Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2139173	05/15/2018
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	An Initial Survey was performed at Clinicore- CLIA ID # 19D2139173 on May 15, 2018. Clinicore was not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director 42 CFR 493.1459 CONDITION: Laboratories performing high complexity testing, General Supervisor 42 CFR 493.1487 CONDITION: Laboratories performing high complexity testing, Testing Personnel Instruments that are identified as "research only and/or forensic testing" are considered laboratory developed tests under CLIA. These instruments, as well as any FDA approved moderate complexity instrument that has been modified are considered high complexity and are subject to the CLIA regulations for Establishment and verification of performance specifications (42 CFR 493.1253(b)(2) and all other high complexity CLIA requirements.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Supervisors and General Supervisor were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 and Personnel 3 serve as the Technical Supervisors. Personnel 6 previously served as a Technical Supervisor, effective March 2018. 2. Further review of the laboratory's CMS-209 form revealed Personnel 4 serves as the General Supervisor. 3. Review of personnel records revealed competency assessments for the duties of Technical Supervisor and General Supervisor were not performed. 4. In interview on May 15,

	2018 at 10:40 am, Personnel 2 stated the laboratory did not perform competency assessments for the identified personnel for the duties of Technical Supervisor and General Supervisor. II. Based on record review and interview with personnel, the laboratory failed to follow their established policy to assess competency of Testing Personnel. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following testing personnel: Personnel 3 Personnel 4 Personnel 5 2. Review of the laboratory's "Quality Assurance Plan" under section "QMS SOP # : CC.2009" revealed the following: "All employees must be evaluated periodically to ensure competency in all areas defined for their position. The evaluation includes assessments of their knowledge and performance through: 1. Direct observation of routine testing 2. Monitoring reporting of test results (if applicable) 3. Direct observation of maintenance procedures and function checks 4. Review of intermediate results and/or worksheets 5. Assessment through performance samples or proficiency testing sample and 6. Assessment of problem solving skills" 3. Review of personnel records revealed the laboratory utilizes the "Procedure Competency Evaluation CC.2004A" form for assessing competency of testing personnel. These forms did not include the identified six (6) procedures as the minimal requirement for assessing the competency of all personnel performing laboratory testing. 4. Further review of the "Procedure Competency Evaluation CC. 2004A" revealed the following procedures are assessed through observation: A." Sample Extraction: B. "MS Data" to include "Calibration curve and QC accuracy" 5. In interview on May 15, 2018 at 10:40 am, Personnel 2 stated the laboratory utilizes the "Competency Evaluation" form for assessing the competency of testing personnel. Personnel 2 confirmed the form did not include the minimal six (6) procedures as required and stated in their policy
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on observation, record review, and interview with personnel, the laboratory failed to monitor the temperature of areas where laboratory supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on May 15, 2018 revealed the laboratory did not monitor the temperature for the following areas: Accession/Reagent Preparation Room and Storage Area 2. Review of the manufacturer requirements on the BD Vacutainer/Microtainer blood collection tubes and reagent bottles revealed the following: a) Blood collection tubes: storage requirement 4-25 degrees Celsius b) Ammonium Hydroxide Optima Grade: store at 15-25 degrees Celsius c) BD Microtainer blood collection tubes: storage requirement 4-25 degrees Celsius 3. Further observation by surveyor during laboratory tour revealed the following items stored without temperature monitors: a) Accession /Reagent Preparation Room BD Vacutainer Serum Blood Collection tubes, Lot # 7096932, Quantity: ninety (90) tubes BD Vacutainer Serum Blood Collection tubes, Lot # 6295839, Quantity: seventy (70) tubes Ammonium Hydroxide Optima Grade, 1

