

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1043269	(X3) Date Survey Completed 08/25/2025
Name of Provider or Supplier Rockford Dermatology Sc	Street Address, City, State 4338 Morsay Drive, Rockford, 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
D5028	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Repeat Condition Based on review of the laboratory's Allegation of Compliance (AoC) response regarding citations from the 03/07/2023 recertification survey, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory director (LD); in a repeated deficiency from 03/07/2023 recertification survey, the laboratory failed to perform bi-annual method accuracy evaluations (peer-reviewed slides/proficiency testing (PT) slides) for histopathology testing in 2023 through date of 08/25/2025. See D5217.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Repeat Deficiency Based on review of the laboratory's Allegation of Compliance (AoC) response regarding citations from the 03/07/2023 recertification survey, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory director (LD); in a repeated deficiency from 03/07/2023 recertification survey, the laboratory failed to perform bi-annual method accuracy evaluations (peer-reviewed slides/proficiency testing (PT) slides) for histopathology</p>

testing in 2023 through date of 08/25/2025. Findings Include: 1. Repeat deficiency from 03/07/2023 recertification survey. 2. Review of the laboratory's AoC, submitted 03/27/2023 in response to deficiencies cited 03/07/2023 and signed by the LD on 03/23/2023, stated, "Proficiency testing will be performed by ... [secondary dermatopathologist] and documented to meet this requirement biannually." 3. Review of laboratory policies and procedures revealed the procedure titled, "Procedure and Form", which stated, under "Quality Control Procedures", "Split samples for testing with another CLIA-certified laboratory ... biann[u]ally." 4. Review of laboratory records found the laboratory failed to perform biannual method accuracy evaluations (peer-reviewed slides/proficiency testing (PT) slides) for the years 2023 through 08/25/2025 for histopathology testing. 5. Interview with the LD on 8/25/2025, at 12:10 pm, confirmed the laboratory failed to perform the bi-annual method accuracy evaluations for histopathology testing in 2023 through the date of survey, 08/25/2025.