

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0949481	(X3) Date Survey Completed 01/17/2020
Name of Provider or Supplier Jose A Monteiro Md, Pc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A CLIA paper desk review of proficiency testing was conducted on 1/17/20 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 unsuccessful proficiency testing performance for the hemoglobin, white blood count, and white blood cell differential analytes in the specialty of Hematology, 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 .
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>

	<p>. Based on an off-site proficiency testing desk review for calendar years 2018 and 2019, 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 hemoglobin, white blood cell count, and white blood cell differential analytes resulting in ongoing unsuccessful proficiency testing performance in the specialty of Hematology. Refer to D2123, D2130, and D2131. .</p>
<p>D2123</p>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review of Medical Laboratory Evaluation proficiency testing results for calendar years 2018 and 2019, the laboratory failed to participate in the first and third testing events of 2019 for the white blood cell differential analyte resulting in scores of zero (0) percent and unsuccessful performance for the analyte as evidenced by the following test scores: White Blood Cell Differential Analyte: 1. 2019 MLE testing event 1 - score of 0 % 2. 2019 MLE testing event 3 - score of 0%.</p>
<p>D2130</p>	<p>HEMATOLOGY 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 and 2019 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 testing event scores: White Blood Cell Differential Analyte: 1. 2018 MLE testing event 1 - score of 66 %. 2. 2018 MLE testing event 3 - score of 53 %. 3. 2019 MLE testing event 1 - score of 0 %. 4. 2019 MLE testing event 3 - score of 0 %. Hemoglobin: 1. 2019 MLE testing event 1 - score of 60 %. 2. 2019 MLE testing event 3 - score of 60 %. White Blood Count: 1. 2019 MLE testing event 1 - score of 60 %. 2. 2019 MLE testing event 3 - score of 40 % . .</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(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</p>

unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on Medical Laboratory Evaluation (MLE) proficiency testing performance review for calendar year 2019, the laboratory failed to achieve an overall testing event score of satisfactory performance for two out of three testing events for the specialty area of Hematology leading to unsuccessful performance as evidenced by the following scores obtained: 1. 2019 MLE testing event 1 - score of 66 %. 2. 2019 MLE testing event 3 - score of 56 % . .

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 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 white blood cell differential, hemoglobin, and white blood count analytes in the specialty of Hematology Refer to D2016, D2123, D2130, and D2131.