Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314705	05/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Consolidated Medical Practices Of Memphis, Pllc	6799 Great Oaks Rd Suite 120, Memphis, TN	

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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, observation of the laboratory, review of manufacturer's control package inserts, laboratory temperature records, lack of documentation, quality control (QC) data, manufacturer reagent package inserts, control assay sheets, the laboratory's QC ranges, patient test reports, maintenance records, and staff interview, the laboratory failed to ensure procedures were approved, signed and dated by the laboratory director (Refer to D5407), failed to ensure temperature ranges for storage of controls was consistent with manufacturer's requirements (Refer to D5413), failed to label controls with corrected expiration date after opening (Refer to D5415), failed to verify the calibration of chemistry analytes performed on the Beckman Coulter DxC 700 AU (Refer to D5439), failed to follow manufacturer's requirement for frequency of quality control performance for the creatinine analyte (Refer to D5445), failed to ensure the laboratory used quality control (QC) ranges for assayed quality controls that were consistent with manufacturer's ranges Refer to (D5469), and failed to have an effective quality assessment process in place to correct problems with the performance of instrument maintenance (Refer to D5793).
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and

	493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, observation of the laboratory, review of manufacturer's control package inserts, laboratory temperature records, control assay sheets, the laboratory's QC ranges, patient test reports, maintenance records, and staff interview, the laboratory failed to ensure procedures were approved, signed and dated by the laboratory director (Refer to D5407), failed to ensure temperature ranges for storage of controls was consistent with manufacturer's requirements (Refer to D5413), failed to label controls with corrected expiration date after opening (Refer to D5415) and failed to ensure the laboratory used QC ranges for assayed quality controls that were consistent with manufacturer ranges (Refer to D5469).
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and staff interviews, the laboratory failed to provide written instructions for collecting, processing and preserving patient specimens to the other laboratories that submitted samples for patient testing. The findings include: 1. Observation of the laboratory on 05/07/24 at 9 a.m. revealed multiple test systems used for patient testing for chemistry, hematology, immunology, and endocrinology. Samples collected at other physician office practices were observed being accessioned into the laboratory's information system. 2. The laboratory was asked to provide a copy of the instructions provided to the other physician office practices that submit samples for patient testing. No document was available. 3. The technical consultant confirmed during the interview on 05/07/24 at 5 p.m. that the laboratory did not have a client services manual that was provided to the facilities that collect and process patient specimens prior to sending them to the laboratory for testing. She stated that approximately 22 other clinics send samples to their laboratory for testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and staff interview, the laboratory director failed to approve, sign and date the procedures used for testing performed on the Beckman Coulter DxC 700 AU and Beckman Coulter DxI 800 chemistry/endocrinology instruments. The findings include: 1. A review of the laboratory's procedure manual revealed that the laboratory used manufacturer package inserts as a part of operating procedures for the Beckman Coulter DxC 700 AU and

	the Beckman Coulter DxI 800 instruments. The laboratory director had not approved, signed, or dated the procedures on the survey date. 2. The technical consultant confirmed the survey findings during interview on 05/07/24 at 5:00 p.m.
