

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0687310	<b>(X3) Date Survey Completed</b>  11/03/2021
<b>Name of Provider or Supplier</b>  Ronald N Shore Md	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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 review of the manufacturer's instructions for use (IFU) and patient test result logs and interview with the laboratory director (LD), the laboratory failed to interpret patient test results within the timeframe defined by the manufacturer for dermatophyte test medium (DTM) testing for 17 of 98 documented positive results. Findings: 1. The IFU from the most recent lot number (D-1425-0621) of Acuderm Inc's "Acu-DTM" was reviewed. 2. The "Intended Use" section stated that "Acu-DTM is a preferred medium for the isolation and early recognition of members of the Microsporum, Trichophyton and Epidermophyton genera by a distinct color change from yellow to red effected by a pH indicator." 3. The "Results" section of the IFU stated that "Color interpretation of test is questionable after 14 days due to the possibility of false positives." 4. The laboratory kept a log of patient test results that included the date the media was inoculated, the date the results were interpreted, and the test result interpretation. 5. The patient test result log was reviewed for patient samples inoculated on 08/16/2019 through the date of the survey on 11/03/2021, which included a total of 264 tests. Of the 264 tests, 98 were documented as having positive results. 6. Based on the date the media was inoculated and the date the results were interpreted, of the 98 results documented as positive, four results were interpreted 15 days after inoculation, four results were interpreted 16 days after inoculation, three results were interpreted 17 days after inoculation, four results were interpreted 18 days after inoculation, one result was interpreted 22 days after inoculation, and one result was interpreted 23 days after inoculation. 7. During the exit interview on 11/03</p>

/2021 at 11:45 AM, the LD confirmed that not all patient test results were interpreted within the acceptable 14 day timeframe defined by the manufacturer.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

This is a repeat deficiency. Based on review of the patient test result log and interview with the laboratory director (LD), the laboratory failed to document patient test results in four of 264 tests and failed to document the interpretation date for seven of 98 positive results for dermatophyte test medium (DTM) testing. Findings: 1. The laboratory kept a log of patient test results that included the date the media was inoculated, the date the results were interpreted, and the test results interpretation. 2. The patient test result log was reviewed for patient samples inoculated on 08/16/2019 through the date of the survey on 11/03/2021, which included a total of 264 tests. Of the 264 tests, 98 were documented as having positive results. 3. Of the 264 tests documented, four did not have results documented on the log. 4. Of the 98 documented positive results, seven did not have documentation of the date the results were interpreted to be able to determine how long after inoculation the results were interpreted. Refer to D5411. 5. During the exit interview on 11/03/2021 at 11:45 AM, the LD confirmed that not all patient test entries documented the results interpretation or the date the results were interpreted.