Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0699024	10/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medical Center, Llp, The	908 Hillcrest Pkwy, Dublin, 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 October 3, 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 review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in five of nine consecutive events (3rd

	event of 2015, 3rd event of 2016, 1st event of 2017 and 1st and 2nd events of 2018), resulting in subsequent unsuccessful occurrence for cholesterol, analyte # 375, failed to maintain satisfactory performance in four of six consecutive events (3rd event of 2016, 2nd event of 2017 and 1st and 2nd events of 2018), resulting in subsequent unsuccessful occurrence for glucose, analyte # 415 and failed to maintain satisfactory performance in three of nine consecutive events (event 3 of 2015, event 2 of 2016 and event 2 of 2018) resulting in subsequent unsuccessful occurrence for calcium, analyte # 345. 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 desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in five of nine consecutive events (3rd event of 2015, 3rd event of 2016, 1st event of 2017 and 1st and 2nd events of 2018), resulting in subsequent unsuccessful occurrence for cholesterol, analyte # 375, failed to maintain satisfactory performance in four of six consecutive events (3rd event of 2016, 2nd event of 2017 and 1st and 2nd events of 2018), resulting in subsequent unsuccessful occurrence for glucose, analyte # 415 and failed to maintain satisfactory performance in three of nine consecutive events (event 3 of 2015, event 2 of 2016 and event 2 of 2018) resulting in subsequent unsuccessful occurrence for calcium, analyte # 345. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed cholesterol analyte # 375 , on event 3 of 2015 with a score of 0%, event 3 of 2016 with a score of 0%, event 1 of 2017 with a score of 60%, event 1 of 2018 with a score of 20% and event 2 of 2018 with a score of 20%. 2. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed glucose, analyte #415 , on event 3 of 2016 with a score of 0%, event 2 of 2017 with a score of 40%, event 1 of 2018 with a score of 40% and event 2 of 2018 with a score of 0%. 3. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed calcium, analyte #345 , on event 3 of 2015 with a score of 40%, event 2 of 2016 with a score of 20%, and event 2 of 2018 with a score of 60%. 4. Desk review of the laboratory's proficiency testing reports from API confirmed the laboratory failed cholesterol , glucose and calcium on the events and with scores listed above resulting in subsequent unsuccessful performance for the three analytes.
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 an in-office desk review of proficiency testing records, the laboratory

	director failed to ensure the laboratory successfully participated in five of nine consecutive PT testing events in the speciality of Routine Chemistry for analyte # 365, cholesterol, four of six consecutive testing events for analyte # 415, glucose and three of nine consecutive testing events for analyte #345, calcium. Findings include: 1. Review of PT records and reports revealed the laboratory failed cholesterol on five of nine consecutive testing events: event 3 of 2015, event 3 of 2016, event 1 of 2017 and events 1 and 2 of 2018, failed glucose on four of six consecutive events: event 3 of 2016, event 2 of 2017 and events 1 and 2 of 2018 and failed calcium on three of nine consecutive events: event 3 of 2015, event 2 of 2016 and event 2 of 2018. Also 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 an in-office desk review of proficiency testing records, the laboratory director failed to ensure the laboratory successfully participated in five of nine consecutive PT testing events in the speciality of Routine Chemistry for analyte # 365, cholesterol, four of six consecutive testing events for analyte # 415, glucose and three of nine consecutive testing events for analyte #345, calcium. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed cholesterol analyte # 375 , on event 3 of 2015 with a score of 0%, event 3 of 2016 with a score of 0%, event 1 of 2017 with a score of 60%, event 1 of 2018 with a score of 20% and event 2 of 2018 with a score of 20%. 2. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed glucose, analyte #415 , on event 3 of 2016 with a score of 0%, event 2 of 2017 with a score of 40%, event 1 of 2018 with a score of 40% and event 2 of 2018 with a score of 0%. 3. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed calcium, analyte #345 , on event 3 of 2015 with a score of 40%, event 2 of 2016 with a score of 20%,and event 2 of 2018 with a score of 60%. 4. Desk review of the laboratory's proficiency testing reports from API confirmed the laboratory failed cholesterol , glucose and calcium on the events and with scores listed above resulting in subsequent unsuccessful performance for the three analytes.