QC Kit.

A VALIDATED SOLUTION FOR VOLUME TRANSFER VERIFICATION ON FREEDOM EVO® WORKSTATIONS

Meet your quality and regulatory demands with Tecan's QC Kit.

As quality and regulatory demands continue to increase, there is growing pressure to provide data verifying that equipment is meeting performance specifications. Tecan has partnered with Artel, Inc. – the worldwide leader in liquid handling quality assurance – to offer the QC Kit, a fully integrated liquid handling performance verification tool for Freedom EVO workstations.

QC Kit workflow

pipette → mix → read → analyze → report

CUSTOMER BENEFITS

Ease-of-use
The QC Kit does not require special facilities or environmental conditions, and is independent of the technician's skill level.

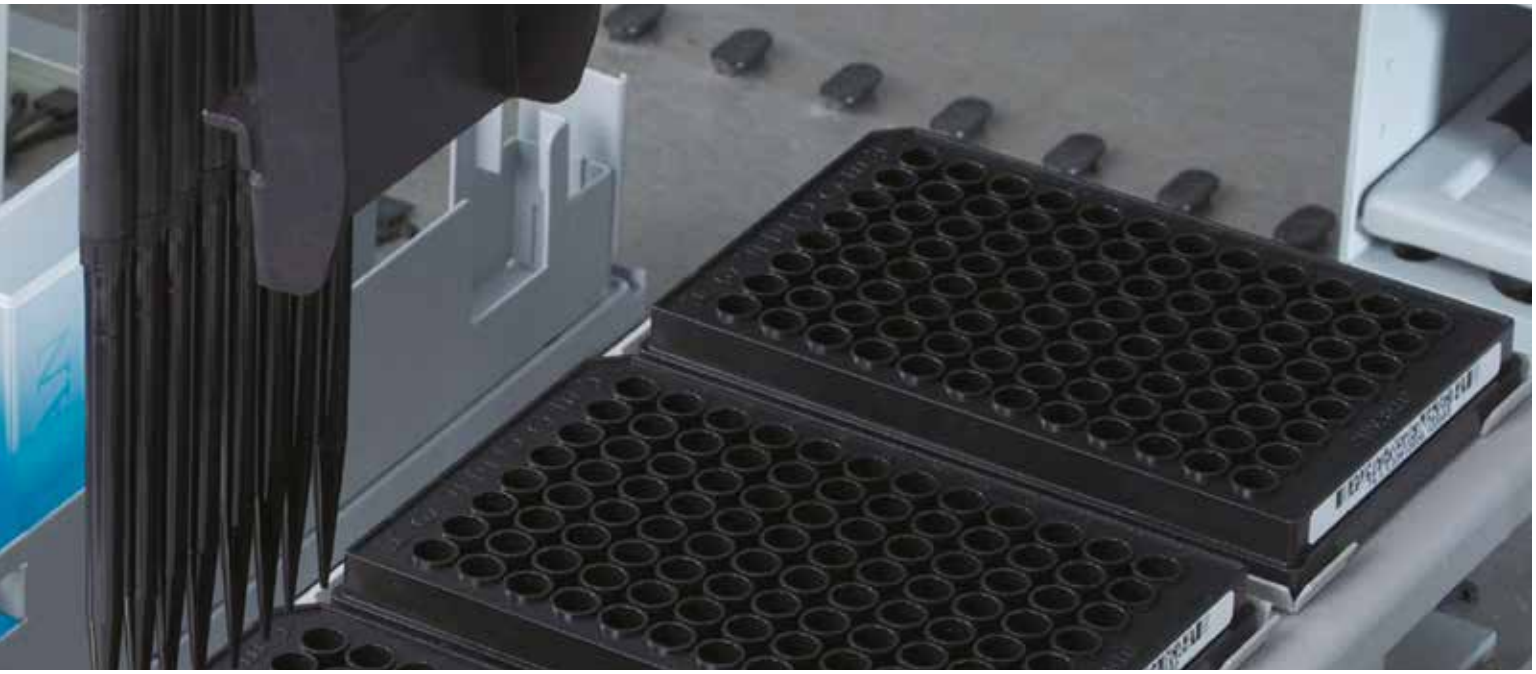
Speed
Compared to existing methods (balance or homebrew colorimetric methods), test results are available much faster – in just 10 to 30 minutes – without the need for sample preparation or standard curve generation.

