



## Assay Customisation Service

ZiP Diagnostics provides customised assays and instrument algorithm installations as a service

- Operate and deploy high-sensitivity molecular tests for your organisation's specific applications
- Custom 4-way multiplex to detect DNA, RNA and/or sample control targets

## Cartridges

Cartridge kits are supplied as a buffer pack and cartridge pack in a box of 20 tests



## Instruments

ZiP-P2 instruments are supplied at standard supply cost



# Basic Supply Schedule



## Additional Services



### Bioinformatics

- High specificity primer design
- Continual tracking of pathogen variants and impact on test performance

### Regulatory Compliance

- The platform can be supplied with regulatory compliance under a quality and supply agreement
- Includes documentation to support human health submissions under TGA, FDA, and IVDR

CATEGORY	DOC. #	REVISION	TITLE	STATUS	NOTES
Plan	D007705	v1.0	Plan, Durian Hitary Filr, DMF, ZIP-CoVx-P2	RELEASED	
	D007537	v2.0	Plan, Quality, ZIP-CoVx-P2 Diagnostic System	RELEASED	
	D007707	v3.0	Plan, Risk Management, ZIP-CoVx-P2 Diagnostic System	RELEASED	
	D007630	v1.3	Plan, Verification and Validation, ZIP-CoVx-P2 Diagnostic System	RELEASED	
	D007624	v1.4	Plan, Performance Validation, ZIP-CoVx-P2 Diagnostic System	RELEASED	
Specification	D007590	v1.0	Specification, Product Requirements System, PRD, ZIP-CoVx-P2 Diagnostic System	RELEASED	
	D008240	v1.0	Specification, User Requirements, URS, ZIP-P2 Instrument	RELEASED	
	D007592	v5.0	Specification, Instrument Requirements, IRS, ZIP-P2 Instrument	RELEASED	
	D007591	v1.0	Specification, Cartridge and Array Requirements, CAS, ZIP-CoVx-P2 Diagnostic System	RELEASED	
Risk Analysis	D007593	v5.0	Risk Analysis, Durian, ZIP-CoVx-P2 Diagnostic System	RELEASED	
	D007594	v3.0	Risk Analysis, Production FMEA, ZIP-CoVx-P2 Project, Cartridge and Array	RELEASED	
	D008195	v1.0	Report, Risk Management, ZIP-CoVx-P2 Diagnostic System	RELEASED	
Traceability	D007596	v1.0	Trace Matrix, PRD-IRS, CAS, ZIP-CoVx-P2 Project, Diagnostic System	RELEASED	
	D008241	v1.0	Trace Matrix, URS-IRS, ZIP-P2 Instrument	RELEASED	
	D007597	v1.0	Trace Matrix, Durian, CAS, ZIP-CoVx-P2 Project, Cartridge and Array	RELEASED	
	D007598	v1.0	Trace Matrix, Test, CAS, ZIP-CoVx-P2 Project, Cartridge and Array	RELEASED	
	D007649	v1.0	Cartridge and Array Testing and Verification Summary Report, ZIP-CoVx-P2 Project	RELEASED	
Durian Output	D007606	v7.0	Technical Description, ZIP-CoVx-P2 Diagnostic System	RELEASED	
	D007613	v2.0	Durian Review, ZIP-CoVx-P2 Project, Cartridge and Array	RELEASED	
Durian Output - Labelling	D008085	v3.0	Technical Description, Labelling and Packaging, ZIP-CoVx-P2 Diagnostic System	RELEASED	
	P002762	v1.4	ZIP-CoVx-P2 Packaging Material - Cartridge Pack	RELEASED	
	P002761	v1.4	ZIP-CoVx-P2 Packaging Material - Buffer Pack	RELEASED	
	P002906	v1.1	Print Label BUO, Cartridge and Buffer Pack, ZIP-CoVx-P2	RELEASED	

### OEM Custom Branding

Standard supply for the platform is with ZiP Diagnostics branding. Original equipment manufacturer (OEM) custom branding service available.



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