Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1010218	05/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Sylvan Grove Hospital	1050 Mcdonough Road, Jackson, 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 proficiency testing desk review was completed on May 21, 2018. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and confirmation from the laboratory manager, the laboratory failed to maintain satisfactory performance on samples provide by the College of American Pathologist (CAP) in three consecutive events

	(2nd and 3rd events of 2017 and 1st event of 2018), resulting in the second unsuccessful occurrence for Routine Chemistry, analyte # 245 including Creatinine, analyte # 405 and Blood Urea Nitrogen (BUN), analyte # 505. Findings include: Refer to D 2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and verbal and email confirmation from the laboratory manager, the laboratory failed to maintain satisfactory performance in three consecutive events (2nd and 3rd events of 2017 and 1st event of 2018), resulting in the second unsuccessful occurrence for Routine Chemistry, analyte number 245 including Creatinine, analyte # 405 and Blood Urea Nitrogen (BUN), analyte # 505. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the subspecialty of # 245 Routine Chemistry including analyte #405, Creatinine and # 505 BUN on events 2 and 3 of 2017 with a score of 0% and event 1 of 2018 with a score of 0%. 2. Verbal and email correspondence with the laboratory manager on March 08, 2018 confirmed the laboratory failed Routine Chemistry, Creatinine and BUN on PT samples provided by the College of American Pathologist (CAP) on Events 2 and 3 of 2017 and Event 1 of 2018 resulting in the second unsuccessful performance.
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and confirmation from the laboratory manager, the laboratory director failed to ensure the laboratory maintained satisfactory performance on samples provide by the College of American Pathologist (CAP) in three consecutive events (2nd and 3rd events of 2017 and 1st event of 2018), resulting in the second unsuccessful occurrence for Routine Chemistry, analyte # 245 including Creatinine, analyte # 405 and Blood Urea Nitrogen (BUN), analyte # 505. Findings include: refer to D 6016 .
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and confirmation from the laboratory manager, the laboratory director failed to ensure the laboratory maintained satisfactory performance on samples provide by the College of American Pathologist (CAP) in three consecutive events (2nd and 3rd events of 2017 and 1st event of 2018), resulting in the second unsuccessful occurrence for Routine Chemistry, analyte # 245 including Creatinine, analyte # 405 and Blood Urea Nitrogen (BUN), analyte # 505. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the subspecialty of # 245 Routine Chemistry including analyte #405, Creatinine and # 505 BUN on events 2 and 3 of 2017 with a score of 0% and event 1 of 2018 with a score of 0%. 2. Verbal and email correspondence with the laboratory manager on March 08, 2018 confirmed the laboratory failed Routine Chemistry, Creatinine and BUN on PT samples provided by the College of American Pathologist (CAP) on Events 2 and 3 of 2017 and Event 1 of 2018 resulting in the second unsuccessful performance. Also refer to D 2096