Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161337	06/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Confirm Laboratory, Llc	2828 Forrest Lane #1119, Dallas, 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	An entrance conference was held with the laboratory representative. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The laboratory representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1240 Pre-Analytic Systems 493.1250 Analytic Systems 493.1441 Laboratory Director, (high complexity) Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of laboratory polymerase chain reaction (PCR) twice annual accuracy assessment records and staff interview, the laboratory failed to test twice annual accuracy assessment samples the same number of times it routinely tests patient samples for 1 of 3 PCR accuracy assessment events in 2020. Findings included: 1. Review of the laboratory's PCR twice annual accuracy assessment results revealed the following three samples were part of the 2020 assessment: PT-1, PT-2, PT-3. The laboratory's accuracy assessment records included final reports that

	revealed 1 of 3 PCR accuracy assessment specimens had multiple test results: PT-1 A; PT-1 B; PT-1 C Infectious Disease Pathogens Organisms Detected: Acinetobacter baumannii; Citrobacter freundii; Enterobacter cloacae; Enterococcus faecium; Klebsiella oxytoca; Morganella morganii; Proteus vulgaris; Providencia stuartii; Staphylococcus aureus; Staphylococcus saprophyticus; Stenotrophomonas maltophilia 2. In an interview with Testing Person (TP) #1 in the conference room at 10:23 AM on 6/14/2021, TP #1 was given the opportunity to review the above findings. After review, Testing Person #1 stated 1 of 3 PCR accuracy assessment events in 2020 had no indications for repeat testing but was tested in triplicate. This confirmed the above findings.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on direct observation, review of the Quant Studio operator's guide, and interview of facility personnel, the laboratory failed to ensure the space and temperature requirements specified for the QuantStudio 12K Flex Real-Time PCR System. Findings: 1. During a tour of the laboratory on 06/15/2021 at 10:55 am, the surveyor noted that the post-PCR room housing the QuantStudio 12K Flex Real-Time PCR System had a wall from top to bottom of windows with open blinds. Observation of the room revealed the QuantStudio was placed on a table in direct sunlight. 2. Review of the Applied BioSystem QuantStudio 12K Flex PCR System Maintenance and Administration User Guide revealed: "1 Getting Started Specifications and layout ... Environmental requirements ... Requirement Altitude Description 15-30C [59-86F] Do not place the QuantStudio 12K Flex Instrument next to heaters, cooling ducts, or in direct sunlight. Temperature fluctuations can affect performance." The laboratory failed to ensure the QuantStudio 12K Flex instrument was not in direct sunlight per manufacturer's instructions. 3. During an interview on 06/15/2021 at 10:55 am, Testing Person-1 confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's polymerase chain reaction (PCR) accuracy assessment records, and staff interview, it was revealed the laboratory failed to review and evaluate the results obtained for 3 of 3 PCR samples in the 2020 accuracy assessment. Findings included: 1. Review of the laboratory's PCR accuracy assessment results revealed the following samples were part of the 2020 event: PT-1, PT-2, PT-3. Further review of the accuracy assessment records revealed there were no listed evaluations or reviews made by the laboratory director for the 3 of 3 PCR accuracy assessment samples in 2020. 2. In an interview with Testing Person (TP) #1 in the conference room at 10:23 AM on 6/14/2021, TP #1 was asked to provide documentation of evaluation or review of the 2020 accuracy assessment samples.

	Testing Person #1 stated an evaluation of results was requested from the laboratory director, but no evaluation was given. This confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory accuracy assessment records (2020) and confirmed in staff interview, the laboratory failed to verify the accuracy of non-regulated analytes at least twice annually in 2020 to ensure accurate and reliable test results. Findings included: 1. Review of laboratory records revealed the laboratory performed testing for the following unregulated analytes on the QuantStudio Real-Time PCR (polymerase chain reaction) (Serial Number 285581468): Enterococcus faecalis Staphylococcus aureus MecA (a gene found in bacterial cells which allows them to be resistant to antibiotics) Staphylococcus epidermidis Staphylococcus lugdunensis Streptococcus pyogenes Streptococcus aglactiae Escherichia coli Klebsiella pneumoniae Proteus mirabilis Pseudomonas aeruginosa Acinetobacter baumanni Bartonella henselea Strenotrophomonas maltophilia Bacteriodes fragilis Aeromonas hydrophila Trichophyton rubrum Trichophyton mentagrophytes Trichophyton tonsurans Epidermophyton floccosum Microsporum canis Geotrichum candidum Aspergillus fumigatus Fusarium keratoplasticum Scopularispsis bravicaulis Alternaria species Curvularia lunata Scytalidinum dimidiatum Candida albicans Candida tropicalis Candida parapsilosis 2. Review of laboratory accuracy assessment records in 2020, revealed the laboratory failed to perform twice annual accuracy assessments for the unregulated analytes listed above. 3. In an interview with Testing Person (TP) #1 at 10:23 AM on 6/14/2021, in the conference room, TP #1 was asked to provide documentation of a second annual accuracy assessment performed in 2020. Testing Person #1 stated an accuracy assessment was only performed once in 2020. This confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory policies, QuantStudio 12K Flex Nail and Wound PCR Panel establishment studies, patient test reports, and staff interview, the laboratory failed to meet the requirements for the preanalytical system, as evidenced by: 1. The laboratory failed to ensure that patient test records included necessary information to provide accurate interpretation of results for 6 of 6 randomly reviewed patient results in April 2021. Refer to D5305 2. The laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Wound PCR Panel

