



Take control

OQ PQ kits for analytical instrument qualification

What is v-kit?

v-kit is a unique independent analytical instrument qualification system for the OQ/PQ qualification of HPLC, GC, LCMS, GCMS and tablet dissolution instruments and processes. The system includes a family of products designed to fit all needs, from the smallest lab to the largest organisation.

What does it consist of?

- Windows-based software to create and manage qualification protocols, and deliver controlled consistent qualification tests
- Traceable chemical reference standards
- Standard operating procedures
- Logbook

Who can use it?

Suitably trained personnel can use v-kit as a tool to provide instrument qualification in regulated laboratories, such as those inspected by the FDA

What do I need to get started?

You begin with an Initial Starter Pack, which contains the software, standard operating procedures and permissions needed for a complete qualification. There are various types of Starter Pack available, depending upon the technique you want to qualify and the number of qualifications you need to perform each year. You'll find full details of these in the comparison table. Chemical reference standards are included in all kits except for the 'lite' versions.

Starter kits are topped up as needed with Refill Packs – for multiple or single additional tests as required. These include all necessary consumables and extra licences, and can be ordered in any quantity.

What are the benefits of using v-kit?

There are many benefits, including time and cost savings of up to 80%:

- v-kit uses one standard approach – regardless of instrument manufacturer, providing the potential of consistent performance across all your equipment on all sites.
- v-kit provides the potential for your lab technicians, usual service providers, or equipment users to perform qualifications.
- Control – you can define qualification protocols to meet your own requirements
- The user-friendly software, SOPs, and reference standards work seamlessly together
- Used correctly, v-kit can aid compliance to regulations issued by international authorities such as FDA (USA), MHRA (UK), IMB (Ireland), etc

www.v-kit.com

v-kit overview



The v-kit family –

v-kit 3.1 lite offers a low cost of entry into the v-kit family of qualification products. v-kit lite is intended for users with fewer than 5 systems to be qualified each year

v-kit 3.1 for HPLC & GC only. For established users, where 3.1 protocols are accepted. Also for new users requiring more than 5 qualifications per year.

v-kit Pro lite for users requiring the advanced features & benefits of v-kit Pro, with low usage and single analytical technique

v-kit Pro For those requiring the advanced features & benefits of v-kit Pro and multiple analytical techniques

v-kit Pro Enterprise For large organisations with each engineer performing 30+ qualifications per year and multiple analytical techniques

(See the comparison table inside for additional info>)



For more information about v-kit, including details of your local distributor, visit the v-kit website or contact v-kit's manufacturer – NLG-Analytical:

www.nlg-analytical.com

t: +44(0)1260 274-266

e: info@nlg-analytical.co.uk



Platform	Product	Target Market	Entry Cost	End-User Refill Cost	Upgrade	Features
	v-kit 3.1 lite	Low-volume end-users requiring less than 5 qualifications per year	Low	Premium	n/a	Suitable for HPLC and GC only
	v-kit 3.1	Established users, where 3.1 protocols are accepted. New users requiring more than 5 qualifications per year	Standard	Standard	From 3.1 lite	Suitable for HPLC and GC only
	v-kit Pro lite	Users requiring the advanced features & benefits of v-kit Pro, with low usage and single analytical technique	Low	Premium	From 3.1 lite & 3.1	Dedicated dongle for single technique only
	v-kit Pro	New users requiring the advanced features & benefits of v-kit Pro	Premium	Standard	From 3.1	Available for all techniques: HPLC, GC, GC/MS, LC/MS, Tablet Dissolution, etc.
	v-kit Pro enterprise	From 3.1 lite	Premium	Low	From v-kit Pro	Not available for resale. Annual subscription. Available with HPLC, GC, GCMS, LCMS, Tablet Dissolution, etc.



LCMS v-kit protocols include:

- Mass Accuracy test
- Signal to noise test
- Pump Flowrate and Gradient proportioning test
- Autosampler Precision, linearity & carryover test
- Temperature Accuracy and Stability for Column and Sample Compartments



GCMS v-kit protocols include:

- Mass Accuracy test
- Signal to noise test
- Autosampler precision/mass ratio test
- RFPA test (suitable for Agilent MS only)
- Column oven, inlet and detector temperature accuracy & stability
- Inlet pressure accuracy and tightness
- Inlet and detector flow accuracy (inc. split, purge)
- Autosampler injection precision, carryover and retention time reproducibility



HPLC v-kit protocols include:

- Pump flow rate accuracy and precision
- Gradient composition accuracy and linearity
- UV/Vis, PDA/DAD and fluorescence detector wavelength accuracy
- UV/Vis, PDA/DAD, fluorescence, refractive index and ELS and conductivity response linearity
- Autosampler injection volume precision and carry-over
- Autosampler injection volume linearity
- Column oven and autosampler tray temperature accuracy



GC v-kit protocols include:

- Column oven, inlet detector and detector temperature accuracy
- Column oven, inlet and detector temperature stability
- Inlet pressure accuracy and tightness
- Inlet and detector flow accuracy (including split, purge, make-up, fuel gases)
- Autosampler injection precision, carryover and retention-time reproducibility
- Detector response linearity (FID/TCD)



v-kit Pro

Released in 2009 v-kit Pro is 4th generation v-kit product based on a completely new platform. Designed to allow the creation of qualifications for any piece of equipment using the supplied and/or customised protocols. v-kit Pro is currently available for all major analytical techniques including hplc, gc, gcms, lcms, and tablet dissolution. Balances, titrators, UV-Vis and IR Spectroscopy are due later in 2010.

