Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2003185	05/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Millennium Physicians Association, Pllc	22710 Professional Dr Suite 108, Kingwood, TX	

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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of participation of the CLIA program The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 D2016 Condition: Successful participation [proficiency testing] 493.1403 D6000 Condition: Laboratories performing moderate complexity testing; laboratory director
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 a desk review of proficiency testing records obtained from the CMS

	(Center for Medicare Services) national database and verified with the proficiency testing company, College of American Pathologists (CAP), it was determined the laboratory had not successfully participated in a proficiency testing program approved by CMS, for each specialty, sub-specialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the sub-specialty of Routine Chemistry. (Refer to D2096 and D2097).
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: . Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's College of American Pathologists (CAP) proficiency test results, it was revealed the laboratory failed to attain a score of at least 80% for the analyte Creatinine, WB (Whole Blood) in 2021 and 2022. Findings included: 1. Event WBCR-B 2021 (2nd event of 2021) - unsatisfactory score of 60% for the analyte Creatinine, WB . 2. Event WBCR-A 2022 (1st event of 2022) - unsatisfactory score of 60% for the analyte Creatinine, WB .
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 a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing records from College of American Pathologists (CAP), it was revealed the laboratory failed to achieve satisfactory performance for the analyte Creatinine, WB (Whole Blood) for 2 of 3 testing events in 2021 and 2022. Findings included: 1. Event WBCR-B 2021 (2nd event of 2021) - an unsatisfactory score of 60% for the analyte Creatinine, WB . 2. Event WBCR-A 2022 (1st event of 2022) - an unsatisfactory score of 60% for the analyte Creatinine, WB .
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) Failure to achieve an overall testing event score of satisfactory performance for 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 a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency

	testing records from College of American Pathologists (CAP), it was revealed the laboratory failed to achieve oveall testing event score of satisfactory performance for 2 of 3 consecutive testing events in the sub-specialty of Routine Chemistry, resulting in an unsuccessful perfomance. Findings included: 1. Event WBCR-B 2021 (2nd event of 2021) - an unsatisfactory overall event score of 60%. 2. Event WBCR-A 2022 (1st event of 2022) - an unsatisfactory overall event score of 60%.
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 a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's College of American Pathologists (CAP) proficiency test results, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. (Refer to D6016)
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 a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's College of American Pathologists (CAP) proficiency test results, it was revealed the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a CMS approved proficiency testing program. (Refer to D2087, D2096 and D2097)