

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0996477	<b>(X3) Date Survey Completed</b>  03/15/2022
<b>Name of Provider or Supplier</b>  Issc Fruitland	<b>Street Address, City, State</b>  811 Nw 12th St, Fruitland, ID	
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 a review of laboratory fungal logs, patient reports and an interview with the laboratory lead on 3/15/2022, the laboratory failed to follow manufacturer's instructions when using dermatophyte test medium. The finding include: 1. A review of the dermatophyte test medium (DTM) instructions for use from Hardy Diagnostics identified that the appearance of white aerial hyphae with red color around the fungal growth is positive for the presence of dermatophyte and a negative result is growth without a color change to red. 2. A review of the patient log for fungal cultures identified that the laboratory failed to follow the manufacturer's instructions and identified organisms other than dermatophyte from the DTM. 3. A review of patient report identified that the laboratory failed to only report positive or negative for dermatophyte from the DTM. 4. An interview with the laboratory lead on 3/15/2022 at 2:45 pm confirmed that the laboratory reported yeast from the DTM without further testing. 5. The laboratory reports 441 dermatophyte cultures annually.</p>