



Reference Stock Culture Shelf-Life

QUESTION

MicroBioLogics® customers often require specific information regarding the microorganism preparations they use and raise the following questions.

“What is the shelf-life of the reference stock culture products and how is the shelf-life determined?”

RESPONSE

A. Shelf-Life and Expiration Date

- ◆ The shelf-life for reference culture preparations such as LYFO-DISK® and KWIK-STIK™ Microorganisms is **twenty-four (24) months** from the date of manufacture.
- ◆ The expiration date is the last day of the month stated on the product label.

B. Recovery Control Limits for Reference Stock Cultures

- ◆ The recovery control limits are a MINIMUM of 100 colony forming units (CFU) per pellet for slow-growing fungi (e.g., Dermatophytes) and a MINIMUM of 1,000 CFU per pellet for the remaining bacteria, yeast and fungus reference stock cultures upon initial release.

C. Shelf-Life Validation

- ◆ Following production, an enumeration is performed on pellets from each lot of final fabricated product. The minimum recovery control limits must be met and are recorded.
- ◆ Validation of our shelf life was performed by enumeration of pellets from retention samples of the final fabricated products. The minimum recovery control limits must be met and are recorded.

D. Product Warranty

- ◆ These products are warranted to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature.
- ◆ The warranty, expressed or implied, is limited when the procedures employed in the laboratory are contrary to printed and illustrated directions and instructions.
- ◆ The warranty, expressed or implied, is limited when the products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

SUMMARY

The information cited offers assurance that all MicroBioLogics® reference stock cultures are of known and defensible quality. Minimum recovery specifications are met throughout the shelf-life of each product and provide documentation for shelf life stability.

Should any additional questions arise please contact MicroBioLogics Technical Services at:

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Thank you for extending the opportunity to MicroBioLogics to serve your needs.