Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2206866	08/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Accelevir Diagnostics Llc	701 E Pratt St Suite 4016, Baltimore, MD	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: I. Based on review of emergency use authorization (EUA) summaries and the standard operating procedure (SOP) and interview with the general supervisor (GS), the laboratory's SOP failed to define specimen acceptability requirements for age of specimen for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) testing. Findings: 1. The laboratory tested saliva specimens that were self-collected with the SalivaDirect At-Home Collection Kit for SARS-CoV-2 using the SalivaDirect RT-PCR assay. 2. The "Inspection of Specimens" section of the EUA summary for the SalivaDirect At-

	Home Collection Kit stated that "prior to the acceptance for testing: Date of shipment received must be less than or equal to 56 hours from the time of sample collection." 3. The "SalivaDirect Unsupervised Collection Kit Sample Accessioning" section of the EUA summary for the SalivaDirect SARS-CoV-2 RT-PCR Assay stated that "In order for the designated laboratory to perform testing, the received samples shall meet the following criteria" which included "Sample acceptability: sufficient sample volume, sample received within 72 hours from sample collection date and time." 4. The "Criteria for Specimen Rejection" section of the laboratory's "Saliva Direct Sample Accessioning and Processing" SOP did not include acceptability or rejection criteria that was specific to the age of specimens received. 5. During the survey on 08/01 /2022 at 2:30 pm, the GS confirmed that the specimen rejection procedure did not include acceptability criteria for saliva specimen age. II. Based on review of the SOP list and interview with the quality assurance (QA) representative, the laboratory did not have a written procedure for issuing a corrected/amended report for SARS-CoV-2 RT-PCR testing. Findings: 1. The laboratory's procedures did not include instructions for when and how to create and issue a corrected/amended final test report. 2. During the survey on 08/01/2022 at 2:30 pm, the QA representative confirmed that the corrected/amended report SOP was currently being drafted for approval. III. Based on review of the SOP and interview with the general supervisor (GS), the laboratory failed to include detailed instructions for performing parallel testing to verify performance of new lots of critical reagents for SARS-CoV-2 RT-PCR testing. Findings: 1. The SOP titled "Parallel Testing Procedure for Comparison of Critical Reagent Lots" included instructions for performing parallel testing for non-clinical and clinical testing. 2. The instructions for parallel testing for clinical testing reagents did not state which reagents were considered critical, the procedure for performing the parallel testing for each reagent, or what the acceptability requirements were to accept a new lot number. 3. During the survey on 08/01/2022 at 2:30 pm, the GS confirmed that the parallel testing SOP did not include detailed instructions for verifying critical reagents for SARS-CoV-2 RT-PCR clinical testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the validation report and interview with the technical supervisor (TS), the laboratory failed to verify that using a manual multichannel pipettor produced the same test results as using an automated pipettor for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) testing. Findings: 1. The laboratory performed all SARS-CoV-2 RT-PCR validation studies using an automatic pipettor. 2. The TS stated that when testing volumes were low the laboratory used a manual multichannel pipettor

	instead of the automatic pipettor. 3. During the survey on 08/01/2022, the TS confirmed that none of the validation studies were performed using the manual multichannel pipettor that was regularly used to perform patient testing.