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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D1044073 | (X3) Date Survey Completed 10/26/2022 |
| Name of Provider or Supplier United Laboratory Services Corp | Street Address, City, State 7095 Sw 47th St Bldg B, 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 |
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| D0000 | A desk review survey of the laboratory's proficiency test results was performed on October 26, 2022 for United Laboratory Services Corp. United Laboratory Services Corp is not in compliance with the Code of Federal Regulations (CFR), Part 493, Laboratory Requirements. The following conditions were not met: 493.803 (a)(b)(c) successful Participation, Condition 493.1441 Laboratory Director, Condition |
| 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 2021 and 2022, the laboratory did not have successful performance in proficiency testing for analytes in the subspecialties of bacteriology and virology. Refer to D 2028 and D 2064. Findings</p> |

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| | <p>include: Review of the American Proficiency Institute (API) proficiency testing records and the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports, on October 26, 2022 on or about 10:00 AM, showed that the laboratory had unsatisfactory proficiency testing scores in bacteriology and in virology. The laboratory performs molecular bacteriology GI (gastrointestinal) and molecular bacteriology respiratory testing on the Biofire instrument. The laboratory performs molecular virology GI, and molecular virology respiratory testing on the Biofire instrument.</p> |
| <p>D2028</p> | <p>BACTERIOLOGY CFR(s): 493.823(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 for two consecutive testing events of proficiency testing in the subspecialty of bacteriology. Findings include: On October 26, 2022 on or about 10:00 AM the American Proficiency Institute (API) proficiency testing records and the CMS 153 and 155 reports were reviewed. The laboratory performs the molecular bacteriology GI panel and the molecular bacteriology respiratory panel on the Biofire instrument. The review showed that the laboratory failed to achieve satisfactory performance for the testing in the subspecialty of bacteriology, as shown below. Event #3, 2021 bacteriology-0% Event #1, 2022 bacteriology-0%</p> |
| <p>D2064</p> | <p>VIROLOGY CFR(s): 493.831(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 for the subspecialty of virology. Findings include: On October 26, 2022 on or about 10:00 AM the American Proficiency Institute (API) proficiency testing records and the CMS 153 and 155 reports were reviewed. The laboratory performs the molecular virology GI panel and the molecular virology respiratory panel on the Biofire instrument. The review showed that the laboratory failed to achieve satisfactory performance in two consecutive testing events for testing in the subspecialty of virology, as shown below. Event #3, 2021 virology-0% Event #1, 2022 virology-0%</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.</p> |

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 the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory maintained a satisfactory score in proficiency testing for analytes found in the subspecialties of bacteriology and virology. Findings include: On October 26, 2022, on or about 10:00 AM, the American Proficiency Institute (API) 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 subspecialties of bacteriology and virology. Refer to D6089.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

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 manner as to achieve and maintain successful performance in proficiency testing in the subspecialties of bacteriology and virology as shown below. Findings Include: The review of the American Proficiency Institute (API) proficiency testing records and the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports on October 26, 2022, on or about 10:00 AM showed that the laboratory received unsatisfactory proficiency testing scores for two out of three testing events for the analytes shown below. The laboratory performs bacteriology and virology testing on the Biofire instrument. In bacteriology the laboratory performs the molecular bacteriology GI panel, and the molecular bacteriology respiratory panel. In the subspecialty of virology the laboratory performs the molecular virology GI panel and the molecular virology respiratory panel. Event #3, 2021 bacteriology-0% virology-0% Event #1, 2022 bacteriology-0% virology-0%