.2. Part A must be completed within 15 calendar days of a Q-PAR being issued Note: Examples of possible nonconformities leading to QPAR: PT score greater than or equal to 80% and less than 100% 2. The laboratory's procedure "DOM08 - Procedures for Quality Preventive Action" states 5.3. Part B: Root Cause Analysis/Action Plan: 5.3.1. In certain instances, a root cause analysis may be required in order to determine the appropriate preventive action steps. A root cause analysis is an in-depth investigation of the underlying causation factors rather than cursory symptom analysis. Root cause analysis may require a process review to include technical procedures, instrumentation utilization and maintenance, controls and standards requirements and employee performance. If a root cause analysis is needed, the selection of action steps should be made by the individual or team performing the root cause analysis whenever possible. 5.3.2. Part B must be

	completed within 15 calendar days of a Q-PAR Part A being issued, whenever practicable. 3. The laboratory record "LRN-C PT Results Report" for 2022 Event 2 states the composite PT result for Blood Metals (Pb, Cd, Hg) was 80%. The record also states under review an comments: "Reviewed and discussed need to further investigate Pb results and consider Pb adjustment for network alignment. QPAR initiated." It is signed on 9/2/2022. The record also has a report created line with a date of 6/29/2022. 65 days elapsed between the laboratory receiving graded results from LRN-C and initiating the QPAR. 4. The laboratory's record QPAR 31434 states it was submitted on 9/12/2022, with an occurrence date of 9/2/2022. The laboratory's proficiency testing records show the samples were submitted to the PT program on 5 /19/2022. The laboratory's QPAR 31434 states a due date of 10/7/2022. The documentation does not have a preventative action plan, and was not completed by laboratory personnel by the date of the survey on 11/9/2022. 5. During an interview on 11/9/2022, around 5 PM the laboratory director confirmed the documentation was incomplete and did not follow the timeline in the laboratory's policies and procedures.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure the reference intervals for urine toxicology drug quantification were available on 2 of 2 patient test reports. 1. During a review of patient final report records on 11/9/2022, sample ID 328157 and sample 319699 reported on 2/7/2022 both had no information under "Reference Interval" for Methadone and EDDP. 2. Laboratory personnel and laboratory director confirmed on the findings on 11/9/2022 around 11:30 AM.