

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0949481	<b>(X3) Date Survey Completed</b>  09/29/2022
<b>Name of Provider or Supplier</b>  Jose A Monteiro Md, Pc	<b>Street Address, City, State</b>  211 Milliken Blvd, Fall River, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA paper desk review of proficiency testing was conducted on 9/29/22 for the Jose A. Monteiro, MD, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of a second occurrence of unsuccessful proficiency testing performance for the subspecialty area of Routine Chemistry and the White Blood Count differential and Hemoglobin analytes, the following Condition level deficiencies were deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. Condition 42 CFR 493.1403 - Laboratory Director. Refer to D2016, D2089, D2097, D2123, D2130, and D6000. .
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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>

This CONDITION is not met as evidenced by:  
 Based on record review on 9/29/22 of calendar years 2019, 2020, 2021 and 2022 proficiency testing results (four testing events), the laboratory failed to successfully participate (achieve a score of 80 percent or more) in the Medical Laboratory evaluation (MLE) proficiency testing program for the subspecialty of Routine Chemistry and the specialty of Hematology as evidenced by the following Routine Chemistry: First Unsuccessful Occurrence: The laboratory failed to participate in the third testing event of 2021 and first event of 2022 for the subspecialty area of Routine Chemistry. This resulted in the first occurrence of unsuccessful performance for the subspecialty area. Refer to D2089. Second unsuccessful occurrence: The laboratory failed to participate in the third event of 2021 and the first and second events of 2022 in the subspecialty of Routine Chemistry. This resulted in the second occurrence of unsuccessful performance for the subspecialty area. Refer to D2089 and D2097. Hematology First Unsuccessful Occurrence: The laboratory obtained a score of zero (0) percent for the first and third testing events of 2019 for the White Blood Count differential analyte. The laboratory obtained a score of sixty (60) percent for the first and third testing events of 2019 for the Hemoglobin analyte. This resulted in the first occurrence of unsuccessful performance for the two analytes. Second Unsuccessful Occurrence: The laboratory obtained a score of twenty (20) percent for the third testing event of 2021 and a score of zero (0) percent (failure to participate - refer to D2123) for the second testing event of 2022 resulting in the second occurrence of unsuccessful performance for the White Blood Count differential analyte. The laboratory obtained a score of sixty (60) percent for the third event of 2020, forty (40) percent for the first testing event of 2022 and a score of zero (0) percent (failure to participate - refer to D2123) for the second testing event of 2022 resulting in the second occurrence of unsuccessful performance for the Hemoglobin analyte. Based on this evidence the laboratory failed to undertake the appropriate training and/or technical assistance necessary to correct the problem of unsuccessful proficiency testing performance for the subspecialty area of Routine Chemistry and the White Blood Count differential and Hemoglobin analytes. .

**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 record review of 2021 and 2022 proficiency testing results (four testing events), the laboratory failed to return proficiency testing results resulting in two unsuccessful occurrences of unsuccessful proficiency testing in the subspecialty area of Routine Chemistry as evidenced by the following: a) First unsuccessful occurrence: A review of the the Medical Laboratory Evaluation (MLE)) proficiency testing results for 2021 revealed that the laboratory had received excused nonparticipation from the proficiency testing company for testing events two and three of 2021 as well as the

first testing event of 2022. However, the laboratory failed to meet the criteria of nonparticipation in the proficiency testing by: 1) failing to notify the State agency of the suspension of patient testing; and, 2) failed to participate in the previous two proficiency testing events (2021 testing event 3) resulting in a score of zero for each of the analytes as well as the subspecialty of Routine Chemistry. This resulted in the first occurrence of unsuccessful performance for the subspecialty area. b) Second unsuccessful occurrence: A review of the the Medical Laboratory Evaluation (MLE) proficiency testing results for 2022 revealed that the laboratory had received excused nonparticipation from the proficiency testing company for the first testing event of 2022 and failed to participate in the second testing event of 2022. The laboratory failed to meet the criteria of nonparticipation in the proficiency testing by: 1) failing to notify the State agency of the suspension of patient testing; and, 2) failed to participate in the previous two proficiency testing events (2021 testing event 3) resulting in a score of zero for each of the analytes as well as the subspecialty of Routine Chemistry. This resulted in the second occurrence of unsuccessful performance for the subspecialty area. c) The laboratory's failure to notify the State agency or participate in the second testing event of 2022 was confirmed through a letter sent by the laboratory director via email on 9/12/22. .

**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 record review of calendar years 2021 and 2022 Medical Laboratory Evaluation (MLE) proficiency testing results, the laboratory failed to attain an overall testing event score of at least 80 percent for the subspecialty of Routine Chemistry as evidenced by the following analyte testing event scores: 1. 2021 MLE testing event 3 - score of 0 % (failure to participate). 2. 2022 MLE testing event 1 - score of 0 % (failure to participate).. 3. 2022 MLE testing event 2 - score of 0% (failure to participate).

**D2123**

**HEMATOLOGY**  
CFR(s): 493.851(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 proficiency testing record review of Medical Laboratory Evaluation (MLE) proficiency testing results for calendar years 2019, 2020, 2021 and 2022, the

	<p>laboratory failed to participate in the second testing event of 2022 for the White Blood Cell differential and Hemoglobin analytes resulting in scores of zero (0) percent for the testing event. .</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review of calendar years 2019, 2020, 2021 and 2022 Medical Laboratory Evaluation (MLE) proficiency testing results, the laboratory failed to attain a testing event score of at least 80 percent for all hematology analytes as evidenced by the following analyte testing event scores: White Blood Cell Differential Analyte: 1. 2019 MLE testing event 1 - score of 0 %. 2. 2019 MLE testing event 3 - score of 0 %. 3. 2021 MLE testing event 3 - score of 20%. 4. 2022 MLE testing event 2 - score of 0% (failure to participate). Hemoglobin: 1. 2019 MLE testing event 1 - score of 60 %. 2. 2019 MLE testing event 3 - score of 60 %. 3. 2020 MLE testing event 3 - score of 60 %. 4. 2022 MLE testing event 1 - score of 40%. 4. 2022 MLE testing event 2 - score of 0% (failure to participate). .</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> 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 the deficiencies cited herein, the laboratory director failed to ensure that effective remedial action was instituted in response to unsatisfactory proficiency testing results resulting in repeated unsuccessful performance for the subspecialty of Routine Chemistry and White Blood Cell differential and Hemoglobin analytes under the specialty of Hematology. Refer to D2016, D2089, D2097, D2123, and D2130.</p>