Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2181639	02/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Select Reference Laboratories, Llc	780 Plantation Drive, Burlington, NC	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of SARS-Co-V-2 test records and SARS-Co-V-2 reporting documentation 2/25/21 - 2/26/21, and interviews with staff 2/26/21, the laboratory failed to report negative SARS-Co-V-2 test results for patients from North Carolina 9 of 9 days reviewed in December 2020 and January and February 2021. Findings: 1. Review of SARS-Co-V-2 test records and reporting documentation for the period 12/1 /20 through 2/25/21 revealed the laboratory tested approximately 9386 patients from North Carolina from 12/1/20 through 2/25/21. 2. Review of SARS-Co-V-2 test records and reporting documentation for 9 random days during the period 12/1/20 through 2/25/21 revealed a total of 1518 patients from North Carolina were tested and 1494 negative results were not reported on the following days: a. On 12/2/20, the laboratory tested 171 patients from North Carolina and failed to report 170 negative test results. b. On 12/16/20, the laboratory tested 118 patients from North Carolina and failed to report 115 negative test results. c. On 12/29/20, the laboratory tested 102 patients from North Carolina and failed to report 98 negative test results. d. On 1/5/21, the laboratory tested 309 patients from North Carolina and failed to report 305 negative test results. e. On 1/8/21, the laboratory tested 168 patients from North

	Carolina and failed to report 166 negative test results. f. On 1/13/21, the laboratory tested 49 patients from North Carolina and failed to report 48 negative test results. g. On 1/26/21, the laboratory tested 231 patients from North Carolina and failed to report 223 negative test results. h. On 2/9/21, the laboratory tested 286 patients from North Carolina and failed to report 285 negative test results. i. On 2/23/21, the laboratory tested 84 patients from North Carolina and failed to report 84 negative test results. 3. During interview 2/26/21 at approximately 10:05 a.m., the corporate compliance consultant stated that with the exception of one county, the laboratory does not report negative SARS-Co-V-2 results for North Carolina patients. During interview 2/26/21 approximately 10:30 -11:00 a.m., the data entry staff confirmed that she reports both positive and negative SARS-Co-V-2 results by email to the health department in one North Carolina county, but only positive results are reported for all other counties. The data entry staff stated that both positive and negative SARS-Co-V-2 results are reported electronically to other states.
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: Based on review of laboratory policies and procedures and interviews with data entry staff and testing personnel (TP) #1 2/25/21 and 2/26/21, the laboratory failed to have a written policy for reporting SARS-Co-V-2 test results and failed to have a written policy for corrective action when quality control results fail or when patient test results require repeat testing. Findings: 1. Review of laboratory policies and procedures revealed the laboratory did not have a written policy or procedure that described the process for reporting positive and negative SARS-Co-V-2 test results. During interview 2/25/21 at approximately 11:00 a.m., data entry staff confirmed that the laboratory did not have a reporting procedure for SARS-Co-V-2 test results. She stated that the procedures were in process. 2. Review of laboratory policies and procedures revealed the laboratory did not have a written policy or procedure that described what corrective action is taken when quality control results fail, or when patient test results require repeat testing, including how to document the corrective action. During interview 2/26/21 at approximately 1:00 p.m., TP #1 confirmed that the laboratory did not have a written policy or procedure for corrective action. He stated

	they have a corrective action form that lab personnel should fill out and personnel are aware of what corrective action should take place, but they did not have a written policy.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory information system (LIS) performance verification records and review of laboratory performance verification records for 3 Applied Biosystems 7500 Fast Dx Real-Time PCR instruments 2/25/21 and 2/26/21, and interview with testing personnel (TP) #1 on 2/26/21, the laboratory failed to ensure the performance of the LIS was verified and failed to ensure verification documentation for 2 of 3 Applied Biosystems 7500 Fast Dx Real-Time PCR instruments (B and C) was reviewed and approved by the laboratory director (LD) before patient testing began. Findings: The laboratory performs COVID-19 polymerase chain reaction (PCR) testing using the "TaqPath COVID-19 Combo Kit" and 3 Applied Biosystems 7500 Fast Dx Real-Time PCR instruments. The data is analyzed and interpreted by the Applied Biosystems COVID-19 Interpretive Software, and electronic files from the interpretive software are then transferred to the LIS. The laboratory began patient testing on PCR instrument A, #275000269, 8/3/2020. The laboratory began patient testing on PCR instrument B, #275030271, 6/17/2020. The laboratory began patient testing on PCR instrument C, #2750109074, 11/12/2020. 1. The laboratory failed to ensure the LIS was performing as required before patient testing began on 6/17/2020. Review of performance verification records for the LIS revealed a "Checklist of Validation Activities" for PCR instrument A, #275000269. The checklist stated "LIS Verification (LIS-100)" and the "date completed" column was initialed and dated "8/3/20". There was no raw data available to verify the LIS verification on 8/3/20 as indicated on the checklist. There was also no additional documentation that the LIS was verified before initial patient testing began on 6/17/2020. Interview with TP#1 on 2/26/21 at approximately 11:30 a.m. confirmed there was no documentation available to confirm the LIS was verified prior to performing patient testing on 6/17/2020. 2. The laboratory failed to ensure the LD reviewed and approved the performance verification of PCR instrument B, #275030271, prior to performing patient testing on 6/17/2020. Review of performance verification records for PCR instrument B, #275030271, revealed a set of raw data that was electronically signed by the LD on 8/24/20, approximately 69 days after patient testing began. Review of performance verification records also revealed a "Checklist of Validation Activities" for PCR instrument B, #275030271. The checklist was blank and included only the instrument # and the electronic signature of the LD. 3. The laboratory failed to ensure the LD reviewed and approved the performance verification of PCR instrument C, #2750109074, prior to performing patient testing on 11/12/2020. Review of performance verification records for PCR instrument C, #2750109074 revealed raw data and a correlation study summary. There was no documentation the

	LD reviewed or approved the raw data or the correlation study summary prior to the laboratory performing patient testing on 11/12/2020. Interview with TP #1 on 2/26/21 at approximately 11:30 a.m. confirmed there was no documentation available to show the LD had reviewed the performance verification records for instruments B, #275030271, and C, #2750109074, prior to patient testing being performed. He stated that he knew everything was completed but he was not the one responsible for the upload of information into the SharePoint files for the laboratory, so he was unsure where the documentation would be.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the GS (general supervisor) and the corporate compliance consultant 2/25/21, the TS (technical supervisor) failed to evaluate the competency of 1 of 8 testing personnel (TP #5) approximately 6 months after training. Review of personnel records revealed TP #5 was trained in May 2020. There was no documentation available to indicate that TP #5's competency had been evaluated in approximately 9 months since training was conducted. During interview 2/25/21 at approximately 2:40 p.m., the GS and the corporate compliance consultant confirmed that there was no documentation of a competency evaluation for TP #5 since he was trained in May 2020.