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: Based on observation of the laboratory, review of the manufacturer control package inserts, review of the laboratory freezer temperature records, and staff interview, the laboratory failed to define frozen storage temperature ranges that were consistent with manufacturer requirements, resulting in the storage of controls outside the manufacturer's requirements for five of five months reviewed in 2024. 1. Observation of the laboratory on 05/07/24 at 9:00 a.m. revealed storage of Biorad controls in the freezer labeled "Upright." Observed controls were Immunoassay Plus, Tumor Marker, Immunology, and Multiqual. The observed freezer temperature range on the temperature recording chart was "0-30C." 2. Review of the manufacturer package insert for all four control types revealed an acceptable frozen storage temperature of -20C to -70C. 3. Review of the 2024 upright freezer temperature records revealed recorded temperatures that were higher than -20C for one of twenty-one days in January 2024, two of twenty-five days in February 2024, twenty-six of twenty-six days in March 2024, twenty-seven of twenty-seven days in April 2024, and six of six days in May 2024. 4. The technical consultant confirmed the survey findings during a phone interview on 05/16/24 at 12:15 p.m. Word Key: C= Celsius
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the control manufacturer package inserts, and staff interview, the laboratory failed to label controls with a corrected expiration date after opening. The findings include: 1. Observation of the laboratory on 05/07/24 at 9 a.m. revealed Biorad control vials stored in the laboratory refrigerator that were labeled with an open date but no corrected expiration date. The control vials observed were Liquichek Tumor Marker, Liquichek Specialty Immunoassay, Liquicheck Immunoassay Plus, Liquichek Immunology Control, Liquid Assayed Multiqual, and Liquichek Microalbumin Control. 2. A review of the Biorad manufacturer control

	package inserts revealed the following: Liquichek Tumor Marker: All analytes were stable for 30 days when stored tightly capped at 2-8C, except CA 125 (10 days), IGF-1 /Somatomedin C (15 days), and ProGRP (Progastrin-Releasing Peptide) (5 days). Liquichek Specialty Immunoassay: All analytes were stable for 30 days when stored tightly capped at 2-8C, except PTH (Intact) which was stable for 7 days. Liquicheck Immunoassay Plus Control: All analytes stable for 14 days after opening when stored tightly capped at 2-8C, except for Estradiol, which was stable for five days after opening, and Folate, which was stable for four days after opening. Liquichek Immunology Control: All analytes stable for 45 days after opening when stored tightly capped at 2-8C, except for Beta-2-Microglobulin which was stable for 21 days and Rheumatoid factor which was good for 10 days. Liquid Assayed Multiqual: All analytes stable for 14 days after opening when stored tightly capped at 2-8C, except for Alkaline Phosphatase, AST/SGOT, Bilirubin (Neonatal and Bilirubin (Total) (nine days), Direct Bilirubin, HDL Cholesterol, Cholinesterase, Creatine Kinase (CK) Phosphorus and Triglycerides (seven days), LAP Acrylamidase (three days). Liquichek Microalbumin Control: Stable for 90 days after opening for all analytes when stored tightly capped at 2-8C. 3. The technical consultant confirmed during interview on 05/07/24 at 5 p.m. that the laboratory failed to label control vials with corrected expiration dates after opening. Word Key: C=Celsius PTH=Parathyroid Hormone AST/SGOT=Aspartate aminotransferase HDL=High Density Lipoprotein
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on laboratory observation, review of manufacturer package inserts, a lack of documentation and staff interview, the laboratory failed to verify the calibration of chemistry tests performed on the Beckman Coulter DxC 700 AU chemistry instrument every six months in 2023 and 2024. The findings include: 1. Observation of the laboratory on 05/07/24 at approximately 9 a.m. revealed two Beckman Coulter DxC 700 AU chemistry instruments used for performing patient testing for general chemistry analytes (system ID# 82682974 and 82604907). During observation, the

	technical consultant stated the laboratory runs three levels of quality control each morning, after calibration, after reagent lot change. She also stated a second QC run is performed if the laboratory is performing testing after 5 p.m. When asked if the three levels are routinely performed twice daily, she stated they are not. 2. A review of the manufacturer's calibrator package inserts revealed that the following analytes are calibrated using less than three levels of calibrator: Albumin, Bicarbonate, Direct Bilirubin, Total Bilirubin, Calcium, Cholesterol, Creatinine, Glucose, HDL Cholesterol, Phosphorus, Iron, Lipase, Magnesium, Total Protein, Triglycerides, Urea Nitrogen, and Uric Acid. 3. The laboratory was asked to provide documentation of verification of calibration that included at least three levels that spanned the reportable range for the tests performed on the Beckman Coulter DxC 700 and was performed at least every six months. No documentation was available. 4. The technical consultant confirmed during an interview on 05/07/24 at 5 p.m. that the laboratory failed to verify the calibration of analytes performed on the Beckman Coulter DxC 700 AU chemistry instrument every six months in 2023 and 2024.
