Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2139173	05/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Clinicore	800 North Causeway, Suite 300, Mandeville, LA	

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 May 24, 2022 through May 25, 2022 at Clinicore, CLIA ID # 19D2139173. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency test records, and interview with personnel, the laboratory failed to document the Laboratory Director's review of corrective actions and forms for one (1) of three (3) proficiency testing events in 2020. Findings: 1. Review of the laboratory's "Proficiency Testing" policy under the "Evaluation of Survey" section revealed "The Laboratory Director will review and sign all PT survey reports, evaluation forms, attestation forms, and corrective action forms on site at least quarterly and will document such review on the Laboratory Director Proficiency Testing Review Form CC.2002B." 2. Review of the laboratory's "Proficiency Testing Review Forms (CC.2002A, CC.2002B, and CC.2002C)" and "Addendum to Corrective Action Form for PT Event K-C Ligand 2020" form revealed a blank signature and date line for the Laboratory Director. There was no documentation of the Laboratory Director's review of the three (3) forms (CC.2002A, CC.2002B, and CC.2002C) or addendum. 3. In interview on May 25, 2022 at 12:21 pm the Technical Consultant confirmed the Laboratory Director did not sign the identified documents.
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 the laboratory's procedures and interview with personnel, the laboratory failed to establish a complete quality control policy for SARS COV-2 testing utilizing the TaqPath Combo kit. Findings: 1. Review of the laboratory's "SARS CoV-2 RT PCR Analysis" procedure revealed the laboratory did not include complete quality control procedures that include, but not limited to, specific controls on each plate, acceptability criteria, and corrective actions. 2. In interview on May 25, 2022 at 2:21 pm , the Technical Consultant confirmed the laboratory's policy did not include all the controls utilized on each plate, acceptability criteria, and corrective actions.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to follow manufacturer's procedures for Viral Transport Media (VTM) preparation utilized for SARS COV-2 sample transport. Findings: 1. In interview on May 24, 2022 at 1:59 pm, the Technical Consultant stated the laboratory makes its own VTM based off of the CDC recipe for transport media. 2. Review of the laboratory's "Viral Transport Media Instructions" and referenced recipe ("Transport and Inactivation medium for viruses-Recipe") revealed the laboratory's instructions did not follow the referenced recipe. Reagents were eliminated from the original recipe a clinical reference for modification was not provided. 3. In interview on May 25, 2022 at 1:55 pm, the laboratory's owner confirmed the laboratory did not follow the referenced recipe or include a clinical reference for the modification. The owner stated the VTM recipe was altered, which included elimination of the SDS reagent, because only looking at the virus.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure reagents did not exceed their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on May 24, 2022 at 10:28 am revealed the following expired items: a) TaqPath COVID-19 Assay Multiplex, Lot 2101228, Expiration date: 2021-12-09, Quantity: one (1) tube b) TaqPath COVID-19 Assay Multiplex, Lot 2012180, Expiration date: 2021-10-28, Quantity: one (1) tube c) TaqMan Open Array Real Time PCR Master Mix, Lot 01066012, Expiration date: 2022-01-31, Quantity: one (1) tube d) TaqPath COVID-19 Control Dilution Buffer, Lot 2106080, Expiration date: 2022-02-24, Quantity: two (2) tubes e) IMCS Rapid Hydrolysis Buffer, Lot RHB21-04001, Expiration date: 04/2022 f) TaqMan Vaginal Microbiota Amplification Control, Lot 1044543 W, Expiration date: 2022-05-07, Quantity: one (1) tube g) MS2 Phage Control, Lot 2101081, Expiration date: 2022-01-13, Quantity: three (3) tubes h) Applied Biosystems MagMax Viral/Pathogen Elution Buffer, Lot 1067108, Expiration date: 2022-03-22, Quantity: one (1) bottle 2. In interview on May 24, 2022 at 10:55 am the Technical Consultant confirmed the identified items were expired.
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 observation by surveyor, review of validation records, and interview with personnel, the laboratory failed to have complete performance verification studies for SARS COV-2 antibody testing. Findings: 1. Observation by surveyor during laboratory tour on May 24, 2022 at 10:28 am revealed the laboratory utilizes the Beckman Coulter Access 2 for SARS COV-2 IgG and IgM testing. 2. Review of the laboratory's validation records revealed an email from a Beckman Coulter applications specialist and a "Method Evaluation Protcol;" however, the laboratory did not have a written summary of the laboratory's studies, to include ,but not limited to the number and type of samples utilized, procedure, and acceptability criteria to verify performance specifications (accuracy, precision, reportable range and reference range). 3. In interview on May 24, 2022 at 2:21 pm, the Technical Consultant confirmed the laboratory did not include a written summary for their SARS COV-2 antibody testing studies to specify the laboratory's procedure.

