

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2107541	(X3) Date Survey Completed 08/13/2026
Name of Provider or Supplier Sunrise Treatment Center	Street Address, City, State 680 Northland Blvd, Cincinnati, OH	
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
D0000	A Federal Surveyor from the Division of Clinical Laboratory Improvement and Quality (DCLIQ) Survey Branch conducted an onsite validation survey on 08/13 /2026. The laboratory was found to be in compliance with condition--level deficiencies. The following standard-level deficiencies were cited.
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 review of the Laboratory Quality System Assessment Policy, employee competency assessment records and an interview with the Quality Assurance Specialist (QAS), the laboratory failed to establish and follow a competency assessment policy to assess the Technical Supervisor (TS) and General Supervisor (GS) supervisory competency for two of two years, in 2024 and 2025. 1. A review of the Laboratory Quality System Assessment Policy, Revision Six, page 11, Employee Competency, revealed competency assessments for the TS and GS were not included in the policy. 2. A review of employee competency assessment records revealed the following: GS: No competency assessments performed in 2024 and 2025. TS: No competency assessment performed in 2025. 3. In an interview on 08/13/2026 at 10:40 AM the QAS confirmed the findings stated above.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from

the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Quality System Assessment Policy, laboratory quality assessment records, and interview with the Quality Assurance Specialist (QAS), the laboratory failed to establish and follow policies and procedures to assess the accuracy and reliability of the Laboratory Information System (LIS) in reporting patient test results for two of two years, in 2024 and 2025. 1. A review of the Laboratory Quality System Assessment Policy, Revision Six revealed no policy and procedure for evaluating the accuracy and timeliness of the LIS in reporting patient test results. 2. A review of laboratory quality assessment records revealed there were no LIS assessments completed in 2024 and 2025. 3. In an interview on 08/13/2026 at 12:00 PM, the QAS confirmed the findings stated above.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of laboratory personnel records and an interview with the Quality Assurance Specialist (QAS), the Laboratory Director failed to specify, in writing, the responsibilities and duties for one of one Technical Supervisor (TS) in 2025. 1. A review of the laboratory personnel records revealed there were no responsibilities and duties specified in writing by the Laboratory director for the TS. 2. In an interview on 08/13/2026 at 10:45 AM, the QAS confirmed the findings stated above.