

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2309996	(X3) Date Survey Completed 08/13/2026
Name of Provider or Supplier Optima Dermatology	Street Address, City, State 215 Commerce Way, Ste 100, Portsmouth, NH	
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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on review of patient test records, quality control (QC) records and interview with the Compliance Manager (CM1), the laboratory (lab) failed to perform and document QC for hematoxylin and eosin (H&E) stain for stain batches on 3 out of 3 days reviewed when H&E patient slides were made in June 2026. Findings include: 1. Review on 8/13/2026 of the lab's policy titled "Daily H&E Slide Quality Review - Office Lab (215 Commerce Way, Portsmouth - CLIA ID 30D2309996)", effective 6/2/2025, revealed instruction on page 1 under "Protocol 1-3 to select one representative patient slides from that day's batch at the beginning of each reading session to assess and document the quality of H&E stain for the intended staining characteristics. The instruction does not specify representative slides made from batches on different days must be assessed separately, even if read the same day. 2. Review on 8/13/2026 of 4 patient (PT1, PT2, PT3, and PT4) test records from June 2026 for H&E slide interpretation revealed the following: PT1 and PT2 samples were collected on 5/27/26 and slides were read on 6/1/2026, PT3 sample was collected 6/10/26 and slides were read on 6/25/26, and PT4 sample was collected on 6/24/26 and slides were read on 6/30/26. There was no documentation when the H&E stain was used to make slides for PT1, PT2, PT3, or PT4. 3. Review on 8/13/2026 of QC records from May, June and July 2026 revealed no documentation of QC for daily batches when H&E stain was used to make slides for PT1, PT2, PT3, and PT4. 4. Interview on 8/13/2026 at 10:15 a. m. with CM1 confirmed the above findings.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's (lab) application, personnel records and interview with the lab's Compliance Manager, the Technical Consultant (TC1) failed to perform assessment of test performances in 2025 and 2026 for 2 out of 3 personnel listed as moderate complexity testing personnel on Form CMS-209 personnel form. Findings include: 1. Review on 8/13/2026 of Form CMS-209 (personnel list), revealed 3 testing personnel for moderate complexity testing. 2. Review on 8/13/2026 of Form CMS-116 (application) revealed the laboratory's listed potassium hydroxide (KOH) microscopy procedures as the only moderate complexity test. 3. Review on 8/13/2026 of personnel competency assessment records from 2025 and 2026 revealed 2 (TP1 and TP2) out of 3 testing personnel failed to successfully complete assessment of test performances in 2025 and 2026. TP1's record included unsuccessful participation in proficiency testing in 2 out of the 2 events TP1 participated in in 2025 with no follow up for additional assessments and no assessments completed in 2026. TP2's personnel record revealed no assessments of test performance in 2025 and 2026. 4. Interview on 8/13/2026 at 9:15 a.m. with the Compliance Manager revealed the lab uses the proficiency testing to assess test performance and no other methods. 5. Review on 8/13/2026 of patient KOH testing logs for 2025 and 2026 revealed TP1 performed 2 KOH's in 2025 and no KOH's in 2026; and TP2 performed no KOH's in 2025 or 2026.