

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2139173	(X3) Date Survey Completed 08/13/2025
Name of Provider or Supplier Clinicore	Street Address, City, State 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 Complaint survey (LA00079526) was performed at Clinicore, CLIA ID 19D2139173, on August 13, 2025. Clinicore was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1441: CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1453: CONDITION: Laboratories performing high complexity testing; Clinical Consultant
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish a written policy for direct to consumer laboratory testing, in which laboratory tests are ordered directly by the patient not through a medical provider. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include a written policy for direct to consumer patient testing including process for ordering, add-on testing, and transmission of results. 2. In interview on August 13, 2025 at 10:24 am, the Technical Supervisor stated the laboratory did not have a written policy related to direct to consumer laboratory testing. II. Based on review of the laboratory's sample receipt log and interview with personnel, the laboratory failed to document the temperature of samples received per laboratory policy for 148 of 148 days reviewed. Findings: 1. Review of the laboratory's "Off Site Sample Condition Log" revealed the laboratory had columns that included room temperature (15-30</p>

degrees Celsius), frozen (-20 degrees Celsius), and refrigerated (2-8 degrees Celsius). 2. Further review of the laboratory's "Off Site Sample Condition Log" for 2025, January 2025 through July 2025, revealed the laboratory staff documented the number of bags received at the applicable temperature and documented "yes, acceptable condition upon arrival" for 148 days reviewed, but the temperature at receipt was not documented. 3. In interview on August 13, 2025 at 10:30 am, the accessioning personnel stated she takes the temperature of the samples upon receipt and documents the number of samples received, not the actual temperature.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(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:

Based on review of random selection of patient test reports and interview with personnel, the laboratory failed to include the name and address of the testing location for samples sent to reference laboratories for nine (9) of fourteen (14) patients reviewed. Findings: 1. In interview on August 13, 2025 at 12:07 pm, the Technical Supervisor stated some tests such as Complete Blood Counts (CBC) and ANA testing are sent to another reference laboratory for testing. 2. Review of random selection of patient test reports revealed the following patients had testing performed at a reference laboratory without the name and address of the testing location listed: January 9, 2025: Patient 115678- CBC test February 19, 2025 Patient 117775 CBC test July 17, 2025 Patient 125032 CBC test July 24, 2025 Patient 125431 CBC test July 24, 2025 Patient 125414 CBC test July 24, 2025 Patient 125400 CBC test July 31, 2025 Patient 125648 CBC test August 2, 2025 Patient 125771 ANA test August 8, 2025 Patient 126003 CBC test 3. In further interview on August 13, 2025 at 12:33 pm, the Technical Supervisor stated he was not sure why the reference laboratory's information did not print out on the final reports.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient final test reports and interview with patients, the laboratory failed to report race-free values for the estimated glomerular filtration rate (eGFR) calculations for twelve (12) of fourteen (14) patients reviewed. Findings: 1. Review random selection of patient final reports revealed the following twelve (12) patients had race based eGFR results reported: January 8, 2025: Patient 115678 February 6,

	<p>2025: Patient 117146 July 9, 2025: Patient 124714 July 15, 2025: Patient 124985 July 15, 2025: Patient 125032 July 23, 2025: Patient 125400 July 23, 2025: Patient 125431 July 23, 2025: Patient 125414 July 30, 2025: Patient 125648 July 31, 2025: Patient 125783 August 7, 2025: Patient 126003 August 8, 2025: Patient 126086 2. In interview on August 13, 2025 at 12:07 pm, the Technical Supervisor confirmed the laboratory reported eGFR results based on race.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5311 II.</p>
<p>D6026</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)</p> <p>(e)(8) Ensure that reports of test results include pertinent information required for interpretation;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Findings: 1. The laboratory failed to include the name and address of the testing location for samples sent to reference laboratories for nine (9) of fourteen (14) patients reviewed. Refer to D5805. 2. The laboratory failed to report race-free values for the estimated glomerular filtration rate (eGFR) calculations for twelve (12) of fourteen (14) patients reviewed. Refer to D5807. 3. The Clinical Consultant failed to ensure race-free estimated glomerular filtration rate (eGFR) calculations were reported. Refer to D6061.</p>
<p>D6036</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to document the temperature of samples received per laboratory policy for 148 of 148 days reviewed. Refer to D5311 II. 2. The laboratory failed to include the name and address of the testing location for samples sent to reference laboratories for nine (9) of fourteen (14) patients reviewed. Refer to D5805.</p>

