

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)
Subject: BLA 125694/0| AveXis, Inc| Information Request 19 (PLEASE RESPOND BY FEBRUARY 15, 2019)
Date: Friday, December 21, 2018 4:09:09 PM
Attachments: [image013.png](#) **Importance:** High

Good afternoon Dr. L'Italien,

We have the following request for information regarding BLA 125694. Please respond by no later than February 15, 2019.

The (b) (4) assay (SOP-137) lacks a positive control for (b) (4) activity. If (b) (4) is omitted from the assay or is not active, the assay may give an inaccurate result due to detection of (b) (4). Please modify SOP-137 to incorporate a control (assay acceptance criterion) that will demonstrate the activity of (b) (4) that is prepared in section 8.2.4 of the protocol.

Please confirm receipt.

Regards,

Candace N. Jarvis
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