

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2139173	(X3) Date Survey Completed 01/16/2020
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 Recertification Survey was performed at Clinicore, CLIA ID # 19D2139173 on January 16, 2020. Clinicore was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1441 CONDITION: Laboratories Performing High Complexity Testing; Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories Performing High Complexity Testing; Technical Supervisor
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency test results from the College of American Pathologists</p>

(CAP) , review of the CMS 155 D Casper Report, and interview with personnel, the laboratory failed to successfully participate in Endocrinology proficiency testing. Refer to D2107.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to achieve satisfactory performance (attain a score of at least 80 percent of acceptable responses) for Endocrinology testing for 2 of 3 consecutive events resulting in an initial unsuccessful participation. Findings: 1. Review of College of American Pathologists (CAP) proficiency results for 2019 revealed the following unsuccessful participation for 2 of 3 consecutive events: 2019 2nd Event K-B Ligand General: Endocrinology overall score: 0% 2019 2nd Event K-B Ligand General: Free Thyroxine (Free T4): 0% 2019 2nd Event K-B Ligand General: TSH: 0% 2019 3rd Event K-C Ligand General: Endocrinology:76 % 2019 3rd Event K-C Ligand: Free Thyroxine (Free T4): 60 % 2019 3rd Event K-C Ligand: TSH: 60% 2. Further review of the laboratory's CAP proficiency results for 2019 revealed the laboratory had documentation of corrective action/assessment for the identified PT failures. 3. In interview on January 16, 2020 at 10:48 am, the General Supervisor stated for the 2nd proficiency event the results were submitted late and the laboratory performed an assessment for the 3rd event failure.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to verify the accuracy of Thyroglobulin antibodies, Thyroperoxidase antibodies, and Insulin at least twice annually. Findings: 1. Review of the laboratory's "Comparison of Test Results/Split Sample Testing" policy revealed "Twice a year, any test (unregulated analyte or regulated analyte) that is not covered by an external proficiency test must be checked for accuracy and reliability." 2. In interview on January 16, 2020 at 10:48 am, the General Supervisor stated the laboratory began patient testing on the Beckman Coulter Access 2 for the following analytes: Total T4, Total T3, Free T4, Free T3, TSH, Thyroglobulin antibodies, Thyroperoxidase antibodies, Folate, Vitamin B-12, Ferritin, Beta HCG, FSH, LH, Sex hormone binding globulin, Total PSA, Free PSA, Prolactin, Insulin, and human growth hormone. 3. Review of the laboratory's 2019 College of American Pathologists (CAP) proficiency testing and split sample testing records revealed the laboratory did not have documentation of verification of accuracy for Thyroglobulin antibodies, Thyroperoxidase antibodies, and Insulin at least twice annually in 2019. 4. The General Supervisor provided the surveyor on January 16, 2020 a "College of American Pathologists Order Acknowledgement" form for Insulin;

order date "16-JAN-2020 (email sent January 16, 2020 11:14 am)." 5. In interview on January 16, 2020 at 11:16 am, the General Supervisor stated Insulin was not included in the CAP proficiency testing the laboratory performed. The General Supervisor confirmed the laboratory did not perform split sample testing for insulin in 2019. 6. In further interview at 12:20 pm, the General Supervisor stated no split sample testing was performed for Thyroglobulin antibodies and Thyroperoxidase antibodies in 2019.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish complete performance studies for Chemistry testing on the Beckman Coulter Access 2 analyzer. Refer to D5423. 2. The laboratory failed to establish their own mean and ranges for Quality Control (QC) material utilized for Chemistry testing as required by the manufacturer. Refer to D5469. 3. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.

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, record review, and interview with personnel, the laboratory failed to establish complete performance studies for Chemistry testing on the Beckman Coulter Access 2 analyzer. Findings: 1. Observation by surveyor during laboratory tour on January 16, 2020 revealed the laboratory utilizes the Beckman Coulter Access 2 for Chemistry testing of the following analytes: Total T4, Total T3, Free T4, Free T3, TSH, Thyroglobulin antibodies, Thyroperoxidase antibodies, Folate, Vitamin B-12, Ferritin, Beta HCG, FSH, LH, Sex hormone binding globulin, Total PSA, Free PSA, Prolactin, Insulin, and human growth hormone. 2. Review of the United States Food and Drug Administration (FDA) CLIA complexity database