Full integration
Straightforward Freedom EVOware® add-on to cover entire workflow, with fully validated processes for most Freedom EVO configurations.

Traceability
Liquid handling test results based on the QC Kit are traceable to the International System of Units (SI), through reference standards maintained by NIST (in the US) and NPL (in the UK). This allows customers to easily compare test results for different sites and instruments.

Liquid handling data
Overall accuracy and precision data, as well as channel-by-channel data, is provided.

Compliance with Documentary Standards
in 2015 the International Organization for Standardization (ISO) published a new document, ISO IWA 15, that describes standardized ways of determining the performance of automated liquid handling systems. Tecan and Artel guarantee compliance to this documentary standard. Upon request, a relevant declaration can be provided.



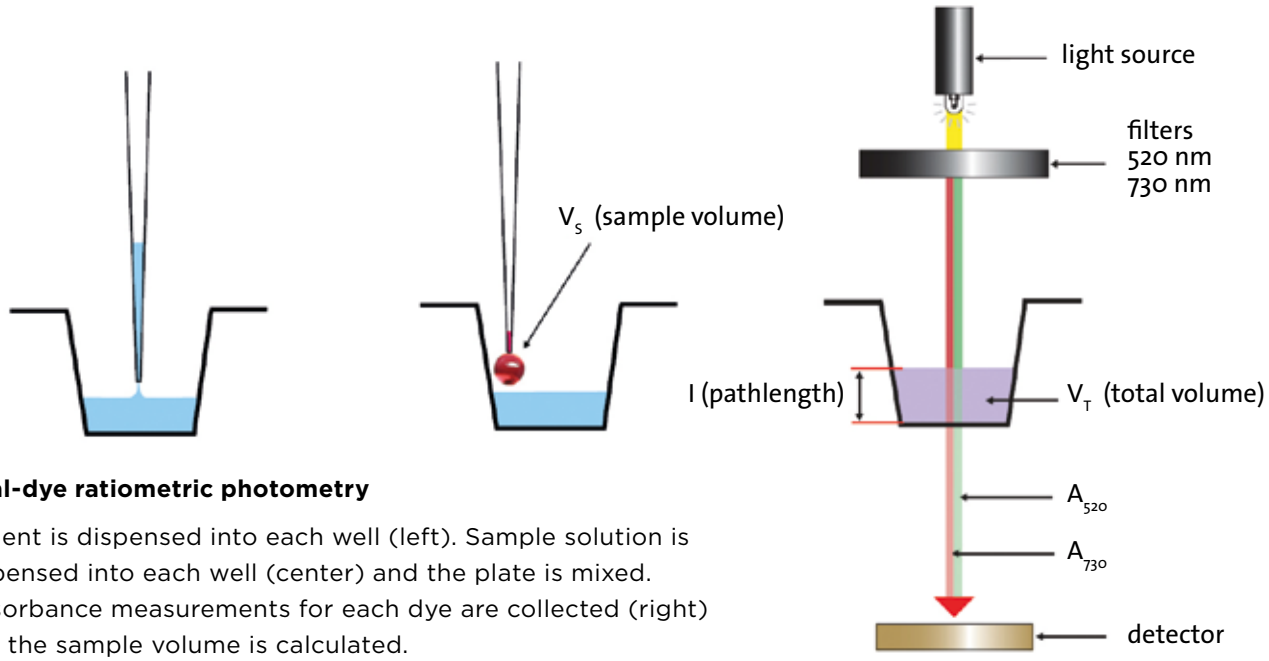
Powered by Artel's proprietary Ratiometric Photometry™ technology

