

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1041391	(X3) Date Survey Completed 11/20/2018
Name of Provider or Supplier Schaumburg Dermatology	Street Address, City, State 911 N Plum Grove Rd, Ste A, Schaumburg, 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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to retain histopathology slides for at least 10 years from the date of examination. Findings include: 1. Review of patient testing logs revealed that the laboratory's testing log was a combination of patients that were tested in-house and those that were sent to reference laboratories. 2. At 10:30 AM, the surveyor selected 7 patients' name from the testing log where it was indicated that the testing was performed in-house. 3. The surveyor requested the corresponding test reports and slides for the 7 patients' names selected. 4. There was no slide available for review for 3 of 7 patients' slides requested. 5. At 11:00 AM on 11/20/18, the practice manager confirmed the surveyor's findings.</p>
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p>

This CONDITION is not met as evidenced by:
 Based on review and interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. Findings include: 1. The laboratory director failed to show that all testing personnel could demonstrate that they were competent to perform and report testing. There were no competency assessments performed on all testing personnel. See tag D5209. 2. The laboratory failed to verify the accuracy of all tests performed at least twice a year. See tag D5217. 3. The laboratory failed to ensure that it only referred patients' specimens to CLIA certified laboratories. See tag D5315. 4. The laboratory failed to have a comprehensive procedures manual for all tests it performs. See tag D5401. 5. The laboratory failed to establish, perform, and document a maintenance protocol for its microscopes. See tag D5433. 6. The laboratory failed to ensure that test reports included location where each part of the test was performed. See tag D5805.

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 review and interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings include: 1. Review of the laboratory's procedures manual revealed that there were no procedures that described who was responsible for Potassium Hydroxide testing. 2. Review of Laboratory Personnel Report - CLIA (FORM CMS 209) revealed that there were a total of 2 testing personnel who were responsible for Potassium Hydroxide (KOH) wet mount testing in the laboratory. 3. Review of personnel records revealed that there was no documentation to show that training and competency assessments were performed on 2 of 2 testing personnel performing KOH testing. 4. At 11:30 AM on 11/20/18, the practice manager confirmed the surveyor's 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 review and interview, the laboratory failed to verify the accuracy of its Potassium Hydroxide testing at least twice annually. Findings include: 1. There were no procedures that described the laboratory's process for verifying the accuracy of its Potassium Hydroxide (KOH) testing. 2. There was no documentation to show that the laboratory verified the accuracy of its KOH testing with all testing personnel who perform KOH testing. 3. At 11:00 AM on 11/20/18, the practice manager confirmed the surveyor's findings.

<p>D5315</p>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c)</p> <p>The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.</p> <p>This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to ensure that it refers a specimens for testing only to CLIA - certified laboratories. Findings include: 1. Review of the laboratory's policies and procedures manual revealed that the laboratory refers biopsy specimens to Consolidated Pathology Consultants (CPC) laboratory. However, there was not a copy of CPC's CLIA certificate made available during the time of survey on 11/20/18 2. Review of the laboratory's log book revealed that there were initials in the laboratory's log book to reflect which laboratories the laboratory referred its specimens. These laboratory's included the following labs: a. Quest b. Lab Corp c. others There was no written procedure to reflect that the laboratory referred its specimens to other laboratories besides CPC. Also, there were no copies of each reference laboratory's CLIA certificates to reflect that the laboratory ensured that they were sending their specimens to CLIA certified laboratories. 3. At 11:00 AM on 11/20 /18, the practice manager confirmed the surveyor's findings.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review and interview, a written procedure for all tests, assays, and examination performed by the laboratory was not available to, or followed by laboratory personnel. 1. Review of the laboratory's application for CLIA Certification revealed that the laboratory initially only entered test volumes for the subspecialty of Histopathology. 2. In an interview with the laboratory director, it was revealed that the laboratory performed Potassium Hydroxide (KOH) wet mounts for the visual detection of mycology and parasitology organisms. After this was revealed, the surveyor instructed laboratory staff to enter the test volumes of KOH tests onto the CLIA application to reflect this. 3. Review of the laboratory's procedures manual revealed that there were no procedures that instruct personnel on how they are to perform and document KOH examinations. 4. At 10:00 AM on 11/20/18, the laboratory director confirmed the surveyor's findings.</p>
<p>D5433</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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</p>

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 review and interview, the laboratory failed to perform and document maintenance activities as specified. Findings include: 1. Review of the laboratory's equipment revealed that there was a microscope that the Physicians Assistants (PAs) used when they examined KOH wet mounts. 2. There were no manufacturer's instructions for the microscope available for review. 3. There were no written procedures that described the laboratory's protocol for maintaining the microscope the PAs used. 4. There was no documentation to show that maintenance was performed on the microscope the PAs used for KOH testing. 5. At 11:30 AM on 11/20/18, the practice manager confirmed the surveyor's findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review and interview, the test report did not indicate the name and address of the laboratory location where the histopathology tests were performed. Findings include: 1. Review of laboratory procedures manuals revealed that pathologist form Consolidated Pathology Consultants came on site to Schaumburg Dermatology to examine this laboratory's histopathology slides. 2. Review of patient testing logs revealed that the laboratory's testing log was a combination of patients that were tested in-house and those that were sent to reference laboratories. 3. At 10:30 AM, on 11/20/18, the surveyor selected 7 patients' name from the testing log where it was indicated that the histopathology testing was performed in-house. 4. Review of test reports for the 7 patients names selected revealed that the name and address location of Schaumburg Dermatology was not included on the test report. However, Consolidated Pathology Consultants name and address was included on 3 of 7 test reports, as the laboratory performing both the gross description and microscopic description of patients' specimens. Note: Consolidated Pathology Consultants is also one of this laboratory's reference laboratories. The surveyor could not distinguish where the test was actually performed. 5. At 11:30 AM, on 11/20/18, the practice manager confirmed the surveyor's findings.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review and interview, the laboratory director failed to ensure that policies and procedures are established for monitoring individuals who conduct testing and assure that they are competent and maintain their competency to perform testing.

Findings include: 1. Review of policies and procedures manuals revealed that there were no procedures that described the process for training and assessing the competency of testing personnel who perform Potassium Hydroxide (KOH) wet mount tests. 2. Review of personnel records revealed that there were no personnel assigned the responsibility of KOH testing. 3. Review of personnel records revealed that there was no documentation to show that testing personnel were trained and assessments performed on 2 of 2 testing personnel performing KOH testing. 4. At 11:30 AM on 11/20/18, the practice manager confirmed the surveyor's findings.

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 review and interview, the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings include: 1. Review of the laboratory's policies and procedures manual revealed that there were no written procedures that described the laboratory's process for performing Potassium Hydroxide tests. 2. At 11:30 AM on 11/20/18, the practice manager confirmed the surveyor's findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review and interview, the laboratory director failed to specify in writing the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the testing process. Findings include: 1. Review of the laboratory's application for CLIA Certification revealed that the laboratory initially only entered test volumes for the subspecialty of Histopathology. 2. In an interview with the laboratory director, it was revealed that the laboratory performed Potassium Hydroxide (KOH) wet mounts for the visual detection of mycology and

parasitology organisms. After this was revealed the surveyor instructed laboratory staff to enter the test volumes onto the CLIA application to reflect this oversight. 3. Review of laboratory policies and procedures revealed that there was no documentation to show which individuals were performing KOH testing. 4. Review of personnel records revealed that there was no documentation to show that the laboratory director assigned individuals the responsibility of performing KOH procedures. 5. At 11:30 AM on 11/20/18, the practice manager confirmed the surveyor's findings.