	establishment studies for specimen storage temperature requirements and failed to ensure specimens were stored at the established temperature. Refer to D5311, I 3. The laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Nail PCR Panel establishment studies for specimen storage temperature requirements for post-extraction nail specimens and failed to ensure specimens were stored at the established temperature. Refer to D5311,II 4. The laboratory failed to establish written policies for patient preparation, collection, labeling, storage and preservation, transportation, processing, and acceptability/rejection criteria for PCR (polymerase chain reaction) specimens received in the laboratory from outside clients. Refer to D5311, III.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of laboratory QuantStudio 12K Flex Nail and Wound PCR Panel establishment studies, laboratory policy, laboratory patient records, and confirmed in staff interview, the laboratory failed to ensure that patient test records included necessary information to provide accurate interpretation of results for 6 of 6 randomly reviewed patient results in April 2021. Findings included: 1. The laboratory QuantStudio 12K Flex Nail PCR Panel establishment studies stated the following: "E. Specificity Studies: ...We also tested potential interference from common chemicals and ointments used to treat nails cosmetically and medically ...The results of this study indicate that Mupriocin 2% ointment and Nail Polish significantly inhibit our PCR reaction. We will use this information to educate our clients in regard to specimen collection and will establish criteria to reject nail specimens treated with these 2 chemicals." 2. The laboratory QuantStudio 12K Flex Wound PCR Panel establishment studies stated the following: "E. Specificity Studies: ...We also tested potential interference from common chemicals and ointments used to treat nails cosmetically and medically ...The results of this study indicate that Ichthammol ointment and Nail Polish significantly inhibit our PCR reaction. We will use this information to educate our clients in regard to specimen collection and will establish criteria to reject nail specimens treated with these 2 chemicals." 3. The laboratory policy titled "Specimen Receiving and Storage Requirements" (signed by the laboratory director 06/08/2021), stated the following: "6. Specimen Rejection: Notify the supervisor at Precise Diagnostics for any of the below issues. The specimen will be received at Confirm Laboratory once the issue has been resolved. When there is a discrepancy between information on the test requisition and the specimen container.

	Do not accept or process the specimen. When there is no identification on a specimen container. When specimen source or the desired test is not marked on the requisition. When a specimen is received in a leaking container, is grossly contaminated, or is in a non-sterile container. Request a new specimen if the specimen is inappropriate for the test requested." The laboratory policy failed to establish criteria to reject nail or wound specimens treated with Mupriocin 2% ointment, Ichthammol ointment, or nail polish. 4. Review of the laboratory's requisition form revealed the laboratory failed to solicit information related to treatment with Mupriocin 2% ointment, Ichthammol ointment, or use of nail polish. 5. A random review of patient requisitions in April 2021 revealed the following 6 patients in which the laboratory failed to solicit information related to treatment with Mupriocin 2% ointment, Ichthammol ointment, or use of nail polish. Received Date: 04/23/2021; Patient CL21-1053 Received Date: 04/23/2021; Patient CL21-1054 Received Date: 04/23/2021; Patient CL21-1055 Received Date: 04/26/2021; Patient CL21-1068 Received Date: 04/26/2021; Patient CL21-1070 Received Date: 04/26/2021; Patient CL21-1075 6. During an interview on 06/14/2021 at 3:16pm in the conference room, the Technical Supervisor was asked if the laboratory solicited information related to treatment with Mupriocin 2% ointment, Ichthammol ointment, or nail polish or had a rejection policy for these substances. He confirmed that the laboratory did not request that information and did not have a rejection policy.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on direct observation, review of laboratory policy, review of QuantStudio 12K Flex Wound PCR Panel establishment studies, and staff interview, the laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Wound PCR Panel establishment studies for specimen storage temperature requirements and failed to ensure specimens were stored at the established temperatures. Findings included: 1. During a tour of the laboratory area on 06/14/2021 at 2:00PM, the following wound specimens collected on a swab were observed stored in the refrigerator at 9.1 C: CL21-1584 CL21-1585 CL21-1586 CL21-1587 CL21-1604 CL21-1608 2. The laboratory policy titled "Specimen Receiving and Storage Requirements" (signed by the laboratory director 06/08/2021), stated the following: "3. Specimen Type, Container Specifications, and Storage Conditions ...3.2 Swabs : Swabs from wound specimens are placed in a biohazard bag at room temperature. Once received in the laboratory, store @ 0-10 C ..." 3. The QuantStudio 12K Flex Wound PCR Panel establishment studies revealed the following: "G. Stability: In order to determine the stability of in common transport media used for analysis of wound samples, we spiked the following transport systems with 10,000 CFU/mL of S. aureus ...Eswab (Copan Diagnostics .... BD Aimes Gel Swab ...Sterile Urine Container ...The transport systems were then stored at room temperature for 24 hr, 1-week, 2-week, and 1-month. Samples were extracted and evaluated at baseline and at the end of each timepoint for recovery and detection in our PCR assay ...we can successfully recover DNA from organisms in

Eswabs and BD swabs that have been stored at room temperature for up to 1 month and in sterile containers for up to 1 week. We also tested the stability of purified DNA samples at refrigerated and frozen temperatures and determined that both conditions of storage ensure stability of our DNA post-extraction for at least 1 month." The laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Wound PCR Panel establishment studies for specimen storage temperature requirements. 4. In an interview on 06/14/2021 at 2:15PM in the conference room, Testing Person #1 was asked how swabbed wound specimens were received. She stated that the specimen is shipped at room temperature to a laboratory associated with Confirm Laboratory. The specimen is accessioned, requested tests are ordered, and the specimen is put into a refrigerator at the receiving laboratory. She further stated she will pick up Confirm Laboratory specimens from the refrigerator and put the swabbed wound specimens in the Confirm Laboratory refrigerator. Testing Person #1 was asked how temperature range of 0-10C was established for swabbed wound specimen storage. She stated that she always refrigerated the specimens and the range was based on the Confirm Laboratory's observed daily readings. The laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Wound PCR Panel establishment studies for specimen storage temperature requirements and failed to ensure specimens were stored at established temperatures. II. Based on direct observation, review of laboratory policy, review of QuantStudio 12K Flex Nail PCR Panel establishment studies, and staff interview, the laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Nail PCR Panel establishment studies for specimen storage temperature requirements for post-extraction nail specimens and failed to ensure specimens were stored at the established temperature. Findings included: 1. Observed during the tour of the laboratory area on 06/14/2021 at 2:00PM, were the following post-extraction nail specimens stored in the freezer at -19.6 C: CL21-1574; CL21-1575; CL21-1576; CL21-1577; CL21-1581; CL21-1585; CL21-1586; CL21-1587; CL21-1588; CL21-1589; CL21-1590; CL21-1591; CL21-1592; CL21-1593; CL21-1594; CL21-1595; CL21-1596; CL21-1597; CL21-1598; CL21-1599; CL21-1600; CL21-1601; CL21-1602; CL21-1603; CL21-1604; CL21-1605; CL21-1606; CL21-1607; CL21-1608; CL21-1609; CL21-1610 2. Review of the laboratory policy titled "Sample Pre-Processing (Purification) of Nails, Swabs and Soft Tissue" (signed by the laboratory director 06/08/2021) stated the following: "9.8 The samples are now ready for automated DNA extraction ....Note: Store pre-processed sample(s) at room temperature (15C to 30C) overnight or store at -25C to -15C for long term storage." 3. The QuantStudio 12K Flex Nail PCR Panel establishment studies stated the following: "G. Stability: In order to determine the stability of organisms in fresh nail, a sample of fresh, healthy nail was spiked with 100 femtogram purified DNA of T. rubrum. The sample was then evaluated for recovery of organism in our PCR assay following 24 hr, 1-week, 2-week, and 1-month storage at room temperature ....We also tested the stability of purified DNA samples at refrigerated and frozen temperatures and determined both conditions of storage ensure stability of our DNA post-extraction for at least 1 month ...." The establishment studies for post-extraction frozen specimens was documented for exactly -20C. The laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Nail PCR Panel establishment studies for post-extraction specimen storage temperature requirements. 4. In an interview on 06/14/2021 at 2:15PM in the conference room, Testing Person #1, after review of the findings, confirmed that post-extraction nail specimens were not stored at -20 C according to QuantStudio 12K Flex Nail PCR Panel establishment studies. 40420 III. Based on review of laboratory policies, CMS (Center for Medicare & Medicaid Services) 116 form, and confirmed in staff interview, the laboratory failed to establish written policies for patient preparation, collection, labeling, storage

