

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0948005	(X3) Date Survey Completed 03/22/2018
Name of Provider or Supplier Southwest Michigan Dermatology	Street Address, City, State 3000 Old Centre Road, Portage, MI	
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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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:</p> <p>. Based on procedure review and interview, the laboratory Based on record review and interview, the laboratory failed to ensure written competency policies contained the six category requirements from subpart M and implemented bi-annually for four (#4, #5, #6, and #11) of four testing personnel performing the mycology and parasitology testing. Findings include: 1. On March 22, 2018 at 11:37 a.m., record review of the competency evaluations for four of four testing personnel revealed the policy did not contain the following six category requirements from subpart M: a. written competency policy did not contain the six requirements from subpart M 1. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. 2. Monitoring the recording and reporting of patient test results. 3. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of test performance through previously analyzed specimens, internal blind testing or proficiency testing samples. 6. Assessment of problem solving skills. 2. On March 22, 2018 at 11:37 a.m. when queried, processing personnel #7 as listed on the CMS-209 was not able to provide the surveyor with one of the two bi-annual evaluations in 2017 for four of four testing personnel performing the mycology and parasitology testing. 3. During the interview on March 22, 2018 at 11:37 a.m., processing personnel #7 confirmed the policy did not contain the six required categories and was not implemented bi-annually in 2017. ***Repeat Deficiency from the December 1, 2011 survey***</p>

<p>D5301</p>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to have a electronic request for patient testing from an authorized person for the virology Tzanck smear for one of 18 patient charts audited. Findings include: 1. On March 22, 2018 at 12:08 p.m., record review for one (#12) of 18 patient charts audited revealed the laboratory did not have a electronic request for the virology Tzanck smear testing that was performed and written on the "Slide Log". 2. On March 22, 2018 at 12:08 p.m. when queried, processing personnel #7 as listed on the CMS-209 was unable to provide the surveyor documentation for a request in the patient's electronic medical records. 2. During the interview on March 22, 2018 at 12:08 p.m., processing personnel #7 confirmed the laboratory did not have an electronic request for the virology testing.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview, the laboratory failed to monitor and document the humidity readings for 23 (April 2016 to March 2018) of 23 months of operation to ensure reliable histology instrument operation. Findings include: 1. On March 22, 2018 at 8:59 a.m., during a tour of the laboratory the surveyor observed the Leica CM 1510S Cryostat instrument in use. Review of the installation manual stated the "maximum relative humidity is less than 60%". 2. On March 22, 2018 at 8:59 a. m., record review revealed the laboratory was not able to provide documentation to show the relative humidity reading were monitored and documented for 23 of 23 months of operation. 3. During the interview on March 22, 2018 at 8:59 a.m., processing personnel #7 as listed on the CMS-209 confirmed the humidity readings were not monitored and documented.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

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 record review and interview, the laboratory failed to include the test results for the virology Tzanck smear for one (#12) of 18 patient charts audited. Findings include: 1. On March 22, 2018 at 12:08 p.m., record review revealed for one of 18 patient charts audited the results for the virology Tzanck smear documented on the "Slide Log" was not included in the patient's electronic medical record (EMR). 2. During the interview on March 22, 2018 at 12:08 p.m., processing personnel #7 as listed on the CMS-209 confirmed the results were not in the patient's EMR records.