

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0279395	(X3) Date Survey Completed 04/16/2021
Name of Provider or Supplier Uhealth Pathology At Mailman	Street Address, City, State 1601 Nw 12th Ave Room 7002, Miami, 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	A recertification survey conducted on 04/1/2021 to 4/16/2021 found the clinical laboratory UHEALTH PATHOLOGY AT MAILMAN was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to remove reagents from the laboratory that expired after February and March 2021. Findings include: During laboratory tour on 04/01/2021 at 10:00 am, the surveyor found: a) In a refrigerator on Microbiology room #6014, the following expired reagents were identified: -96 Well Spectral Calibration Plate with JUN Dye for Multiplex qPCR lot 2010087 expired on 3/24/21 -96 Well Spectral 0.2 ml Calibration Plate lot 2062075 expired on 3/3/21 -96 Well Spectral Calibration Plate lot 2002067 expired on 3/7/21 -96 Well Spectral 0.2 ml Calibration Plate lot 2002063 expired on 2/2/21 b) In the second Microbiology room Binwax Now Streptococcus Control Swabs lot 107210 and 107833 was on a shelf expired on 3/28/21. c) In Cytogenetics room at 10:30 am Straight From TM Whole Blood CD138 Microbeads lot 5200906145 reagent was in a refrigerator expired on 3/19/21. During an interview on 4/1/2021 at 10:00 am with Microbiology Supervisor, she explained that the materials of reference were not currently in use. An interview with Cytogenetics Supervisor at 10:30 am, she explained that the laboratory was not using the reagent of reference.</p>
D5427	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c)</p>

(c) Documentation. The laboratory must document all activities specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to provide documentation of COVID-19 validation instrument data printouts with serial numbers for the following instruments: ABI 7500 Fast (ABIF1), ABI 7500 fast (ABIF2), ABI 7500 (ABIS), QuantStudio 7 (QS7), ABI 7500 (ABIS2), QuantStudio 7-2 (QS7-2), QuantStudio 7-1 (QS7-1) and QuantStudio 7-3 (QS7-3). Findings include: Review of COVID-19 testing records revealed the following instruments in use : 1.ABIF1 used for CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC-EUA) starting on 4/21/2020. 2.ABIF2 used for CDC-EUA starting on 4/28/2020. 3.ABIS used for PerkinElmer New Coronavirus Nucleic Acid Detection Kit (PE-EUA) and Direct PCR for detection of SARS-COV2 (LDT) starting on 7/8/2020. 4.QS7 used for PE-EUA, CDC-EUA starting on 7/27/2020. 5.ABIS2 used for PE-EUA and LDT starting on 9/14/2020. 6.QS7-2 used for PE-EUA, LDT starting on 10/2/2020. 7.QS7-1 used for LDT starting on 1/26/2021. 8.QS7-3 used for LDT starting on 2/12/2021. Review of COVID-19 validation instrument records revealed no documentation of instrument data printouts with serial numbers for ABI 7500 Fast, ABI 7500 fast, ABI 7500, QuantStudio 7, ABI 7500, QuantStudio 7-2 , QuantStudio 7-1 and QuantStudio 7-3. During an interview on 4/16/2021 at 12pm, the laboratory director confirmed no documentation of instrument data printouts was provided for ABI 7500 Fast, ABI 7500 fast, ABI 7500, QuantStudio 7, ABI 7500, QuantStudio 7-2, QuantStudio 7-1 and QuantStudio 7-3 in Covid-19 validations.