Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0660967	05/03/2023
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's approved Rapid Plasma Reagin (RPR) Test for Syphilis (Document ID P-MIC-026) procedure, Syphilis RPR Run Worksheet, and interview with the Technical Supervisor (TS#2), the laboratory failed to document quality control for the antigen-dispensing needle when a new lot of antigen was put into use. Findings include: 1. Record review conducted on 05/02/2023 of the laboratory's approved Syphilis Rapid Plasma Reagin (RPR) Test for Syphilis (Document ID P-MIC-026) procedure manual, revealed under section 6.4, "The antigen-dispensing needle is checked after a new needle or new lot of antigen is put into use." 2. Record review conducted on 05/02/2023 of the laboratory's approved Syphilis Rapid Plasma Reagin (RPR) Run Worksheet (Document ID: Micro 618E Rev. 0) revealed: "For each new lot of antigen and each new needle check needle drops per 0.5 mL 30 +/- 1 drop is acceptable." 3. Record review conducted on 05/02 /2023 of Syphilis Rapid Plasma Reagin (RPR) quality control (QC) records for the period of May 2022- May 2023 revealed no documentation that the antigen-dispensing needle was checked after antigen Lot #1032448 was put into use. 4. Staff interview with TS#2 on 05/02/2023 at 2:45 PM confirmed the findings above. 5. The laboratory performed 245 RPR tests annually.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
A. Based on record review of 2022 and 2023 Tecan Freedom EVO Workstation preventive maintenance records and an interview with the laboratory Technical Supervisor (TS#3), the laboratory failed to document the Tecan Freedom EVO Workstation daily preventive maintenance procedures according to the laboratory's approved procedure instructions. Findings include: 1. Record review conducted on 05/03/2023 of the Enzyme-linked Immunosorbent Assay (ELISA) Urine Drug Screen Using the Immunalysis/Tecan Freedom EVO Workstation approved procedure (Document ID: P-ORTOX-26, Revision 5) revealed daily instrument checks under the section 4.6.5 Instrument Preparation. 2. Record review conducted on 05/03/2023 revealed a lack of documentation confirming the daily instrument preparation checks were performed. 3. TS#3 confirmed on 05/03/2023 at 11:00 AM that the laboratory performed the daily instrument preparation checks, but did not document that they were performed. 4. The laboratory reported approximately 24,000 patient results annually during 2022. B. Based on record review of 2022 and 2023 GeneXpert System preventive maintenance records and interviews with the laboratory technical supervisors (TS#1 and TS#2), the laboratory failed to document the GeneXpert Systems daily preventive maintenance procedures according to the manufacturer instructions and the laboratory's approved procedure Findings include: 1. Record review conducted on 05/02/2023 of the GeneXpert Systems Operator Manual for systems SN# 84493 and SN# 810709, revealed manufacturer System Maintenance Tasks under Section 9.1 and System Maintenance Log under Section 9.2 (document 302-0528). 2. Record review conducted on 05/02/2023 of the GeneXpert CT/NG Assay Procedure (Document ID P-MIC-061) revealed under section 7.1 Preventive Maintenance and Backup, "Refer to the GeneXpert System Maintenance Log (Micro 658, Appendix I) for system maintenance schedules" 3. Record review conducted on 05/02/2023 of GeneXpert Systems Maintenance documentation (SN# 84493 and SN# 810709) for the period revealed the following documented system maintenance: 4. SN# 810709 for the period of January 2023 - April 2023: No quarterly system maintenance performed in 2023 No documentation of monthly system maintenance performed in April 2023, February 2023, and January 2023. No documentation of weekly system maintenance for the weeks of April 10, 18 & 26, 2023, March 2023, February 2023, and January 4 & 24, 2023. 5. SN# 844993 for the period of May 2022 - April 2023: No documentation of quarterly system maintenance for the period of 05/2022-04/2023. No documentation of monthly system maintenance for April 2023, March 2023, February 2023, January 2023, July 2022, June 2022, and May 2022. No documentation of weekly system maintenance for the weeks of May 10, 2022, July 11 & 20, 2022, August 25, 2022, September 7, 2022, October 7, 2022, December 13, 2022, January 19, 2023, and March 1, 2023. 6. TS#1 and TS#2 confirmed the findings above on 05/02/2023 at 12:13 PM. 7. The laboratory reported approximately 1,200 patient GeneXpert results during 2022.