Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2066157	07/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Medlogic, Llc	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	A Complaint Survey was performed at Medlogic, LLC- CLIA ID 19D2066157 on July 29, 2020 through July 29, 2020. Medlogic, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and testing of samples 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure proficiency testing samples were not referred to another laboratory for testing. Refer to D2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its

certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on direct observation by surveyors, review of the laboratory's proficiency testing (PT) records and CLIA 116 application, as well as interview with the Technical Supervisor and manager, the laboratory failed to ensure 2019 and 2020 College of American Pathologists (CAP) proficiency samples for respiratory and COVID testing issued to the laboratory (19D2066157) were not referred to another CLIA laboratory (19D2185370) for testing. Findings: 1. In interview on July 27, 2020 at 10:16 am, Technical Supervisor 1 of their sister laboratory (19D2185370 - Molecular) stated prior to June 3, 2020 the Respiratory Panel and COVID testing were performed under this laboratory's CLIA Identification number, 19D2066157. 2. Review of the laboratory's (19D2066157) CLIA 116 Application revealed the laboratory is enrolled in Chemistry and Hematology specialties, not in Bacteriology and Virology. 3. Interview with the Technical Supervisor on July 29, 2020 at 9:30am revealed the laboratory (19D2066157) ceased testing in February 2020. 4. Review of the CLIA 116 Initial Application for the sister-molecular laboratory 19D2185370 revealed the Louisiana State Agency received their CLIA application June 1, 2020. The specialties for testing indicated on the application were Bacteriology and Virology. 5. Review of the Disclosure of Ownership and CLIA 116 applications for this laboratory 19D2066157 and the sister-molecular laboratory 19D2185370 revealed the laboratories share the same owner but different Laboratory Directors. 6. Review of the laboratory's (19D2066157) PT documents revealed the following three (3) PT events referred to the sister molecular laboratory (19D2185370): IDR-B 2019 Infectious Disease, Respiratory; Method: Lab-Developed Test; Original Evaluation: 08 /16/2019 IDR-C 2019 Infectious Disease, Respiratory; Method: Lab-Developed Test; Original Evaluation: 1/10/2020 COV2-A 2020; SARS-CoV-2, Molecular 2020; Original Evaluation: 07/02/2020 7. In interview on July 27, 2020 at 11:00 am, Testing Personnel 1 from the sister-molecular laboratory (19D2185370) stated he did not keep instrument printouts, but that he manually wrote patient results prior to June 2020 for Respiratory Panel testing. 8. Further review of the 2019 PT documents for laboratory 19D21066157 revealed Technical Supervisor 1 of the sister-molecular laboratory (19D2185370) signed the CAP evaluation forms for both events on May 26, 2020. 9. Further review of the CAP PT 2019 & 2020 evaluation forms revealed the laboratory performed PT testing on five (5) samples of each for the following viruses and bacteria: Influenza A virus, Influenza B virus, Parainfluenza, RSV, Rhinovirus /Enterovirus, Metapneumovirus, Adenovirus, Chlamydophila pneumonia, Mycoplasma pneumonia, Legionella pneumophila, Bordetella pertussis, Bocavirus, Parainfluenza virus IV, and Coronavirus. 10. Review of proficiency test records for Respiratory and COVID testing revealed the laboratory did not include the following: a) 2019 IDR-B Infectious Disease, Respiratory: signed attestation statement and raw instrument data b) 2019 IDR-C Infectious Disease, Respiratory: signed attestation

	statement and raw instrument data c) 2020 COV2-A: signed attestation statement 11. Review of CAP records for COV2-A 2020 revealed the PT event was issued to 19D2066157 on May 18, 2020. Raw data reviewed confirmed the samples were tested on June 10, 2020 by Testing Personnel 1 of the sister laboratory (19D2185370). The event was signed by the laboratory director of the sister laboratory (19D2185370) on July 29, 2020. The testing performed by the sister laboratory (19D2185370) was evaluated by CAP and copied to CMS under 19D2066157 on July 2, 2020. 12. In interview on July 27, 2020 at 10:05 am the Quality Assurance personnel for the sister laboratory (19D2185370) stated the sister laboratory began COVID testing on May 15, 2020. In interview on July 27, 2020 at 10:09 am Technical Supervisor 1 of the sister laboratory (19D2185370) stated the sister laboratory began respiratory testing on April 26 or 28, 2020. In interview on July 27, 2020 at 11:05 am, Testing Personnel from sister laboratory (19D2185370) stated the sister laboratory began respiratory testing in March 2020. 13. Defined date when patient testing or proficiency testing moved from the original laboratory to the sister laboratory is undetermined. 14. Direct observation by surveyors on July 27, 2020 at 11:27 am, revealed the sister laboratory (19D2185370) had the 2020 second event "IDR-B 2020 Infectious Disease, Respiratory Panel" CAP PT paperwork in the laboratory testing area. Review of the 2020 second event PT records for Respiratory Panel revealed the CLIA ID number indicated on the PT paperwork was 19D2066157, not the sister molecular laboratory (19D2185370). 15. In interview on July 27, 2020 at 11:27 am, Testing Personnel from the sister laboratory (19D2185370) stated the laboratory performed a CAP PT testing event for respiratory in December 2019. 16. In interview on July 29, 2020 at 10:28 am, the Manager of the sister laboratory (19D2185370) stated for 2020 the first PT event was missed for respiratory tested. The Manager further stated he ordered respiratory and COVID PT events from CAP on May 15, 2020. 17. In interview on July 29, 2020 at 3:44 pm, the Manager of the sister laboratory (19D2185370) stated he had contacted CAP about the CLIA ID number within the last 3 weeks. He further stated he thought the CLIA ID number on the 2020 second event was corrected to 19D2185370 and was unsure of why it had not been changed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2013.