| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 46D2162903 | 08/27/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Utah Podiatry Group | 24 S 1100 E, Suite 210, Salt Lake City, UT | |

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 |
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| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on nail fungus assay validation record review and interview with staff, the laboratory failed to include validation samples of the same matrix as the patient samples tested to verify analytical specificity for 22 of 22 fungal organisms included in their nail fungus panel. The laboratory began patient testing in 03/2019 and had tested approximately 100 samples. Findings include: 1. Laboratory validation records failed to include documentation the laboratory had performed studies using the same sample matrix (nail samples in COPAN E Swab transport media) in verification studies to assure nail samples did not include interfering substances that might affect test results. 2. In an interview with the technical consultant at approximately 1:00 PM, the consultant confirmed that testing had been performed with target organisms in transport media, but did not include testing using the same sample types that were tested in the laboratory (nail clippings). |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g) |

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| | 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on patient test records review, quality control record review, lack of documentation, and interview with staff, the laboratory failed to include a positive control each day of testing for 22 of 22 fungal targets included in their nail fungus test panel. That laboratory began testing in 03/2019 and had tested approximately 100 samples. Findings include: 1. Quality control records reviewed for 3 dates patient samples were tested (03/17/2019, 04/10/2019, and 04/17/2019) lacked documentation of a positive control for each of the 22 fungal organisms included in the panel. 2. The laboratory lacked documentation of a Individualized Quality Control Plan (IQCP) demonstrating they could perform quality control at a reduced frequency (less than each day of testing) that would provide equivalent quality testing. 3. The laboratory technical supervisor stated during interview on 08/27/2019 at approximately 1:00 PM, the laboratory used Bacillus Atrophaeus as an extraction control, but failed to include a positive control for each fungal target each day of testing |