Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0660967	06/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Vermont Dept Of Health Laboratory	359 South Park Drive, Colchester, VT	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) or technical supervisor (TS) failed to sign attestation statements documenting that proficiency testing (PT) samples were tested in the same manner as patient samples. Findings include: 1. Record review conducted on 06/16/2021 of 2020 and 2021 Urine Drug Testing and Chemical Terrorism PT records revealed the following: College of American Pathologists (CAP) 2020 Urine Toxicology (UT) PT attestation statements: a) UT-A 2020: LD or Designee signature missing, not signed. b) UT-C 2020: LD or Designee signature missing, not signed. Wadsworth Center Trace Elements PT attestation statement: a) Trace Elements 2020 Event 1: LD or Designee signature missing, not signed. CAP 2021 Urine Drug Adulterant/Integrity PT attestation statement: a) DAI-A 2021: LD or Designee signature missing, not signed. 2. Staff interview on 06/16/2021 at 10:45 am with the Urine Drug Testing Technical (TS1) and Chemical Terrorism Technical Supervisors (TS2) confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and

	negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview with the Bacteriology Technical Supervisor (TS), the laboratory failed to document quality control (QC) for Oxidase, Catalase, Urea/PDA Discs, Gram Stain, and E. coli O157:H7 Latex Agglutionation Kit for the months of July 2019 through September 2019, Decemember 2020, and April 2020. Findings include: 1. Record review conducted on 06/16/2021 of 2019 and 2020 Bacteriology Quality Control Documentation Sheets (Micro 158. Rev.2 (5 /2013)) revealed no documented QC for the following reagents for the months of July 2019, August 2019, September 2019, December 2020, and April 2020: Oxidase Test (Performed each Week of Use), Catalase Test: (Perform Each Week of Use), Urea /PDA Discs: (Perform Each Day of Use), Gram Stain (Perform Each Week of Use), E. coli O157:H7 Latex Agglutination Kit: (Perform Each Day of Use). 2. Record review conducted on 06/16/2021 of Enteric Bacteriology Daily Worksheets- Plates (Micro 698 Rev. 5 (10/13)) revealed that patient samples were tested during the months of July 2019, August 2019, September 2019, December 2020, and April 2020. 3. Staff interview with the Bacteriology TS conducted on 06/16/2021 at 2:30 pm confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review of the Vermont Department of Health Laboratory (VDHL) Avioq Oral Fluid HIV-1 ELISA Standard Operating Procedure (SOP), VDHL Instructions for the Collection and Packaging of Orasure Oral Fluid Specimens for HIV-1 testing, Oral Fluid EIA HIV-1 test results, and interview with the Laboratory Director (LD), the laboratory failed to report specimens received greater than 21 days from the date of collection as Unsatisfactory for testing as stated in the VDHL Avioq Oral Fluid HIV-1 ELISA SOP and Collection and Packaging of Orasure Oral Fluid Specimens for HIV-1 Instructions. This is a repeat deficiency. Findings include: 1. Record review conducted on 06/15/2021 of the approved Avioq Oral Fluid HIV-1 ELISA SOP (P-MIC-133, Revision 3, Date Effective 08/27/19, Section 4.4 stated: "Criteria for specimen rejection: Specimens received at the VDHL more than 21 days after the date of collection. (Specimens verified to have been stored and shipped frozen may be acceptable even if received more than 21 days after the date of collection. Refer to the package insert.)" 2. Record review conducted on 06/15/2021 of the VDHL Instructions for the Collection and Packaging of Oral Fluid Specimens for HIV-1 stated under Collection of Specimen: a) "#12 Collected specimens may be stored at 4-37 C for a maximum of 21 days (including the time for shipping and

	testing). Please ship as soon as possible, but within 14 days of collection, so that testing may be completed within the 21 days of collection." b) "The specimen may be rejected if specimens are greater than 21 days old." 3. Record review conducted on 06 /15/2021 of 684 HIV-1 Oral Fluid EIA test results of samples received from July 2019 to June 2021 revealed 4 test results were reported as "Nonreactive" and were received by the laboratory unfrozen and greater than 21 days from the sample collection date. Sample numbers included (20-061211-HIV-1), (20-009267-HIV-1), (20-031829-HIV-1), and (19-000456-HIV-1). The review also revealed that 51 samples that were received by VDHL unfrozen and more than 21 days from the date of collection, but were reported as "Not Tested". 4. Interview with the LD on 06/15/2021 at 4:30 PM confirmed the findings above.