Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2064518	09/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Millennium Physicians Dba Millenium Oncology	17323 Red Oak Drive, Houston, 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 conditions not met were: D2016- 42 C.F.R. 493.803 Condition: Successful participation in a proficiency testing program D6000 - 42 C.F.R. 493.1403 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 HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of routine chemistry for the analyte: Creatinine for two consecutive events in 2020. (Refer to D2087, 2096)
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 review of the Centers for Medicare and Medicaid Services (CMS) national database and verified with laboratory's College of American Pathologists (CAP) proficiency testing results from 2020, the laboratory failed to achieve successful score of 80% on 2 of 2 events for the analyte of Creatinine in Chemistry. The findings were: 1. A review of CMS national database testing results from 2020 first and second events, revealed the laboratory failed to achieve a successful score of 80% on 2 of 2 events for the analyte creatinine in chemistry. Chemistry Creatinine 2020- First event : 40% Creatinine 2020- Second event: 40% 2. A review of the laboratory's CAP proficiency testing results from 2020 first and second events, revealed the laboratory failed to achieve a successful score of 80% on 2 of 2 events for the analyte creatinine in chemistry Creatinine 2020 - First event: 40% CAP Specimen Result Expected result 1 7.35 8.59 - 11.63 (unacceptable) 4 2.56 3.03 - 4.11 (unacceptable) 5 4.54 4.98 - 6.75 (unacceptable) Creatinine 2020 - Second event: 40% CAP Specimen Result Expected result 6 4.13 4.76 - 6.46 (unacceptable) 8 2.63 2.88 - 3.91 (unacceptable) 9 1.53 1.67 - 2.28 (unacceptable)
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based upon a review of Centers for Medicare and Medicaid Services (CMS) national data base and College of American Pathologists (CAP) proficiency desk review from 2020, the laboratory failed to attain an overall testing event score of at least 80 % for the first and second Chemistry events. Findings were: 1. Review of the (CMS) national data base, revealed the laboratory failed to achieve an overall testing score of at least 80% in the 2020 1st Testing Event and the 2020 2nd testing event for Chemistry. Chemistry - 2020- First event: 40% 2020- Second event: 40% 2. Review of the CAP proficiency testing records for 2020 revealed the laboratory failed to attain an overall testing event score of at least 80 % for 2 of 2 Chemistry testing events. CAP Chemistry 2020- First event : 40% 2020- Second event: 40%
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 review of the Centers for Medicare and Medicaid Services (CMS) national database and verified with laboratory's College of American Pathologists (CAP) proficiency testing results from 2020, the laboratory failed to achieve successful score of 80% on 2 of 2 events for the analyte of Creatinine in Chemistry, which constitutes unsuccessful performance. The findings were: 1. A review of CMS national database testing results from 2020 first and second events, revealed the laboratory failed to achieve a satisfactory score of 80% on 2 of 2 events for the analyte creatinine in chemistry. Chemistry Creatinine 2020- First event : 40% Creatinine 2020- Second event: 40% 2. A review of the laboratory's CAP proficiency testing results from 2020 first and second events, revealed the laboratory failed to achieve a satisfactory score of 80% on 2 of 2 events for the analyte creatinine in chemistry Chemistry CAP Creatinine 2020 - First event: 40% CAP Creatinine 2020 - Second event: 40% Score of less than 80 percent are unsatisfactory performance. Unsatisfactory performance on two (2) consecutive events or two out of three (2 out of 3) events is unsuccessful performance.
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 review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2020, it was revealed the laboratory failed to achieve an overall testing event score of satisfactory performance of 80% or greater for 2 of 2 consecutive testing events for the specialty of chemistry. Two out of two overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of 40 % for the 2020 Chemistry first event and second event. 2. A proficiency desk review of the College of American Pathologists proficiency testing records from 2020 confirmed that the laboratory received a chemistry score of 40% for the 2020 Chemistry first event and second event.
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 HHS approved proficiency testing program. (Refer to D2087, D2088, 2096, 2097).