Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2287599	01/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Physician Services Of The Gulf Coast Llc	2369 Pass Rd, Biloxi, 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
D0000	A complaint survey was conducted on 1/25/2024 at Physician Services of the Gulf Cost LLC, 2369 Pass Road, Biloxi, Mississippi 39531.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(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 molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedures,quality control records, patient test logs for Real Time-Polymerase Chain Reaction (RT-PCR) testing with the Applied Biosystem QuantStudio 5 amplification instruments, and interview with the testing personnel, the laboratory failed to include a positive control each day of patient testing for 16 of 16 weeks reviewed for each organism or gene on the four pathogen identification panels tested. Findings included: 1. Review of the laboratory's standard operating procedure manual revealed no documentation of the establishment of an Individualized Quality Control Plan (IQCP) for pathogen identification performed with the two Applied Biosystem QuantStudio 5 amplification instruments, in order to reduce the frequency of daily quality control 2. Review of quality control records and patient test logs for RT-PCR testing with the two Applied Biosystems QuantStudio 5 amplification instruments, Instrument #1 (Serial #27514490) and Instrument #2 (Serial #272514220), from 10/9/23 through 1/23/24 revealed a positive control was not included for each organism or gene tested on these panels each day of patient testing for 16 of 16 weeks with each of the QuantStudio 5 amplification instruments. Quality

control records revealed only weekly positive controls were performed for the organisms and antibiotic resistant genes in the panels listed below, alternating between Instrument #1 and Instrument #2. (a) Respiratory Pathogen (RP) Lite panel (which included 8 organisms--Influenza A, Influenza B, respiratory syncytial virus, SARS-Coronavirus-2, Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae,Streptococcus pyogenes) positive controls were not performed for each day of patient testing on Instrument #1 (panel put into use on 10/11/23) for the following 6 weeks of 16 testing weeks: 10/23/23 through 10/28/23 11/6/23 through 11 /11/23 11/20/23 through 11/25/23 12/4/23 through 12/9/23 12/25/23 through 12/30/23 1/15/24 through 1/20/24 RP Lite panel positive controls were not performed for each day of patient testing on Instrument #2 (panel put into use on 12/27/23) for the following 2 weeks of 5 testing weeks: 1/1/24 through 1/6/24 1/8/24 through 1/13/24 In an interview on 1/25/2024 at 3:30 p.m., the testing personnel stated that patient RP Lite panels were performed on Instrument #1 from 10/11/2023 through 1/23/2024 five days per week and on Instrument #2 from 12/27/23 through 1/23/24 five days per week. A total of 213 patient RP Lite panels were tested during this time frame. (b) Respiratory Pathogen Plus (RPP) panel (which included 35 organisms and one antibiotic resistant gene--adenovirus, bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Epstein-Barr virus, enterovirus, human metapneumovirus A, human metapneumovirus B, Influenza A, Influenza B, parainfluenza 1, parainfluenza 2, parainfluenza 3, parainfluenza 4, rhinovirus, respiratory syncytial virus, SARS-Coronavirus-2, Acinetobacter baumannii, Bordetella pertussis, Chlamydophila pneumoniae, Enterobacter cloacae, Haemophilus influenzae, Klebsiella aerogenes,Klebsiella pneumoniae, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, methicillin/oxacillin resistance) positive controls were not performed each day of patient testing on Instrument #1 for the following 6 weeks of 8 testing weeks: 12/5/23 through 12/9/23 12/18/23 through 12/23 /23 12/25/23 through 12/30/23 1/1/24 through 1/6/24 1/8/24 through 1/13/24 1/15/24 through 1/20/24 RPP panel positive controls were not performed on each day of patient testing on Instrument #2 for the following 3 weeks of 8 testing weeks: 12/11 /23 through 12/16/23 12/18/23 through 12/23/23 12/25/23 through 12/30/23 In an interview on 1/25/2024 at 3:50 p.m., the testing personnel stated that patient RPP panels were performed on both Instrument #1 and Instrument #2 from 12/5/2023 through 1/23/2024 five days per week. A total of 82 patient RPP panels were tested during this time frame. (c) Sexually Transmitted Infection (STI) panel (which included 9 organisms--Atopobium vaginae, Chlamydia trachomatis, Gardnerella vaginalis, Haemophilus ducreyi, Herpes Simplex Virus-1, Herpes Simplex Virus-2, Neisseria gonorrhoeae, Treponema pallidum, Trichomonas vaginalis) positive controls were not performed on each day of patient testing on Instrument #1 for the following 4 weeks of 10 testing weeks: 12/4/23 through 12/9/23 12/18/23 through 12 /23/23 12/25/23 through 12/30/23 1/8/24 through 1/13/24 STI positive controls were not performed on each day of patient testing on Instrument #2 for the following 5 weeks of 10 testing weeks: 12/4/23 through 12/9/23 12/11/23 through 12/16/23 12/25 /23 through 12/30/23 1/1/24 through 1/6/24 1/15/24 through 1/20/24 In an interview on 1/25/2024 at 3:50 p.m., the testing personnel stated that patient STI panels were performed on both Instrument #1 and Instrument #2 from 11/21/2023 through 1/23 /2024 five days per week. A total of 44 patient STI panels were tested during this time frame. (d) UTI/Wound panel (which included 20 organisms--Acinetobacter baumannii, Bacteroides fragilis, Citrobacter freundii, Citrobacter braakii, Citrobacter koseri, Enterobacter cloacae, Entercoccus, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella michiganensis, Klebsiella pneumoniae, Morganella

	morganii, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus saprophyticus, Streptococcus pyogenes; and 9 antibiotic resistant genes--Class A Beta-lactamase, Class A Beta-lactamase CTX-M-Group 1, Class B metallo Beta-lactamase, fluoroquinolones, methicillin/oxacillin resistance, sulfonamides, trimethoprim, Vancomycin A, Vancomycin B) positive controls were not performed on each day of patient testing on Instrument #1 for the following 4 weeks of 11 testing weeks: 12/4 /23 through 12/9/23 12/18/23 through 12/23/23 1/1/24 through 1/6/24 1/8/24 through 1 /13/24 UTI/Wound panel positive controls were not performed on each day of patient testing on Instrument #2 for the following 5 weeks of 11 testing weeks: 12/4/23 through 12/9/23 12/11/23 through 12/16/23 12/18/23 through 12/23/23 12/25/23 through 12/30/23 1/15/24 through 1/20/24 In an interview on 1/25/2024 at 3:50 p.m., the testing personnel stated that patient UTI/Wound panels were performed on both Instrument #1 and Instrument #2 from 11/17/2023 through 1/23/2024 five days per week. A total of 140 patient UTI/Wound panels were tested during this time frame. 3. In an interview on 1/25/2024 at 3:50 p.m., the individual designated as testing personnel on the CMS 209 personnel form confirmed an IQCP for pathogen identification panels was not established for the four panels performed on the two Applied Biosystems QuantStudio 5 amplification instruments, Instrument #1 (Serial #27514490) and Instrument #2 (Serial #272514220).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for 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. This STANDARD is not met as evidenced by: Based on review laboratory procedures, quality control records, patient test logs for RT-PCR testing with the Applied Biosystem QuantStudio 5 amplification instruments, and interview with the testing personnel, the technical supervisor failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance for RT-PCR testing when the laboratory failed to include a positive control each day of patient testing for 16 of 16 weeks reviewed for each organism or gene on the four pathogen identification panels tested. Refer to D5455.