

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0660967	(X3) Date Survey Completed 07/24/2025
Name of Provider or Supplier Vermont Dept Of Health Laboratory	Street Address, City, State 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
D0000	A recertification survey was performed on 07/22/25 through 07/24/25. Standard-level deficiencies cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's written procedure, testing worksheets, and interview with general supervisor #12 (GS #12), the laboratory failed to follow its written procedure for one of one lot change for the antigen needle used for syphilis testing. Findings included: 1. Review of the laboratory's written procedure titled "Procedure for the Rapid Plasma Reagin (RPR) Test for Syphilis" section, "6.4 Antigen Dispensing Needle" stated, "6.4.1 The antigen-dispensing needle is checked after a new needle or new lot of antigen is put into use.". 2. Review of the "Syphilis RPR Run Worksheets" revealed no evidence of an antigen-dispensing needle check for one of one antigen lot number 4033530. 3. In an interview on 07/23/25 at 10:30 am, GS #12 confirmed the findings.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent</p>

information required for proper use.

This STANDARD is not met as evidenced by:

I. Based on observation and interview with staff, the laboratory failed to label laboratory prepared media tubes with the name of the media, storage requirements, preparation and expiration dates for two of two media. Findings included: 1. During a tour of the Bacteriology Laboratory (Room 220A) on July 24, 2025, at approximately 10:30am, the following laboratory prepared media was observed in Refrigerator SP1395: a. A test tube rack with a label on the front on the rack with the following: "TSI Slants.. A Procedure pH 7.36 ...Preparation Date 4/1/2 (QC PASSED sticker covered the remaining date)..Expiration Date 10/1/2 (QC PASSED sticker covered the remaining date)..Prepared By" (written initials were not legible) ... Storage Room ... Refrig. The rack contained unlabeled tubes of media. b. A test tube rack with a label on the front on the rack with the following: Motility Test Medium ...pH 7.27.. Preparation Date 4/11/25 ...Expiration Date 10/1/25 ...Prepared By (written initials were not legible) ... Storage Room ... Refrig. The rack contained unlabeled tubes with media. 2. During interview on July 24, 2025, at approximately 10:30am, the laboratory's Quality Assurance staff confirmed the above findings. 47272 II. Based on the laboratory's written procedure, observation, and interview with technical supervisor #7 (TS #7), the laboratory failed to document the expiration date for two of two bottles of L-Ascorbic Acid. Findings included: 1. Review of the laboratory's written procedure titled, "Cyanide in Blood By Headspace GC/MSD" section, "1.2 Identification of the Method" stated, "Cyanide in whole blood is analyzed at the Vermont Department of Health Laboratory (VDHL) using static headspace sampling on an Agilent 5977B mass spectrometer coupled with 8890 gas chromatograph and a Gerstel Robotic PRO MultiPurpose Sampler (MPS) system. ... L-ascorbic acid is used to prevent the conversion of the thiocyanate (SCN-) in blood to HCN." 2. Observation on 07/23/25 at 09:30 am in the Chemical Threat Organic Laboratory revealed no expiration dates for two bottles of two containers of Fisher Chemical L-Ascorbic Acid bottles (Lot#213733 and Lot# 235732). 3. In an interview on 07/23/25 at 09:35 am, TS#7 confirmed the findings. Word Key: HCN = Hydrogen Cyanide III. Based on the laboratory's written procedure, direct observation, and interview with general supervisor #12 (GS #12), the laboratory failed to document the expiration date for one of one container of Sulfuric Acid. Findings included: 1. Review of the laboratory's written procedure titled, "Enzyme-linked Immunoassay for Qualitative Detection of Antibody to Hepatitis C Virus (Anti-HCV) in Human Serum stated the following: a. Section, "4.7. Materials" stated, "4N H2SO4, Fisher Scientific 500 mL bottle, Catalog # SA818-500" b. Section, "4.8. ELISA Procedure" stated, "s. Add 50 ? L of 4N sulfuric acid (H2SO4) to all wells, including 1A. Ensure proper mixing taking care to avoid splashing." 2. Observation on 07/23/25 at 10:05 am revealed no expiration date documented on one container of Sulfuric Acid (lot# 244182). 3. In an interview on 07/23/25 at 10:10 am, GS#12 confirmed the findings. Word Key: ELISA = Enzyme-linked Immunoassay L= Microliter

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient

testing is conducted.