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 observation by surveyor, review of validation studies, and interview with personnel, the laboratory failed to perform complete specificity studies for SARS COV-2 testing of saliva samples. Findings: 1. Observation by surveyor during the laboratory tour on May 24, 2022 at 10:28 am revealed the laboratory utilizes the Quantstudio 12 K Flex instrument with the TaqPath Combo Kit for SARS COV-2 testing on nasopharyngeal and saliva samples. 2. Review of the laboratory's specificity studies revealed the laboratory did not include potential interfering substances for saliva samples. 3. In interview on May 24, 2022 at 2:01 pm, the Technical Consultant stated the laboratory did not include interfering substances/actions, such as eating or drinking, that may affect saliva samples in their specificity studies.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's polices and interview with personnel, the laboratory failed to perform quality checks of laboratory prepared viral transport media (VTM) prior to use. Findings: 1. In interview on May 24, 2022 at 1:59 pm, the Technical Consultant stated the laboratory makes its own VTM based off of the CDC recipe for transport media. 2. Review of the laboratory's "Viral Transport Media Instructions" revealed the laboratory did not include written instructions, as well as documentation, to check the quality of the prepared media to ensure acceptability of use with samples. 3. In interview on May 25, 2022 at 12:54 pm, the Technical Consultant stated that the "NTC" added to each batch is a test of the VTM. The Technical Consultant stated the prepared VTM media is checked the next testing day. The Technical Consultant confirmed the laboratory did not have written procedures for quality checks of the laboratory prepared VTM.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: I. Based on review of patient final test reports, test menu, and interview with personnel, the laboratory failed to indicate specimen source on patient final reports for SARS COV-2 testing. Findings: 1. In interview on May 24, 2022 at 1:36 pm the Technical Consultant stated the laboratory accepts saliva and nasopharyngeal samples for SARS COV-2 testing. 2. Review of random selection of patient final test reports revealed the specimen type was not included. 3. In interview on May 24, 2022 at 3:26 pm, the Technical Consultant confirmed the specimen type was not included on patient final reports. 4. Review of the laboratory's test menu revealed the laboratory performs 6,000 SARS COV-2 tests annually. II. Based on observation by surveyor, review of manufacturers' instructions, patient final test reports, test menu, and interview with personnel, the laboratory failed to include the United States Food and Drug Administration (FDA) Emergency Use Authorization statement for SARS COV-2 patient final reports. Findings: 1. Observation by surveyor during the laboratory tour on May 24, 2022 at 10:28 am revealed the laboratory utilizes the Quantstudio 12 K Flex instrument with the TaqPath Combo Kit for SARS COV-2 testing. 2. Review of the manufacturer's instructions revealed "This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories." 3. Review of random patient final test report for SARS COV-2 revealed the laboratory did not include the identified Emergency Use Authorization statement on the patient final reports. 4. In interview on May 24, 2022 at 3:26 pm, the Technical Consultant confirmed the laboratory did not include the identified EUA disclaimer on patient final report. 5. Review of the laboratory's test menu revealed the laboratory performs 6,000 SARS COV-2 tests using the TaqPath Combo tests.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the the United States Food and Drug

	Administration (FDA) Emergency Use Authorization (EUA) instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to patients for EUA SARS COV-2 tests. Findings: 1. Observation by surveyor during laboratory tour on May 24, 2022 at 10:28 am and review of the laboratory's test menu revealed the laboratory utilizes the following systems for SARS COV-2: a) SARS COV 2 Ig G and Ig M: Beckman Coulter Access 2 (500 Ig G and 500 Ig M tests annually) b) TaqPath Combo Kit: Quant Studio 12 K Flex (6,000 tests annually) 2. Review of the manufacturers' instructions revealed "Authorized laboratories * using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on May 24, 2022 at 9:39 am, the Technical Consultant stated "Fact Sheets" are not provided to patients.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing evaluation forms were signed by the Laboratory Director. Refer to D5221.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for SARS COV-2 testing utilizing saliva samples. Refer to D5423.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods are required. Findings: 1. The laboratory failed to follow manufacturer's procedures for Viral Transport Media (VTM) preparation utilized for SARS COV-2 sample transport. Refer to D5411. 2. The laboratory failed to ensure reagents did not exceed their expiration dates. Refer to D5417.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5477.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on review of patient final reports and interview with personnel, the Laboratory Director failed to ensure patient final reports included required information. Findings: 1. The laboratory failed to indicate specimen source on patient final reports for SARS COV-2 testing. Refer to D5805 I. 2. The laboratory failed to include the United States Food and Drug Administration (FDA) Emergency Use Authorization statement for SARS COV-2 patient final reports. Refer to D5805 II. 3. The laboratory failed to include "Fact Sheets" to patients for EUA SARS COV-2 tests. Refer to D5809.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to establish a complete quality control policy for SARS COV-2 testing utilizing the TaqPath Combo kit. Refer to D5403. 2. The laboratory failed to indicate specimen source on patient final reports for SARS COV-2 testing. Refer to D5805 I. 3. The laboratory failed to include the United States Food and Drug Administration (FDA) Emergency Use Authorization statement for SARS COV-2 patient final reports. Refer to D5805 II. 4. The laboratory failed to include "Fact Sheets" to patients for EUA SARS COV-2 tests. Refer to D5809. 5. The laboratory failed to follow manufacturer's procedures for Viral Transport Media (VTM) preparation utilized for SARS COV-2 sample transport. Refer to D5411. 6. The laboratory failed to ensure reagents did not exceed their expiration dates. Refer to D5417.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance specification for COVID testing utilizing saliva samples. Refer to D5423.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure that a quality control program was maintained to assure the quality of laboratory prepared Viral Transport Media. Refer to D5477.