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: Based on observation of the laboratory, review of the manufacturer's reagent package insert, review of quality control data, and staff interview, the laboratory failed to perform QC for the creatinine analyte with the frequency required by the manufacturer in April 2024. The findings include: 1. Observation of the laboratory on 05/07/24 at 9:00 a.m. revealed two Beckman Coulter DxC 700 AU chemistry instruments used for patient testing for chemistry analytes. 2. A review of the manufacturer's reagent package insert for creatinine revealed the following under the calibration and quality control (QC) sections: "Run QC at a minimum of every 8 hours." 3. A review of the April 2024 QC data for creatinine revealed that creatinine QC was not performed every eight hours as the manufacturer required. 4. The technical consultant confirmed by electronic mail received on 05/14/24 at 10:05 a.m. that the laboratory did not follow the manufacturer's requirements for performing creatinine QC every eight hours in April 2024.
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 of the laboratory, review of the Biorad QC limit assay sheets, review of the laboratory's QC ranges, review of patient test results and staff interview, the laboratory failed to ensure it used QC ranges that were consistent with the QC limits provided by the manufacturer for the controls used for chemistry and endocrinology. The findings include: 1. Observation of the laboratory on 05/07/24 at 9:00 a.m. revealed the Beckman Coulter DxC 700 AU in use for patient testing. 2. Review of the Biorad quality control limit assay sheets for the Liquichek Microalbumin Control parent lot 96880, Liquichek Immunoassay Plus-parent lot 85320, and Multiqual parent lot 45930, revealed the following statement in all three package inserts: "The mean values and corresponding + 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product." 3. A review of the laboratory's QC ranges compared to the manufacturer-assigned values revealed the laboratory used standard deviations to determine QC ranges that exceed the manufacturer's standard deviation as follows: December 2023 QC Liquichek Microalbumin Control Parent Lot=96880 Level One - Lot 96881 Level Two - Lot 96882 Creatinine Level One - Manufacturer 1 SD = 2.07, Lab 1 SD = 3.1 Level Two - Manufacturer 1 SD = 5, Lab 1 SD = 7.5 Microalbumin Level One - Manufacturer 1 SD = .19, Lab 1 SD = .29 Level Two - Manufacturer 1 SD = .22, Lab 1 SD = .34
_____ January 2024 Quality Control Liquicheck Immunoassay Plus Control Parent Lot = 85320 (Level One Lot 85321, Level Two Lot 85322, Level Three Lot 85323) Prostate Specific Antigen (PSA) Level One - Manufacturer 1 SD = .028, Lab 1 SD = .041 Level Two - Manufacturer 1 SD = .26, Lab 1 SD = .38 Level Three- Manufacturer 1 SD = .1.87, Lab 1 SD = 2.55 Human Chorionic Gonadotropin (hCG) Level One - Manufacturer 1 SD = .37, Lab 1 SD = .55 Level Two - Manufacturer 1 SD = 1.2, Lab 1 SD = 1.8 Level Three- Manufacturer 1 SD = 22.5, Lab 1 SD = 33.75 Thyroid Stimulating Hormone (TSH) Level One - Manufacturer 1 SD = .028, Lab 1 SD = .049 Level Two - Manufacturer 1 SD = .26, Lab 1 SD = .48 Level Three- Manufacturer 1 SD = .1.87, Lab 1 SD = 2.83
_____ March 2024 Quality Control: Multiqual Parent lot=45930 (Level One-lot 45931, Level Two-lot 45932, Level Three-Lot 45933) Sodium: Level One - Manufacturer 1 SD = 3.16, Lab 1 SD = 4.75 Level Two - Manufacturer 1 SD = 2.66, Lab 1 SD = 4.0 Level Three- Manufacturer 1 SD = 2.66, Lab 