Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314705	02/20/2019
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of patient number ten test report, the laboratory's 2018 proficiency testing records, email communication with the laboratory proficiency testing provider, and interview with the lead testing personnel, the laboratory failed to enroll in proficiency testing for the antinuclear antibody (ANA) analyte in 2018. The findings include: 1) Observation of the laboratory on February 19, 2019 at 8:30 am revealed the Biorad PhD lx (serial number PB7G193502) in use for patient testing for ANA. 2) Review of the first patient reported from the Biorad PhD lx instrument (patient number 10) revealed a test start date of March 22, 2019. 3) Review of an email communication from the laboratory's proficiency testing provider revealed that proficiency testing for the ANA analyte was available for shipment on April 2, 2018. 4) Review of the laboratory's 2018 proficiency testing records revealed the laboratory did not enroll and participate in proficiency testing for the ANA analyte in 2018. 5) Interview with the lead testing personnel on February 19, 2019 at 2:30 pm confirmed the laboratory failed to enroll in proficiency testing for the ANA analyte in 2018 with patient testing performed. _____

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, calibration records for the complete blood count (CBC) instrument, and interview with the lead testing personnel, the laboratory failed to follow procedure for six month calibration of the CBC instrument in 2018. 1) Review of the laboratory procedure titled "HEMATOLOGY QUALITY CONTROL POLICY" revealed that the CBC instrument is to be calibrated "At least once every six months." 2) Review of the calibration records for the CELL-DYN Ruby CBC instrument (serial number 55382BG) revealed that calibration due June 2018 was not performed. 3) Interview with lead testing personnel on February 20 at 11:20 am confirmed six month calibration for CELL-DYN Ruby CBC instrument (serial number 55382BG) was not performed in June 2018. The laboratory failed to follow procedure for six month calibration of the CBC instrument in 2018. _____
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory instrument comparison records, and interview with the lead testing personnel, the laboratory failed to perform twice a year comparison for the Tosoh G8 instruments in 2018. The findings include: 1) Observation of the laboratory on February 19, 2019 at 8:30 am revealed two Tosoh G8 instruments in use for patient testing for glycated hemoglobin (Hgb A1c) (serial numbers 12431207 and 10245408). 2) Review of instrument comparison records for the Tosoh G8 instrument revealed comparison were not performed twice a year in 2018. 3) Interview with the lead testing personnel on February 20, 2019 at 10:30 am confirmed comparisons between the two Tosoh G8 instruments used for performing Hgb A1c was not performed twice in 2018. _____
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the lead testing personnel, the patient test report for complete blood count (CBC) and erythrocyte sedimentation rate (ESR) failed to include units of measure in 2017, 2018, and 2019. The findings include: 1) Review of patient numbers one (dated 7.10.17), three (dated 1.12.18), and eight (2.6.19) CBC final test reports revealed no units of measure for neutrophil number, lymphocyte number, monocyte number, eosinophil number, basophil number, red blood cell count, hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), and platelet count. 2) Review of patient numbers two (dated 7.8.2017), seven (dated 6.9.18), and eleven (dated 2.20.19) final report revealed no units of measure for ESR. 3) Interview with the lead testing personnel on February 20, 2019 at 11:45 am confirmed the laboratory failed to include units of measure for CBC parameters and ESR on the final patient test report in 2017, 2018, and 2019. _____
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient data logs and patient number 10 test report, verification of performance specification (VoPS) studies for the Tosoh G8 and Biorad PhD lx instrument and interview with the lead testing personnel, the laboratory director failed to ensure the technical consultant approved VoPS prior to patient testing for the Tosoh G8 instrument in 2017 and the Biorad PhD lx instrument in 2018. The findings include: 1) Observation of the laboratory on February 19, 2019 at 8:30 am revealed the Tosoh G8 instrument (serial number 10245408-Tosoh G8 #2) and the Biorad PhD lx (serial number PB7G193502) in use for patient testing. 2) Review of the patient data log for Tosoh G8 instrument (serial number 10245408-Tosoh G8 #2) revealed that patient testing for glycated hemoglobin (Hgb A1c) began on June 27, 2017. 3) Review of the VoPS studies performed for the Tosoh G8 revealed approval by the technical consultant on December 14, 2017. 4) Review of the first patient reported from the Biorad PhD lx instrument (patient number ten) revealed a test start date of March 22, 2018. Patient testing for the Biorad PhD lx includes anti-nuclear antibody (ANA), Sjogren's antigen A/Sjogren's antigen B (SSA/SSB)

