

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 50D1085511	(X3) Date Survey Completed 08/22/2023
Name of Provider or Supplier North Pacific Dermatology, Ps	Street Address, City, State 1200 112th Ave Ne Ste C-187, Bellevue, WA	
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
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 a review of the laboratory proficiency Testing/Peer review (PTPR) documentation, the laboratory personnel records, and an interview with the laboratory Compliance Manager (CM), the laboratory failed to verify, twice annually, the accuracy of Histopathology Micrographic surgical (Mohs) testing. Findings include: 1. The laboratory's PTPR procedure 7.15 "Proficiency Testing Policy" states, " The initial Mohs Surgeon and the laboratory Director will review the findings of the review and sign the Peer Review for Mohs Micrographic Surgery Form." 2. Review of 18 PTPRs records for 2021, and 2022, to the survey date, revealed that for 15 of 18 PTPRs, the Laboratory Director (LD) and initial surgeon (a testing personnel) failed to document review of the PTPRs for 2021, 2022 and 2023. Three of the PTPRs for 2023 to date of survey were were not signed by the LD . Year Month Mohs Case# LD /Surgeon Review 2021 July M21-169 No Signatures 2021 July M21-202 No Signatures 2021 July M21-285 No Signatures 2022 Jan. M22-603 No Signatures 2022 Jan. M22-558 No Signatures 2022 Jan. M22-447 No Signatures 2022 June M22-279 No Signatures 2022 June M22-152 No Signatures 2022 June M22-67 No Signatures 2022 Dec. M22-489 No Signatures 2022 Dec. M22-639A No Signatures 2022 Dec. M22-848 No Signatures 2023 May M23-286 No Signatures 2023 May M23-341 No Signatures 2023 May M23-343 No Signatures 2023 June M23-272 No LD Signature 2023 June M23-366 No LD Signature 2023 June M23-381 No LD Signature 3. The CM confirmed by interview on August 22, 2023, at 11:20 AM the lack of review and signatures by the Laboratory Director and the initial Mohs' surgeon (testing personnel). 4. The laboratory reports performing 5413 Mohs Micrographic patient tests annually.</p>

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review of proficiency testing/Peer review (PTPR) records, review of the laboratory's Quality Assessment Plan, and interview with the laboratory Compliance Manager (CM) and Histotechnologist Testing personnel #1 (HTP-1), the laboratory failed to follow their established Quality Assessment (QA) plan. Findings include: 1. A review of 18 PTPR records, and four (4) Mohs' patient case logs revealed transcription errors on 1 of 18 PTPR records, and 2 of four patient case logs. a. Mohs case Record 2021 M21-202, was listed and reviewed by Peer Reviewer as 2021 M21-169. b. Mohs Case record 2022 M22-13 recorded 4 slides created, the slide review count on day of the survey revealed 5 slides created. c. Mohs Case record 2022 M657 recorded 8 slides created, the slide review count on day of the survey revealed 9 slides created. 2. Review of the laboratory's QA program (9.1) item #6 states, " the results of all peer review proficiency testing (PTPR) will be reviewed by the laboratory director upon completion... This information will be recorded and kept with the proficiency testing records." 3. Request for documentation of the laboratory's QA plan assessments for 2021 and 2022, to date of survey, revealed the laboratory failed to perform and document QA activities as outlined in the QA Plan. 4. The laboratory CM and testing personnel #1 confirmed by interview on 08/22/2023 at 11:53 PM, the laboratory failed to document QA assessments as established by the laboratory. 5. The laboratory reports performing 5413 Histopathology tests annually.