1 SD = 4.0 Potassium: Level One - Manufacturer 1 SD = .05, Lab 1 SD = .08 Level Two - Manufacturer 1 SD = .07, Lab 1 SD = .11 Level Three- Manufacturer 1 SD = .11, Lab 1 SD = .17 Chloride: Level One - Manufacturer 1 SD = 1.42, Lab 1 SD = 2.15 Level Two - Manufacturer 1 SD = 1.6, Lab 1 SD = 2.4 Level Three- Manufacturer 1 SD =1.8, Lab 1 SD = 2.75 Glucose: Level One - Manufacturer 1 SD = 1.8, Lab 1 SD = 2.8 Level Two - Manufacturer 1 SD = 3.66, Lab 1 SD = 5.5 Level Three- Manufacturer 1 SD =11.17, Lab 1 SD = 16.75 Total Bilirubin: Level One - Manufacturer 1 SD = .04, Lab 1 SD = .06 Level Two - Manufacturer 1 SD = .14, Lab 1 SD = .21 Level Three- Manufacturer 1 SD =.3, Lab 1 SD = .45 4. Review of patient test reports revealed the following patients reported during the periods when the incorrect QC ranges were in use: Patient number 290088 - urine albumin/creatinine

	ratio reported on 12/06/23. Patient 140157-prostate specific antigen reported on 01/05 /24. Patient numbers 250789 and 118074-comprehensive metabolic panel (CMP) reported on 03/08/24. 5. The technical consultant confirmed the following during interview on 05/07/24 at 5 p.m.: The laboratory's protocol was to use the control ranges provided by the manufacturer. The laboratory had used the manufacturer's range as a two-standard deviation range instead of a three-standard deviation range, as indicated in the manufacturer's package insert. This confirmed the survey findings. SD=Standard Deviation
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 review of maintenance records and staff interview, the laboratory's quality assessment process was not effective in identifying problems with lack of performance of required maintenance tasks and use of incorrect maintenance forms in 2023 and 2024. 1. A review of the October 2023 monthly maintenance form for the DxH 900 complete blood count (CBC) instrument revealed no documentation that the monthly maintenance for cleaning the pneumatic supply module fan filter had been performed. The form had been reviewed by the technical consultant, and no corrective action was performed. 2. A review of the maintenance log used to record maintenance for the Beckman Coulter DxC 700 AU chemistry instrument revealed that the laboratory had used the log for the previous chemistry instrument (Beckman Coulter AU 680) for the months of December 2023 and March 2024. The form had been reviewed by the technical consultant, and no corrective action was performed for use of the incorrect form. 3. Review of the DxC 700 AU maintenance log for "Device No. 2022072871" printed from the instrument revealed the following maintenance tasks that had not been completed: Weekly maintenance: Clean the Pre-dilution Bottle - due 09/21/23. Monthly: Clean Sample Probe Wash Well - due 01/29/24, Clean Reagent Probe Wash Wells - due 12/27/23, Clean the Mix Bar Wash Wells-due 01/18/24, Clean the Deionized Water Filter-due 01/18/24, Clean the Sample Probe Filter - due 09/18/23, Clean the Deionized Water Tank - due 09/18/23. Three Month Maintenance: Clean the Air Filters - due 11/18/23, Replace the Wash Solution Roller Pump Tubing - due 11/18/23. Six Month Maintenance: Clean the Cuvettes and the Cuvette Wheel-due 02/18/24. 4. The technical consultant confirmed during a phone interview on 05/16/24 at 12:15 p.m. that the monthly reviews of instrument maintenance were not effective in identifying and correcting problems with the use of incorrect maintenance forms and the lack of performing required maintenance tasks in 2023 and 2024.