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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0687310 | (X3) Date Survey Completed 04/30/2025 |
| Name of Provider or Supplier Ronald N Shore Md | Street Address, City, State 4701 Randolph Road Ste 207, Rockville, MD | |
| 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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| D5411 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's instructions for use (IFU) and patient log record review and interview with the laboratory director (LD), the laboratory failed to follow the manufacturer's instructions for performing dermatophyte testing. Findings: 1. The laboratory performs dermatophyte screening on patient specimens. Patient information is entered on the "Patients Test Results Log, Fungal Culture Media" log. The log has columns for the "Date" (date of inoculation), "Specimen #" (location where the vial is stored), and "Results +/-." 2. The manufacturer's IFU states, "Incubate media at room temperature (15-30C.), aerobically, for up to fourteen days" and under "LIMITATIONS" it states, "False-positive reactions may result, if interpretations are made beyond 14 days of incubation." 3. A review of patient logs from 01/02/2024 through 03/19/2025 showed that 12 out of 86 patients tested were read/interpreted after 14 days of incubation and one patient was logged with no documented date for the interpretation. 4. Two of the 12 patients which were read after 14 days were interpreted as "positive" ("Patient A," inoculated 06/25/2024, "Specimen #" "C-1," results interpreted at 15 days on 07/09/2024 and "Patient B," inoculated 07/11/2024, "Specimen #" "C-2," results interpreted at 15 days on 07/26/2024). 5. During an interview on 04/30/2025 at 11:00 AM, the LD confirmed that the laboratory failed to follow the IFU for performing dermatophyte testing.</p> |