	L, Lot # 7217020, Quantity: one (1) bottle b) Storage Room BD Microtainer Z (no additive tubes), Lot # 7145781, Quantity: fifty one (51) tubes BD Microtainer Z (no additive tubes), Lot # 7145854, Quantity: one hundred fifty (150) tubes BD Microtainer Z (no additive tubes), Lot # 7248715, Quantity: one hundred (100) tubes 4. In interview on May 15, 2018 at 10:00 am , Personnel 2 stated the laboratory no longer uses the Vacutainer tubes. Personnel 2 confirmed the laboratory does not have a thermometer in the accession/reagent preparation room. 5. In interview on May 15, 2018 at 10:15 am, Personnel 4 stated the laboratory does not monitor the temperature of the storage room. Personnel 4 stated he was unaware blood collection tubes had a temperature requirement. II. Based on observation and interview with personnel, the laboratory failed to properly store ammonium formate as required by the manufacturer. Findings: 1. Observation by surveyor on May 15, 2018 revealed the ammonium formate (Lot # 173879, Quantity 1 bottle) was stored in the accession /reagent preparation room. The temperature in the accession/reagent preparation room was not monitored. 2. Further observation by surveyor on May 15, 2018 revealed the following storage requirement for the ammonium formate: "store at 4 degrees Celsius." 3. In interview on May 15, 2018 at 10:00 am, Personnel 2 stated the laboratory does not use the ammonium formate. Personnel 2 confirmed the laboratory did not store the Ammonium Formate per manufacturer requirements.
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 and interview with personnel, the laboratory failed to ensure supplies and reagents have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on May 15, 2018 revealed the following expired items: Located in Panasonic Refrigerator a) Hormones Low QC unlabeled b) Hormones Mid QC 120180206-MQC, Expiration date: 05/06/18, Quantity: one (1) vial c) Hormones High QC 120180206-HQC, Expiration date: 05/06 /18, Quantity: one (1) vial Located in Accession/Reagent Prep Room a) K2EDTA Microtainer tubes, Lot # 5247603, Expiration date: 2017-02, Quantity: fifteen (15) tubes 2. In interview on May 15, 2018 at 9:48 am, Personnel 4 stated the expiration date for the hormone quality controls are listed on the batch sheets. Personnel 4 further stated the identified hormone quality controls were expired. Personnel 4 stated the expired quality controls were utilized for a stability study. 3. In interview on May 15, 2018 at 9:50 am, Personnel 2 stated the identified microtainer tubes are not used by the laboratory.
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 reference ranges for Endocrinology and Vitamin D testing. Findings: 1. Observation by surveyor during laboratory tour on May 15, 2018 revealed the laboratory utilizes the Shimadzu LCMS-8060 for Endocrinology testing: Aldosterone, Androstenedione, Corticosterone, Cortisol, Cortisone, 11-Deoxycorticosterone, 21-Deoxycortisol, Dexamethasone, DHEA, DHEA-Sulfate, DHT, 17-beta-Estradiol, Estriol, Estrone, Pregnenolone, 17-alpha-OH-Progesterone, Progesterone, Testosterone, and 25-OH-Vitamin D3. 2. Review of the laboratory's performance verification studies revealed the laboratory utilizes reference ranges from the following sources, not a clinical reference: Aldosterone: Quest Diagnostics Androstenedione: Quest Diagnostics Corticosterone: Quest Diagnostics Cortisol: LabCorp Cortisone: ARUP 11-Deoxycorticosterone: Mayo Clinic 21-Deoxycortisol: Mayo Clinic Dexamethasone: Quest Diagnostics DHEA: LabCorp DHEA-Sulfate: Quest Diagnostics DHT: LabCorp 17-beta-Estradiol: Mayo Clinic Estriol: Quest Diagnostics Estrone: Quest Diagnostics Pregnenolone: Quest Diagnostics 17-alpha-OH-Progesterone: Quest Diagnostics Progesterone: Quest Diagnostics Testosterone: Quest Diagnostics 25-OH-Vitamin D: ARUP 3. In interview on May 15, 2018 at 1:40 pm, Personnel 2 stated the laboratory utilizes reference ranges from the identified laboratories until the laboratory can obtain enough samples to establish their own. Personnel 2 confirmed the laboratory did not establish their own reference range or utilize a reference range from a clinical literature source prior to patient testing. 4. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs 18,200 Endocrinology and Vitamin D tests annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish a protocol to verify performance of high performance liquid chromatography (HPLC) columns when changed. Findings: 1. Observation by surveyor during the laboratory tour on May 15, 2018 revealed the laboratory utilizes Phenomenex Kinetex columns on the Shimadzu LCMS-8060 for Endocrinology and Vitamin D testing. 2. Review of the Phenomenex HPLC column's Certificate of Quality Assurance package insert under the receipt of the column section revealed "Test the column to verify performance." 3. Review of the laboratory's policy and