	and preservation, transportation, processing, and acceptability/rejection criteria for PCR (polymerase chain reaction) specimens received in the laboratory from outside clients. Findings included: 1. Review of the laboratory's policy manual revealed the laboratory failed to establish written policies for patient preparation, collection, labeling, storage and preservation, transportation, processing, and acceptability /rejection criteria for PCR (polymerase chain reaction) specimens received in the laboratory from outside clients. The laboratory was asked to provide a client services manual, and none was provided. 2. Review of the CMS 116 form provided by the laboratory at the time of the survey revealed the laboratory had an annual volume of 102,500 PCR specimens. 3. During an interview on 06/14/2021 at 12:00 pm, Testing Person-1 stated the laboratory did not have a client services manual, confirming the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation review of laboratory policy, laboratory records, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements, as evidenced by: 1. The laboratory failed to ensure freezer temperature ranges were within manufacturer's specifications for 9 of 9 boxes of Applied BioSystems MagMax Viral/Pathogen Ultra Enzyme mix. Refer to D5413, I 2. The laboratory failed to ensure room temperature ranges were within manufacturer's specifications for 5 of 63 days in 2020 (10/2020-12/2020). Refer to D5413, II. 3. The laboratory failed to document complete establishment studies for all organisms tested on human nail and embedded nail specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Refer to D5423, I. 4. The laboratory failed to document complete establishment studies for all organisms tested on wound specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Refer to D5423, II. 5. The laboratory failed to document complete establishment studies for Quality Control (QC) material tested by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology for the Nail PCR Panel and the Wound PCR Panel. Refer to D5423, III. 6. The laboratory failed to perform weekly maintenance as required on the QuantStudio 12K Flex Instrument for 42 of 42 weeks in 2020 (03/2020-12/2020) and 20 of 20 weeks in 2021 (01/2021-05/2021). Refer to D5429. 7. The laboratory failed to document a negative and positive control each day patient specimens were analyzed for 7 of 7 tests on the QuantStudio 12K Flex PCR system (Nail Panel and Wound Panel). Refer to D5449.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory's policy manual, and interview with staff, the laboratory failed to ensure a written procedure for twice annual accuracy assessments of unregulated analytes was established. Findings included: 1. Review of the Centers for Medicare and Medicaid Services (CMS)-116 form revealed the laboratory performed polymerase chain reaction(PCR) testing on the following unregulated analytes: Enterococcus faecalis Staphylococcus aureus MecA (a gene found in bacterial cells which allows them to be resistant to antibiotics) Staphylococcus epidermidis Staphylococcus lugdunensis Streptococcus pyogenes Streptococcus aglactiae Escherichia coli Klebsiella pneumoniae Proteus mirabilis Pseudomonas aeruginosa Acinetobacter baumanni Bartonella henselea Strenotrophomonas maltophilia Bacteriodes fragilis Aeromonas hydrophila Trichophyton rubrum Trichophyton mentagrophytes Trichophyton tonsurans Epidermophyton floccosum Microsporum canis Geotrichum candidum Aspergillus fumigatus Fusarium keratoplasticum Scopularispsis bravicaulis Alternaria species Curvularia lunata Scytalidinum dimidiatum Candida albicans Candida tropicalis Candida parapsilosis 2. Review of the laboratory's policy/procedure manual revealed the laboratory did not have a written procedure for twice annual accuracy assessment for the above analytes. 3. In an interview with Testing Person (TP) #1 at 10:23 AM on 6/14/2021, in the conference room, TP #1 was asked if the facility had a policy for twice annual accuracy assessments. TP #1 stated the facility did not possess a twice annual accuracy assessment policy. This 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:

