

Tracer-QC™

Automated optical testing for PET-QC

www.lablogic.com

 **LabLogic**
EXPERIENCE & EXPERTISE

A universal solution for PET radiotracer quality control

The Tracer-QC is an automated solution that utilises only an optical plate reader, a pipetting robot and single-use consumable kits for release testing of PET radiotracers.

- ✓ 1 Sample
- ✓ 1 Analytical Instrument
- ✓ All QC Tests
- ✓ 1 Traceable and Objective Report

Ease of compliance

- No chance of missing a process, record or signature.
- Objective measurements traceable to standards, without any human interaction.
- Data flow from measurement to batch record.
 - Automated.
 - Uneditable.
 - Completely traceable.
- Regular, automated suitability testing with a permanent record.
- Enables FDA 21 CFR Part 11 (Electronic Signatures) and Part 212 (GMP) compliance.
- No cross-contamination with Tracer-QC, as the sample never leaves the disposable kits.
- Ease of (regulatory or internal) audits with instantaneous data retrieval.

Cost reduction

- Cumulative annual QC cost reduction of 30% or more.
- Fewer and less skilled personnel required.
- Faster and cheaper training.
- Faster and cheaper audits.
- Electronic access/auditing of records.
- Minimise the cost of addressing 483's.
- Reduce risk of 483's by around 84%.
- One analytical instrument to maintain.

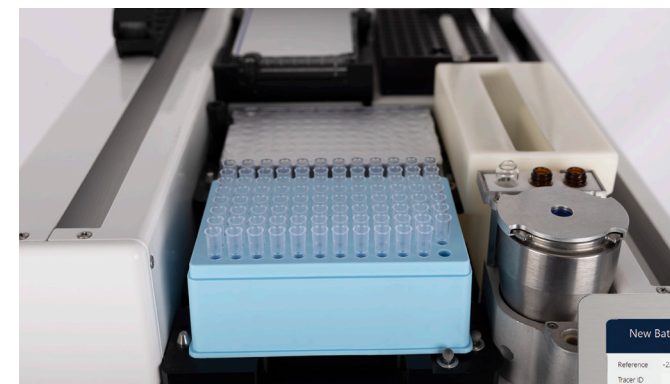


Improved safety

- Reduced risk of radioactive spills and contamination.
- 69% reduction of personnel exposure.
- Single sample.
- Minimal sample handling with the use of a shielded pig.
- Attenuated exposure.

Improved efficiency

- 1 electronic report with all QC results, automatically generated.
- 83% reduction in SOP's.
- 57% reduction in time spent on QC-related activities.
- Run QC unattended from sample to report.
- Increased throughput to enable scale-up.
- No cleaning or equilibration required with Tracer-QC due to the use of a disposable kit.
- Inventory reduction, eliminating the need to track individual expiry dates of multiple supplies/standards.
- Process standardisation across sites and/or products.
- Single sample injection for all analyses.



QC tests

- ✓ Colour
- ✓ Clarity
- ✓ pH
- ✓ Kryptofix concentration
- ✓ Endotoxin concentration
- ✓ Residual solvents
- ✓ Radionuclidic identity (half-life)
- ✓ Radioactivity concentration
- ✓ Radiochemical identity
- ✓ Radiochemical purity
- ✓ Chemical purity and specific activity

About Trace-Ability Inc.

Trace-Ability is a growing, California-based company that answered the FDA call for modernisation of testing technologies in radiopharmaceutical production, which it has enabled using optical techniques. The FDA funding and collaboration have enabled optimisation and focused validation of Tracer-QC technology, leading to successful completion of the FDA-collaborative project exceeding all improvement objectives.

