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## Monitoring multivalent vaccine antigens using a multiplex mesoscale discovery platform assay

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The quantification of antigens and assessment of product potency are important aspects of vaccine testing. The development f in vitro assays that can help reduce time, cost, and animal usage associated with such testing is an increasing priority for vaccine manufacturers. Here, we describe the assessment of a multiplex antigenicity assay applied to TdaP vaccine using the MesoScale Discovery (MSD) platform. The assay is capable of measuring six different antigens simultaneously in the vaccine. Specific antibody pairs for each of the TdaP antigens were selected for the multiplex assay, and antibody cross-reactivity and assay precision was assessed. To investigate the ability of the multiplex assay to detect changes in vaccine antigen profile and stability, samples of a TdaP vaccine were subjected to increasing temperatures during accelerated heat degradation studies (up to 60°C for 12 weeks). The treated samples were then tested using the multiplex MSD antigenicity assay and simultaneously using three animal-based tests: 1) A component pertussis (cP) mouse immunogenicity assay; 2) the USPHS Diphtheria Potency assay, and; 3) the USPHS Tetanus Potency assay. Results confirmed that the multiplex MSD antigenicity assay is stability indicating, as it was able to detect changes in the antigenic profile of the vaccine. The MSD assay showed a decline in measured antigenicity values for most of the TdaP antigens over time at the elevated temperatures. In concordance, the cP mouse immunogenicity test results showed decreasing antibody titers for each of the antigens that displayed a drop in antigenicity, while the USPHS Diphtheria and Tetanus potency assays also showed a decrease and/or loss in potency upon heat degradation. Overall, the results support that the MSD in vitro multiplex antigenicity assay, with further development, could potentially act as a surrogate assay used to measure vaccine potency traditionally assessed using animal assays.

## **Biography**

Jason Szeto is a scientist in the Analytical Sciences Immunology Platform (Toronto) at Sanofi-Pasteur. He graduated with a PhD in Microbiology and Immunology from the University of Ottawa in 2004, and did post-doctoral work at the Hospital for Sick Children (Toronto) before joining Sanofi-Pasteur in 2008.

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