

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2142233	(X3) Date Survey Completed 04/22/2021
Name of Provider or Supplier Mid City Specialty Center, Llc	Street Address, City, State 3600 Florida Blvd, Suite 2000, Baton Rouge, 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 Mid City Specialty Center, LLC - CLIA ID 19D2142233 on April 21-22, 2021. Mid City Specialty Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1210 CONDITION: Routine Chemistry 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing; Technical Consultant
D5016	<p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>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 in the specialty of Routine Chemistry. Findings: 1. The laboratory failed to obtain a written request from the physician for two (2) of two (2) patients reviewed. Refer to D5301. 2. The laboratory failed to ensure the policy manual contained complete policies and procedures. Refer to D5403. 3. The laboratory failed to perform complete reference range studies for the EPOC analyzer. Refer to D5421. 4. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Refer to D5445 I. 5. The laboratory failed to follow the Individualized Quality Control Plan (IQCP) for one (1) of four (4) months of testing reviewed. Refer to D5445 II. 6. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 7. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391. 8. The laboratory</p>

failed to ensure appropriate reference ranges were available on the final report. Refer to D5807.

D5301

TEST REQUEST
CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to obtain a written request from the physician for two (2) of two (2) patients reviewed. Findings: 1. Review of a random selection of patient test requisitions revealed the laboratory failed to acquire a written request from the physician on for following two (2) of two (2) patients for whom had EPOC testing: a) Patient 000300002403 for Sodium (NA), Potassium (K), Calcium (CA), Chloride (CL), Hematocrit (Hct), Hemoglobin (Hgb), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), and Carbon Dioxide (CO2) b) Patient 000300002401 for Blood Gases (pH, pCO2, pO2, cHCO3, BE(b), cSO2), Sodium (NA), Potassium (K), Calcium (CA), Chloride (CL), Hematocrit (Hct), Hemoglobin (Hgb), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), and Carbon Dioxide (CO2) 2. Interview with the Technical Consultant and the Respiratory Manager on April 22, 2021 at 2:00pm confirmed the laboratory did not obtain a written requests for patient testing. Personnel revealed all EPOC testing is performed during surgery and upon request of the physician; however, the charts did not reflect the physician request of test performance or the specific analyte or panels to be performed.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have a Quality Assurance Policy to identify any of the deficiencies identified with the preanalytic system. 2. The laboratory failed to obtain a written request from the physician for two (2) of two (2) patients reviewed. Refer to D5301. 3. In interview on April 27, 2021 at 2:35 pm, the Technical Consultant confirmed the laboratory did not have written quality assurance policies and procedures specific to the preanalytic system for EPOC testing.

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 policy and procedure manual and interview with personnel, the laboratory failed to ensure the policy manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include detailed written instructions for the following: a) Quality Control to include but not limited to: frequency of quality control performance, who is to perform quality control, rotation of quality control among all testing personnel b) Calibration Verification frequency, who is to perform calibration verification c) Critical Values defined by the laboratory, how the laboratory is to record and communicate critical values 2. In interview on April 27, 2021 at 2:56 pm, the Technical Consultant and Respiratory Manger confirmed the laboratory's policies did not include the above items.

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, record review, and interview with personnel, the laboratory failed to perform complete reference range studies for the EPOC analyzer. Findings: 1. Observation by surveyor during laboratory tour on April 27, 2021 revealed the laboratory utilizes one (1) EPOC BGEM analyzer for blood gas testing in surgery suites. 2. Review of the laboratory's performance verification studies revealed the reference or normal range was not addressed or stated for analytes on the EPOC to include Blood Gases (pH, pCO₂, pO₂, cHCO₃, BE(b), cSO₂), Sodium (NA), Potassium (K), Calcium (CA), Chloride (CL), Hematocrit (Hct), Hemoglobin (Hgb), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Creat), and Carbon Dioxide

(CO2). 3. In further interview on April 27, 2021 at 3:30 pm, the Respiratory Manager stated the laboratory did not perform any studies for normal or reference ranges prior use of the EPOC BGEM analyzer.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

