| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 14D0892292 | 12/10/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Semen Analysis Lab | 1101 S Canal St - Ste 202a, Chicago, 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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| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the laboratory director (LD) the laboratory failed to ensure accuracy of 16 of 16 samples not evaluated by the PT provider for five of five PT events in the specialty of hematology from the last event in 2023 through to the date of survey, 12/10/2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Proficiency Testing", which stated, under "G. Response to Unscored /Ungraded Results (Where Grading was Anticipated)", "4. Documentation. Response to unscored/ungraded may be documented in the following ways, at the discretion of the Lab Director." "a. 118.1.3.2.4. Proficiency Testing Unscored/Ungraded Analyte b. 118.1.2.2. Incident Report Form c. A written report using the format of the PT provider of at the Lab Director's discretion" 2. Review of API comparative evaluation summaries for the following PT events of 2023 through 2025 revealed the following 16 ungraded PT samples for sperm morphology classification: PT Event: Analyte: Sample: 2023 Event 3 Morphology SCL-14 2023 Event 3 Morphology SCL-19 2023 Event 3 Morphology SCL-20 2024 Event 1 Morphology SCL-05 2024 Event 1 Morphology SCL-08 2024 Event 1 Morphology SCL-10 2024 Event 3 Morphology SCL-13 2024 Event 3 Morphology SCL-14 2024 Event 3 Morphology SCL-18 2024 Event 3 Morphology SCL-19 2024 Event 3 Morphology SCL-20 2025 Event 1 Morphology SCL-04 2025 Event 1 Morphology SCL-06 2025 Event 1 Morphology SCL-07 2025 Event 1 Morphology SCL-08 2025 Event 3 Morphology SCL-19 3. Review of laboratory records found no documented review of the above 16 ungraded |

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| | PT samples in the specialty of hematology in 2023 through 2025. 4. Interview with the LD on 12/10/2025, at 2:35 pm, confirmed the laboratory failed to ensure accuracy of 16 of 16 PT samples not evaluated by the PT provider for five of five PT events in the specialty of hematology from the last event in 2023 through to the date of survey, 12/10/2025. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for one of three semen analysis measurements performed, sperm motility, in the specialty of hematology from 2024 through the date of survey, 12/10/2025. Findings include: 1. Review of laboratory records revealed the laboratory performed semen analysis measurements including sperm count, sperm motility, and sperm morphology in the specialty of hematology. 2. Review of API PT records revealed the laboratory lacked bi-annual method accuracy evaluations for the semen analysis measurement of sperm motility. 3. Interviews with the LD on 12/10/2025, at 10:53 am, confirmed the laboratory failed to perform bi-annual method accuracy evaluations for one of three semen analysis measurements performed, sperm motility, in the specialty of hematology from 2024 through the date of survey, 12/10/2025. |