

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0279395	(X3) Date Survey Completed 12/21/2020
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 desk review survey of the laboratory's proficiency test results was performed on December 21, 2020 for UHealth Pathology at Mailman. The laboratory, UHealth Pathology at Mailman, is not in compliance with Code of Federal Regulations (CFR), Part 493, Laboratory Requirements.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2020, the laboratory did not have successful performance in proficiency testing for the subspecialty of Mycobacteriology. Refer to D2037. Findings include: Review of the Collage of American Pathologists (CAP) proficiency testing records and the review of</p>

	<p>the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports, on December 21, 2020 on or about 10:00 AM, showed that the laboratory had unsatisfactory testing scores for the subspecialty of mycobacteriology for two consecutive testing events in 2020.</p>
<p>D2037</p>	<p>MYCOBACTERIOLOGY CFR(s): 493.825(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory did not have successful performance in proficiency testing in the subspecialty of mycobacteriology. Findings include: On December 21, 2020 on or about 10:00 AM the College of American Pathologists (CAP) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory failed to achieve satisfactory performance for the subspecialty of mycobacteriology, as shown below. Event #1, 2020 Mycobacteriology-16% Event #2, 2020 Mycobacteriology-16%</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory maintained a satisfactory score for proficiency testing in the subspecialty of mycobacteriology Findings include: On December 21, 2020, on or about 10:00 AM, the College of American Pathologists (CAP) proficiency records and the Centers for Medicare & Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the laboratory had unsatisfactory testing scores for two consecutive testing events in the subspecialty of mycobacteriology. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D2037.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing scores, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a</p>

manner as to achieve and maintain successful participation in proficiency testing in the subspecialty of mycobacteriology Findings Include: The review of the College of American Pathologists (CAP) proficiency testing records and the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports on December 21, 2020 on or about 10:00 AM showed that the laboratory received unsatisfactory proficiency testing scores as shown below. Event #1, 2020 Mycobacteriology-16% Event #2, 2020 Mycobacteriology-16%