

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2064518	(X3) Date Survey Completed 12/30/2020
Name of Provider or Supplier Millennium Physicians DbA Millenium Oncology	Street Address, City, State 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: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D2017 - 42 C.F.R. 493.807 (a) - Reinstatement After Failure D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the College of American Pathologist (CAP) proficiency testing records from 2020, it was determined the laboratory has not successfully participated in a proficiency testing program, 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 chemistry for the analytes: TOTAL CREATININE; (Refer to D2087, D2088, D2096, 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 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 determined the laboratory had not successfully participated in proficiency testing for the satisfactory performance in the specialty of chemistry for the analyte TOTAL CREATININE resulting in a non-initial PT failure. Findings were: 1. A review of the CMS national proficiency testing database from 2019-2020 revealed the laboratory failed to attain a satisfactory score of 80% or greater for Creatinine in 3 of 3 Chemistry testing events in 2020. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20% 2. A proficiency desk review of the CAP proficiency testing records from 2020 confirmed that the laboratory received the following chemistry score in Creatinine for 3 of 3 consecutive testing. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20% 3. The laboratory must demonstrate sustained satisfactory performance ($\geq 80\%$) on two consecutive testing events for reinstatement.

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 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 determined the laboratory failed to attain a score of

80% or greater for the analyte Creatinine for 3 of 3 testing events in 2020. Findings were: 1. A review of the CMS national proficiency testing database from 2019-2020 revealed the laboratory failed to attain a satisfactory score of 80% or greater for Creatinine in 3 of 3 Chemistry testing events in 2020. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20% 2. A proficiency desk review of the CAP proficiency testing records from 2020 confirmed that the laboratory received the following Creatinine score for 3 of 3 consecutive Chemistry testing events in 2020. WBCR-A 2020 - 40% WBCR-01 lab result 7.35 (acceptable range 8.59 - 11.63) WBCR-04 lab result 2.56 (acceptable range 3.03 - 4.11) WBCR-05 lab result 4.54 (acceptable range 4.98 - 6.75) WBCR-B 2020 - 40% WBCR-06 lab result 4.13 (acceptable range 4.76 - 6.46) WBCR-08 lab result 2.63 (acceptable range 2.88 - 3.91) WBCR-09 lab result 1.53 (acceptable range 1.67 - 2.28) WBCR-C 2020 - 20% WBCR-11 lab result 4.22 (acceptable range 4.77 - 6.47) WBCR-12 lab result 2.28 (acceptable range 2.92 - 3.96) WBCR-14 lab result 7.69 (acceptable range 8.33 - 11.28) WBCR-15 lab result 1.65 (acceptable range 1.66 - 2.27)

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 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 determined the laboratory failed to attain a score of 80% or greater for the specialty of Chemistry for 3 of 3 testing events in 2020 resulting in an unsatisfactory performance for the specialty of Chemistry. Findings were: 1. A review of the CMS national proficiency testing database from 2019-2020 revealed the laboratory failed to attain a satisfactory score of 80% or greater in the specialty of Chemistry in 3 of 3 Chemistry testing events in 2020. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20% 2. A proficiency desk review of the CAP proficiency testing records from 2020 confirmed that the laboratory received the following Chemistry score for 3 of 3 consecutive testing in 2020. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20%

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 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 determined the laboratory failed to achieve satisfactory performance (80% or greater) for the analyte Creatinine in 3 of 3 consecutive testing events in 2020 which resulted in unsuccessful performance for the analyte Creatinine in 2020. Findings were: 1. A review of the CMS national proficiency testing database from 2019-2020 revealed the laboratory failed to attain a

	<p>satisfactory score of 80% or greater for Creatinine in 3 of 3 Chemistry testing events in 2020. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20% 2. A proficiency desk review of the CAP proficiency testing records from 2020 confirmed that the laboratory received the following Creatinine score for 3 of 3 consecutive Chemistry testing events in 2020. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20%</p>
<p>D2097</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(g)</p> <p>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.</p> <p>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 determined the laboratory failed to achieve satisfactory performance (80% or greater) for the specialty of Chemistry in 3 of 3 consecutive testing events in 2020. Findings were: 1. A review of the CMS national proficiency testing database from 2019-2020 revealed the laboratory failed to attain a satisfactory score of 80% or greater for the specialty of Chemistry in 3 of 3 Chemistry testing events in 2020. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20% 2. A proficiency desk review of the CAP proficiency testing records from 2020 confirmed that the laboratory received the following Chemistry score for 3 of 3 consecutive Chemistry testing events in 2020. WBCR-A 2020 - 40% WBCR-B 2020 - 40% WBCR-C 2020 - 20%</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Findings were: 1. A review of the laboratory proficiency testing results revealed that the laboratory director failed to ensure that the laboratory participated successfully. (refer to D6016) By not providing overall management and direction of the laboratory, the laboratory director could not ensure the accuracy or reliability of all laboratory services provided by the facility.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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</p>

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 results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an approved proficiency testing program. (refer to D2088, D2097)