	I. Based on direct observation, review of Applied BioSystems MagMax Viral /Pathogen Ultra Enzyme mix storage specifications, laboratory policy, laboratory environmental records (06/2021), and confirmed in interview, the laboratory failed to ensure freezer temperature ranges were within manufacturer's specifications for 9 of 9 boxes of Applied BioSystems MagMax Viral/Pathogen Ultra Enzyme mix. Findings included: 1. During a tour of the laboratory area on 06/14/2021 at 2:00PM, 9 boxes of Applied BioSystems MagMax Viral/Pathogen Ultra Enzyme mix (Lot number 2105022, Expiration date 05/12/2022) were observed. 2. Review of the manufacturer's storage specifications located on the box revealed an acceptable storage temperature of -15C to -25C. 3. The laboratory policy titled," Temperature and Humidity Monitoring" (signed by the laboratory director 06/08/2021) stated, "Scope" 2.1. This SOP covers the monitoring of temperatures in refrigerators and freezers used for the chilling and storage of specimens and reagents. The applicable range of the digital thermometer used for refrigerators is 0 to 10C. The range for freezers in -35 to -5C." The freezer temperature range defined in the laboratory policy failed to ensure proper storage temperatures for Applied BioSystems MagMax Viral/Pathogen Ultra Enzyme mix. 4. Review of the laboratory environmental record titled, "Pre-PCR Room Maintenance Log" (06/2021) revealed an acceptable freezer temperature range of -35 to -5 C. The freezer temperature range defined in the laboratory environmental log failed to ensure proper storage temperatures for Applied BioSystems MagMax Viral /Pathogen Ultra Enzyme mix. 5. In an interview on 06/14/2021 at 2:15PM in the conference room, Testing Person #1, after review of the data, confirmed the above findings. 40420 II. Based on direct observation, review of the laboratory's environmental monitoring records, and confirmed in staff interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for 5 of 63 days in 2020 (10/2020-12/2020). Findings: 1. During a tour of the laboratory on 06/15/2021 at 10:55 am, the surveyor observed the following reagents stored on the shelves of the storage room or on the floor of the storage room: Casework Extraction Kit; storage temperature range 15-30C MagMax Viral/Pathogen Kit; storage temperature range 15-30C QuantStudio 12K Flex OpenArray Accessories Kit; storage temperature range 15-30C OpenArray 384-Well Sample Plates; storage temperature range 15-30C OpenArray Accufill Tips; storage temperature range 15-25C Gene Jet FFPR DNA Purification Kit; storage temperature range 15-25C 2. A review of the laboratory's environmental monitoring records from 10/2020 through 06 /2021 revealed the laboratory had an established an acceptable room temperature range for the laboratory of 15-35C. The laboratory failed to ensure room temperature ranges were within manufacturer's specifications of 15-25C. 3. Further review of the laboratory's environmental monitoring records revealed the following 5 of 63 days when the temperature was out of the manufacture's acceptable range of 15-25C in 2020: Date: 10/06/2020; Temperature: 25.2C Date: 10/07/2020; Temperature: 27.1C Date: 10/08/2020; Temperature: 26.3C Date: 10/09/2020; Temperature: 26.2C Date: 12/09/2020; Temperature: 25.2C 4. During an interview on 06/15/2021 at 11:35 am, Testing Person-1 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:
I. Based on direct observation, laboratory QuantStudio 12K Flex PCR system establishment studies, laboratory patient records, and confirmed in interview, the laboratory failed to document complete establishment studies for all organisms tested on human nail and embedded nail specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Findings included: 1. During a tour of the laboratory on June 14, 2021 at 10:05am, a QuantStudio 12K Flex (Serial Number 285881468) was observed. This instrument was used to perform laboratory developed testing for bacterial and fungal pathogens from human nail and embedded nail specimens. 2. Review of the laboratory QuantStudio 12K Flex Nail PCR Panel establishment studies (approved by the laboratory director 12/30/2019) revealed fresh human nail and embedded nail specimens were tested for the following fungal targets and one bacterial target: Trichophyton rubrum Trichophyton mentagrophytes Trichophyton tonsurans Epidermophyton floccosum Microsporum canis Geotrichum candidum Aspergillus fumigatus Fusarium keratoplasticum Scopularispsis bravicaulis Alternaria species Curvularia lunata Scytalidinum dimidiatum Candida albicans Candida tropicalis Candida parapsilosis Pseudomonas aeruginosa 3. Review of laboratory patient records revealed the laboratory also tested human nail and embedded nail specimens for the following bacterial targets using the QuantStudio 12K Flex System: Enterococcus faecalis Staphylococcus aureus MecA (a gene found in bacterial cells which allows them to be resistant to antibiotics) Staphylococcus epidermidis Staphylococcus lugdunensis Streptococcus pyogenes Streptococcus aglactiae Escherichia coli Klebsiella pneumoniae Proteus mirabilis Pseudomonas aeruginosa Acinetobacter baumanni Bartonella henselea Strenotrophomonas maltophilia Bacteriodes fragilis Aeromonas hydrophila 4. Further review of laboratory patient records revealed the laboratory also tested human nail and embedded nail specimens for the following antibiotic resistance markers using the QuantStudio 12K Flex System: TEM; Cephalosporin and Carbapenem vanA1; Vancomycin vanA2; Vancomycin vanB; Vancomycin ampC; Actinomycin, Cephaolosporin, Monobactam KPC; Cephalosporin and Carbpenem QnrA; fluoroquinolone SHV; Cephalosporin and Carbpenem OXA-1; Cephalosporin and Monobactam IMP-16; Cephalosporin and Carbpenem IMP-7; Cephalosporin and Carbpenem MecA; Methicillin The QuantStudio 12K Flex Nail PCR Panel establishment studies failed to include bacterial targets and antibiotic resistance markers on human nail and embedded nail specimens. 5. Further review of the QuantStudio 12K Flex Nail PCR Panel establishment studies revealed the following: "G. Stability: In order to determine the stability of organisms in fresh nail, a sample of fresh, healthy nail was spiked with 100 femtogram purified DNA of T. rubrum. The sample was then evaluated for recovery of organism in our PCR assay following 24 hr, 1-week, 2-week, and 1-month storage at room temperature ....We also tested the stability of purified DNA samples at refrigerated and frozen temperatures and determined both conditions of storage ensure stability of our DNA post-extraction for at least 1 month ...." The establishment studies for specimen stability failed to define a room temperature range. The establishment studies for post-extraction refrigerated specimens were documented for exactly 4C. The establishment studies for post-extraction frozen specimens were documented for exactly -20C. The establishment studies for specimen stability failed to test organisms other than T.

