

From: [Gildner, Jean](#)  
To: [Janice Castillo \(jcastillo@Portola.com\)](mailto:jcastillo@Portola.com)  
Subject: BI125586 Information Request  
Date: Friday, November 17, 2017 4:39:59 PM  
Attachments: [image001.png](#)

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Dear Janice,

Please see the following information request. Please respond on or before November 28. If you are not able to meet this deadline please let me know. Please acknowledge receipt of this email.

***In your August 03, 2017 response to question 2bi in our August 17, 2016 Complete Response Letter, you stated that “a newly implemented (b) (4) assay was established for the (b) (4) (Section 3.2.S.4.3.1.11).” However, based on the submitted information, this assay is used to assess (b) (4), not the (b) (4). Please include (b) (4) as a parameter in the (b) (4) specifications with a reference to a validated method, as the Agency had requested previously.***

Sincerely, Jean

*Jean F. Gildner* MSHS, MT (ASCP)

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