| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 44D0686235 | 02/26/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mid-South Dermatology, Pc | 6644 Summer Knoll Circle, Bartlett, TN | |

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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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the twice per year comparison for accuracy records and interview with the practice manager, the laboratory failed to compare for accuracy the fungal element slides and scabies slides twice per year in 2018. The findings include: 1) Review of the twice per year comparison for accuracy records revealed the fungal elements slides and scabies slides were compared for accuracy on 11-5-18 and no other date. 2) Interview on February 26, 2018 at 11:45 a.m. with the practice manager confirmed the fungal element slides and scabies slides comparison for accuracy were not performed twice per year in 2018. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of potassium hydroxide (KOH) procedure, patient number one final report and interview with the lead nurse, the laboratory failed to follow the KOH procedure and interview with the lead nurse, the laboratory failed to follow the KOH quality control (QC) procedure in 2017 and 2018. The findings |

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| | include: 1) Observation of the laboratory on February 26, 2018 at 10:30 a.m. revealed a bottle of KOH solution in use for patient testing. The solution in the KOH bottle appeared cloudy with floating black blobs. 2) Review of the KOH procedure revealed the following: "QC procedure: 10% KOH will be examined annually for contamination. This will be done by placing one drop of KOH solution on a microscope slide, coverslip and examine at 40x for the presence of yeast and scabietic elements. ..." 3) Review of patient number one final report revealed on January 29, 2019 a KOH was performed and reported. 4) Interview on February 26, 2019 at 11:30 a.m. with the lead nurse confirmed the KOH solution was cloudy with black blobs. The KOH solution was not examined for contamination in 2017 and 2018. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the 2017 and 2018 histology maintenance records, the laboratory quality assessment (QA) plan and interview with the laboratory director, the laboratory failed to review the 2017, 2018 and 2019 equipment maintenance records, temperature logs, and reagent solution records. The findings include: 1) Review of the 2017 and 2018 equipment maintenance records, temperature logs, reagent solution records revealed the laboratory director did not review the histology records for quality assessment. 2) Review of the laboratory QA plan revealed, "The Laboratory Director or designee, reviews all quality control charts and logs on an as needed basis". 3) Interview on February 26, 2019 at 12:45 p.m. with the laboratory director confirmed the histology equipment maintenance records, temperature logs, and reagent solution records were not reviewed in 2017 and 2018. |