The QC Kit incorporates Artel's proprietary Ratiometric Photometry technology onto the Freedom EVO system. In a first step, the blue diluent solution is dispensed into the well of the dimensionally-characterized QC Kit verification plate. The red sample solution is then dispensed, followed by mixing the two dyes with the QC Kit shaker. Finally, the absorbance is measured at 520 nm (A_{520}) and 730 nm (A_{730}) with the QC Kit reader, and the absolute dispensed sample volumes are calculated from the measured absorbance values:

$$V_S = V_T \left(\frac{a_b}{a_r} \right) \left(\frac{A_{520}}{A_{730}} \right)$$

The absorbance per unit pathlength for both the diluent and sample dyes, ab and ar, are determined at the factory when producing the dye solutions, and are provided on the barcode of the dye solution bottles. VT is calculated from the plate dimensions and the pathlength, l, which is calculated independently from A_{730} and ab:

$$l = A_{730} / a_b$$



Dual-dye ratiometric photometry

Diluent is dispensed into each well (left). Sample solution is dispensed into each well (center) and the plate is mixed. Absorbance measurements for each dye are collected (right) and the sample volume is calculated.

QC Kit hardware.

Tecan's QC Kit comprises hardware, software and consumables that provide a total liquid handling verification solution to satisfy quality and regulatory requirements for liquid handling performance verification of Freedom EVO® platforms. All QC Kit hardware components are validated as part of a total solution.

QC Kit calibrator plate
Primary daily calibration component of the QC Kit. Required to make absorbance readings and calculated volume dispense results fully traceable to international standards.

QC Kit reader
Tecan has validated three readers for use with the QC Kit:
- Infinite® F50 for 96-well verification plates
- Infinite F200 PRO and Infinite M200 PRO for 96- and 384-well verification plates

QC Kit shaker
Essential for effective mixing of red sample and blue diluent solutions, as well as removing bubbles.

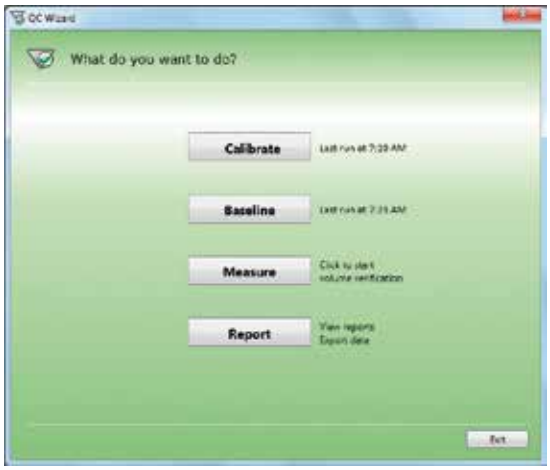
QC Kit barcode scanner
Essential for scanning all barcodes from the QC Kit calibrator plate, the dye solutions and verification plates throughout the workflow to ensure full traceability.

The Freedom EVOware QC Kit Wizard guides the operator through the QC Kit workflow, step by step

The QC Kit software is fully integrated with Freedom EVOware, enabling seamless, step-by-step control of the entire workflow. The Freedom EVOware Add-on controls pipetting, shaking, reading, data analysis and reporting providing a straightforward pass/fail result.

The Freedom EVOware QC Kit Wizard can generate the following reports:

- **QC Kit Report** – designed to meet quality and regulatory needs, with a one page summary of the verification test results and a pass/fail analysis
- **QC Kit Extended Data Report** – a multi-page report displaying all data captured by the QC Kit, including volume per well information helpful for troubleshooting and liquid handling optimization
- **CSV export** – all the data from multiple tests can be exported into a single file enabling further data analysis such as trending, multi-plate comparisons, and impact of liquid class alterations



QC Kit verification plates and solutions

Tecan offers a range of QC Kit consumables to cover both 96- and 384-well plate formats, and volume ranges from 100 nl to 200 µl and 30 nl to 55 µl respectively.

