

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2061541	(X3) Date Survey Completed 02/10/2026
Name of Provider or Supplier Skinpath Diagnostics, Llc	Street Address, City, State 951 Hwy 654, Mathews, LA	
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 Recertification survey was performed at Skinpath Diagnostics, LLC, CLIA ID 19D2061541, on February 10, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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: Based on review of the laboratory's policies, records, test menu, and interview with personnel, the laboratory failed to verify the accuracy of Histopathology testing at least twice annually as required for two (2) of two (2) years reviewed. Findings: 1. Review of the laboratory's policies revealed "The semi-annual peer review process will be utilized to assess diagnostic accuracy/competency of interpretation, assess the quality of slide preparation including processing, embedding, microtomy and staining, and assess the quality of services for cases referred." 2. Review of the laboratory's records revealed the laboratory did not have documentation of verification of the accuracy of Histopathology testing at least twice annually for 2024 and 2025. 3. In interview on February 10, 2026 at 8:54 am, the Office Manager stated the peer review process is done differently each time due to the low volume of testing performed by the Laboratory Director. The Office Manager confirmed the accuracy of Histopathology testing was not performed at least twice annually for 2024 and 2025. 4. Review of the laboratory's test menu revealed the laboratory performs ten (10) cases annually.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p>

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient final test reports and interview with personnel, the laboratory failed to include the address of the laboratory where testing was performed for eleven (11) of sixteen (16) patients reviewed. Findings: 1. Review of 2024 and 2025 patient final test reports revealed the address of the laboratory that performed the testing was not included for the following eleven (11) patients: Patient RM25-0204-A Patient RM25-0430 Patient RM25-0671 Patient RM25-0821 Patient RM25-1234 Patient RM25-1244 Patient RM25-1437 Patient RM25-1797 Patient RM25-1917 Patient RM25-1918 Patient RM25-1925 2. In interview on February 10, 2026 at 9:22 am, the Office Manager confirmed the identified patient final reports did not include the correct address of the laboratory that performed the testing.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5217.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(8)

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.