rubrum as part of the QuantStudio 12K Flex Nail PCR Panel to ensure stability for all organisms. The establishment studies for specimen stability failed to include bacterial targets and antibiotic resistance markers. 6. During an interview on 06/14/2021 at 3: 16pm in the conference room, the Technical Supervisor was asked to provide documentation of QuantStudio 12K Flex Nail PCR Panel establishment studies that included the bacterial targets and antibiotic resistance markers on human nail and embedded nail specimens, for establishment studies that defined temperature ranges for specimen stability, and establishment studies for specimen stability for bacterial targets and antibiotic resistance markers for human nail and embedded nail specimens. The laboratory was asked to provide establishment studies for specimen transport environmental conditions. No documentation was provided. This confirmed the above findings. The laboratory failed to document complete establishment studies for all organisms tested on the QuantStudio Flex 12K System Open Array technology, for specimen stability, and for specimen transport for human nail and embedded nail specimens. II. Based on direct observation, laboratory QuantStudio 12K Flex PCR system establishment studies, laboratory patient records, and confirmed in interview, the laboratory failed to document complete establishment studies for all organisms tested on wound specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Findings included: 1. During a tour of the laboratory on June 14, 2021 at 10:05am, a QuantStudio 12K Flex (Serial Number 285881468) was observed. This instrument was used to perform laboratory developed testing for bacterial and fungal pathogens from wound specimens. 2. Review of the laboratory QuantStudio 12K Flex Wound PCR Panel establishment studies (approved by the laboratory director 01/18/2020) revealed wound specimens were tested for the following bacterial targets: Enterococcus faecalis Staphylococcus aureus MecA (a gene found in bacterial cells which allows them to be resistant to antibiotics) Staphylococcus epidermidis Staphylococcus lugdunensis Streptococcus pyogenes Streptococcus aglactiae Escherichia coli Klebsiella pneumoniae Proteus mirabilis Pseudomonas aeruginosa Acinetobacter baumanni Bartonella henselea Strenotrophomonas maltophilia Bacteriodes fragilis Aeromonas hydrophila 3. Review of laboratory patient records revealed the laboratory also tested wound specimens for the following fungal targets using the QuantStudio 12K Flex System: Trichophyton rubrum Trichophyton mentagrophytes Trichophyton tonsurans Epidermophyton floccosum Microsporum canis Geotrichum candidum Aspergillus fumigatus Fusarium keratoplasticum Scopularispsis bravicaulis Alternaria species Curvularia lunata Scytalidinum dimidiatum Candida albicans Candida tropicalis Candida parapsilosis 4. Further review of laboratory patient records revealed the laboratory also tested wound specimens for the following antibiotic resistance markers using the QuantStudio 12K Flex System: TEM; Cephalosporin and Carbapenem vanA1; Vancomycin vanA2; Vancomycin vanB; Vancomycin ampC; Actinomycin, Cephaolosporin, Monobactam KPC; Cephalosporin and Carbpenem QnrA; fluoroquinolone SHV; Cephalosporin and Carbpenem OXA-1; Cephalosporin and Monobactam IMP-16; Cephalosporin and Carbpenem IMP-7; Cephalosporin and Carbpenem MecA; Methicillin The QuantStudio 12K Flex Wound PCR Panel establishment studies failed to include fungal targets and antibiotic resistance markers for wound specimens. 5. Further review of the QuantStudio 12K Flex Wound PCR Panel establishment studies revealed the following: "G. Stability: In order to determine the stability of in common transport media used for analysis of wound samples, we spiked the following transport systems with 10,000 CFU/mL of S. aureus ...Eswab (Copan Diagnostics .... BD Aimes Gel Swab ...Sterile Urine Container ...The transport systems were then stored at room temperature for 24 hr, 1-week, 2-week, and 1-month. Samples were extracted and evaluated at baseline and at the end of each timepoint for recovery and detection in our PCR assay ...we can successfully recover DNA from organisms in

Eswabs and BD swabs that have been stored at room temperature for up to 1 month and in sterile containers for up to 1 week. We also tested the stability of purified DNA samples at refrigerated and frozen temperatures and determined that both conditions of storage ensure stability of our DNA post-extraction for at least 1 month." The establishment studies for specimen stability failed to define a room temperature range. The establishment studies for post-extraction refrigerated specimens were documented for exactly 4C. The establishment studies for post-extraction frozen specimens were documented for exactly -20C. The establishment studies for specimen stability failed to test organisms other than S. aureus as part of the QuantStudio 12K Flex Wound PCR Panel to ensure stability for all organisms. The establishment studies for specimen stability failed to include fungal targets and antibiotic resistance markers. 6. During an interview on 06/14/2021 at 3:16pm in the conference room, the Technical Supervisor was asked to provide documentation of QuantStudio 12K Flex Wound PCR Panel establishment studies that included the fungal targets and antibiotic resistance markers on wound specimens, establishment studies for defined temperature ranges for specimen stability, and establishment studies for wound specimen stability for fungal targets and antibiotic resistance markers. The laboratory was asked to provide establishment studies for specimen transport environmental conditions. No documentation was provided. This confirmed the above findings. The laboratory failed to document complete establishment studies for all organisms tested on the QuantStudio Flex 12K System Open Array technology, for specimen stability, and for specimen transport for wound specimens. III. Based review of laboratory QuantStudio 12K Flex PCR system establishment studies, patient records, and confirmed in interview, the laboratory failed to document complete establishment studies for Quality Control (QC) material tested by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology for the Nail PCR Panel and the Wound PCR Panel. Findings included: 1. Review of the laboratory QuantStudio 12K Flex Nail PCR Panel establishment studies (approved by the laboratory director 12/30/2019) stated the following: "J. Quality Control Material: DNA isolated from the 16 ATCC organisms listed in Table 1 will be used as Positive Control for this assay. DNA from these organisms can either be used individually and rotated each day of testing or 4 multi-analyte DNA samples can be made by mixing the DNA of 4 organisms and run on each day of testing. Negative extraction/Negative Template control (NEC/NTC) will be E. coli in saline ...Table 1. List of ATCC organisms: Trichophyton rubrum; ATCC ID 28188 Trichophyton mentagrophytes; ATCC ID 9533 Trichophyton tonsurans; ATCC ID 28942 Epidermophyton floccosum; ATCC ID 52066 Microsporum canis; ATCC ID 36299 Geotrichum candidum; ATCC ID 34614 Aspergillus fumigatus; ATCC ID 204305 Fusarium keratoplasticum; ATCC ID 36031 Scopularispsis bravicaulis; ATCC ID 58636 Alternaria species; ATCC ID 20084 Curvularia lunata; ATCC ID 42011 Scytalidinum dimidiatum; ATCC ID 39807 Candida albicans; ATCC ID 26790 Candida tropicalis; ATCC ID 750 Candida parapsilosis; ATCC ID 22019 Pseudomonas aeruginosa; ATCC ID 27853D-5" The laboratory was asked to provide documentation of QC material storage and stability studies for the QC material listed above. No documentation was provided. 2. Review of the laboratory QuantStudio 12K Flex Wound PCR Panel establishment studies (approved by the laboratory director 12/30 /2019) stated the following: "J. Quality Control Material: DNA isolated from the 16 ATCC organisms listed in Table 1 will be used as Positive Control for this assay. DNA from these organisms can either be used individually and rotated each day of testing or 4 multi-analyte DNA samples can be made by mixing the DNA of 4 organisms and run on each day of testing. Negative extraction/Negative Template control (NEC/NTC) will be T. rubrum in saline ...Table 1. List of ATCC organisms: Enterococcus faecalis; ATCC ID 29212 Staphylococcus aureus; ATCC ID 25933

