

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2228726	(X3) Date Survey Completed 01/23/2024
Name of Provider or Supplier Covenant Laboratories Llc	Street Address, City, State 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, lack of verification of accuracy, and interview with the technical supervisor, the laboratory failed to verify the accuracy, at least twice annually, of Real Time-Polymerase Chain Reaction (RT-PCR) testing with the Applied Biosystem QuantStudio 5 amplification instrument for organisms and antibiotic resistant genes on three, of four, identification panels, used for patient testing. Findings include: 1. Review of proficiency testing records since the last survey on 5/19/2022 and lack of documentation of verification of accuracy revealed the laboratory failed to verify the accuracy, at least twice annually, for the following three, of four, RT-PCR identification panels used for patient testing since 5/19/2022: (a) Sexually Transmitted Infection (STI) panel, which included 11 organisms--Chlamydia trachomatis, Gardnerella vaginalis, Haemophilus ducreyi, Herpes Simplex Virus-1, Herpes Simplex Virus-2, Mycoplasma genitalium, Mycoplasma hominis, Neisseria gonorrhoeae, Treponema pallidum, Trichomonas vaginalis, Ureaplasma urealyticum. The laboratory's annual volume for STI panels was 1,238. (b) Urinary Tract Infection (UTI) panel, which included 19 organisms--Candida albicans, Candida glabrata, Candida parapsilosis, Candida tropicalis, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Mycoplasma hominis, Proteus mirabilis, Providencia stuartii, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus saprophyticus, Streptococcus agalactiae, Ureaplasma urealyticum. The laboratory's annual volume for UTI panels was 1,857. (c) Antibiotic Resistant Gene (ABR) panel, which included 6 antibiotic resistant genes--Verona integron-encoded metallo-Beta-lactamase, Klebsiella pneumoniae</p>

carbapenemase, Sulphydryl Variable-Beta-lactamase, Methyl Resistant Staphylococcus aureus, Vancomycin A, Vancomycin B. 2. In an interview on 1/23 /2024 at 2:45 p.m., the technical supervisor confirmed the laboratory failed to verify the accuracy of the UTI, STI, and ABR panels, at least twice annually.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of RT-PCR pathogen identification test reports in patients' electronic medical records and interview with the owner of the laboratory, the laboratory test reports reviewed in the electronic medical record system did not include one of seven test report indicators. Findings include: 1. Review of test reports in patients' electronic medical records failed to include one of seven test report indicators. The laboratory's patient test report did not include the address of the laboratory location where the tests were performed. 2. Interview with the owner of the laboratory on 1/23/2024 at 1:30 p. m. revealed the current electronic medical record system was put in use on 11/20 /2023.