	antibody, Smooth muscle/Nuclear ribonucleoprotein (Sm/RNP) antibody, double stranded deoxyribonucleic acid (ds-DNA) antibody, topoisomerase 1 (SCL-70) antibody, and cyclic-citrullinated peptide antibody (anti-CCP). 5) Review of the VoPS studies performed for the Biorad PhD lx revealed no approval by the technical consultant. 6) Review of the policy titled "Technical Consultant Responsibilities" revealed the technical consultant is responsible for "verification of test procedures and establishment of test performance characteristics." 7) Interview with the lead testing personnel on February 19, 2019 at 2:30 pm confirmed the laboratory director did not ensure the technical consultant approved VoPS prior to patient testing for the Tosoh G8 number two instrument in 2017 or the Biorad PhD lx instrument in 2018.
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 of the laboratory, review of verification of performance specification (VoPS) records for the Tosoh G8 instrument, and interview with the lead testing personnel, the laboratory director failed to ensure VoPS procedures were approved in 2017. The findings include: 1) Observation of the laboratory on February 19, 2019 at 8:30 am revealed the Tosoh G8 instrument (serial number 10245408-Tosoh G8 #2) in use for patient testing for glycated hemoglobin (Hgb A1c). 2) Review of the VoPS for the Tosoh G8 instrumend performed June 8, 2017 revealed no approval signature of the laboratory director. 3) Interview with the lead testing personnel on February 19, 2019 at 2:30 pm confirmed the laboratory director failed to approve the VoPS studies performed for the Tosoh G8 instrument in 2017. _____
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory director failed to ensure proficiency testing reports were reviewed in 2017 and 2018. The findings include: 1) Review of the laboratory's proficiency testing records revealed that no performance evaluation

	reports were present for 2017 Chemistry Miscellaneous 2nd Event, 2017 Immunology /Immunohematology 3rd event, and 2018 Hematology/Coagulation 3rd event. 2) Review of performance evaluation reports received during the survey revealed unacceptable testing event scores for the 2017 Chemistry Miscellaneous 2nd event and 2018 Hematology/Coagulation 3rd event. 3) Interview with the lead testing personnel on February 19, 2019 at 2:30 pm confirmed the laboratory director failed to ensure all proficiency testing reports for 2017 and 2018 were reviewed. _____
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 observation of the laboratory, review of testing personnel competency assessment records and interview with the lead testing personnel, the technical consultant failed to ensure competency assessment for the Tosoh G8 instrument was performed in 2018 for seven of seven testing personnel. 1) Observation of the laboratory on February 19, 2019 at 8:30 am revealed the moderately complex Tosoh G8 instrument in use for patient testing for glycated hemoglobin (Hgb A1c). 2) Review of the 2018 testing personnel competency assessment records revealed that competency assessment for the Tosoh G8 instrument was not performed for seven of seven testing personnel. 3) Interview with the lead testing personnel on February 19, 2019 at 11:30 am confirmed the technical consultant failed to ensure competency assessment for the Tosoh G8 instrument was performed in 2018 for seven of seven testing personnel. _____
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of testing personnel (TP) competency assessment records and interview with the lead testing personnel, the technical consultant failed to ensure blind testing was included as part of competency assessment for all moderately complex test systems in 2017 and 2018. The findings include: 1) Observation of the laboratory on February 19, 2019 at 8:30 am revealed the following moderately complex test systems in use for patient testing: Tosoh G8 (Glycated hemoglobin), CELL-DYN Ruby (complete blood count), Beckman coulter AU 680 (chemistry), Beckman Coulter DXI 800 (immunology), Alifax Roller (erythrocyte sedimentation rate), and the Biorad PhD lx (immunology). 2) Review of testing personnel competency assessment records revealed the following: TP #1-October 2018-6 month competency assessment-No blind testing documented for any instrument. TP #2- 2017 competency assessment-No blind testing documented for the Beckman coulter AU 680, Beckman Coulter DXI. 2018 competency assessment-No

	blind testing documented for any instrument. TP #3- 2017 competency assessment-No blind testing documented for the Beckman Coulter AU 680, Beckman Coulter DXI. 2018 competency assessment-No blind testing documented for the Beckman Coulter AU 680, Beckman Coulter DXI, Biorad PhD lx. TP #4- 2017 competency assessment-No blind testing documented for the Beckman Counter AU 680, Beckman Coulter DXI. 2018 competency assessment- No blind testing documented for the Beckman Coulter AU 680, Beckman Coulter DXI. TP #5- 2017 competency assessment-No blind testing documented for the Beckman Coulter AU 680, Beckman Coulter DXI. 2018 competency assessment-No blind testing documented for the CELL-DYN Ruby, Alifax Roller, Beckman coulter AU 680, Beckman Coulter DXI. _____ 3) Interview with the lead testing personnel on February 19 at 11:30 am confirmed the technical consultant failed to ensure blind testing was included as part of competency assessment for all moderately complex test systems in 2017 and 2018.