

**From:** Khurana, Taruna  
**Sent:** Thursday, January 05, 2017 2:48 PM  
**To:** nadine\_margaretten@merck.com  
**Cc:** Sweeney, Colleen; Steele, Matthew; Khurana, Taruna  
**Subject:** BLA STN 125592 HDM SLIT (b) (4) Assay Information Request

Dear Nadine,

We have the following request for additional information;

1. Please provide the data and the analysis on which the system suitability criteria for the DP (b) (4) procedure are based.
2. Please provide all the tracking and trending data, including all data from rejected assays, for the control sample. Please include data from both the Analytical and QC laboratories from the time of validation to the present. Please ensure that the data are legible and represented in mDU/mL.

We request that you provide this information by COB Friday January 6, 2017.

Thank you

**Taruna Khurana, PhD**

*Biologist (Regulatory)*

**Center for Biologics Evaluation and Research**

**Office of Vaccines Research and Review**

**U.S. Food and Drug Administration**

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