Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0684378	**(X3) Date Survey Completed** 08/16/2018
Name of Provider or Supplier Wellstar Medical Group West Cobb Med Ctr	**Street Address, City, State** 3707 Largent Way Nw, Marietta, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 16, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to test the PT samples with the patient workload by testing personnel (TP) who routinely perform the laboratory tests as required. Findings include: 1. Medical Laboratory Evaluation (MLE) PT document review revealed Staff #1 (CMS 209) performed the Total Bilirubin PT for 2018 Events 1 and 2. 2. An interview with the Technical Consultant (CMS 209) in the breakroom on 8/16/18 at approximately 1:00 p.m. confirmed the same TP performed Total Bilirubin PT testing for 2018 Events1 and 2.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory

	that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to retain all PT records for at least 2 years as required. Findings include: Refer to D3037
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to retain all PT records for at least 2 years as required. Findings include: 1. Medical Laboratory Evaluation (MLE) PT document review revealed the laboratory failed to keep the Total Bilirubin log sheets for all three PT events for 2017 and the first two events of 2018. 2. An interview with the Technical Consultant on 8/16/18 in the breakroom at approximately 1:00 p.m. confirmed the Total Bilirubin log sheets were not retained for the aforementioned PT events. This is a repeat deficiency.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), proficiency test (PT) documents, and staff interview, the laboratory director (LD) failed to provide oversight for the overall operation and administration of the laboratory as required. Findings include: 1. Review of the laboratory (SOP), review of PT documents, and staff interview revealed the LD failed to ensure testing personnel (TP) were rotated for testing of PT samples as required in the laboratory SOP. 2. An interview with the Technical Consultant in the breakroom on 8/16/18 at approximately 1 p.m. confirmed the TP were not rotated for testing of the PT samples as required in the laboratory SOP.