

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2169618	(X3) Date Survey Completed 09/14/2020
Name of Provider or Supplier Great Lakes Foot And Ankle	Street Address, City, State 32743 23 Mile Rd Suite 110, Chesterfield, 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
D5805	<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 condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure the name and address of the laboratory location where tissue microscopic examinations were performed was on the test report for 8 (Patients 1-8) of 8 patient testing records reviewed. Findings include: 1. An interview with TP1 on 9/14/20 at 10:44 am revealed slides, once prepared, are sent to another location for the microscopic examination. 2. A record review of patient testing records revealed patient test reports did not have the name and address of the laboratory performing the tissue microscopic examinations for the following patients: a. Patient 1 b. Patient 2 c. Patient 3 d. Patient 4 e. Patient 5 f. Patient 6 g. Patient 7 h. Patient 8 3. An interview on 9/14/20 at 10:48 am with TP1 confirmed the laboratory did not list the name and address of the laboratory performing the microscopic tissue examinations on test reports.</p>
D6122	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not</p>

limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1), the Technical Supervisor failed to evaluate the recording and reporting of test results for 1 (TP1) of 1 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's CMS-209 form revealed there was one testing personnel listed (TP1). 2. A review of the laboratory's competency assessment records revealed a lack of documentation for monitoring the recording and reporting of test results for TP1's competency assessment performed on 5/1/20. 3. An interview on 9/14/20 at 11: 15 am with TP1 confirmed the Technical Supervisor did not evaluate the recording and reporting of test results for TP1 during the 5/1/20 competency assessment.