| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 36D1039033 | 08/13/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Associates In Dermatology Inc | 2205 Crocker Rd, Suite 109, Westlake, OH | |

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** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and an interview with the Clinical Team Lead, the laboratory failed to indicate, on 4 out of 7 final test reports, an accurate specimen source for each KOH (potassium hydroxide) procedure performed. This deficient practice had the potential to affect all patients tested under the subspecialty of mycology. Findings Include: The Surveyor reviewed 7 final test reports for KOH. 1. Review of 4 of the 7 KOH final test reports found the following specimen sources: Date Patient Source 10-10-17 291480 "right heel" 1-15-18 866880 "scalp right upper thigh" 3-7-18 620040 "right foot" 8-22-18 52816 "right lateral foot" 2. Review of the 4 corresponding KOH interim test records listed on the "KOH and Scabies prep log" found the following specimen sources: Date Patient Source 10-10-17 291480 "R. lower leg" 1-15-18 866880 "R. thigh" 3-7-18 620040 "lf foot" 8-22-18 528160 "L foot" 3. An interview with the Clinical Team Lead, on 8/12/19 at 11:29 am, confirmed the specimen sources listed on the final test report were not the same as the specimen sources listed on the test records, and thus, were not accurate. |