

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2201242	(X3) Date Survey Completed 03/20/2023
Name of Provider or Supplier Upper Line Healthcare Pc	Street Address, City, State 2835 West Deleon Street Suite 101, Tampa, FL	
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 announced CLIA recertification survey was conducted at Upperline Healthcare PC on 03/10/2023 - 03/20/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400- Analytic Systems 493.1250
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to have a uni-directional workflow while performing Molecular testing on nails and wounds since testing began 10/2021. Findings Included: During a tour of the Molecular Testing room on 03 /10/2023 at 12:00 PM it was observed that the laboratory was not set up for uni-directional workflow which could cause cross contamination of the specimens. During an interview on 03/10/2023 at 1:00 PM with the Molecular Testing Person it was confirmed the lab was not set up in a uni-directional workflow.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p>

This CONDITION is not met as evidenced by:
Based on review of Validation of the Wound TaqMan DNA based pathogen detection assay, Validation of the Fungal TaqMan DNA based pathogen detection assay, and staff interviews the laboratory failed to complete a laboratory developed test validation (by not establishing interfering substances) since testing began on 10/2021 (See D5423) and failed to perform maintenance on the centrifuge used for Molecular testing for 2 out of 2 years (2021-2023) reviewed (See D5429).

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 review of Validation of the Wound TaqMan DNA based pathogen detection assay, Validation of the Fungal TaqMan DNA based pathogen detection assay, and staff interviews the laboratory failed to complete a laboratory developed test validation (by not establishing interfering substances) since testing began in October of 2021. Findings Included: Review of the Validation of the Wound TaqMan DNA based pathogen detection assay titled "Summary Report for Wound Microbiota TaqMan Assays on the Applied Biosystems QuantStudio 12K Flex Taqman Array Card (TAC) Platform" and Validation of the Fungal TaqMan DNA based pathogen detection assay titled "Summary Report for Nail Fungus Microbiota TaqMan Assays on the Applied Biosystems QuantStudio 12K Flex Taqman Array Card (TAC) Platform" revealed there were no interfering substances established for either specimen type. Interview with the Molecular Testing Person on 03/10/2023 at 12:00 PM confirmed interfering substances were not established during the Validation of the Laboratory Developed Test. Interview via email on 03/20/2023 at 10:46 AM with the Laboratory Manager revealed 219 Fungal Patient Assays and 14 Wound Patient Assays were performed year to date (YTD).

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 the maintenance of the centrifuge and interview, the laboratory

failed to perform preventative maintenance on the Thermo Scientific Sorval ST Plus Series Centrifuge for 2 out of 2 years (2021-2023) reviewed. Findings Included: Review of the policy "General Laboratory Maintenance" last signed by the Laboratory Director on 05/09/2022 revealed "Centrifuges must be calibrated annually to ensure they are in proper working order. A third party can be hired to perform this service. Documentation of calibration must be kept for a minimum of two years." Interview with the Molecular Testing Person on 03/10/2023 at 2:00 PM confirmed no documentation of preventative maintenance was performed on the centrifuge in the Molecular testing room.