revealed the Access 2 with the identified analytes are classified as moderate. 3. In interview on January 16, 2020 at 11:53 am, Technical Supervisor 1 stated blood samples are received spun at room temperature from Louisiana and Arizona. Technical Supervisor 1 further stated providers use overnight shipping. 4. In interview on January 16, 2020 at 12:16 pm, the General Supervisor stated on Saturdays the laboratory receives samples; no testing performed. The General Supervisor further stated the laboratory spins the samples received and stores them in the freezer. 5. Review of the manufacturer's reagent package inserts revealed "for shipment freeze at -20 degrees Celsius." 6. Review of the laboratory's validation studies for the Beckman Coulter Access 2 revealed the laboratory did not include specificity and sensitivity studies; due to the modification of the pre-analytic (sample handling) phase. 7. In interview on January 16, 2020, Technical Supervisor 1 stated the laboratory performed a "stability" study and "spun vs unspun sample" study. The Technical Supervisor 1 further stated he thought no further studies were needed and the complexity remained moderate.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the laboratory failed to establish their own mean and ranges for Quality Control (QC) material utilized for Chemistry testing as required by the manufacturer. Findings: 1. Observation by surveyor during laboratory tour on January 16, 2020 revealed the laboratory utilizes the Beckman Coulter Access 2 for Chemistry testing of the following analytes: Total T4, Total T3, Free T4, Free T3, TSH, Thyroglobulin antibodies, Thyroperoxidase antibodies, Folate, Vitamin B-12, Ferritin, Beta HCG, FSH, LH, Sex hormone binding globulin, Total PSA, Free PSA, Prolactin, Insulin, and human growth hormone. 2. Further observation by surveyor during laboratory tour on January 16, 2020 revealed the laboratory utilizes the following Bio-Rad quality control material: a) Bio-Rad Liquichek Immunoassay Plus, Lot # 40990 b) Bio-Rad Liquichek Specialty Immunoassay, Lot # 60280 3. Review of the package inserts for the Bio-Rad controls under the "Assignment of Values:" section revealed "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 4. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for the establishment of QC means, ranges, or acceptability criteria. 5. In interview on January 16, 2020 at 12:15 pm, the General Supervisor stated the laboratory did not establish their own range and means for the identified control; the manufacturer's ranges are used.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to establish complete performance studies for Chemistry testing on the Beckman Coulter Access 2 analyzer. Refer to D5423. 2. The laboratory failed to establish their own mean and ranges for Quality Control (QC) material utilized for Chemistry testing as required by the manufacturer. Refer to D5469.

D5807

TEST REPORT

CFR(s): 493.1291(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 record review and interview with personnel, the laboratory failed to ensure reference ranges for Post-Menopausal Follicle Stimulating Hormone (FSH) on final reports matched the laboratory's validation studies. Findings: 1. Review of the laboratory's validation studies for the Beckman Coulter Access 2 revealed the following reference range: "FSH Post Menopausal: 16.47-113.59" 2. Review of random selection of FSH patient final test reports from 2019 revealed the following reference range: "FSH Postmenopausal: 23.0-116.0 mIU/mL" 3. In interview on January 16, 2020 at 3:30 pm, the General Supervisor confirmed the identified reference range did not match the laboratory's final report. 4. Review of the laboratory's test menu revealed the laboratory performs 1,470 FSH tests annually.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to establish complete performance specifications for Chemistry testing. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable

results. Refer to D6087. 3. The Laboratory Director failed to ensure proficiency samples are satisfactory as required. Refer to D6089. 4. The Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D6093. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6094. 6. The Laboratory Director failed to ensure final reports included required pertinent information. Refer to D6098.

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, record review, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for Chemistry testing. 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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable results. Refer to D5217.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are satisfactory as required. Refer to D2107.

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:

	<p>Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5469.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.</p>
D6098	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p> <p>The laboratory director must 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 final reports included required pertinent information. Refer to D5807.</p>
D6108	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Findings: 1. The Technical Supervisor(s) failed to provide technical and scientific oversight for the laboratory. Refer to D6112. 2. The Technical Supervisor(s) failed to ensure the laboratory established complete performance specification studies for Chemistry testing. Refer to D6115. 3. The Technical Supervisor(s) failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D6117. 4. The Technical Supervisor(s) failed to ensure semi-annual competency assessment was performed for two (2) of three (3) testing personnel reviewed. Refer to D6127.</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</p>

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, record review, and interview with personnel, the Technical Supervisor(s) failed to provide technical and scientific oversight for the laboratory. Refer to D5217.

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, record review, and interview with personnel, the Technical Supervisor(s) failed to ensure the laboratory established complete performance specification studies for Chemistry testing. 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 observation, record review, and interview with personnel, the Technical Supervisor(s) failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D5469.

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 record review and interview with personnel, the Technical Supervisor(s) failed to ensure semi-annual competency assessment was performed for two (2) of three (3) testing personnel reviewed. Findings: 1. In interview on January 16, 2020 at 10:48 am, the General Supervisor stated the laboratory started patient testing on the Beckman Coulter Access 2 on December 1, 2018. 2. Review of personnel records revealed the General Supervisor and Testing Personnel 3 received initial training on the Access 2 in October 2018. 3. Further review of personnel records revealed the

identified personnel did not have documentation of semi-annual competency assessments. 4. In interview on January 16, 2020 at 10:44 am, the General Supervisor confirmed the identified personnel did not have a semi-annual competency assessment for the Access 2 performed.