QC Kit Verification Plates undergo a thorough well-by-well characterization. It eliminates the impact of well-by-well differences on the QC Kit results and therefore improves accuracy and the overall performance.

Full traceability of QC Kit results to international standards is established by the characterization of the QC Kit verification plates and solutions by Artel, as well as the characterization of the QC Kit reader. All measurements are carried out using regularly calibrated instruments with certified reference materials. The use of these three components allows the QC Kit to provide standard volume measurement results to any Freedom EVO used anywhere in the world.

1 QC Kit verification plates

Material Number	Product
30062826	QC Kit verification plates 96-well, 25 plates per unit
30062827	QC Kit verification plates 384-well, 25 plates per unit

2 QC Kit solutions

Material Number	Product
30062828	QC Kit baseline solution, 220 ml, required for baseline measurement prior to verification testing
30062829	QC Kit diluent dye solution, 500 ml, required for verification testing

	Sample solutions required for verification testing	96-well volume range	384-well volume range
30062840	QC Kit Range A sample dye solution, 500 ml	50–200 µl	10–55 µl
30062841	QC Kit Range B sample dye solution, 110 ml	10–49.99 µl	2.5–9.99 µl
30062842	QC Kit Range C sample dye solution, 110 ml	2.0–9.99 µl	0.50–2.499 µl
30062843	QC Kit Range D sample dye solution, 110 ml	1.0–1.99 µl	0.30–0.499 µl
30062844	QC Kit Range E sample dye solution, 110 ml	0.1–0.999 µl	0.03–0.299 µl

QC Kit calibrator plate recertification service

The QC Kit calibrator plate must be recertified annually. Recertification of the QC Kit calibrator plate includes 'as found' testing of each of the four sealed cuvettes and the pane of neutral density glass to identify any changes in absorbance since the previous measurement by the reference spectrophotometer. All components of the plate are meticulously cleaned and any degraded or damaged parts are exchanged. Each standard is then remeasured with the reference spectrophotometer, and data is encoded on the calibrator plate barcode.

All data collected by the reference spectrophotometer is traceable to the International System of Units (SI) through reference standards developed and maintained by the National Institute of Standards and Technology (NIST) in accordance with the requirements of ISO/IEC 17025 and ANSI/NCSL Z540 Standards. This unbroken chain of traceability to NIST allows inter-laboratory comparison of data, and is the key component necessary for generating standardized volume measurements.

For recalibration, please contact your local helpdesk for further instructions.

In Use

- Ensure standardized results for 12 months

Expiration

- QC Kit Software notifies you that your calibrator plate is due for recertification
- Contact Tecan's global helpdesk service
- Send calibrator plate in for recertification

Recertification

- Calibrator Plate is re-certified using ISO 17025 accredited methods
- Rigorously calibrated by comparison to optical absorbance reference standards
- Barcode accuracy and performance is verified using reference readers
- Returned to user with ILAC endorsed certificate

QC KIT SPECIFICATIONS

QC Kit system specifications

Reader type	CV (%)	Accuracy (%)
Infinite F50	1	3
Infinite F200/M200 PRO (96-well plates)	1	3
Infinite F200/M200 PRO (384-well plates)	2	3.5

Tecan – Who we are

Tecan is a leading global provider of laboratory instruments and solutions in biopharmaceuticals, forensics, clinical diagnostics, academic centers and life science industries, and specializes in the development and production of automation solutions, detection instruments such as microplate readers, microarray-related products and washers.

Founded in Switzerland in 1980, Tecan has manufacturing, research and development sites in both North America and Europe, and maintains a sales and service network in 52 countries. To date, Tecan has distributed approximately 20,000 microplate readers worldwide and is committed to continuous technological improvements and compliance to global quality standards.

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