Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2245388	07/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Us Lab Holdings Llc Dba Modus Laboratories	2500 East T C Jester Blvd, Suite 201, Houston, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on the review of the laboratory's test menu and policies, patient results in July 2022, and confirmed in an interview found the laboratory failed to have a client service manual to include acceptability and rejection criteria for both the PCR wound and urinary tract microbiota (UTM) panel for 2 of 2 specimen type: wound and urine. The findings were: 1. Review of the laboratory's records revealed the laboratory performed the laboratory developed polymerase chain reaction (PCR) assays of wound and urinary tract microbiota (UTM) panel for on 2 of 2 specimen type: wound and urine. Wound Panel Bacterial targets: Acinetobacter baumannii Anaerococcus vaginalis Bacteroides fragilis Bartonella henselae Campylobacter coli, Campylobacter jejunii Citrobacter freundii Clostridioides difficile toxins A and B Clostridium botulinum Clostridium perfringens Corynebacterium striatum, Corynebacterium jeikeium Enterobacter cloacae, Klebsiella aerogenes Enterococcus spp Escherichia coli. Escherichia coli EIEC Escherichia coli EPEC Escherichia coli ETEC Escherichia coli serotype O157 Fusobacterium canifelinum, Fusobacterium nucleatum Haemophilus influenzae Klebsiella spp. Listeria monocytogenes Morganella morganii Mycobacerium marinum Mycobacerium tuberculosis complex Mycobacerium chelonae, Mycobacerium fortuitum Mycobacerium kansasii Mycobacerium ulcerans

	Mycobacteroides abscessus Mycoplasma hominis, Mycoplasma genitalium Pasteurella multocida Peptoniphiliu spp. Peptrostreptococcus spp. Prevotella spp. Proteus mirabilis Pseudomonas aeruginosa Salmonella enterica Serratia marcescens Staphylococcus aureus and enterotoxins A and B Staphylococcus haemolyticus, Staphylococcus lugdunensis Stenotrophomonas maltophilia Streptococcus agalactiae Streptococcus pneumoniae Streptococcus pyogenes Vibrio spp. Yersinia enterocolitica Fungal targets: Candida albicans, Candida parapsilosis, Candida glabrata, Candida tropicalis Candida auris Trichophyton mentagrophytes, Trichophyton tonsurans, Trichophyton interdigitable, Trichophyton rubrum Trichophyton rubrum Trichophyton soudanense, Trichophyton violaceum Viral targets: Human Papilloma virus HPV16 Human herpesvirus 3, Varicella Zoster virus Urinary tract microbiota (UTM) Panel Bacterial targets: Acinetobacter baumannii Actinobaculum schaalii Aerococcus urinae Alloscardovia omnicolens Citrobacter freundii Citrobacter koseri Corynebacterium riegelii Enterobacter cloacae Enterococcus faecalis Enterococcus faecium Escherichia coli Klebsiella aerogenes Klebsiella oxytoca Klebsiella pneumoniae Morganella morganii Mycoplasma hominis Pantoea agglomerans Proteus mirabilis Proteus vulgaris Providencia stuartii Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Streptococcus agalactiae Staphylococcus urealyticum Viridans Goup Strep Fungal targets: Candida albicans Candida auris Candida glabrata Candida parapsilosis 2. Review of the laboratory's policies revealed no documentation of the required criteria for specimen acceptability and rejection provided to the clients for two of two specimen sources: Wound and urine samples. 3. Review of the laboratory's patient results for wound and urine revealed the first patient report for wound was on 7/8/22 and the first patient report for urine was on 7/18/22. 