Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2228726	05/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Covenant Laboratories Llc	290 Hancock Square Dr, Bay Saint Louis, MS	

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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records and patient test logs for Real Time-Polymerase Chain Reaction (RT-PCR) testing with the Applied Biosystem QuantStudio 5 amplification instrument from 9/13/21 through 12/31/21, review of the laboratory's PCR Standard Operating Procedure manual, lack of documentation of an Individualized Quality Control Plan (IQCP), and confirmation by the general supervisor, the laboratory failed to include a positive control each day of patient testing during this time frame for each organism on the three pathogen panels tested. A total of two patient Sexually Transmitted Infection (STI) panels, nine patient Urinary Tract Infection (UTI) panels, and nineteen patient Respiratory Pathogen panels (RPP) were tested and results reported on fourteen testing days during this time frame when a positive control for each organism was not performed. Findings include: Review of the PCR Standard Operating Procedure manual revealed the PCR test procedure states, "Once a week a QC plate (containing all of the validated molecular assays on that instrument) will be run to confirm the stability of the chemistry and all analytical systems for all assays." However, there was no documentation of the establishment of an Individualized Quality Control Plan (IQCP) for pathogen identification performed with the Applied Biosystem QuantStudio 5 amplification instrument, in order to reduce the frequency of quality control to weekly. The general supervisor confirmed an IQCP was not established. Review of quality control records and patient test logs for RT-PCR testing with the Applied Biosystem QuantStudio 5

	amplification instrument from 9/13/21 through 12/31/21 revealed a positive control was not included for each organism tested on these panels on the following days when patient specimens were tested and results reported: STI Panel Testing (includes 11 organisms) 9/16/21--Patient #1B21I15001. 11/10/21--Patient #1921K09001. UTI Panel Testing (includes 19 organisms) 9/16/21--Patient #1B21I15001. 9/22/21--Patients #1B21I21001, #1B21I21002. 10/8/21--Patients #1921J08002, #1921J08003, #1921J08004. 10/22/21--Patient #1C21J22001. 12/18/21--Patient #1921L17002. 12/28/21--Patient #1921L27003. RP Panel Testing (includes 27 organisms) 9/22/21--Patient #1521I21001. 10/22/21--Patient #1321J21001. 12/17/21--Patient #1921L16001, #1B21L17001, #1B21L17002, #1B21L17003, #1B21L17004, #1B21L17005. 12/18/21--Patient #1921L17001, #1B21L18001, #1I21L18001. 12/29/21--Patient #1921L28001, #1921L28003, #1921L28004, #1921L28006, #1921L28007. 12/30/21--Parient #1B21L30006, #1921L29003, #1921L29009.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control records and patient test logs for Real Time-Polymerase Chain Reaction (RT-PCR) testing with the Applied Biosystem QuantStudio 5 amplification instrument from 9/13/21 through 12/31/21, review of the laboratory's PCR Standard Operating Procedure manual, lack of documentation of an Individualized Quality Control Plan (IQCP), and confirmation by the general supervisor, the laboratory director failed to ensure a quality control program was established to include a positive control each day of patient testing for each organism on the three pathogen panels tested. A total of two patient Sexually Transmitted Infection (STI) panels, nine patient Urinary Tract Infection (UTI) panels, and nineteen patient Respiratory Pathogen panels (RPP) were tested and results reported on fourteen testing days during this time frame when a positive control for each organism was not performed. Refer to D5449 (Failure to ensure a positive and negative control were performed each day of patient testing).