

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2324661	(X3) Date Survey Completed 07/07/2026
Name of Provider or Supplier Sollis Health Palo Alto	Street Address, City, State 555 Middlefield Rd Ste 102, Palo Alto, CA	
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, seven randomly chosen patient records, lack of personnel competency documentation, and an interview with the laboratory supervisor (LS) on July 7, 2026, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform the personnel competency assessment prior to patient testing. The findings include: 1. The laboratory had a written and approved policy for personnel competency assessment that stated: Competency must be assessed at the following frequency: a. During the first year of an individual's duties, competency must be assessed at least annually. b. After an individual has performed his/her duties for one year, competency must be assessed at least annually. 2. The surveyor reviewed seven patient records wherein the tests were performed by the multiple testing personnel (TP). The laboratory lacked competency assessment records for the year 2026 and that no corrective action documentation was available at the time of the survey. a. TP1 completed an initial competency on May 8, 2025, and no subsequent assessments were performed. b. TP2 completed an initial competency on May 27, 2025, and no further competency records were found. 3. The LS confirmed in an interview on July 7, 2026, at approximately 11:10 a.m. that the competency assessments following the initial competency for all TP were not performed. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory reported and performed approximately 1,900 patient samples annually, including the time when the competency assessment policy was not performed following the initial competencies of all testing personnel.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on review of testing records, laboratory documentation for individual competency assessments, the lack of records, and an interview with the laboratory supervisor on July 7, 2026, it was determined that the technical consultant was deficient in fulfilling the responsibility to evaluate and document personnel competency in performing laboratory testing at least annually in 2026. See D5209.