Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0424105	08/07/2018
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's policies, procedures and records, and an interview with the laboratory manager, the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Microbiology testing, affecting 6 out of 6 testing personnel (TP). Findings: 1. The CMS 209 lists 6 licensed physicians performing Potassium Oxide (KOH), Scabies, and Tzanck testing in the laboratory. 2. The personnel documents revealed that 6 out of 6 TP have not received competencies for the years of 2016 thru 2018, but were performing patient testing during this period. 3. The laboratory's manual does not include an established competency policy and step-by-step procedure for TP performing KOH, Scabies, and Tzanck testing that includes the following personnel assessment requirements: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; b). Monitoring the recording and reporting of test results (for example, recording patients and their results in the labs' test log and/or EMR system); c). If applicable, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d). Direct observation of performance of instrument maintenance and function checks (i.e. microscope maintenance, etc.); e). Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f). Assessment of problem solving skills; and g). Evaluating and documenting the performance of individuals responsible for moderately complex

	testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually. 4. On a Recertification survey conducted on 08/07/2018 at 1:35 PM, the laboratory manager confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies, procedures, test records, and an interview with the laboratory manager; the laboratory failed to verify the accuracy of tests performed in the specialty of Microbiology at least twice annually, affecting 242 patients. Findings: 1. The manual and test records reveal that the laboratory performs the following tests: Potassium Hydroxide (KOH), Tzancks, and scabies. 2. The laboratory's manual does not define the method and procedure the laboratory will use to verify the accuracy of its KOH, Tzancks, and scabies testing. 3. During the period of 07/30/2018 through 07/06/2018, the laboratory performed KOH testing on 242 patients. 4. On a Recertification survey conducted on 08/07/2018 at 1: 30 PM, the laboratory manager confirmed the above findings.
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 the surveyor's review of the laboratory's manual, records and an interview with the laboratory manager; the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings: 1. The laboratory's freezer temperature charts revealed the following: a). It states that the acceptable temperature range of the freezer is -27 to -30 degrees. b). The recorded temperatures from December of 2017 through August 2018 were not within the required temperature range. c). No written evidence that the decreasing temperatures recorded on the charts (from 12/2017 thru 08/2018) had been identified as being out of the required temperature range. d). No documented evidence was provided to show corrective actions were taken to resolve the decreasing temperature of the freezer; and e). No written evidence that the temperature charts (from 12/2017 thru 08/2018) had been reviewed by the technical supervisor. 2. On a Recertification survey conducted on 08/07/2018 at 1:30 PM, the laboratory manager confirmed the above findings.