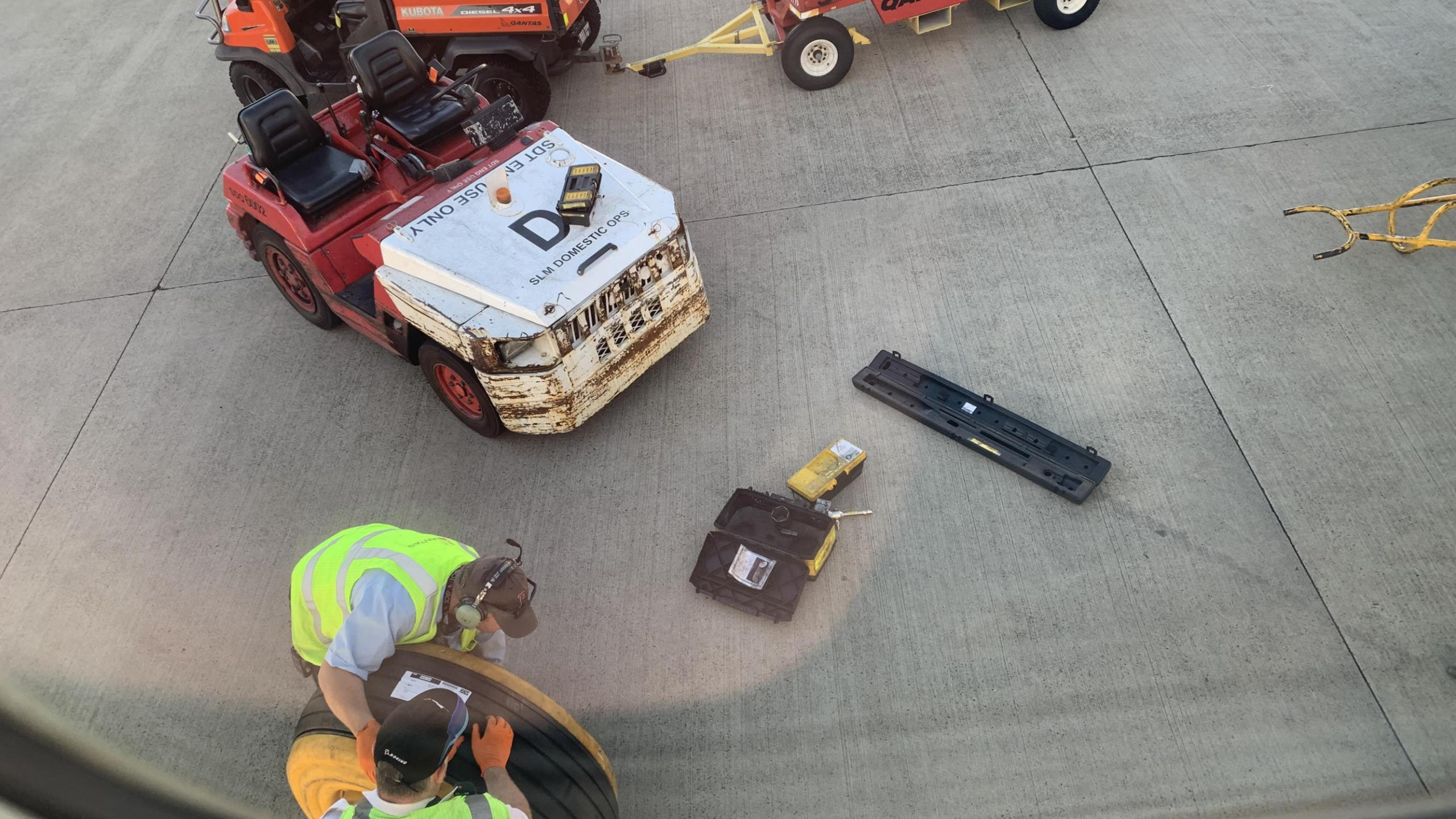
Building Governance and Regulatory Frameworks to Deliver Testing at the Point of Care

PANEL DISCUSSION

POC23 – SYDNEY

15TH MARCH 2023


KUBOTA
DIESEL 4x4
QANTAS
SDT EMPLOYEE USE ONLY
SLM DOMESTIC OPS

Existing Governance and Regulations

- TEST KITS
- TESTING SITES
- PERSONNEL

Existing Governance and Regulations - Pre-market registration of IVDs

LABORATORY TESTING

IVDs manufactured under ISO 13485

Must be registered for use (TGA, FDA, EU)