	(MSSA); Staphylococcus aureus; ATCC ID 43300 (MRSA) Staphylococcus epidermidis; ATCC ID 12228 Staphylococcus lugdunensis; ATCC ID 49576 Streptococcus pyogenes; ATCC ID 49399 Streptococcus aglactiae; ATCC ID 12386 Escherichia coli; ATCC ID 35421 Klebsiella pneumoniae; ATCC ID 13048 Proteus mirabilis; ATCC ID 12453 Pseudomonas aeruginosa; ATCC ID 27853D-5 Acinetobacter baumanni; ATCC ID 19606 Bartonella henselea; ATCC ID 49882D-5 Strenotrophomonas maltophilia; ATCC ID 17666 Bacteriodes fragilis; ATCC ID 25285 Aeromonas hydrophila; ATCC ID 0910P" The laboratory was asked to provide documentation of QC material storage and stability studies for the QC material listed above. No documentation was provided. 3. Review of laboratory patient records revealed the laboratory also tested specimens for the following antibiotic resistance markers using the QuantStudio 12K Flex System: TEM; Cephalosporin and Carbapenem vanA1; Vancomycin vanA2; Vancomycin vanB; Vancomycin ampC; Actinomycin, Cephaolosporin, Monobactam KPC; Cephalosporin and Carbpenem QnrA; fluoroquinolone SHV; Cephalosporin and Carbpenem OXA-1; Cephalosporin and Monobactam IMP-16; Cephalosporin and Carbpenem IMP-7; Cephalosporin and Carbpenem MecA; Methicillin The laboratory was asked to provide establishment studies for quality control material for the antibiotic resistance markers listed above. No documentation was provided. 4. During an interview on 06/14/2021 at 3:16pm in the conference room, the Technical Supervisor was asked to provide documentation of QuantStudio 12K Flex PCR Panel establishment studies that included storage and stability requirements for QC material and complete QC material studies for the antibiotic resistance markers. No documentation was provided. This confirmed the above findings. Work Key: C = Celsius T = Trichophyton Hr=hour S. = Staph DNA = Deoxyribonucleic Acid BD = Becton Dickinson E. = Escherichia ATCC = American Type Culture Collection MSSA = Methicillin Sensitive Staphylococcus aureus MSRA = Methicillin Resistant Staphylococcus aureus
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, maintenance logs, and confirmed in staff interview, the laboratory failed to perform weekly maintenance as required on the QuantStudio 12K Flex Instrument for 42 of 42 weeks in 2020 (03 /2020-12/2020) and 20 of 20 weeks in 2021 (01/2021-05/2021). 1. Review of the laboratory's policy "Standard Operating Procedure: PCR Analysis Using the QuantStudio 12K Flex Instrument with OpenArray Block (Accufill System)" stated: "14. MAINTENANCE AND CALIBRATION SCHEDULE Table 14.1 Maintenance and Calibration Schedule Frequency Weekly Maintenance Task Check the computer disk space. If necessary, archive or back up your experiment files and instrument settings. Power off the computer that controls the QuantStudio 12K Flex System, then after 30 seconds, power on the computer. Clean the surface of the QuantStudio 12K Flex System with a lint-free cloth. Perform a QuantStudio 12K Flex Instrument self test." 2. Review of "Applied Biosystems QuantStudio 12K Flex Real-Time PCR System: OpenArray Plate Quick Reference" manual page 22 revealed: "Frequency Weekly Maintenance Task Check the computer disk space. If necessary, archive or back up your experiment files and instrument settings. Power off the computer that

	controls the QuantStudio 12K Flex Real-Time PCR instrument, then after 30 seconds, power on the computer. Clean the surface of the QuantStudio 12K Flex Real-Time PCR instrument with a lint-free cloth. Perform a QuantStudio 12K Flex Real-Time PCR instrument self test." 3. Review of the laboratory's "QuantStudio 12K Flex and Accufill Maintenance Log" from March 2020 through May 2021 revealed the required weekly tasks to be performed as: "Clean/disinfect exterior surfaces". Weekly tasks performed were documented with a initials of the person who performed the task. The log did not indicate the following as tasks to be performed as required by the manufacturer: "Check the computer disk space. If necessary, archive or back up your experiment files and instrument settings. Power off the computer that controls the QuantStudio 12K Flex Real-Time PCR instrument, then after 30 seconds, power on the computer. Perform a QuantStudio 12K Flex Real-Time PCR instrument self test". The laboratory failed to perform all required weekly tasks from March 2020 through May 2021 on the QuantStudio 12K Flex Real-Time PCR instrument. 4. During an interview on 06/15/2021 at 12:30 pm, Testing Person-1 confirmed the laboratory failed to perform all required weekly maintenance on the QuantStudio 12K Flex Real-Time PCR instrument.
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 laboratory policy, laboratory QuantStudio 12K Flex PCR system establishment studies, laboratory quality control records and confirmed in interview, the laboratory failed to document a negative and positive control each day patient specimens were analyzed for 7 of 7 tests on the QuantStudio 12K Flex PCR system (Nail Panel and Wound Panel). Findings included: 1. The laboratory policy titled, "Quality Control" (signed by the Laboratory Director 06/08/2021) stated, "Nail PCR Bacterial and Fungal Panel QC: Nail PCR Bacterial and Fungal Panel will be evaluated for performance by running positive and negative quality control standards. A serial quality control is used to monitor recovery efficiency and to identify false negative results such as the presence of PCR inhibitors in molecular detection workflows. TaqMan Universal DNA Spike-In Control serves as an exogenous process control of a known concentration that is spiked into a sample at specific stages throughout the PCR process ...Daily review of QC results for each run to ensure validity and to prevent the release of unreliable results to clients." 2. The laboratory QuantStudio 12K Flex Nail PCR Panel establishment studies (approved by the laboratory director 12/30/2019) stated the following: "J. Quality Control Material: DNA isolated from the 16 ATCC organisms listed in Table 1 will be used as Positive Control for this assay. DNA from these organisms can either be used individually and rotated each day of testing or 4 multi-analyte DNA samples can be made by mixing the DNA of 4 organisms and run on each day of testing. Negative extraction/Negative Template control (NEC/NTC) will be E. coli in saline ...Table 1. List of ATCC organisms: Trichophyton rubrum; ATCC ID 28188 Trichophyton mentagrophytes; ATCC ID 9533 Trichophyton tonsurans; ATCC ID 28942 Epidermophyton floccosum; ATCC ID 52066 Microsporum canis; ATCC ID 36299 Geotrichum

