

Table 1: Pros and cons of regulating POCT IVDs and risk mitigating measures.

Advantages	Disadvantages, risks and mitigation measures
Improved safety of devices, particularly high-risk devices, and tests.	Risk of overregulation inhibiting competition and innovation, reducing consumer choice, and potentially falling behind international standard of care.
Supports better health outcomes.	Mitigation: risk-appropriate regulation.
Aligns with international regulatory frameworks.	Need to resource the regulatory machinery, which if under resourced can create an inefficient system with no true benefits.
Supports clinical governance of POCT in the community and in hospitals.	Mitigation: risk-appropriate regulation, scoping, building on existing systems.
Supports funding bodies fund devices (and tests) that are fit for purpose, using tax-payer money judiciously.	Potentially increased cost to manufacturers and suppliers.
Complements pro-equity measures.	Potential delays in availability and access to the New Zealand consumer/s.
Aligns with Code of Health and Disability Services Consumers' Rights, in particular right four: "Right to services of an appropriate standard".	Mitigation: an agile and responsive regulatory system.
Informs commercial entities, such as pharmacies, deciding on choice of devices and tests.	Potentially disproportionate delays in availability and access of devices/tests for rare disorders.
Gives the clinicians and consumers a measure of confidence.	Mitigation: an agile and responsive regulatory system.
Improved traceability and supply chain management.	Research and development leaving New Zealand.
Maximises efficiencies in the healthcare sector, which has broader societal benefits.	Mitigation: support innovation within an accountable and transparent regulatory system.
Patient-centric focus, which is responsive to unmet needs of New Zealanders	