Thermo Fisher Scientific ANZ – Response 8

CDx identification guide
No comments – we understand this is a clarification of current TGA position.
Companion testing plan
We support this change (introduction of a companion test plan) as it provides additional options for drug companies to identify a CDx test for their drug, as opposed to requiring parallel submissions of the drug and the CDx.
Case studies
"The Case studies are helpful. Case Study 2 - Is the TGA able to publish a percentage agreement and Confidence Level for bridging studies that will be accepted? Case Study 3 – No change: This example confirms that panels of tests will continue to require a Clinical Evaluation Report that includes bridging studies."
Further feedback
"We support the TGA CDx List is a useful communication tool. We support the clinical guidance around complementary diagnostic clinical testing that ensures that the level of data required is not diminished for subsequent CDx tests, including subsequent laboratory-developed tests (LDT). We would be concerned if poorly designed or controlled CDx studies were used to support the use of laboratory-developed tests, due to the lack of review required for class 3 IVD LDT."