

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2092695	(X3) Date Survey Completed 03/12/2019
Name of Provider or Supplier John L Niles Md, Pllc	Street Address, City, State 101 Merrimac St 1st Fl, Boston, 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 John L Niles MD, PLLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with testing person number 2 (TP2), the laboratory failed to effectively review and evaluate unsatisfactory PT results as evidenced by the following: A review of calendar years 2017 and 2018 (six testing events) PT records for hematology and urinalysis performed on 3/12/19 revealed that the laboratory had received an unacceptable score of 50% for urine sediment for the second testing event of 2018. There was no documentation of remedial action or interpretation of these unacceptable PT results. TP 2 confirmed in an interview on 3/12/19 at 2:10 P.M. that the unsatisfactory urine sediment PT results had not been addressed.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on PT record review and interview with TP2 on 3/12/19, the laboratory failed to document reviews of PT evaluations as evidenced by the following: A review of</p>

calendar years 2017 and 2018 (six testing events) PT records for hematology and urinalysis performed on 3/12/19 revealed no documented review by the laboratory director for one (1) of six (6) testing events (2017 second testing event). TP2 confirmed in an interview on 3/12/19 at 2:10 P.M. that the PT evaluation reports were not reviewed by the laboratory director for the 2017 second testing event for hematology and urinalysis.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview with TP2, 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: Review of the CMS 209 Laboratory Personnel Report on 3/12/19 showed that there were three (3) new testing personnel hired and performing testing since the last CLIA recertification survey on 4/28/17. Review of the personnel competency records on 3/12/19 revealed that a semiannual competency evaluation was not performed and documented for one (1) out of three (3) new testing personnel for calendar year 2018. TP2 confirmed in an interview on 3/12/19 at 1:25 P.M. that the TC failed to perform and document semiannual competency evaluations for TP2.

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 record review and interview with the TP2 on 3/12/19, the TC failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year as evidenced by the following: Review of the personnel competency records on 3/12/19 revealed that an annual competency evaluation was not performed and documented for one (1) out of three (3) testing personnel for calendar year 2018. TP2 confirmed in an interview on 3/12/19 at 1:25 P.M. that the TC failed to perform and document annual competency evaluations for TP4.