4. Random review of patient results in July, 2022 revealed 10 patient samples. Wound samples: 7/11/22 Accession#: W-22-000111 7/22 /22 Accession#: W-22-000118 7/25/22 Accession#: W-22-000127 Urine samples: 7/18 /22 Accession#: U-22-000112 7/18/22 Accession#: U-22-000113 7/18/22 Accession#: U-22-000114 7/20/22 Accession#: U-22-000115 7/20/22 Accession#: U-22-000116 7 /25/22 Accession#: U-22-000122 7/25/22 Accession#: U-22-000124 4. An interview with the general supervisor on 7/27/22 at 2:30 pm in the processing room confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the review of the manufacturer specification of the refrigerator, the manufacturer's product information sheet, the laboratory's temperature log in July 2022, policies, patient results, and confirmed in an interview found the laboratory failed to follow the manufacturer's instructions of storage temperature for three of 20 days reviewed for three of three control lot numbers. The findings were: 1. Surveyor's direct observation on 7/27/22 at 4:00 pm in the freezer portion of POST AMP FRIDGE 1 revealed three lot numbers of TaqMan

	Comprehensive Microbiota Controls. Lot#: 3225970 Exp: Jan-22 Opened date: 3/16 /22 Lot#: 3225968 Exp: Jan-22 Lot#: 3225969 Exp. Jan-22 2. Surveyor's direct observation on 7/27/22 at 4:05 pm at the post amplification room revealed the refrigerator was manufactured by Frigidaire. Model No: FRTD2021ASO SN: 4A1460773 3. Review of the manufacturer specification Top Freezer Refrigerator 20.5 Cu. Ft. Top Freezer Refrigerator FRTD2021AS, FRTD2021AW, FRTD2021AB (Version: 09/21) revealed under Freezer "Automatic Defrost: Yes". Note: frost-free freezers eliminate frost by raising the temperature inside the freezer a few times a day, from about 0 degrees to 32 4. Review of the Applied Biosystems TaqMan Comprehensive Microbiota Control Product Information Sheet (Pub. No. MAN0024964 Rev. C.0) revealed under Contents and storage, "Store the TaqMan Comprehensive Microbiota Control at -25C to -15C." 5. Review of the laboratory's temperature log in July 2022 revealed the temperature was out of acceptable range for POST AMP FRIDGE 1 for three of 20 days reviewed. 7/18/22 -6.6C 7/20/22 -6.6C 7 /25/22 -6.6C 6. Review of the laboratory's policy titled PCR Prep Accufill and Quantstudio 12K Loading, signed by the laboratory director on 5/5/22, under Sample Plate Preparation revealed "5....a. For UTM Use TaqMan Comprehensive Microbiota Control (A50382)." 7. Random review of the patient results on urine samples for 7/18 /22, 7/20/22, and 7/22/22 revealed seven patients tests were performed. 7/18/22 Accession#: U-22-000112 7/18/22 Accession#: U-22-000113 7/18/22 Accession#: U-22-000114 7/20/22 Accession#: U-22-000115 7/20/22 Accession#: U-22-000116 7/25 /22 Accession#: U-22-000122 7/25/22 Accession#: U-22-000124 8. An interview with the general supervisor on 7/27/22 at 4:14 pm in the office confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on the review of the laboratory's stability study, the manufacturer's inserts, the patient reports in July 2022, and confirmed in an interview found the laboratory failed to have documentation for preanalytical studies to include all bacterial, fungal, and viral targets on patient reports for two of two samples types in a laboratory developed polymerase chain reaction (PCR) of wound and urinary tract microbiota (UTM) panels. A. Wound swabs B. Urine samples The findings were: 1. Review of the patient reports in July 2022 revealed the laboratory tests two sample types: wound swab and urine samples. A. Wound swabs 2. Review of the laboratory's stability validation records titled "Addendum to Clinical Validation of ThermoFisher TaqMan Wound pathogen Assays and Antibiotic Resistance on the QuantStudio 12K Flex OpenArray Platform" under 2.1 Stability Study revealed "Contrived samples were purchased from ZeptoMetrix utilizing the NATtrol BC/GN Panel." 3. Review of the