<p>D6061</p>	<p>CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c)</p> <p>(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and</p> <p>This STANDARD is not met as evidenced by: Based on review of random selection of patient final reports and interview with personnel, the Clinical Consultant failed to ensure race-free estimated glomerular filtration rate (eGFR) calculations were reported. Refer to D5807.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6087. 2. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6098. 3. The Laboratory Director failed to ensure personnel providing consultation met Clinical Consultant qualification requirements. Refer to D6101. 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106.</p>
<p>D6087</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5311 II.</p>
<p>D6098</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p> <p>(e)(8) Ensure that reports of test results include pertinent information required for interpretation;</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.</p>
D6101	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11)</p> <p>(e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure personnel providing consultation met Clinical Consultant qualification requirements. Refer to D6135.</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5311 I.</p>
D6112	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to document the temperature of samples received per laboratory policy for 148 of 148 days reviewed. Refer to D5311 II. 2. The laboratory failed to include the name and address of the testing location for samples sent to reference laboratories for nine (9) of fourteen (14) patients reviewed. Refer to D5805.</p>
D6134	<p>CLINICAL CONSULTANT CFR(s): 493.1453</p> <p>The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.</p>

This CONDITION is not met as evidenced by:
Based on review of the laboratory's CMS-209, review of patient final test reports, and interview with personnel, the laboratory failed to ensure personnel providing clinical consultation met Clinical Consultant qualifications. Findings: 1. The laboratory failed to ensure personnel providing consultation related to diagnosis, treatment, and management of patient care met Clinical Consultant qualifications. Refer to D6135. 2. The Clinical Consultant failed to provide consultation to five (5) of fourteen (14) patients reviewed. Refer to D6136.

D6135

CLINICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1455

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3) for the subspecialty of oral pathology, 493.1443(b)(5); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's CMS-209 form, personnel records, review of direct to consumer patient final test reports, and interview with personnel, the laboratory failed to ensure personnel providing consultation related to diagnosis, treatment, and management of patient care met Clinical Consultant qualifications. Findings: 1. Review of the laboratory's CMS-208 form (Laboratory Personnel Report) revealed the Laboratory Director served as the laboratory's Clinical Consultant. 2. Review of the laboratory's personnel records revealed a "Delegation of Duties Form" and "Job Description: Clinical Consultant" completed for the Laboratory Director for his duties as Clinical Consultant. 3. In interview on August 13, 2025 at 10:40 am, the Technical Supervisor stated the laboratory's Director of Business Operations or the CEO transmitted final test reports to patients who received direct to consumer laboratory services. 4. Review of random selection of patient final test reports revealed the CEO, who did not meet the qualifications of Clinical Consultant, provided consultation concerning treatment and management of patient care. Refer to D6136. 5. In interview on August 13, 2025 at 10:48 am, the Technical Supervisor stated clinical questions and consultation are directed to the Laboratory Director, who serves as the Clinical Consultant. The Technical Supervisor confirmed the CEO was not the Clinical Consultant for the laboratory.

D6136

CLINICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1457

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's personnel records, direct to consumer patient final test reports, and interview with personnel, the Clinical Consultant failed to provide

consultation to five (5) of fourteen (14) patients reviewed. Findings: 1. Review of the laboratory's personnel records revealed a "Delegation of Duties Form" and "Job Description: Clinical Consultant" completed for the Laboratory Director for his duties as Clinical Consultant. 2. Review of random selection of direct to consumer patient final test reports revealed the CEO provided consultation to the following five (5) patients: a) Reported July 18, 2025: Patient 125032 b) Reported July 28, 2025: Patient 125414 c) Reported August 4, 2025: Patient 125648, 125771 (same patient) d) Reported August 8, 2025: Patient 125783 e) Reported August 9, 2025: Patient 126003 3. In interview on August 13, 2025 at 2:46 pm, the Technical Supervisor confirmed the CEO, who was not a Clinical Consultant for the laboratory, provided consultation related to the identified patients' laboratory results.