candidum; ATCC ID 34614 Aspergillus fumigatus; ATCC ID 204305 Fusarium keratoplasticum; ATCC ID 36031 Scopularispsis bravicaulis; ATCC ID 58636 Alternaria species; ATCC ID 20084 Curvularia lunata; ATCC ID 42011 Scytalidinum dimidiatum; ATCC ID 39807 Candida albicans; ATCC ID 26790 Candida tropicalis; ATCC ID 750 Candida parapsilosis; ATCC ID 22019 Pseudomonas aeruginosa; ATCC ID 27853D-5" 3. The laboratory QuantStudio 12K Flex Wound PCR Panel establishment studies (approved by the laboratory director 12/30/2019) stated the following: "J. Quality Control Material: DNA isolated from the 16 ATCC organisms listed in Table 1 will be used as Positive Control for this assay. DNA from these organisms can either be used individually and rotated each day of testing or 4 multi-analyte DNA samples can be made by mixing the DNA of 4 organisms and run on each day of testing. Negative extraction/Negative Template control (NEC/NTC) will be T. rubrum in saline ...Table 1. List of ATCC organisms: Enterococcus faecalis; ATCC ID 29212 Staphylococcus aureus; ATCC ID 25933 (MSSA); Staphylococcus aureus; ATCC ID 43300 (MRSA) Staphylococcus epidermidis; ATCC ID 12228 Staphylococcus lugdunensis; ATCC ID 49576 Streptococcus pyogenes; ATCC ID 49399 Streptococcus aglactiae; ATCC ID 12386 Escherichia coli; ATCC ID 35421 Klebsiella pneumoniae; ATCC ID 13048 Proteus mirabilis; ATCC ID 12453 Pseudomonas aeruginosa; ATCC ID 27853D-5 Acinetobacter baumanni; ATCC ID 19606 Bartonella henselea; ATCC ID 49882D-5 Strenotrophomonas maltophilia; ATCC ID 17666 Bacteriodes fragilis; ATCC ID 25285 Aeromonas hydrophila; ATCC ID 0910P" 4. A random review of the laboratory's quality control records (07/2020, 01 /25/2021 through 06/11/2021) titled "QuantStudio 12K Flex with OpenArray Accufill System" revealed the following dates when the laboratory used a known positive patient sample as a positive control and no documentation of a negative control: 07/02 /2020 Case CL20-0590; Positive Control #1 S. lug; Positive Control #2 T. rub; Positive Control #3 FemA TaqMan Open Array PCR Plate; Lot number 3746837 No documentation of a negative control. 01/25/2021 Case CL20-01336; Positive Control #1 S. lug; Positive Control #2 S aureus; Positive Control #3 mecA TaqMan Open Array PCR Plate; Lot number 3933864 No documentation of a negative control. 02/03 /2021 Case CL20-01336; Positive Control #1 S. lug; Positive Control #2 S aureus; Positive Control #3 mecA TaqMan Open Array PCR Plate; Lot number 3933864 No documentation of a negative control 03/24/2021 Case CL20-01339; Positive Control #1 S. lug; Positive Control #2 S aureus; Positive Control #3 mecA TaqMan Open Array PCR Plate; Lot number 3933864 No documentation of a negative control 03/30 /2021 Case CL20-01339; Positive Control #1 S. lug; Positive Control #2 S aureus; Positive Control #3 mecA TaqMan Open Array PCR Plate; Lot number 3933864 No documentation of a negative control 05/06/2021 Case CL20-01349; Positive Control #1 C para; Positive Control #2 FemA; Positive Control #3 mecA TaqMan Open Array PCR Plate; Lot number 4070022 No documentation of a negative control 06/09/2021 Case CL20-01349; Positive Control #1 C para; Positive Control #2 FemA; Positive Control #3 mecA TaqMan Open Array PCR Plate; Lot number 4070022 No documentation of a negative control 06/11/2021 Case CL20-01349; Positive Control #1 C para; Positive Control #2 FemA; Positive Control #3 mecA TaqMan Open Array PCR Plate; Lot number 4070022 No documentation of a negative control The laboratory failed to ensure that a negative control and a positive control for each fungal target, bacterial target and antibiotic resistant target was performed each day of patient testing. 5. During an interview on 06/14/2021 at 3:16pm in the conference room, Testing Person #1 was asked what was used for a positive control. She stated that she used a previously positive patient sample as a positive control. She further stated that she would use the patient sample as a positive control as long as the readings were strong. Testing person #1 was asked to provide documentation of positive control material that incorporated each fungal target, each bacterial target,

	and each antibiotic resistant target. No documentation was provided. During an interview on 06/14/2021 at 3:16pm in the conference room, the Technical Supervisor was asked to provide documentation of positive control material that incorporated each fungal target, each bacterial target, and each antibiotic resistant target. No documentation was provided. This confirmed the above findings. The laboratory failed to ensure that a negative control and a positive control for each fungal target, bacterial target and antibiotic resistant target was performed each day of patient testing. The laboratory failed to perform quality control using quality control material specified in the QuantStudio 12K Flex Nail and Wound PCR Panel establishment studies. Word Key: S lug = Staphylococcus lugdunensis T rub = Trichophyton rubrum FemA = Aminoacyltransferase FemA S aureus = Staphylococcus aureus mecA = Methicillin C para = Candida parapsilosis
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 review of the laboratory policies, laboratory records, and patient records, the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The laboratory director failed to ensure testing systems provided quality laboratory services. Refer to D6079, D6086, and D6093.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies, laboratory QuantStudio 12K Flex PCR system establishment studies, patient test records, and confirmed by staff interview, the Laboratory Director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance as evidenced by: 1. The laboratory failed to ensure that patient test records included necessary information to provide accurate interpretation of results for 6 of 6 randomly reviewed patient results in April 2021. Refer to D5305. 2. The laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Wound PCR Panel establishment studies for specimen storage temperature requirements and failed to ensure specimens were stored at established temperature. Refer to D5311, I. 3. The

