

APPROVED

By Jean Gildner at 4:05 pm, Dec 12, 2016

From: [Margarita Aguilera](#)
To: [Gildner, Jean](#)
Cc: [Lorien Armour](#)
Subject: BLA 125603 : Re-Sending (b) (4) Sterility testing re-validation Report
Date: Thursday, October 06, 2016 4:32:31 PM
Attachments: [GTR-168-03-01-A MACI Validation Limit of Detection Using \(b\) \(4\) Report.pdf](#)

Dear Jean,

Per our conversation today, attached please find the formatted version of the report that will go with the BLA submission. I trust that this will be an acceptable version for the FDA reviewing team. Due to the holiday on Monday, the submission will be send to the BLA on Tuesday, October 11.

Our apologies for any inconvenience.

Thanks and regards,
Margarita

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