IVDs classified into class 1 - 4

Sponsors must provide

- Conformity assessment – quality, safety and performance
- Evidence of performance – clinical and analytical
- Undertake post market monitoring
- Have a recall process

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TGA requires Sponsors of Class 4 devices outside of accreditation system to ensure users participate in an appropriate quality assurance program

Existing Governance and Regulations - Testing Regulations

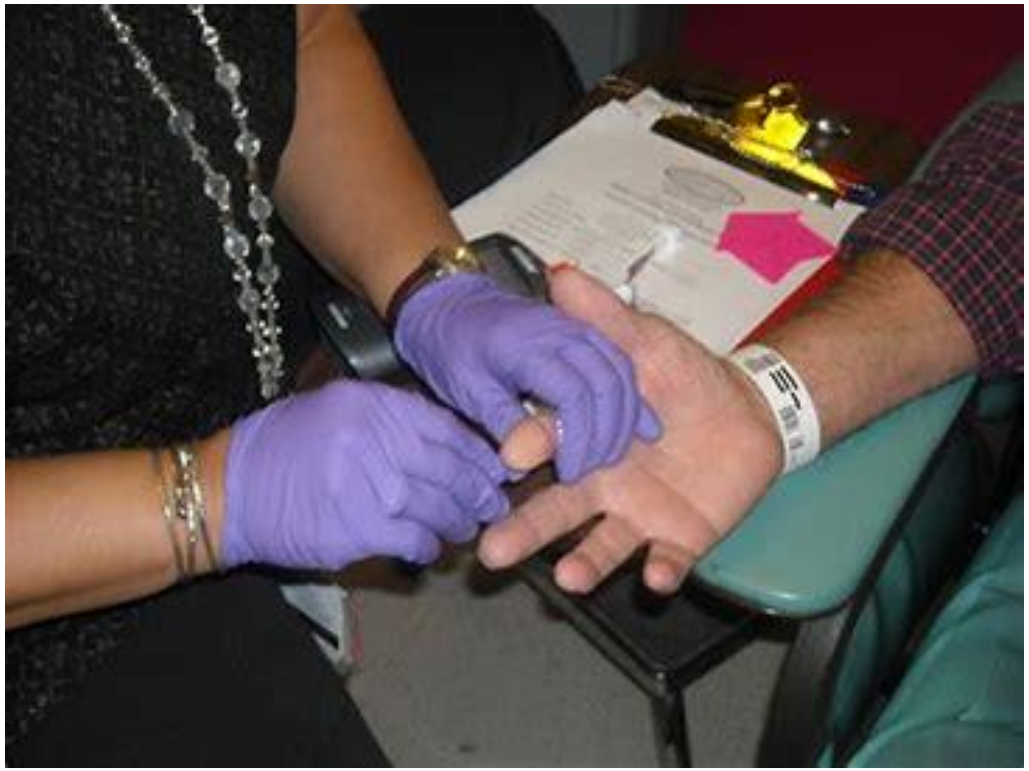
LABORATORY TESTING

To claim Medicare Benefits a laboratory must –

- Be accredited to ISO 15189
- Comply with NPAAC Guidelines & NATA-specific requirements
- Evidence of validation of tests for each sample type
- Participate in an accredited EQA/PT
- Have a QC program and review results
- Secure facilities, controlled environment
- Monitored/maintained equipment

Mandatory periodic external audit by NATA

POC TESTING



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POC TESTING

If **claiming** Medicare Benefits a PoC test site must –

- Be under the scope of accreditation of a laboratory
- Comply with all requirements of accreditation

If **not claiming** Medicare a PoC site –

- Can use NPAAC PoCT guideline as a reference but not compelled to adhere
- No existing mandatory governance structure
- No regulatory oversight by NATA/DoH/TGA

Existing Governance and Regulations - Governance

LABORATORY TESTING

Clinical governance overseen by Medical Pathologist

Testing performed by tertiary qualified scientist or technicians

Minuted, clinical governance meetings required

Corrective actions for detected non conformances monitored

Evidence of training and competency mandatory

Testing result covered through medical insurance

POC TESTING

If **claiming** Medicare Benefits a PoC test site must –

- Be under the scope of accreditation of a laboratory
- Comply with all requirements of accreditation

If **not claiming** Medicare a PoC site –

- Can use NPAAC PoCT guideline as a reference but not compelled to adhere
- Some best practice examples in place
- No existing mandatory governance structure
- No regulatory oversight by NATA/DoH/TGA