	laboratory failed to ensure laboratory policy corresponded to QuantStudio 12K Flex Nail PCR Panel establishment studies for specimen storage temperature requirements for post-extraction nail specimens and failed to ensure specimens were stored at established temperature. Refer to D5311, II. 4. The laboratory failed to establish written policies for patient preparation, collection, labeling, storage and preservation, transportation, processing, and acceptability/rejection criteria for PCR (polymerase chain reaction) specimens received in the laboratory from outside clients. Refer to D5311, III. 5. The laboratory failed to ensure freezer temperature ranges were within manufacturer's specifications. Refer to D5413. 6. The laboratory failed to ensure room temperature ranges were within manufacturer's specifications for 5 of 63 days in 2020 (10/2020-12/2020). Refer to D5413, II. 7. The laboratory failed to document complete establishment studies for all organisms tested on human nail and embedded nail specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Refer to D5423, I. 8. The laboratory failed to document complete establishment studies for all organisms tested on wound specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Refer to D5423, II. 9. The laboratory failed to document complete establishment studies for Quality Control (QC) material tested by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology for the Nail PCR Panel and the Wound PCR Panel. Refer to D5423, III. 10. The laboratory failed to perform weekly maintenance as required on the QuantStudio 12K Flex Instrument for 42 of 42 weeks in 2020 (03/2020-12/2020) and 20 of 20 weeks in 2021 (01/2021-05/2021). Refer to D5429.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure establishment studies were complete, as evidenced by: 1. The laboratory failed to document complete establishment studies for all organisms tested on human nail and embedded nail specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Refer to D5423, I. 2. The laboratory failed to document complete establishment studies for all organisms tested on wound specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Refer to D5423, II. 3. The laboratory failed to document complete establishment studies for Quality Control (QC) material tested by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology for the Nail PCR Panel and the Wound PCR Panel. Refer to D5423, III.
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 laboratory policies, quality control records, laboratory records, and confirmed in staff interview, it was revealed the laboratory director failed to ensure that the quality control program was established and maintained to ensure the quality of laboratory services provided, as evidenced by: 1. The laboratory failed to document a negative and positive control each day patient specimens were analyzed for 7 of 7 tests on the QuantStudio 12K Flex PCR system (Nail Panel and Wound Panel). Refer to D5449.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the Center for Medicare & Medicaid Services (CMS) 209 form, personnel records, and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties for the clinical consultant (CC-1), general supervisor (GS-1), and 1 of 3 Testing Persons (TP-3) engaged in high complexity testing. Findings included: 1. Review of CMS 209 form listed CC-1/TS-1 (technical supervisor) as a consultant of high complexity procedures in the areas of bacteriology and mycology. The laboratory director did not specify, in writing, the duties and delegations of the clinical consultant, as applicable. 2. Review of the CMS 209 form listed GS-1/TP-1 as a supervisor of high complexity procedures in the areas of bacteriology and virology. The laboratory director did not specify, in writing, the duties and delegations of the supervisor, as applicable. 3. Review of the CMS 209 form listed TP-3 as a testing person performing high complexity procedures in the areas of bacteriology and mycology. The laboratory director did not specify, in writing, the duties and delegations of the testing person, as applicable. 4. During an interview on 06/14/2021 at 11:56 am, GS-1 confirmed the above findings.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies and confirmed in interview, the technical supervisor failed to ensure establishment studies for non- FDA approved testing on the QuantStudio Flex 12K System Open Array were complete prior to patient testing, as evidenced by: 1, The laboratory failed to document complete establishment studies for all organisms tested on human nail and embedded nail

	specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Refer to D5423, I. 2. The laboratory failed to document complete establishment studies for all organisms tested on wound specimens by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology. Refer to D5423, II. 3. The laboratory failed to document complete establishment studies for Quality Control (QC) material tested by Polymerase Chain Reaction (PCR) testing using the QuantStudio Flex 12K System Open Array technology for the Nail PCR Panel and the Wound PCR Panel. Refer to D5423, III.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy manual, Center for Medicare & Medicaid Services (CMS) form 209, personnel records, and interview with staff, the Technical Supervisor (TS-1) failed to evaluate competency of 2 of 3 testing persons (TP-1, TP-3) responsible for high complexity testing, at least semiannually during the first year of testing. Findings included: 1. Review of the laboratory's policy manual "General laboratory Policies" page 7 stated: "7. COMPETENCY TESTING The purpose of the Competency Testing of Laboratory Personnel policy is to evaluate the competency of all laboratory personnel in their abilities to perform required patient specimen testing. 7.1 Requirements The competency of each person to perform the duties assigned must be assessed following training: post initial training, six months after initial training and at least annually thereafter. Each of the employee's competency must be assessed twice during the first year of employment." 2. Review of the CMS 209 form revealed TP-1 and TP-3 perform high complexity testing. 3. Review of personnel records for TP-1 performing high complexity testing included documented training on 06/16 /2020. Records did not include documented semiannual competency assessments for TP-1. Review of personnel records for TP-3 performing high complexity testing included documented training on: 08/14/2020. Further review of records included a documented competency assessment for TP-3 that was signed on 02/23/2021 by the general supervisor who was NOT the technical supervisor. The TS-1 did NOT evaluate and document semiannual competency assessments for all testing personnel performing high complexity testing. 4. During an interview on 06/14/2021 at 11:56 am, GS-1/TP-1 stated that there were no semiannual competency assessments for her only the initial training. She also stated that she had performed the initial training and semiannual competency assessment for TP-3. This confirmed the above findings.