Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0685379	02/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rutgers Rwjms Center For Dermatology	1 World'S Fair Drive, Somerset, NJ	

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 surveyor review of the Procedure Manual (PM) and interview with the Registered Nurse (RN), the laboratory failed to follow and establish a Competency Assessment (CA) procedure which included the elements required to assess competency of the two Histopathology Testing Personnel (TP) from 07/24/18 to the date of survey. The findings include: 1. The CA procedure stated "Laboratory Personnel will be evaluated and assessed at 6 and 12 months", but there was no documented evidence to show CA was performed. 2. The CA form in use at the lab was entitled "Robert Wood Johnson Medical" but the facility is Rutgers Division of Dermatology. 3. The CA form had the following criteria Mohs TP do not participate in: a. "Accurate test performance has been proven by external Proficiency Testing (PT)" b. "Quality Control and PT test records are reviewed and acted upon when necessary" 4. The CA form does not require documentation of he element used to assess the TP. 5. The RN confirmed on 2/25/21 at 1:20 PM that the laboratory did not establish the CA procedure. Note: Competency Assessment was cited on the last survey performed 7/24/18.
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: a. Based on surveyor review of the Biannual Assessment (BA) records, Procedure Manual (PM) and interview with the Registered Nurse (RN), the laboratory failed to verify the accuracy of Histopathology testing twice annually from 7/24/18 to the date of the survey . The findings include: 1. The Quality Control procedure in the PM states the laboratory reviews "5 cases annually", but review of the BA records revealed 2 cases were reviewed in 2019 and 2020.. 2. There was no comparison of results documented on the BA record 3. The RN confirmed on 2/25/21 at 1:20 pm that the laboratory did not verify the accuracy of the Histopathology testing twice annually. Note: This was cited on the previous survey performed on 7/24/2018 b. Based on lack of the BA records, review of the PM and interview with the RN, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) and Scabies testing twice annually from 7/24/18 to the date of survey. The RN confirmed on 2/25 /21 at 1:45 pm that the laboratory did not verify the accuracy of tests stated above twice annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Registered Nurse (RN), the laboratory failed to have written procedures for Potassium Hydroxide (KOH) and Scabies tests from 7/24/18 to the date of the survey.. The RN confirmed on 2/25/2021 at 1:20 pm that the laboratory did not have written procedures for all tests and examinations performed by the laboratory.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Records (TR) and interview with the Registered Nurse (RN), the laboratory failed to document Room Temperature (RT) where Histopathology test reagents were stored and tests were performed from 7/24 /18 to the date of the survey. The findings include: 1. There were no temperatures recorded on the RT chart. 2. The RN confirmed on 2/25/2021 at 1:15 pm that the laboratory failed to accurately record RT.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of Histology reagents and interview with the Registered Nurse (RN), the laboratory failed to discard expired Histopathology reagents from 3/ 2020 to the date of survey. The findings include: 1. On the date of the survey the laboratory used expired Tissue Marking Dye reagents as follows: a. Yellow - Lot 064986 expired 3/2020 b. Blue - Lot 065113 expired 3/2020 c. Red - Lot 065078 expired 3/2020 d. Green - Lot 065445 expired 3/2020 2. Approximately 500 patients were tested with expired reagents. 3. The RN confirmed on 2/25/21 at 1:30 pm that the laboratory used expired reagents.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Registered Nurse (RN), the laboratory failed to perform and document QC on each day of patient testing for Potassium Hydroxide (KOH) and Scabies test from 7/24/18 to the date of the survey. The RN confirmed on 2/25/21 at 1:10 pm that the laboratory did not perform QC each day of patient testing on tests stated above.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Book (AB) and interview with the Registered Nurse (RN), the laboratory failed to maintain an accurate information system for Potassium Hydroxide (KOH) tests from 6/3/20 to the date of the survey.

	The findings include: 1. Review of the AB and revealed: a. Patients were identified with two initials in 16 of 16 entries b. "Patient No" was not completed in 16 of 16 entries c. " Dr/Ward#" was identified by initials in 12 of 16 entries d. "Dr/Ward#" was not completed in 3 of 16 entries e. The date recorded was identified as "Date Sent" but AB stated "test performed" f. "Date Rec" was not completed for 16 of 16 entries 2. The RN confirmed at 2:45 pm on 2/25/21 the laboratory did not main an accurate information system for KOH tests.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on surveyor review of a Procedure Manual (PM) and interview with the Registered Nurse (RN), the Laboratory Director (LD) failed to have an approved PM for Histopathology testing from 7/24/18 to the date of the survey. The RN confirmed on 2/25/21 at 2:00 pm that the LD did not ensure an approved PM was available.