

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0685379	<b>(X3) Date Survey Completed</b> 11/08/2023
<b>Name of Provider or Supplier</b> Rutgers Rwjms Center For Dermatology	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL to perform Mycology and Parasitology testing from 2/27/21 to date of survey. A Surveyor from the NJCLL Program confirmed on 11/13/23 that the laboratory did not have a NJCLL.</p>
<b>D5217</b>	<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 lack of the Biannual Assessment (BA) records, review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) tests for Mycology twice annually from 2/25/21 to the date of survey. The LD confirmed on 11/8/23 at 9:00 am that the laboratory failed to verify the accuracy of KOH tests twice annually. Note: This was cited previously on the survey performed on 2/25/21.</p>
<b>D5417</b>	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 Histopathology reagents and dyes, surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD) the laboratory used and failed to discard expired Histopathology dyes from 03/2020 to the date of survey. The findings include: 1. The procedures 4.2.2 and 4.3.2 in the PM stated " Do not use reagent after expiration date." 2. The following Tissue Marking Dyes were observed passed the Manufacturers Expiration date: a. Black - Lot 114240 expired 1/31/23 b. Blue - Lot 065113 expired 3/2020 c. Green - Lot 112722 expired 12 /31/22 d. Green - Lot 065445 expired 3/2020 e. Red- Lot 065078 expired 03/2020 3. The laboratory performs approximately 420 Histopathology tests annually. 4. The LD confirmed on 11/8/23 at 9:20 am that the laboratory used and failed to discard expired tissue marking dyes used in Histopathology testing. Note: This was previously cited on the survey performed on 2/25/21.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of the Procedure Manual, Proficiency Testing records and interview with the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 2/25/21 to the date of the survey. 1. The LD failed to ensure the laboratory provided quality laboratory services for all aspects of test performance for Mycology and Parasitology . Cross refer to D6082. 2. The LD failed to ensure that the laboratory was enrolled in an HHS-approved proficiency testing program for Parasitology testing. Cross refer to D6088

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Microscopy Log (ML) and interview with the Laboratory Director (LD), the LD failed to ensure the laboratory provided quality laboratory services for all aspects of test performance for Mycology and Parasitology tests from 10/13/22 to the date of the survey. The findings include: 1. The laboratory

failed to maintain an accurate record system for Potassium Hydroxide (KOH) and Scabies tests. a. 2 out of 5 entries did not have a 2nd identifier. b. Patient Identification "KM" had an inaccurate test performed date of "10/18/3." 2. The LD confirmed on 11/8/23 at 9:25 am the laboratory failed to maintain an accurate record system.

**D6088**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:  
Based on the lack of Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the LD failed to ensure that the laboratory was enrolled in a Health and Human Services (HHS) approved proficiency testing program for Parasitology testing from 2/25/21 to the date of survey. The LD confirmed on 11/8/23 at 9:00 am the laboratory did not perform PT testing for Parasitology.