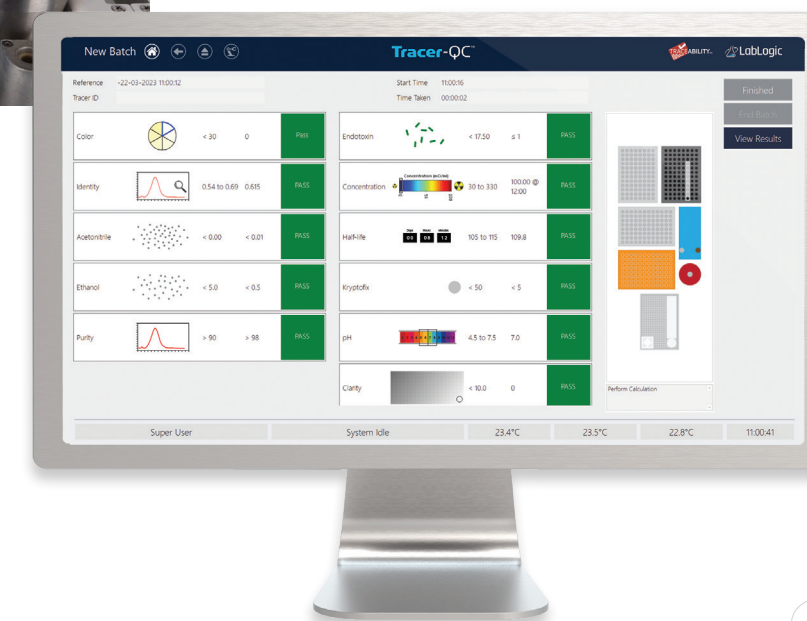


The LabLogic/Trace-Ability Partnership

Trace-Ability have focused on the technical aspects of bringing Tracer-QC to market, including development and validation of the core Tracer-QC technology and production of consumables.

LabLogic leveraged years of experience and expertise in software development, to deliver an intuitive software interface, built with FDA 21 CFR Part 11 (Electronic Signatures) and Part 212 (GMP) compliance in mind.

Commercialisation of Tracer-QC is a joint effort.



Tracer-QC™

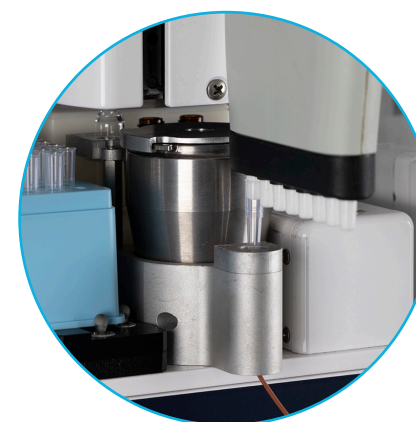
Automated system for radiopharmaceutical quality control



Tracer-QC radio-HPLC™

Automated system with integrated radio-HPLC for radiopharmaceutical quality control

Integrated radio-HPLC Coupling

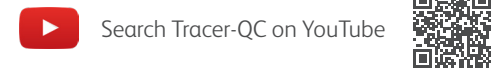


Easy-to-use compliant software

The Tracer-QC software enables FDA 21 CFR Part 11 (Electronic Signatures) and Part 212 (GMP) compliance.

- Electronic signatures.
- Audit trail.
- Access levels.
- Maintenance records.
- Automatic reports.
- Direct interface to PETra LIMS.
- Export to other 3rd party applications.

