



ZIP-VAL-P2: Cleaning Validation Molecular Test System

Manufacturers, suppliers and users of medical devices often need to ensure DNA-free decontamination and cleaning processes in assembly, parts acceptance and service activities, and general usage. ZIP Diagnostics supplies instruments, test kits and positive controls optimised for validation of DNA decontamination processes. These systems allow formal protocols to be run onsite without laboratory facilities or complex sample transport. These tests use high sensitivity molecular DNA amplification methods comparable to PCR. Qualitative and semi-quantitative outputs provide simple results and outputs for protocol reporting and to support process improvement investigations. Regardless of the decontamination or cleaning method used (e.g. plasma-ion, chemical, temperature cycling, solvent, irradiation, or UV), the ZIP-VAL-P2 system can confirm the impact of the cleaning process and successful decontamination.

Sealed single-use room temperature stored kits and an easy-to-use portable instrument allow application of these tests in commercial production environments. Real-time testing and reporting supports process improvement, process optimisation and the operation of formal validation protocols. ZIP supplies synthetic DNA positive controls not found in nature as room temperature stable kits. In typical operation, the parts under test are selectively applied with positive control material using a foam swab which dries in place. Protocol methods are then used to test surface swabs from the part both before and after decontamination.



ZIP-VAL Instrument, Cartridge and DNA Controls

- Easy to use; use directly onsite in standard work environments with minimally trained operators.
- Starter kit supplied with instrument, 100 test cartridges, 100 positive controls, training and accessories.
- Test kit includes example user manual and example DNA cleaning test protocol.
- Instrument check and QC workflows verify the instrument and test cartridge works at the time of use.



ZIP-P2 Portable Instrument



Test Cartridge Package,
Room Temperature Storage



Positive Control Material

Intended Use

The ZiP-VAL-P2 test system allows users to undertake high quality molecular validation testing of cleaning protocols onsite or within a production environment without investment in laboratory systems. The ZiP-VAL-P2 system is cost effective and direct.

Positive Control Sample

Positive control samples are provided with the ZiP-VAL-P2 system to allow pre-treatment of equipment or materials under test. The standard ZiP-VAL-P2 test is provided with a proprietary synthetic DNA target not found in nature. This target material is supplied as lyophilised bead suitable for extended room temperature storage for up to 12 months.

When required, positive controls are reconstituted with the supplied buffer to make up 1 mL of control material. Lint free foam swabs in several sizes are provided to allow pre-treatment of equipment under test. This approach allows treating large areas of equipment or materials, exceeding 1 m² in total. In a typical test protocol, only selected areas of equipment or parts would be pre-treated consistent with typical contamination. In a typical test protocol, 60 minutes of dry time is recommended prior to commencing testing.

Other Test Targets Supported

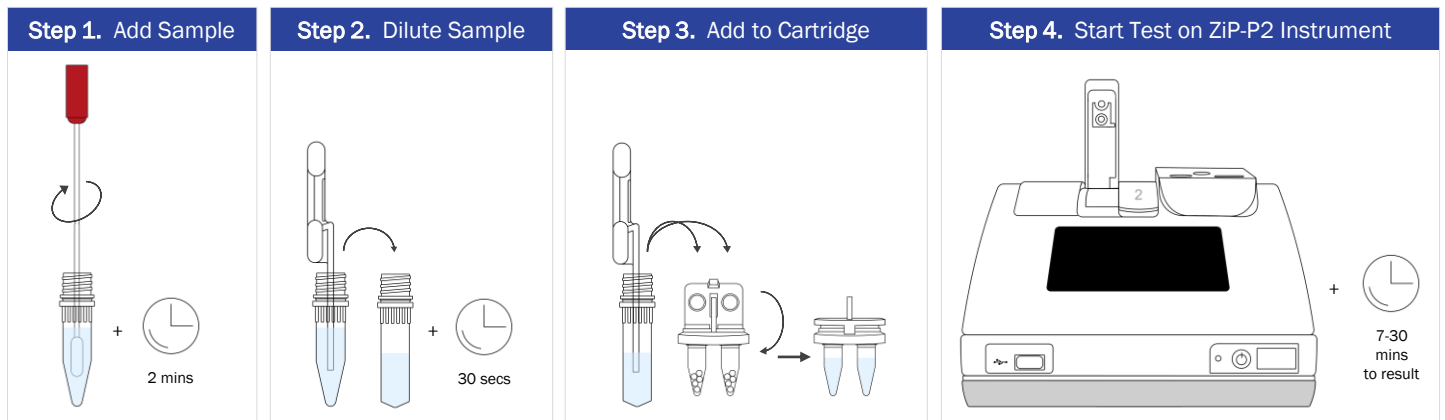
The ZiP-VAL-P2 system, test cartridges and positive controls can be supplied to support other DNA targets including: *E. coli*, human cells, fungal targets and alternative synthetic DNA sequences.

QMS, Instrument Check and QC.

The ZiP-VAL-P2 system supports self-test and QC (Quality Control) workflows to confirm correct operation of instruments and reagents. ZiP supports critical supplier information for your QMS process including ISO-13485 certification and supply agreement.

Simple Workflow

The ZiP-VAL-P2 system provides a simple self-contained 30-minute test workflow for up to 2 tests.



Kit Contents and Ordering Information


ZiP-VAL-P2 Kit Contents

- ZiP-P2 instrument
- 100 x VAL#1 tests kits (synthetic DNA – ZiP type #1)
- 100 x positive control kits (synthetic DNA – ZiP type #1)
- Foam swabs
- Training pack (includes 10 training test kits) and documentation
- Example test protocol
- System traceability documentation and COC records to support test records

Supplies and Accessories

- Additional tests kits (box of 20 test kits)
- Additional positive controls (box of 5 kits)
- Additional foam swabs, pack of 100
- Label printer
- External barcode reader

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Laboratory Equipment Safety,
Europe, UK and USA, Australia