	manufacturer's insert ZeptoMetrix (COANATBCGN-NNS PCA#21-112 & 21-172) for NATtrol BC/GN Panel-NNS revealed it contains the following targets: K. oxytoca (Z115) P. aeruginosa (Z139, VIM1) E. coli (ETEC) A. baumannii (307-0294) P. mirabilis (Z050) C. freundii (Z064) E. colacae (Z101) Providencia sp. (Z137, NDM1) K. pneumoniae (KPC2) K. pneumoniae (Z135) K. pneumoniae (Z138, OXA 48, CTX-M) Negative 4. Review of patient reports in July 2022 revealed 44 of 52 bacterial, fungal, and viral targets were not included in the stability study for wound swab. Bacterial targets: Anaerocuccus vaginalis Bacteroides fragilis Bartonella henselae Campylobacter coli, Campylobacter jejunii Clostridioides difficile toxins A and B Clostridium botulinum Clostridium perfringens Corynebacterium striatum, Corynebacterium jeikeium Enterococcus spp. Escherichia coli EIEC Escherichia coli EPEC Escherichia coli serotype O157 Fusobacterium canifelinum, Fusobacterium nucleatum Haemophilus influenzae Listeria monocytogenes Morganella morganii Mycobacerium marinum Mycobacerium tuberculosis complex Mycobacerium chelonae, Mycobacerium fortuitum Mycobacerium kansasii Mycobacerium ulcerans Mycobacteroides abscessus Mycoplasma hominis, Mycoplasma genitalium Pasteurella multocida Peptoniphiliu spp. Peptrostreptococcus spp. Prevotella spp. Salmonella enterica Serratia marcescens Staphylococcus aureus and enterotoxins A and B Staphylococcus haemolyticus, Staphylococcus lugdunensis Stenotrophomonas maltophilia Streptococcus agalactiae Streptococcus pneumoniae Streptococcus pyogenes Vibrio spp. Yersinia enterocolitica Fungal targets: Candida albicans, Candida parapsilosis, Candida glabrata, Candida tropicalis Candida auris Trichophyton mentagrophytes, Trichophyton tonsurans, Trichophyton interdigitable, Trichophyton rubrum Trichophyton rubrum Trichophyton soudanense, Trichophyton violaceum Viral targets: Human Papilloma virus HPV16 Human herpesvirus 3, Varicella Zoster virus 5. Random review of patient results in July, 2022 revealed three patient reports on wound swabs samples. 7/11/22 Accession#: W-22-000111 7/22/22 Accession#: W-22-000118 7/25/22 Accession#: W-22-000127 B. Urine samples 6. Review of the laboratory's stability validation records titled "Clinical Validation of ThermoFisher Urinary Tract Microbiota TaqMan Assays and Antibiotic Resistance Markers on the QuantStudio 12K Flex OpenArray Platform" under Table 2: Stability Experiment revealed the sample used was U_04. Under Table 9 Known Positives revealed U-04 contains Aerococcus urinae, Enterococcus faecalis, Streptococcus agalactiae, and Streptococcus epidermidis positive targets. 7. . Review of patient reports in July 2022 revealed 27 of 30 bacterial and fungal targets were not included in the stability study for urine samples. Bacterial targets: Acinetobacter baumannii Actinobaculum schaalii Alloscardovia omnicolens Citrobacter freundii Citrobacter koseri Corynebacterium riegelii Enterobacter cloacae Enterococcus faecium Escherichia coli Klebsiella aerogenes Klebsiella oxytoca Klebsiella pneumoniae Morganella morganii Mycoplasma hominis Pantoea agglomerans Proteus mirabilis Proteus vulgaris Providencia stuartii Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus urealyticum Viridans Goup Strep Fungal targets: Candida albicans Candida auris Candida glabrata Candida parapsilosis 8. Random review of patient results in July, 2022 revealed seven patient reports on urine samples. 7/18/22 Accession#: U-22-000112 7/18/22 Accession#: U-22-000113 7/18 /22 Accession#: U-22-000114 7/20/22 Accession#: U-22-000115 7/20/22 Accession#: U-22-000116 7/25/22 Accession#: U-22-000122 7/25/22 Accession#: U-22-000124 9. An interview with the general supervisor on 7/27/22 at 2:30 pm in the processing room confirmed the above findings.