

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0949481	(X3) Date Survey Completed 06/29/2021
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 recertification survey was conducted 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.
D6045	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: . Based on personnel training record review and interview with testing person #1 (TP1) on 6/29/21, the technical consultant (TC) failed to identify training needs and assuring each testing person (TP) receives appropriate training and education prior to patient testing as evidenced by the following: The surveyor asked for the personnel training records for review. The review revealed that the TC failed to document that two (2) out of four (4) TP's performing moderate complexity testing received training before reporting patient results. TP1 confirmed in an interview on 6/29/21 at 11:45 AM that TP1 and TP2 did not have any training documentation on file for moderate complexity testing. The laboratory performs 72,139 Routine Chemistry tests and 18,325 CBC's annually. .</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:
. Based on personnel competency record review and interview with Testing Person #1 (TP1) on 6/29/21, the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: The surveyor asked for the personnel competency records for review. The review revealed that semiannual competency evaluations were not performed and documented for two (2) out of the four (4) testing persons (TP) in their first year of performing moderate complexity testing. TP1 confirmed in an interview on 6/29/21 at 11:45 AM that the TC failed to perform and document semiannual competency evaluations for TP1 and TP2 in their first year of performing moderate complexity testing. The laboratory performs 72,139 Routine Chemistry tests and 18,325 CBC's annually.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
. Based on personnel competency record review and interview with Testing Person #1 (TP1) on 6/29/21, the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year the individual tested patient specimens as evidenced by the following: The surveyor asked for the personnel competency records for review. The review revealed that annual competency evaluations were not performed and documented at least annually for two (2) out of the four (4) testing persons (TP) after the first year of performing moderate complexity testing. TP1 confirmed in an interview on 6/29/21 at 11:45 A.M. that the TC failed to perform and document annual competency evaluations for TP1 and TP2 after the first year of performing moderate complexity testing. The laboratory performs 72,139 Routine Chemistry tests and 18,325 CBC's annually.