

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D2266828     | <b>(X3) Date Survey Completed</b><br><br>04/17/2025 |
| <b>Name of Provider or Supplier</b><br><br>Sollis Health San Francisco   | <b>Street Address, City, State</b><br><br>1005 Van Ness Ave, San Francisco, CA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
|---------------------------|--|
| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of personnel competency assessment records, review of Ten (10) randomly selected patient test results and interview with the Technical Consultant (TC), the laboratory failed to assess employee competency. The findings include: 1. It was the practice of the laboratory to perform General Immunology, Routine Chemistry and Hematology testing. The Laboratory Technicians and Nurse Practitioners were responsible for performing daily maintenance and function check. 2- The laboratory's Technical Consultant affirmed on April 17, 2025, at approximately 12:00 pm, that the laboratory maintained no documentation for the competency assessments for 14 of 16 Testing personnels. 3- The laboratory's testing declaration form, signed by the laboratory director on April 17, 2025, stated that the laboratory performed approximately 2360 tests annually.</p> |
| <b>D5469</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials</p>  |

must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on interview with the Technical Consultant (TC) on April 17, 2025, and review of Chemistry Quality Control (QC) records from 09/10/2024 through 04/17/2025, the laboratory failed to verify the stated values of the commercially assayed chemistry QC materials in use at the time of the survey. The findings include: 1. It was the practice of the laboratory to use NOVA-ONE commercially assayed chemistry QC materials to monitor patient chemistry testing using Piccolo analyzer. The TC stated that the laboratory switched the QC materials from the old lot # 528223003 to the new lot number of lot# 528024002 on 09/10/2024. 2. The laboratory maintained no documentation to indicate the stated values of chemistry QC materials lot number 528024002 had been verified for Piccolo analyzer by the laboratory prior to testing patient samples. 3. On April 17, 2025, at approximately 11:00 am, the technical consultant affirmed that the laboratory did not verify the value of QC materials provided by the manufacturer. 4. The laboratory did not verify the Chemistry QC materials for 8 of 8 months. The laboratory's testing declaration form, signed by the laboratory director on April 17, 2025, stated that the laboratory performed 1650 chemistry tests annually.

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

This STANDARD is not met as evidenced by:

Based on review of personnel competency assessment record, chemistry quality control record, review of Ten (10) randomly selected patient test results, and interview with the Technical Consultant (TC) on April 17, 2025, it was determined that the TC failed to provide technical and scientific consultation to the laboratory. The findings include: 1. The Laboratory failed to verify the manufacturer-established values of the commercially assayed chemistry QC materials of the new QC lot. See D5469. 2. The laboratory failed to follow written policies and procedures to assess testing personnel competency. See D5209