

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0724185	<b>(X3) Date Survey Completed</b> 06/25/2025
<b>Name of Provider or Supplier</b> Synergy Hematology Oncology	<b>Street Address, City, State</b> 8737 Beverly Blvd Ste 203, Los Angeles, 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>D2066</b>	<p><b>SYPHILIS SEROLOGY</b> CFR(s): 493.835(a)</p> <p>(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interviews with the technical consultant (TC) and the testing personnel (TP); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent for the first event of 2022 (Q1-2022). The findings include: 1. The laboratory performed Rapid Plasma Reagin (RPR) using ASI card test kit and enrolled its proficiency testing program with AAB-MLE. 2. The laboratory attained an overall unsatisfactory performance of 60% for RPR test in the Q1-2022 event. 3. The TC and TP affirmed in interviews on June 25, 2025 at approximately 10:00 a. m. that the laboratory attained the unsatisfactory scores as mentioned in statement #2. The quality and reliability of patient tests reported cannot be assured. 4. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported approximately 461 RPR tests including the time the laboratory received the unsatisfactory scores. .</p>
<b>D2075</b>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.837(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p>

This STANDARD is not met as evidenced by:  
 Based on surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, ten randomly chosen patient reports, and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for high sensitive C-Reactive protein (hs-CRP) and Rheumatoid Factor (RF) analytes. The findings include: 1. The laboratory was enrolled with AAB-MLE PT program and obtained unsatisfactory scores for RF during the first event of 2023 (Q1-2023) and hs-CRP on the first event of 2025 (Q1-2025). The result as follows: a. RF analyte on Q1-2023, Overall score: 60% Specimen Reported Expected 1 \*1 3.0 - 11.0 2 121 85.0 - 159.0 3 121 85.0 - 158.0 4 67 46.0 - 86.0 5 \*1 2.0 - 10.0 b. hs-CRP analyte on Q1-2025, Overall score: 20% Specimen Reported Expected 1 0.07 0.0 - 1.43 2 \*0.43 3.15 - 5.86 3 \*0.71 5.09 - 9.45 4 \*0.21 1.12 - 3.12 5 \*0.7 5.09 - 9.46 Legend: \* = unsatisfactory score 2. The TC and TP affirmed on June 25, 2025, at approximately 10:00 a.m. that the laboratory received the unsatisfactory PT scores of for RF and hs-CRP as mentioned in statement#1. 3. The quality and reliability of patient results reported cannot be assured during the time when the laboratory obtained the unsatisfactory scores. 4. According to the testing declaration form submitted at the time of survey, the laboratory tested and reported approximately 2,914 hs-CRP and 404 RF patient samples annually for the subspecialty of General Immunology.

**D2087**

**ROUTINE CHEMISTRY**  
 CFR(s): 493.841(a)

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:  
 Based on the surveyor's review of the laboratory's policy/procedure, American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interviews with the technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Iron analyte in the second event of 2024 (Q2-2024). The findings include: 1. The surveyor reviewed the PT records for Q2-2024, wherein AAB-MLE reported an unsatisfactory score of 60% for the Iron analyte. 2. The TC and TP affirmed by interviews on June 25, 2025, at approximately 10:00 a.m. that the laboratory obtained the PT unsatisfactory scores mentioned in statement #1. Thus, the accuracy and reliability of patient test reported cannot be determined. 3. According to the testing declaration form submitted on the day of the survey, the laboratory performed approximately 2,040 Iron patient test samples including the time the laboratory received an unsatisfactory proficiency testing score.

**D2098**

**ENDOCRINOLOGY**  
 CFR(s): 493.843(a)

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:  
 Based on the surveyor's review of the laboratory's policy/procedure, American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for the Thyroglobulin analyte in the first event of 2025 (Q1-2025). The findings include: 1. The surveyor reviewed the PT records for Q1-2025, where API reported an unsatisfactory score. The results were as follows: a. Thyroglobulin PT Q1-2025 Overall score: 0% Specimen Reported Expected 1 \*3.2 82.2 - 115.0 2 \*7.1 45.3 - 57.1 3 \*4.9 64.1 - 86.5 4 \*8.8 23.6 - 31.3 5 \*12.6 2.7 - 4.7 Legends: \* = unsatisfactory score reported 2. The TC and TP affirmed by interviews on June 25, 2025, at approximately 10:00 a.m. that the laboratory obtained the PT unsatisfactory score mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 201 Thyroglobulin patient test samples during the time the laboratory received an unsatisfactory proficiency testing score. Thus, the accuracy and reliability of patient test reports cannot be determined.

**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 the surveyor's review of the proficiency testing results from the American Association of Bioanalysts - Medical Laboratory Evaluation, and interviews with the technical consultant (TC) and testing personnel on June 12, 2025; this deficient practice is cited due to failure of the TC to provide technical and scientific oversight of the laboratory. The findings include: 1. Unsatisfactory proficiency testing score for SYphilis Serology. See D2066. 2. Unsatisfactory proficiency testing score for General Immunology. See D2075. 3. Unsatisfactory proficiency testing score for Routine Chemistry. See D2087. 4. Unsatisfactory proficiency testing score for Endocrinology. See D2098.