

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2066157	(X3) Date Survey Completed 06/21/2019
Name of Provider or Supplier Medlogic, Llc	Street Address, City, State 340 East Parker Street, Baton Rouge, LA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Medlogic, LLC-CLIA ID # 19D2066157 on June 19, 2019 through June 21, 2019. Based on review of the laboratory's Allegation of Compliance and Plan of Correction, record review, and interview with personnel, the laboratory failed to follow policies for personnel competency assessment. Findings: 1. Review of the laboratory's Allegation of Compliance and Plan of Correction revealed the following: a) "Laboratory director to perform competency assessments directly, or delegate this authority to the laboratory supervisor as appropriate. Delegation form to be signed and competency of personnel to be assessed as CLIA schedule dictates. Completion date: 4/30/19" b) "Delegation of authority form from lab director to be signed to allow lab supervisor to perform certain competency assessments. Completion date: 4/30/19" 2. Surveyors requested competency records for Testing Personnel 1 on June 20, 2019. 3. Surveyors were given competency records for Testing Personnel 1 on June 21, 2019. Review of the competency records revealed the "Medonic Training Checklist, AU480 Training Checklist, Access2 Training Checklist, Chemistry Access2 Competency Quiz, and Hematology Competency Quiz" were completed on June 18, 2019. The identified competency quizzes did not include graded scores, to indicate if met " > 80 %" passing requirement. 4. Further review of the competency records revealed the "Director or Designee" did not perform or approve/sign the assessment. 5. In interview on June 21, 2019, Testing Personnel 2 confirmed she performed the identified competency assessments for Testing Personnel 1.</p>

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

A Revisit survey was performed at Medlogic, LLC-CLIA ID # 19D2066157 on June 19, 2019 through June 21, 2019. Based on review of the laboratory's Allegation of Compliance and Plan of Correction, observation, record review, and interview with laboratory personnel, the Technical Consultant failed to provide technical and scientific oversight of the laboratory. Findings: 1. The laboratory failed to follow their Allegation of Compliance and Plan of Correction for written request from physicians. Refer to D5301. 2. The laboratory failed to ensure test requisitions included all tests performed at the laboratory. Refer to D5305 I. 3. The laboratory failed to ensure test requisitions included the collection time. Refer to D5305 II. 4. The laboratory failed to ensure patient blood samples for Chemistry and Hematology testing are stored per manufacturer requirements. Refer to D5311. 5. The laboratory failed to document the time specimens are received into the laboratory. Refer to D5313. 6. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 7. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 8. The laboratory failed to ensure the procedure manual contained complete policies and procedures. Refer to D5403. 9. The laboratory failed to ensure supplies and reagents have not exceeded their expiration date. Refer to D5417. 10. The laboratory failed to follow their plan of correction to ensure the collection and report dates and times are accurately being transferred from the point of entry, through the testing process to final report destination. Refer to D5801 I. 11. The laboratory failed to ensure patient test results were reported within 48 hours per the laboratory's Plan of Correction. Refer to D5801 II. 12. The laboratory failed to ensure patient test results were reported. Refer to D5801 III. 13. The laboratory failed to ensure the laboratory's LIS transmitted accurate results. Refer to D5801 IV. 14. The laboratory failed to provide documentation of provider notification of unacceptable samples. Refer to D5805 I. 15. The laboratory failed to ensure the name and address of the reference laboratory that performed testing was included on patient final reports. Refer to D5805 II. 16. The laboratory failed to provide reference intervals on final test reports for all Chemistry tests performed. Refer to D5807 I. 17. The laboratory failed to ensure reference intervals provided on final reports reflect the laboratory's established values. Refer to D5807 II. 18. The laboratory failed to have system in place to ensure providers are notified of critical values. Refer to D5813.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

A Revisit survey was performed at Medlogic, LLC-CLIA ID # 19D2066157 on June 19, 2019 through June 21, 2019. Based on review of the laboratory's Allegation of

	<p>Compliance and Plan of Correction, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.</p>
<p>D6042</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Medlogic, LLC-CLIA ID # 19D2066157 on June 19, 2019 through June 21, 2019. Based on review of the laboratory's Allegation of Compliance and Plan of Correction, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5441 and D5469.</p>
<p>D6043</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5)</p> <p>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Medlogic, LLC-CLIA ID # 19D2066157 on June 19, 2019 through June 21, 2019. Based on review of the laboratory's Allegation of Compliance and Plan of Correction, record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: A Revisit survey was performed at Medlogic, LLC-CLIA ID # 19D2066157 on June 19, 2019 through June 21, 2019. Based on review of the laboratory's Allegation of Compliance and Plan of Correction, record review, and interview with personnel, the Technical Consultant failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D5209.</p>