I. Based on observation, review of laboratory studies, policies and procedures and quality control records, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Findings: 1 Observation by surveyor during the laboratory tour on April 27, 2021 revealed the laboratory utilized the EPOC analyzer for blood gas and chemistry testing in surgery suites. 2. Review of the laboratory's IQCP Quality Control Plan revealed the plan did not include in house quality control to support the reduction in quality control to monthly or new lot/shipment. Further review identified no quality assessment plan was detailed to monitor the reduction in quality control frequency. 3. In interview on April 27, 2021 at 3:30pm, the Respiratory Manager confirmed the laboratory did not have in-house QC data to support the QC reduction to monthly. The Respiratory Manager and Technical Consultant also confirmed the IQCP did not detail the quality assessment plan for ongoing monitor of the IQCP. II. Based on observation, review of laboratory studies, policies and procedures and quality control records, and interview with personnel, the laboratory failed to follow the Individualized Quality Control Plan (IQCP) for one (1) of four (4) months of testing reviewed. Findings: 1. Observation by surveyor during the laboratory tour on April 27, 2021 revealed the laboratory utilized the EPOC analyzer for blood gas and chemistry testing in surgery suites. 2. Review of the laboratory's IQCP plan detailed that the laboratory reduced the frequency of quality control to monthly or new lot/shipment of test cards. 3. Review of the quality control records revealed no liquid quality control performed in February 2021. External quality control was performed in January 2021 and then again in mid-March 2021. 4. In interview on April 27, 2021 at 3:30pm, the Respiratory Manager confirmed the laboratory did not perform monthly quality control in February 2021.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (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 failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to ensure the policy manual contained complete policies and procedures. Refer to D5403. 2. The laboratory failed to perform complete reference range studies for the EPOC analyzer. Refer to D5421. 3. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Refer D5445 I. 4. The laboratory failed to follow the Individualized Quality Control Plan (IQCP) for one (1) of four (4) months of testing reviewed. . Refer D5445 II. 5. In interview on April 27, 2021 at 3:35 pm, the Respiratory Manager confirmed the laboratory did not identify above problems in the analytic system.

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 review of final reports, instrument tapes, manufacturer instructions and laboratory policy as well as interview with personnel, the laboratory failed to ensure appropriate reference ranges were available on the final report. Findings: 1. Review of the laboratory's verification of performance specifications revealed the laboratory did not mention normal or reference ranges for venous or arterial blood. 2. Review of the manufacturer instructions detailed separate reference ranges for venous and arterial blood. Further review of patient instrument printouts revealed Reference Ranges for an excerpt of analytes tested. The Reference Ranges listed by the instrument printout did not include all analytes tested. 3. Review of laboratory's patient final report listed Reference Range 12-99 Years Arterial. Review of the reference ranges on the final report revealed no ranges listed for Sodium (Na), Chloride (Cl), Calcium (Ca), and TCO₂ (Total, CO₂). 4. Comparison of the laboratory's final report and reference ranges from the instrument print-outs revealed disparate reference ranges for Hematocrit, Hemoglobin, Glucose, Potassium, SO₂ and pO₂. 5. Interview with the Respiratory Manager on April 27, 2020 at 4:00pm stated that the laboratory final report was from the hospital's respiratory downtime report displaying the hospital's reference range for arterial samples and the reference ranges on the instrument printout were from the manufacturer. The Respiratory Manager and the Technical Consultant confirmed the reference ranges did not match and the ranges were not verified prior to patient testing.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation by surveyor during laboratory tour, 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 reference range studies for the EPOC analyzer were completed. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality systems were maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022 4. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 5. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D6030 6. The Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D6031.

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 reference range studies for the EPOC analyzer were completed. Refer to D5421.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) 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 the laboratory personnel were performing test methods as required. Refer to D5301.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

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 that a quality systems were maintained to assure the quality of laboratory services provided and to identify failures as they occur.

Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Refer to D5445 I. 2. The laboratory failed to follow the Individualized Quality Control Plan (IQCP) for one (1) of four (4) months of testing reviewed. Refer to D5445 II. 3. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 4. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test menu, patient final test reports, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5807.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) 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 for assessing personnel competency were

	<p>established and maintained. Findings: 1. The Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of four (4) testing personnel reviewed. Refer to D6053.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5403.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of four (4) testing personnel reviewed. Refer to D6053.</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.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, 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 obtain a written request from the physician for two (2) of two (2) patients reviewed. Refer to D5301. 2. The laboratory failed to ensure the policy manual contained complete policies and procedures. Refer to D5403.</p>

<p>D6040</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>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.</p> <p>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 verification studies were complete. Refer to D5421.</p>
<p>D6042</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) 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;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Refer to D5445 I. 2. The laboratory failed to follow the Individualized Quality Control Plan (IQCP) for one (1) of four (4) months of testing reviewed. Refer to D5445 II. 3. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 4. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year for eight (8) of eight (8) testing personnel reviewed. Findings: 1. Review of personnel records on April 21, 2020 at 3pm revealed initial training performed prior to patient testing in June 2020. Further review of personnel records revealed no assessment or evaluation of testing personnel competency had been performed since initial training. 2. In interview on April 22, 2021 at 2pm, the Technical Consultant and</p>

Respiratory Manager stated there had been a change in personnel during COVID and confirmed the semi-annual competency evaluation was not completed for personnel performing EPOC testing.