This STANDARD is not met as evidenced by:

Based on review of laboratory documents and staff interview, the laboratory failed to calibrate the timers on the centrifuges in the Mycobacteriology and Parasitology laboratories for 2 of 2 years. Findings included: I. Mycobacteriology Laboratory a. Review of the laboratory's procedure "Mycobacteriology Procedure Manual, Version: 9.0, P-MIC-002", page 10 revealed the following : "g. Centrifuge the tube at 3800xG for 15 minutes, using aerosol-free sealed centrifuge cups". b. Review of the laboratory's "Centrifuge Verification Worksheet" for the Mycobacteriology Laboratory /BLS 3 (Biosafety Level 3) found two centrifuges in use. Rotunda 35 R serial number 0002079-04-00 located in room 2404 and Eppendorf serial number 54240N647015 located in room 2401 B. The documentation provided did not include calibration of the centrifuges' timers. c. The surveyor requested and was not provided documentation of the two centrifuges' timer calibration for 2 of 2 years (2023 and 2024). d . During interview on July 23,2025 at approximately 3:30pm, the Technical Supervisor for the Mycobacteriology Laboratory confirmed the laboratory did not perform calibration of the two centrifuge timers in the BLS3 laboratories. II. Parasitology Laboratory a. During tour of the Parasitology laboratory area on July 23, 2025 at approximately 3:15pm, a centrifuge with serial number 0002199-04-00 was observed in use for parasitology testing. b. Review of the laboratory's procedure "Parasitology Procedure Manual, Version: 10.0, P-MIC-003", page 16 revealed the following: "g. Centrifuge at 500 x g (approximately 1700 rpm) for 10 minutes. The centrifuge in the Parasitology room (Room 2220) is preset." c. The surveyor requested and was not provided documentation of the centrifuge timer calibration for 2 of 2 years (2023 and 2024). d. During interview on July 23,2025 at approximately 3:30pm, the Technical Supervisor for the Parasitology Laboratory confirmed the laboratory did not perform calibration of the centrifuge timer.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) 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.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with laboratory staff, the laboratory failed to perform quality control for three of three reagents used for a microbial identification system. Findings included: 1. Review of the laboratory's quality control worksheets revealed the laboratory utilizes the bioMerieux API 20E test strip to identify gram negative rods. 2. Review of the bioMerieux API 20E instructions for use ("REF 20100 / 20150") provided to the surveyor by the laboratory stated on page 3 the following: "TDA test: add 1 drop of TDA reagent ... Indole test: add 1 drop of JAMES reagent ... VP test: add 1 drop of each VP 1 and VP 2 reagents.." 3. The surveyor requested quality control records for the TDA, Indole and VP reagents and found the laboratory used Hardy Diagnostics reagents rather than bioMerieux reagents. The laboratory failed to provide quality control records for the

Hardy Diagnostics reagents used with the bioMerieux API 20E test strip. 4. During interview on July 24, 2025, at approximately 10:00am, the Technical Supervisor for the Enteric Laboratory section confirmed the laboratory did not perform quality control testing for the above named Hardy Diagnostics reagents used for the bioMerieux API 20E test strip. Word Key: TDA - Tryptophan deaminase (Ferric Chloride) VP: Voges-Proskauer

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with technical supervisor #2 (TS #2), the laboratory failed to evaluate the relationship of measles testing performed on three different analyzers at least twice a year in 2024. Findings included: 1. On 07/24/25 at 12:15 pm, TS #2 confirmed the laboratory performed measles testing using three Applied Biosystem 7500x (serial numbers: 275030091, 275012276, and 275030549). 2. A record review of the laboratory's 2024 analyzer comparison studies revealed no evidence the laboratory evaluated the relationship between the three instruments in 2024. 3. In an interview on 07/24/25 at 12:30 pm, TS #2 confirmed the findings.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of Centers for Medicare and Medicaid (CMS) Personnel Form 209, the laboratory's quality system manual, personnel records, and interview with the laboratory director (LD), the technical supervisor failed to evaluate one of eight testing persons performing high complexity testing at least annually in 2024. Findings included: 1. Review of the submitted CMS 209 form, signed and dated by the LD on 07/08/25, revealed Testing Person #7 (TP #7) listed to perform high complexity testing. 2. Review of the laboratory's "Quality System Manual", section "19.8 On-Going Demonstration of Capability (ODOC) or Continued Proficiency/Competency" stated, " Competency must be demonstrated annually (based on the date of the initial training) and can be demonstrated on the test system" 3. Review of 2024 personnel records for eight testing persons performing high complexity testing revealed no annual competency assessed for TP #7. 4. In an interview on 07/22/25 at 10:00 am, the LD confirmed the findings.