

# Tracer-QC™

Automated optical testing for PET-QC

Now with  
integrated  
rHPLC



# A universal new solution for PET/SPECT 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/SPECT 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 (FDA 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.
- Remote 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.
- Reduced personnel exposure.
- Single sample.
- Minimal sample handling with the use of a lead pig.
- Attenuated exposure.

## Improved Efficiency

- 1 electronic report with all QC results, automatically generated.
- Rapid QC results.
- Increased throughput to enable scale-up.
- No cleaning or equilibration required with Tracer-QC due to use of a disposable kit.
- Inventory reduction, eliminating 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
- ✓ Sample concentration
- ✓ Radionuclidic identity (half-life)
- ✓ Radioactivity concentration
- ✓ Radiochemical identity
- ✓ Radiochemical purity

## 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. Years of experience in PET industry allowed the founders to recognise the opportunity to revolutionise and simplify PET-QC testing using optical techniques. The FDA funding and collaboration have enabled optimisation and focused validation of Tracer-QC technology.



## 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 rHPLC™

Automated system with integrated HPLC for radiopharmaceutical quality control.



## Easy-to-use compliant software

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

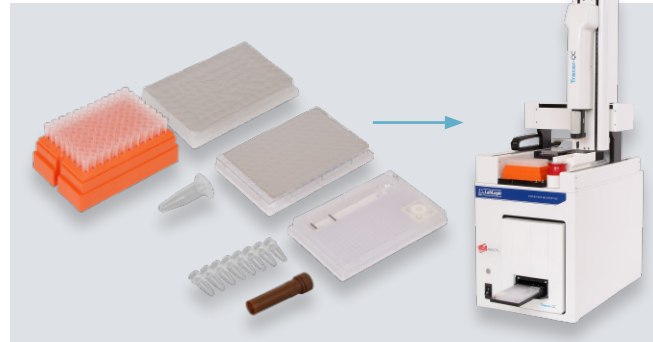
- Electronic signatures
- Audit trail
- Access Levels
- Maintenance Records
- Automatic Reports
- Export to PETra LIMS and other applications

## The Process

### 1. Scan the consumables pack.



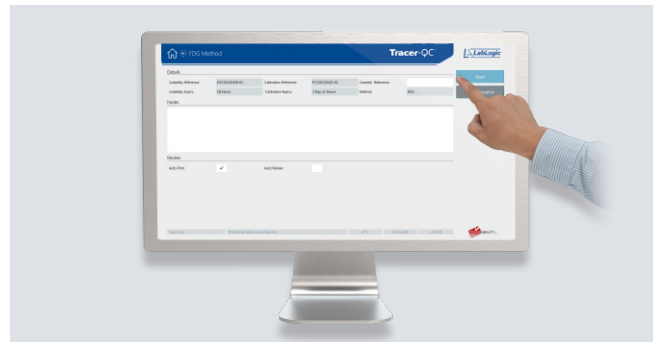
### 2. Add the consumables to the Tracer-QC.



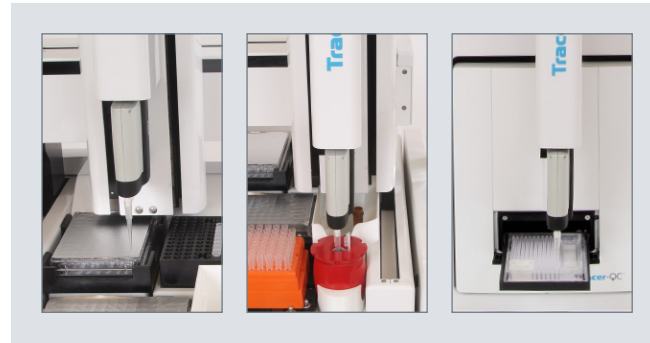
### 3. Add the sample vial to the shielded pig.



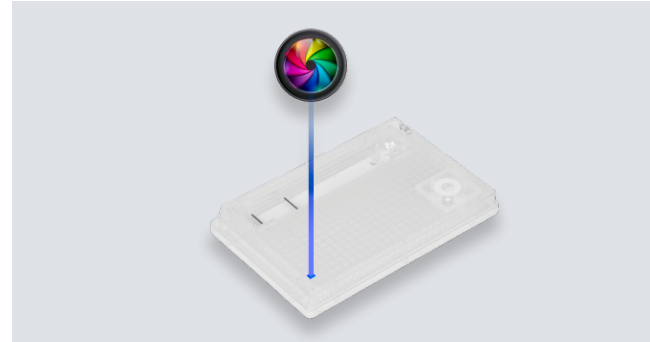
### 4. Initiate the analysis.



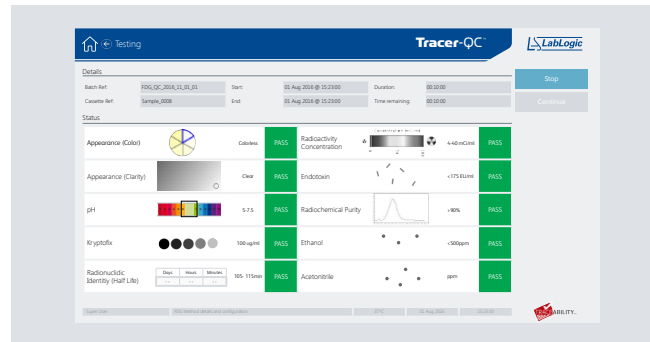
### 5. Tracer-QC mixes and dispenses the sample



### 6. Tracer-QC Analysis Starts



### 7. Analysis is complete



### 8. Collect the report



## Tracer Specific Kits

Trace-Ability have developed kits that are tried and tested for the release criteria of F-18, C-11 and N-13 radiotracers. The kits are available both with or without the HPLC function.



## 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.



## Research and Development Kits

Research & Development Kits allow users to develop their own kits for QC testing which have not yet been developed by Trace-Ability.

Once a kit has been developed, Trace-Ability are able to supply these kits.







## 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 instruments 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.

## Related Products

### Scan-RAM™

PET/SPECT radio-TLC Scanner



### Flow-RAM™

PET/SPECT radio-HPLC Detector



### Bubble-Point™

Filter Integrity Tester



### Posi-RAM™

PET Metabolite radio-HPLC Detector



### EC-Detector

PET/SPECT EC (Electrochemical) Detector



**PETra™**  
PET LIMS Software



**Laura for PET™**  
PET/SPECT Radiochromatography  
Instrument Control, Data Collection  
and Analysis Software



**QC Solutions**  
The Complete PET Quality Control Service

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Certificate No: 1535  
ISO 9001



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