Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2064518	06/29/2021
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 following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 D2016 Condition: Successful participation [proficiency testing 493.807 D2017 Reinstatement After Failure 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 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. (Refer to D2096 and D2097)
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. 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 records from College of American Pathologists (CAP), it was determined the laboratory had not successfully participated in proficiency testing for the analyte Creatinine under the specialty of Routine Chemistry for 3 of 3 consecutive testing events and has not demonstrated sustained satisfactory performance on two consecutive proficiency events since the unsuccessful scores. Findings include: 1. WBCR -B 2020 (Whole Blood Creatinine second event) the laboratory received an unsatisfactory score of 40% for the specialty of Routine Chemistry. 2. WBCR- C 2020 (Whole Blood Creatinine third event) the laboratory received an unsatisfactory score of 20% for the specialty of Routine Chemistry. 3. WBCR- A 2021 (Whole Blood Creatinine first event) the laboratory received an unsatisfactory score of 0% for the specialty of Routine Chemistry.
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 in 2020 and 2021.

	Findings include: 1. WBCR -B 2020 (Whole Blood Creatinine second event) the laboratory received an unsatisfactory score of 40% for the analyte Creatinine. 2. WBCR- C 2020 (Whole Blood Creatinine third event) the laboratory received an unsatisfactory score of 20% for the analyte Creatinine. 3. WBCR- A 2021 (Whole Blood Creatinine first event) the laboratory received an unsatisfactory score of 0% for the analyte Creatinine.
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 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 an overall testing score of at least 80% in the specialty of Routine Chemistry for 3 of 3 events in 2020 and 2021. Findings include: 1. WBCR -B 2020 (Whole Blood Creatinine second event) the laboratory received an unsatisfactory score of 40% for the specialty of Routine Chemistry. 2. WBCR- C 2020 (Whole Blood Creatinine third event) the laboratory received an unsatisfactory score of 20% for the specialty of Routine Chemistry. 3. WBCR- A 2021 (Whole Blood Creatinine first event) the laboratory received an unsatisfactory score of 0% for the specialty of Routine Chemistry.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. 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 participate in the Whole Blood Creatinine first event for 2021(WBCR-A 2021), resulting in unsatisfactory performance. Findings include: 1. WBCR- A 2021 (Whole Blood Creatinine first event) the laboratory failed to participate and received an unsatisfactory score of 0%.
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 for 3 of 3 consecutive testing events in 2020 and 2021. Findings include: 1. WBCR -B 2020 (Whole Blood Creatinine second event) the laboratory received an unsatisfactory score of 40% for the analyte Creatinine. 2. WBCR- C 2020 (Whole Blood Creatinine third event) the laboratory received an unsatisfactory score of 20% for the analyte Creatinine. 3. WBCR- A 2021 (Whole Blood Creatinine first event) the laboratory received an unsatisfactory score of 0% for the analyte Creatinine. Three out of three unsatisfactory scores results in subsequent (non-initial) unsuccessful proficiency testing 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 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 specialty of Routine Chemistry for 3 of 3 consecutive testing events in 2020 and 2021. Findings include: 1. WBCR -B 2020 (Whole Blood Creatinine second event) the laboratory received an unsatisfactory score of 40% for the specialty of Routine Chemistry. 2. WBCR- C 2020 (Whole Blood Creatinine third event) the laboratory received an unsatisfactory score of 20% for the specialty of Routine Chemistry. 3. WBCR- A 2021 (Whole Blood Creatinine first event) the laboratory received an unsatisfactory score of 0% for the specialty of Routine Chemistry. Two out of three unsatisfactory scores results in unsuccessful proficiency testing 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 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 D6018)
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; 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 D2096 and D2097)