

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D2050294	<b>(X3) Date Survey Completed</b> 03/12/2020
<b>Name of Provider or Supplier</b> Wesson Dermatology	<b>Street Address, City, State</b> 1010 Northern Blvd, Suite 120, Great Neck, NY	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 lack of competency assessment written procedure and an interview with the office manager, the laboratory failed to establish a written procedure for competency assessment for the testing personnel performing KOH and fungal cultures. FINDINGS: The office manager confirmed on March 12, 2020 at approximately 10:30 AM, that the laboratory failed to establish and follow written procedures for competency assessment based on specific skills for personnel performing KOH and fungal culture testing.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 the lack of twice yearly verification and confirmed at survey with the office manager, the laboratory failed to verify the accuracy for KOH and fungal culture testing at least twice per year.</p>
<b>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p>

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on surveyor's review of records and an interview with the office manager, the laboratory failed to ensure that the: 1. laboratory followed the manufacturer's temperature requirements for the fungal media, refer to D5413; 2. laboratory established and followed policies and procedures, refer to D5403; 3. laboratory discontinued the use of the expired KOH reagent, refer to D5417; 4. laboratory follow the established microscope maintenance policy, refer to D5433; 5. laboratory perform and document quality control for the fungal media, refer to D5445.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on surveyor review of laboratory's records and interview with the office manager, the laboratory failed to establish a written policy/procedures for: 1. Requirements for patient preparation; specimen collection, labeling, processing. 2. Corrective action for inadequate slides. 3. Step-by-step procedure, for microscopic examination of KOH and interpretation of results. 4. Twice per year verification and remediation of any discrepant results found during the twice yearly verification of KOH and fungal cultures; 5. Preventive maintenance of the microscope.

**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 a lack of refrigerator temperature, room temperature, and humidity records and an interview with the office manager, the laboratory failed to follow the manufacturer's instructions to monitor and document the refrigerator temperature, room temperature and humidity where testing is performed. Findings Include: It was confirmed by the office manager, on March 12, 2020 at approximately 10:30 AM that the laboratory failed to monitor and document the temperature of the refrigerator where the DTM Media were stored and failed to monitor and document the room temperature and humidity where fungal culture testing is performed from January 2019 through survey date.

**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 a surveyor observation and confirmation by the office manager, the laboratory failed to discontinue the use of expired testing material for patient testing. FINDINGS: 1. The surveyor observed one bottle of 10% Potassium hydroxide (KOH) reagent, lot # 1831812 expiration date 11/14/2019. 2. On March 12, 2020 at approximately 11:00 AM, the office manager confirmed surveyor's findings that the laboratory used expired KOH reagent from 11/15/2019 through the survey date; 3. Approximately 2 patient samples were tested and reported for KOH from 11/15/2019 through the survey date.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on lack of maintenance records and confirmed in an interview with the office manager, the laboratory failed to establish and follow the microscope maintenance policy and perform a cleaning of the microscope after each day of use for KOH.

<p><b>D5445</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) records for the fungal media and an interview with the office manager, the laboratory failed to perform quality control on the fungal media from January 2019 through survey date. FINDINGS: 1. The office manager confirmed on March 12, 2020, at approximately 10:40 AM, the surveyor findings, that the laboratory failed to perform QC to ensure the reactivity of the media, physical characteristics and sterility for the fungal media from January 2019 to survey date. 2. Approximately 90 patient samples were tested and reported for fungal culture during the above time frame.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of Quality Assessment (QA) records and confirmed at survey with the office manager, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on a surveyor's review of the personnel records and confirmed in an interview with the office manager, the laboratory director failed to ensure that two of three testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma prior to performing patient testing. Refer to D6065</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b></p>

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a surveyor's review of personnel records and confirmed in an interview with the office manager at the time of the survey, the laboratory director failed to ensure that the two of three testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma prior to performing patient testing.

**D8100**

**INSPECTION REQUIREMENTS**

CFR(s): 493.1771

Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.

This CONDITION is not met as evidenced by:

Based on surveyor review of records and an interview with the office manager, the laboratory failed to meet the requirements in 493.1773 and 493.1775 to obtain the certificate of compliance prior to testing moderate complexity Mycology DTM culture testing.

**D8201**

**INSPECTION OF COW OR PPMP LABS**

CFR(s): 493.1775(b)

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

This STANDARD is not met as evidenced by:

Based on surveyor review of records and an interview with the office manager, the

laboratory director failed to ensure that the laboratory is not testing beyond the scope of the certificate held by the laboratory. Findings: 1. The laboratory currently has the certificate of Provider-Performed Microscopy Procedures (PPMP). 2. On March 12, 2020 at approximately 10:00 AM the office manager confirmed surveyor findings that the laboratory has been performing fungal culture which requires a certificate of compliance.