

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0644555	<b>(X3) Date Survey Completed</b>  07/27/2020
<b>Name of Provider or Supplier</b>  Dr Katherine A Kelley State Public Health Lab	<b>Street Address, City, State</b>  395 West St, Rocky Hill, CT	
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>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview the laboratory failed to provide a procedure manual with updated step-by- step instructions for SARS CoV 2 testing based on the recently FDA approved updated EUA Instructions for Use (IFU) for the TaqPath COVID-19 Combo Kit approved on July 17, 2020, and laboratory corrective actions recorded on 7/24/2020. Findings include: 1. Surveyor observation on 7/27/2020 at 1:30 PM of the SARS CoV 2 procedure of control and specimen curve review demonstrated by testing personnel #1 (TP1) revealed, amplification curves are reviewed and must pass specific criteria to determine</p>

acceptability of controls and patient results. 2. Surveyor observation on 7/27/2020 at 2:30 PM of the SARS CoV 2 vortexing procedure as demonstrated by TP1 revealed the following: a. The vortex is turned on using the continuous mode. b. The vortex is allowed to come to maximum speed (3000) before vortexing sample plate. c. The sample plate is vortexed for 10 seconds using a sliding motion to slide the plate across the surface of the vortex. 3. Record review on 07/27/2020 of TaqPath (Trademark) COVID-19 Combo Kit Instructions for Use (IFU) Multiplex real-time RT-PCR test for the qualitative detection of nucleic acid from SARS CoV 2, Revision F.0, dated 15 July 2020, revealed the following FDA approved procedural updates: a. "Added Applied Biosystems (Trademark) COVID 19 Interpretive Software v1.3 and Applied Biosystems (Trademark) COVID 19 Interpretive Software v2.3.in the revision" b. "Removed instructions to mix by pipetting up and down 10 times when preparing RT-PCR plates. Added instructions to vortex the plates to ensure proper mixing". 4. Record review of a draft copy of the Quality Investigative and Corrective Action Report, Corrective (remedial) Action(s) section, item #2 recorded on 07/24/2020 stated, "Run files of all positive samples are now visually viewed. Any amplification curves not consistent with the amplification of the 3 targets are retested with the Cepheid GenXpert". 5. Record review conducted on 07/27/2020 of an email sent to laboratory staff titled "Visual Check of TPC data in the 7500 Fast System SDS Software" from TP#1 dated July 21, 2020 stated, "Because of false positive results, as a quality control measure we need to visually inspect all positive results." 6. Record review on 7/27/2020 of laboratory's 'Detection of SARS CoV 2 RNA by TaqPath COVID 19 Combo Kit' procedure,' AMD 005 00 put into use on 07/20/2020 revealed the lack of step-by-step instructions and did not reflect the procedure currently in use, specifically: a. Instructions on the review and evaluation of acceptability of patient specimen and control amplification curve by testing personnel was not listed. b. Vortexing step listed a vortex time of 10 30 seconds. c. Vortexing step did not include allowing the vortex to come to maximum speed or sliding the plate across the vortex. d. References in Section 12 do not refer to the current manufacturer's instructions for use. 7. Staff interview with the laboratory director (LD) on 7/27/2020 at 3:30 PM confirmed the findings above.

**D5407**

PROCEDURE MANUAL  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory director (LD) failed to approve changes in the SARS CoV 2 laboratory procedure before laboratory use. Findings include: 1. Record review on 7/27/2020 of the 'Detection of SARS CoV 2 RNA by TaqPath COVID 19 Combo Kit' procedure,' AMD 005 00 revealed: a. Section 7.3.2.5.2, pipetting step was crossed out and initialed by the Virology Supervisor on 7/20/2020. b. Section 7.3.2.6 vortex time was crossed off, 10- 30 written beside it and initialed by the Virology Supervisor on 7/20/2020. c. The last signature date of the LD was 6/11/2020. d. The first page included the following, " Per Virology Supervisor 10:30 AM, in use 07/20/2020." 2. Staff interview on 7/27 /2020 at 10:30 AM with the LD, Quality Assurance Manager and Virology Supervisor confirmed the laboratory director did not sign the above procedure changes before placing the new procedure in use. The Virology Supervisor further revealed the procedure was put into use on 07/20/2020.