Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2015 - 2016, 10 February 2016

Ref No: SQ16-000215

OUTCOME: 3 - Access to Medical and Dental Services

Topic: ELISA and Western Blot Tests

Type of Question: Written Question on Notice

Senator: Madigan, John

Question:

Please state the type and manufacturer of all test kits used by the laboratories providing Medicare funded ELISA and Western blot tests for Lyme disease in Australia.

Answer:

The selection of commercial test kits (also called in vitro diagnostic devices or IVDs) is a matter for laboratories. However, the chosen commercial kit must be listed on the Australian Register of Therapeutic Goods (ARTG), which means it meets the requirements set out in the *Therapeutic Goods Act 1989 (Cth)*, and in the Therapeutic Goods (Medical Devices) Regulations 2002.

Laboratories may also use kits that have been developed in-house. Further information on the regulation of IVDs may be found at www.tga.gov.au