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To: [Kim M. Sullivan \(SULLIVAN@smarthealth.com\)](#)
Cc: [Houck, Christina M](#); [Valenti, Elizabeth](#)
Subject: IR, STN 125579/0
Date: Friday, March 25, 2016 2:52:42 PM

Dear Kim,

We are reviewing your BLA for STN 125579/0 for Rubber Panel T.R.U.E. TEST (Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test) for “use as an aid in the diagnosis of allergic contact dermatitis in persons six years of age and older whose history suggests sensitivity to one or more of the five substances included on the Rubber Panel T.R.U.E. TEST.” After further review we have the following information request:

Lot release results for the two lots of Rubber Panel that were submitted in support of this application have not been received. Please submit completed protocols to include release test results for Lots 96452 and 96700.

Thank you, Betsy

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