User Interface

vkit-pro software runs in a modern, web browser-based interface usually installed onto the qualification technician's laptop PC.

Control of Qualification Protocol

- Managers duplicate, edit, publish and secure protocols via the **Protocol Manager** tool.
- Technicians can run instances of protocols (qualifications) via the **Protocol Runner** tool.



Traceability Documents

One mouse click gives immediate access to quality documents such as:

- Standard Operating Procedure
- Certificate of Analysis for standards
- Tool Calibration Certificate

Failure Action & Deviation Reporting

The audit trail provides a detailed history of the qualification. It is time and date stamped and shows the test outcomes and deviations.



Summary Report

Upon completion of the protocol a summary is available for reporting, giving an 'at a glance' status of the whole qualification

Electronic Qualification Logbook

The final stage of the completion of the qualification protocol is compiling the test data. This is normally a time-consuming process with plenty of opportunity for error. v-kit Pro simplifies and speeds up this process with an electronic logbook function, resulting in a comprehensive document pack containing the items below, (stored as a single file) ready for inclusion into the instrument logbook:

- Summary report & audit trail report
- Qualification reports
- Standard Operating Procedures
- Certificates of calibration (for tools)
- Engineer training records
- Raw data (eg: chromatograms, spectra)
- Any other, relevant, user-specified documents



Standard operating procedures

Writing and maintaining SOPs is a time-consuming process. Each v-kit is supplied with one or more SOPs detailing the qualification procedure.

These include the calculations used to allow auditors to quickly verify the integrity of the reports.

Change Control information is also included highlighting the changes since the previous revision.

The correct SOP is accessed directly from the relevant screen in the user interface and can be incorporated into the qualification logbook at the click of a button

Qualification Certificate

Qualification certificates can be printed many times and can be accessed directly from the v-kit Pro database. However the test can never be re-processed

Each qualification protocol may consist of several individual tests – for example a detector may need qualifying for response linearity, signal to noise and wavelength accuracy. Each test has an SOP, a certificate of analysis or calibration, raw data, and a test certificate.



v-kit HPLC and GC tools

v-tools are the recommended tools for HPLC/GC OQ and integrate with the v-kit software and procedures. The range of tools has been designed to ensure accuracy as well as to help to speed up the instrument testing process. The calibration on all tools is valid for one year and includes traceable calibration certificates.



HPLC Liquid Flowmeter
Specially designed for HPLC, the v-kit liquid flowmeter enables easy and accurate measurement of flow rates of common solvents used in HPLC pumps. VKIT-LFM (1,2,3,4)



GC Gas Flowmeter
The v-kit gas flowmeter enables easy and accurate measurement of flow rates of all gases used in gas chromatography. VKIT-GFM






Digital Thermometer
This 2-channel device allows connection of standard Type K-thermocouples and all v-kit specific temperature probes. VKIT-1531



Gas Pressure Meter
Permits easy and accurate measurement of pressure for all gases used in gas chromatography. VKIT-DMA

Temperature Probes
NLG has designed a number of probes to measure temperatures during HPLC and GC qualification

HPLC Autosampler Tray Temperature Probe VKIT-1514	
Injection Port Temperature Probe VKIT-1517	
GC Column Oven Temperature Probe VKIT-1519	

NLG Analytical calibrates HPLC and GC tools We offer a fast turnaround and a cost-effective calibration service on all the above devices, as well as other popular brands. For more information visit: <http://www.v-kit.com/products/v-kit/calibration>

find out more...

There's lots more information on the v-kit website at:

www.v-kit.com

On the site you'll find details of v-kit's application to specific techniques including:

- HPLC
- GC
- LCMS
- GCMS
- Tablet Dissolution

There are downloadable datasheets for each technique, plus more on the wide range of v-kit tools, reference standards and accessories.

Qualification using v-kit is also available on a service delivery basis by NLG Analytical – the inventor of v-kit, or through its network of approved service providers. Details can be found in the service section of the v-kit website, or on:

www.nlg-analytical.com

For general queries, quotations, and details of your local v-kit distributor, please call NLG Analytical on:

+44 (0)1260 274266

email: info@nlg-analytical.co.uk