Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0424105	12/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Rush Univ Med Center Dermatology Patient Svcs	1725 W Harrison St, Ste 264, Chicago, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory records, and interview with the laboratory representative; the laboratory failed to test proficiency testing (PT) samples by personnel who routinely perform potassium hydroxide (KOH) testing in the subspecialty of mycology for five of five events in 2024 and 2025. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form and laboratory competency records revealed 37 testing personnel (TP) authorized to perform KOH testing in the subspecialty of mycology. 2. Review of American Proficiency Institute (API) PT documentation and interview with the laboratory representative on 12/08/2025, at 1:44 pm, revealed five of five PT events were performed by TP #8. Year, Event: TP #: 2024 - Event 1 8 2024 - Event 2 8 2024 - Event 3 8 2025 - Event 1 8 2025 - Event 2 8 3. Interview with the laboratory representative on 12/08/2025, at 1:44 pm, confirmed the laboratory failed to test PT samples by personnel who routinely perform KOH testing in the subspecialty of mycology for five of five events in 2024 and 2025.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to ensure attestation statements were completed for five of five proficiency testing (PT) events for potassium hydroxide (KOH) testing in the subspecialty of mycology in 2024 and 2025. Findings include: 1. Review of American Proficiency Institute (API) PT records for 2024 and 2025 revealed a lack of attestation statements for five of five KOH events in the subspecialty of mycology in 2024 and 2025. Year, Event: Attestation Completed: 2024 - Event 1 No 2024 - Event 2 No 2024 - Event 3 No 2025 - Event 1 No 2025 - Event 2 No 2. Interview with the laboratory representative on 12/08/2025, at 1:40 pm, confirmed the laboratory failed to ensure attestation statements were completed for five of five PT events for KOH testing in the subspecialty of mycology in 2024 and 2025.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed Mohs micrographic surgery results) for eight of eight events from the beginning of 2024 through the date of survey, 12/08/2025, in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "[Quality Control/Quality Assurance] QC/QA Program", which stated, "3. Five surgical cases per quarter shall be reviewed by a Dermatopathologist. Their diagnoses shall be compared against each other and against the original diagnoses. If needed, appropriate action shall be taken and documented." 2. Review of laboratory records revealed a lack of documentation of evaluations of results upon receipt of peer reviewed Mohs micrographic surgery results for eight of eight reviewed biannual method accuracy events. Year, Quarter (Q): Results Reviewed: 2024 - Q1 No 2024 - Q2 No 2024 - Q3 No 2024 - Q4 No 2025 - Q1 No 2025 - Q2 No 2025 - Q3 No 2025 - Q4 No 3. Interview with the laboratory representative on 12/08/2025, at 2:11 pm, confirmed the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed Mohs micrographic surgery results) for eight of eight events from the beginning of 2024 through the date of survey, 12/08/2025, in the subspecialty of histopathology.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by:

	Based on review of laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to document dermatopathology special stain known reactivity and immunohistochemical (IHC) stain positive and negative reactivity for two of three patients tested from the beginning of 2025 through the date of survey, 12/08/2025. Findings include: 1. Review of patient testing records for dermatopathological interpretations revealed one of three patients tested failed to document special stain known reactivity with each patient slide or group of patient slides. Report Date: Case #: Special Stain(s): 01/22/2025 DU25-00198 Periodic acid-Schiff (PAS) Gram Stain (GMS) 2. Review of patient testing records for dermatopathological interpretations revealed one of three patients tested failed to document IHC stain positive and negative reactivity each time of use. Report Date: Case #: IHC Stain(s): 06/09/2025 DU25-02307 PRAME SOX10 Melan-A P16 HMB45 3. Interview with the laboratory representative on 12/08/2025, at 4:53 pm, confirmed the laboratory failed to document dermatopathology special stain known reactivity and immunohistochemical (IHC) stain positive and negative reactivity for two of three patients tested from the beginning of 2025 through the date of survey, 12 /08/2025.