

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0971985	(X3) Date Survey Completed 06/28/2018
Name of Provider or Supplier Rush Copley Dermatology	Street Address, City, State 1012 W 95th St, Ste 1, Naperville, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory director (LD); the laboratory failed to establish policies and procedures to assess employee competency. Findings Include: 1. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of personnel listed on the CMS-209. 2. On survey date 06-28-2018 at 12:15 pm, the LD confirmed the laboratory failed to establish a competency assessment policy.</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: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for Mohs histopathology testing in 2016 through date of survey (06-28-2018) in 2018. Findings Include: 1. Review of proficiency testing documentation found no documented Mohs histopathology bi-annual method accuracy evaluations. 2.</p>

	<p>Interview with the LD on 06-28-2018, at 12:15 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for Mohs histopathology testing in 2016 through 2018.</p>
<p>D5219</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for scabies wet mount testing in 2016 through date of survey (06-28-2018) in 2018. Findings Include: 1. Review of proficiency testing documentation found no documented wet mount bi-annual method accuracy evaluations. 2. Interview with the LD on 06-28-2018, at 12:15 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for scabies wet mount testing in 2016 through 2018.</p>
<p>D5409</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to document the initial use and discontinuance of all laboratory procedures. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "V-9. Laboratory Procedure Manual Staining Procedures", which failed to document the date of discontinuance. 2. On survey date 6-28-2018, at 12:15 pm, the LD confirmed the laboratory was not performing any of the staining procedures identified in the above mentioned procedure but had not discontinued the procedure.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the technical consultant failed to ensure new testing personnel (TP) received documented competency examinations semiannually during the first year of testing. Findings Include: 1. Review of the laboratory personnel report (CMS-209) identified 1 new moderate complexity testing personnel (TP), TP#3. 2. Review of competency</p>

assessment records found no documented competency assessments for TP#3. 3. On survey date 6-28-2018, at 12:15 pm, the laboratory director confirmed that semi-annual competency assessments were not documented for 1 of 1 new moderate complexity TP.