| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>14D0646585 | **(X3) Date Survey Completed**<br><br>11/17/2025 |
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| **Name of Provider or Supplier**<br><br>Unilab, Inc | **Street Address, City, State**<br><br>418 N Austin Blvd, Oak Park, IL | |
| 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** | Based on a desk review of proficiency testing records from the Certification and Survey Provider Enhanced Reporting (CASPER) database and verified with the proficiency testing provider the laboratory was found to be out of compliance with the following CONDITION level deficiencies: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency |

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| | Institute (API) Proficiency Testing (PT) records, the laboratory failed to achieve satisfactory performance for the routine chemistry analytes Glucose and Iron, total for two consecutive PT events in 2025 (events 2 and 3 of 2025) resulting in the initial unsuccessful PT performance. Refer to D2096. |
| **D2096** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(f)<br><br>(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory failed to achieve satisfactory performance for the routine chemistry analytes Glucose and Iron, total for two consecutive PT events in 2025 (events 2 and 3 of 2025) resulting in the initial unsuccessful PT performance. Findings include: 1. Review of the CASPER Report 0155D, generated on 11-03-2025, the laboratory received the following unsatisfactory scores for the routine chemistry analytes Glucose and Iron, total. Glucose Initial Unsuccessful PT Performance EVENT 2, 2025 - 40% Unsatisfactory EVENT 3, 2025 - 40% Unsatisfactory Iron, total Initial Unsuccessful PT Performance EVENT 2, 2025 - 20% Unsatisfactory EVENT 3, 2025 - 60% Unsatisfactory 2. Review of API PT evaluation reports (Chemistry - Core) confirmed the above unsatisfactory scores that resulted in the initial unsuccessful PT performance for the routine chemistry analytes Chloride and Iron, total. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory director failed to ensure successful participation in a Health and Human Services (HHS) approved PT program for the routine chemistry analytes Glucose and Iron, total resulting in the laboratory's initial unsuccessful PT performance. Refer to D6089. |
| **D6089** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(i)<br><br>(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;<br><br>This STANDARD is not met as evidenced by: |

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| | Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory director failed to ensure successful participation in a Health and Human Services (HHS) approved PT program for the routine chemistry analytes Glucose and Iron, total resulting in the laboratory's initial unsuccessful PT performance. Refer to D2096. |