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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 44D2223802 | (X3) Date Survey Completed 11/05/2024 |
| Name of Provider or Supplier Unkefer Dermatology Pllc | Street Address, City, State 125 Mountain View Dr, Ste 300, Vonore, 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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| D5473 | <p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Hematoxylin and Eosin (H&E) stain control slide log, laboratory procedure, and staff interview, the laboratory failed to define the predicted characteristics of the H&E stain in 2023 through the survey date (11.05.2024). The findings include: 1. A review of the laboratory's H&E stain control slide logs revealed no documentation of the predicted characteristics of the H&E stain quality in 2023 through the survey date (11.05.2024). 2. A review of the laboratory's "Mohs Micrographic Surgery Lab" procedure revealed that it did not define predictable characteristics of the H&E stain quality. 3. An interview with the laboratory lead on 11.05.2024 at 10:30 a.m. confirmed the above survey findings.</p> |