	procedure manual revealed the laboratory did not include a policy/procedure for HPLC column changes. 4. In interview on May 15, 2018 at 11:40 am, Personnel 2 stated when the column is changed the retention time is checked. Personnel 2 stated there is not a written procedure for column changes to verify its performance. 5. In further interview on May 15, 2018 at 11:45 am, Personnel 2 stated the laboratory currently marks on the box when a column is changed. Personnel 2 further stated the column in use has not been changed since the instrument's installation due to low volume.
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 to the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory established reference ranges for Endicrinology and Vitamin D testing. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D6087. 3. The Laboratory Director failed to ensure the establishment of maintenance procedures as required. Refer to D6095. 4. The Laboratory Director failed to ensure all personnel had the appropriate state licensure for performing high complexity testing. Refer to D6102. 5. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6103. 6. The Technical Supervisor failed to document the competency of one (1) of three (3) testing personnel prior to patient testing. Refer to D6120.
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 ensure the laboratory established reference ranges for Endocrinology and Vitamin D 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 observation, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to monitor the temperature of areas where laboratory supplies are stored per manufacturer requirements. Refer to D5413 I. 2. The laboratory failed to properly store ammonium formate as required by the manufacturer. Refer to D5413 II. 3. The laboratory failed to ensure supplies and reagents have not exceeded their expiration date. Refer to D5417.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the establishment of maintenance procedures as required. Refer to D5435.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all personnel had the appropriate state licensure for performing high complexity testing. Findings: 1. The laboratory failed to ensure the General Supervisor met State of Louisiana licensure requirements. Refer to D6143. 2. The laboratory failed to have current licenses issued by the State of Louisiana (R. S. 37: 131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow one (1) of three (3) testing personnel to perform high complexity testing. Refer to D6170.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed

	to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Technical Supervisors and General Supervisor were complete. Refer to D5209 I. 2. The laboratory failed to follow their established policy to assess competency of Testing Personnel. Refer to D5209 II. 3. The Technical Supervisor failed to document the competency of one (1) of three (3) testing personnel prior to patient testing. Refer to D6120.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to document the competency of one (1) of three (3) testing personnel prior to patient testing. Findings: 1. Review of the laboratory's "Quality Assurance Plan" under section "QMS: SOP# CC.2009" revealed "Education , experience, and competencies for each individual is documented in the employee's file. All employees must be evaluated periodically to ensure competency in all areas defined for their position." 2. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed Personnel 4 was listed as testing personnel. 3. Review of Personnel 4's "Procedure Competency Evaluation 6 Month" form (completed March 22, 2018) revealed documentation of "PASS" of "FAIL" was not indicated. 4. In interview on May 15, 2018 at 10:40 am, Personnel 2 confirmed documentation of Personnel 4 passing or failing competency was not included. Personnel 2 stated it was an oversight.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the General Supervisor met licensure requirements. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or

paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to ensure the General Supervisor met State of Louisiana licensure requirement. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 4 is listed as General Supervisor. 2. Review of personnel records revealed Personnel 4 maintained a current State of Louisiana Specialist license for Specialty in

	Molecular Biology (American Association of Bioanalysts). 3. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs high complexity Routine Chemistry and Endocrinology (Chemistry) testing. 4. In interview on May 15, 2018 at 10:40 am, Personnel 2 confirmed Personnel 4's specialist license is in Molecular Biology. Personnel 2 stated he thought Personnel 4's current Louisiana State license was acceptable for testing.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure testing personnel met licensure requirements to perform high complexity testing. Refer to D6170.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have current licenses issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow one (1) of three (3) testing personnel to perform high complexity testing. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 4 is listed as Testing Personnel. 2. Review of personnel records revealed Personnel 4 maintained a current State of Louisiana Specialist license for Specialty in Molecular Biology (American Association of Bioanalysts). 3. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs high complexity Routine Chemistry and Endocrinology (Chemistry) testing. 4. In interview on May 15, 2018 at 10:40 am, Personnel 2 confirmed Personnel 4's specialist license is in Molecular Biology. Personnel 2 stated he thought Personnel 4's current Louisiana State license was acceptable for testing.