

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2066157	(X3) Date Survey Completed 04/30/2018
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
D0000	An Initial Certification Survey was conducted on April 30, 2018 at Medlogic, LLC - CLIA ID # 19D2066157. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure that proficient testing (PT) documents were signed appropriate personnw1. Findings: 1. Review of the laboratory's PT records for 2017 and 2018 revealed the attestation statements were signed by the testing personnel only. The laboratory director did not sign all PT documents. 2. In interview on April 30, 2018, Personnel 2 stated the laboratory director was not on site to sign all documents but comes quarterly and reviews all proficiency testing documents. Personnel 2 confirmed that testing personnel also listed as general supervisor had signed PT documents.</p>
D6091	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p>

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to ensure all proficiency test reports attestation statements were signed. Refer to D2015.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure competency was assessed for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed competency assessment forms for all stages of high complexity testing for both platforms as well as accessioning competency. 2. Review of competency assessment available for Testing Personnel revealed only an accessioning competency was performed. 3. In interview on April 30, 2018 , Personnel 2 confirmed the full competency to cover all testing platforms and stages of testing was not documented for testing personnel.