| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D0923416 | 06/10/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Star Medical Offices Pc | 415 Oceanview Avenue, Ground Floor, Brooklyn, NY | |

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 Proficiency Testing (PT) desk review survey performed on June 10, 2026, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation. D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity. |
| **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 review of Centers for Medicare & Medicaid Services (CMS) PT Certification and Survey Provider Enhanced Reporting system (CASPER 0155D), |

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| | American Proficiency Institute (API) PT summary reports, the laboratory failed to successfully participate in the CMS approved PT program for two out of three consecutive testing events in the General Immunology specialty for the C-Reactive Protein (High Sensitivity) test analyte in 2025 and 2026 resulting in unsuccessful performance. Refer to D2084 and 2085. |
| **D2084** | GENERAL IMMUNOLOGY<br>CFR(s): 493.837(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 CMS PT CASPER 0155D and API summary reports from 2025 and 2026, the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three consecutive testing events in the General Immunology specialty for the analyte C-Reactive Protein (High Sensitivity). FINDINGS: a. A review of the CASPER 155 report revealed the following unsatisfactory scores: 1. C-Reactive Protein (High Sensitivity) Test Analyte: 2025 Third Event = 60% 2026 First Event = 20% b. A review of the PT scores from API (2025 and 2026) confirmed the above test event findings. |
| **D2085** | GENERAL IMMUNOLOGY<br>CFR(s): 493.837(g)<br><br>(g) 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on CMS PT CASPER 0155D and API summary reports from 2025 and 2026, the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three consecutive testing events in the General Immunology specialty. FINDINGS: a. A review of the CASPER 155 report revealed the following unsatisfactory scores: 1. General Immunology Specialty: 2025 Third Event = 60% 2026 First Event = 20% b. A review of the PT scores from API (2025 and 2026) confirmed the above test event findings. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of CMS PT CASPER 0155D and API summary reports from 2025 and 2026, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory services. Refer to D6016. |

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| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(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:<br>Based on review of CMS PT CASPER 0155D and API 2025-3 and 2026-1 summary reports, the LD failed to ensure successful participation in a CMS-approved PT program. Refer to D2084 and D2085. |