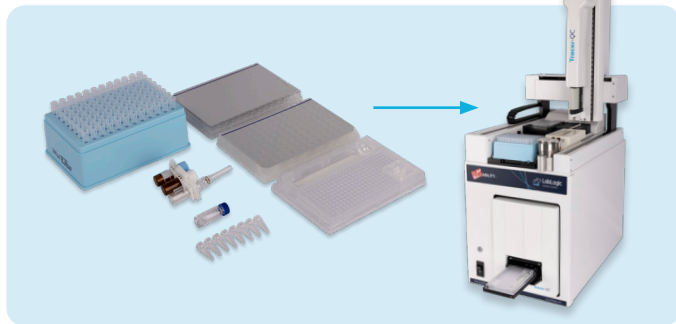
The Process



1. Scan the consumables kit



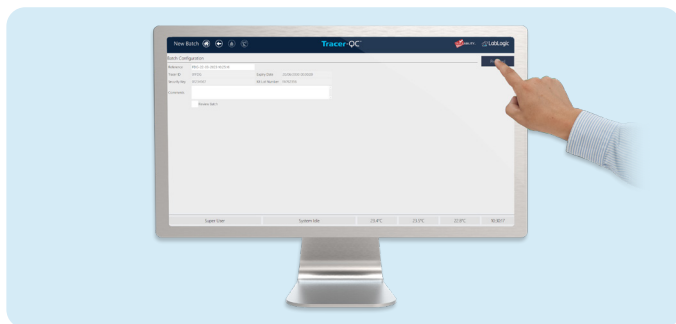
2. Add the consumables to the Tracer-QC



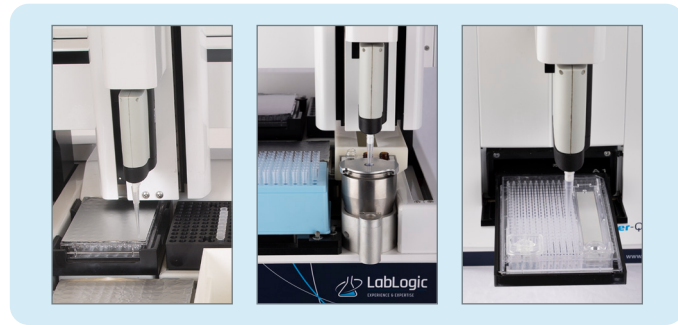
3. Deliver QC sample in a shielded pig



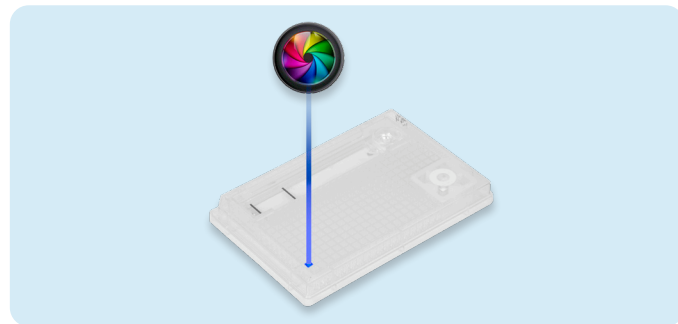
4. Initiate the analysis



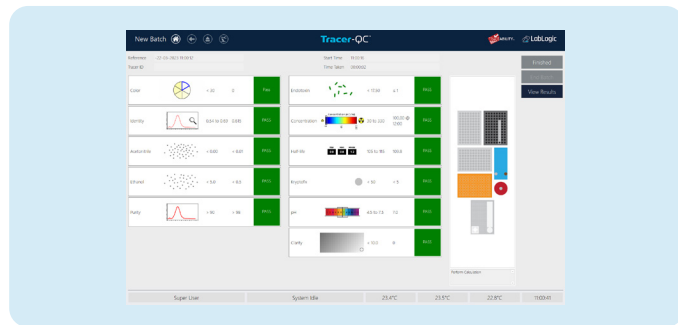
5. Tracer-QC mixes and dispenses the sample



6. Tracer-QC analysis starts



7. Analysis is complete



8. Collect the report



FDG Kits

Trace-Ability have developed kits that are tried and tested for the release criteria of FDG both with or without the HPLC.

The kit includes single-use consumable items which are individually packaged and labelled. They are designed so that they only fit onto the Tracer-QC in one way, making the set-up of the system very simple.



Universal Kits

The majority of the tests available on the Tracer-QC are generic QC tests, which are not tracer specific.

Universal Kits allow users to run these non-tracer specific tests on any sample.



Service and Support

Users of our systems can benefit from our comprehensive, fully inclusive service and support.

We can give reassurance that if things go wrong or you need expert advice, help is only an e-mail or phone call away.



Validation Services

Our Validation Service enables you to implement and get maximum value from your investments as soon as possible.

We work as a partner with your Quality Manager, System Manager and users to provide a tailored Validation Plan, suited to your needs. Our Validation Specialists have years of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet company and regulatory requirements.

Training

LabLogic can provide a variety of training courses and workshops to help you get the most out of your instrument and software.

All training is performed by our expert Product and Support Specialists who have many years experience in the development and use of the instruments and software.

Certificates can be provided to complement your internal GLP training records.

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