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Walkersville, 24 October 2019

Shelf Life: X-VIVO™ 10, X-VIVO™ 15, X-VIVO™ 20 Media

To Whom It May Concern

Establishing an appropriate shelf life for X-VIVO™ Products is challenging as the media may be utilized for a variety of applications. Currently, Lonza makes no warranty or claim about the functionality of X-VIVO™ Media. Tests relevant to the intended applications of X-VIVO™ Media must be conducted to establish an appropriate shelf life.

At this time, bottled X-VIVO™ Products produced at Lonza Walkersville are labeled with the date of manufacture allowing users to determine an appropriate expiration date based on process specific functionality data. Bottled X-VIVO™ Products produced at Lonza Verviers are labeled with a 15-month shelf life based on a dendritic cell study performed on the X-VIVO™ 15 Formulation. Bagged X-VIVO™ Products are labeled with only a production date. Due to the therapeutic use of bagged products, a risk assessment for how this critical raw material will be used in customer specific applications is needed in order for the customer to determine an appropriate expiration date.

Lonza Walkersville is currently assessing Jurkat cell growth promotion over an extended time period to develop appropriate shelf-lives for all X-VIVO™ Formulations. Thus far, the data from these studies supports a 15-month shelf life for bottled X-VIVO™ Media. As the study progresses, updates to the labeling and customer facing documentation will be completed. For all other applications, customers have used the medium for up to 24 months from the date of manufacture.

For additional information, please contact Scientific Support via bioscience.lonza.com.

Yours sincerely,

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