

From: [Patel, Manisha](#)
To: [Giordano, Erica](#)
Cc: [Riggins, Cindy](#); [Ahmed, Narin](#); [Azevedo Santos, Joana](#); [Wonnacott, Keith](#)
Subject: RE: BL 125646 DBSQC Information Request
Date: Tuesday, May 02, 2017 11:54:41 AM
Attachments: [image001.png](#)
Sensitivity: Confidential

Dear Erica,

I confirm receipt of this request.

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Tuesday, May 02, 2017 11:52 AM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 DBSQC Information Request
Sensitivity: Confidential

Good afternoon,

Please see the information request below and provide a response by noon on May 16, 2017.

Vector (b) (4) Product

For mycoplasma validation study, AE51SP.300200PSQ.BUK, please clarify if mycoplasma species at (b) (4) was added to test sample prior to or during DNA extraction when evaluating specificity, limit of detection and precision of the (b) (4) method.

Please confirm receipt of this response.

Thank you,

Erica Giordano

Regulatory Project Manager

Center for Biologics Evaluation and Research

Office of Tissues and Advanced Therapies

U.S. Food and Drug Administration

Tel: 240-402-8298

Erica.Giordano@fda.hhs.gov



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