

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 47D0660967	<b>(X3) Date Survey Completed</b> 05/22/2019
<b>Name of Provider or Supplier</b> Vermont Dept Of Health Laboratory	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5517</b>	<p>MYCOLOGY CFR(s): 493.1263(a)(c)</p> <p>The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s). (c) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review of Mycology quality control (QC) records and staff interview with the Mycology Technical Supervisor (TS), the laboratory failed to check each batch and shipment of lactophenol cotton blue for intended reactivity prior to use for reporting patient results. Findings include: 1. Record review conducted on 05/21/2019 of Mycology QC records revealed no documentation confirming the laboratory tested each batch and shipment of lactophenol cotton blue for reactivity with control organisms prior to use. 2. Staff interview with the Mycology TS on 05/21/2019 at 4: 15 PM confirmed this finding. The interview further revealed that the lactophenol cotton blue was used by the laboratory to support the mycology testing identification process.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

acceptability.

This STANDARD is not met as evidenced by:

A. Based on record review of the Vermont Department of Health Laboratory (VDHL) Cepheid GeneXpert Norovirus Real-Time RT- PCR Assay Standard Operating Procedure (SOP), Cepheid GeneXpert Norovirus manufacturer instructions, Norovirus PCR test reports, and interview with Virology Technical Supervisor (TS), the laboratory failed to report positive and negative Norovirus PCR tests results according to the Cepheid GeneXpert Norovirus Real-Time RT- PCR Assay SOP and manufacturer instructions. Findings include: 1. Record review conducted on 05/22/2019 of 3 Norovirus PCR test reports issued from 04/18/2019 through 05/06/2019 revealed 2 positive Norovirus PCR results for sample numbers (19VIR00114 and 19VIR00118) and 1 negative Norovirus PCR result for sample (19VIR00125). The review revealed Norovirus PCR results reported as "Positive" for samples 19VIR00114 and 19VIR00118 and "Negative" for sample 19VIR00125. 2. Record review conducted on 05/22/2019 of the approved Cepheid GeneXpert Norovirus manufacturer instructions (301-2441, Rev. B January 2015) revealed in Section 15 Interpretation of Results, Table 1. Xpert Norovirus Assay Results: NORO GI DETECTED, NORO GII NOT DETECTED NORO GI NOT DETECTED, NORO GII DETECTED NORO GI DETECTED, NORO GII DETECTED NORO GI NOT DETECTED, NORO GII NOT DETECTED 3. Interview with the Virology TS on 05/22/2019 at 10:00 AM confirmed these findings. B) 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 and HIV-2, HIV-1 Oral Fluid EIA test results, and interview with the Diagnostic Immunology Technical Supervisor (TS), the laboratory failed to report specimens missing sample collection date and received greater than 21 days from the date of collection as Unsatisfactory for testing as stated in the VDHL Avioq Oral Fluid HIV-1 Eliza SOP and Collection and Packaging of Orasure Oral Fluid Specimens for HIV-1 and HIV-2 Instructions. Findings include: 1. Record review conducted on 05/22/2019 of 378 HIV-1 Oral Fluid EIA test results of samples received from 01/02/2019 to 05/20/2019 revealed 20 test results were reported as "Nonreactive" and missing date of collection. 2. Record review conducted on 05/22/2019 of the approved Avioq Oral Fluid HIV-1 ELISA SOP (P-MIC-133, Revision 2, Date Effective 06/21/2017, Section 4.4: "Specimen Rejection: Specimens to be rejected (c) received at VDHL unfrozen more than 21 days from the date of collection." 3. Record review conducted on 05/22/2019 of the VDHL Instructions for the Collection and Packaging of Oral Fluid Specimens for HIV-1 and HIV-2 stated under Collection of Specimen: a) "#13 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) "#14, "Fill out the Vermont Department of Health "Clinical Microbiology Request Form" (Micro 220) completely. The following information is required to ensure accurate and efficient processing of the specimen and reporting of test results: Date of Collection" c) "The specimen may be rejected if date of collection is missing on form and if specimens are greater than 21 days old." 4. Interview with the Diagnostic Immunology TS on 05/22/2019 at 12:20 PM confirmed the findings above. 5. Record review conducted on 05/22/2019 of 378 HIV-1 Oral Fluid EIA test results of samples received from 01/03/2019 to 05/20/2019 revealed 18 test results were reported as "Nonreactive" and were received by the laboratory greater than 21 days from the sample collection date. Sample numbers ( 19-000807-HIV-1), (19-000803-HIV-1), (19-000808-HIV-1), (19-

000809-HIV-1), (19-000804-HIV-1), (19-000805-HIV-1), (19-000806-HIV-1), (19-002924-HIV-1), (19-002931-HIV-1), (19-002922-HIV-1), (19-002921-HIV-1), (19-002929-HIV-1), (19-002920-HIV-1), (19-002919-HIV-1), (19-002186-HIV-1), (19-001907-HIV-1), (19-001905-HIV-1), and (19-002928-HIV-1).