Tracer-QC™

Automated optical testing for PET-QC

TRACEABILITY INC

LabLogic
EXPERIENCE & EXPERTISE

A radical new solution for quality control of PET radiotracers

The Tracer-QC is a completely automated solution for reporting on 10 QC tests associated with PET and SPECT radiotracers, utilizing only an optical plate reader, a pipetting robot and a set of simple-to-handle consumables.

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.
- The Tracer-QC enables FDA 21 CFR Part 11 (Electronic Signatures) and Part 212 (GMP) compliance.
- No cross-contamination, 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.
- Minimize 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.

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 trial.
- Access Levels.
- Maintenance Records.
- Automatic Print.
- Export to PETra LIMS, other third party software and Microsoft Excel.

Improved Efficiency

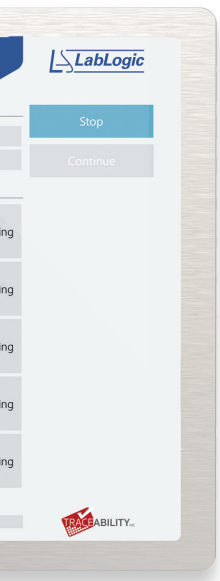
- 1 electronic report with all QC results, automatically generated.
- Rapid QC results.
- Increased throughput to enable scale-up.
- No cleaning or equilibration required due to a disposable kit.
- Inventory reduction, eliminating need to track individual expiry dates of multiple supplies/standards.
- Process standardization across sites and/or products.
- Single sample injection for 10 analyses.

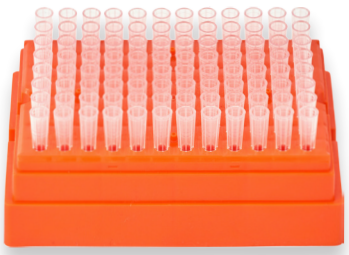
Validation in partnership with the FDA (U01FD005517)

QC tests

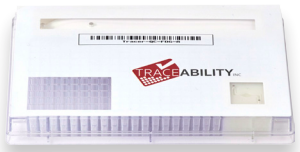
- ✓ Color
- ✓ Clarity
- ✓ pH
- ✓ Kryptofix concentration
- ✓ Endotoxin concentration
- ✓ Ethanol concentration
- ✓ Acetonitrile concentration
- ✓ Radionuclidic identity (half-life)
- ✓ Radioactivity concentration
- ✓ Radiochemical identity
- ✓ Radiochemical purity

Kit B: Reagent Set





Pipetting Tips

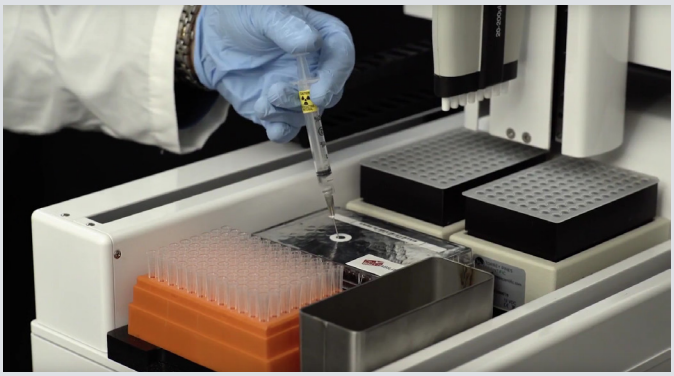


Kit A: Analysis Plate

The Process

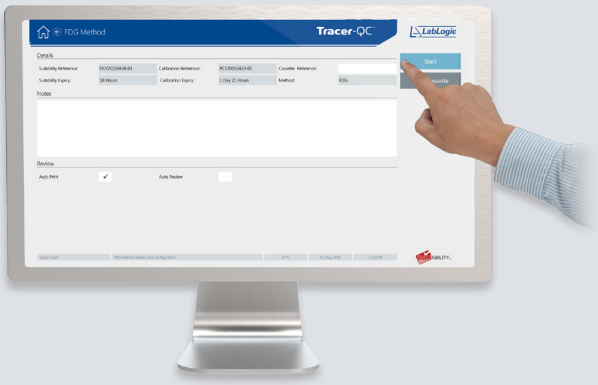
1. Add the sample and consumables

User installs a set of consumables and adds the product sample.



2. Initiate the analysis

User initiates the analysis using the software.



3. Tracer-QC Robot mixes and dispenses the sample

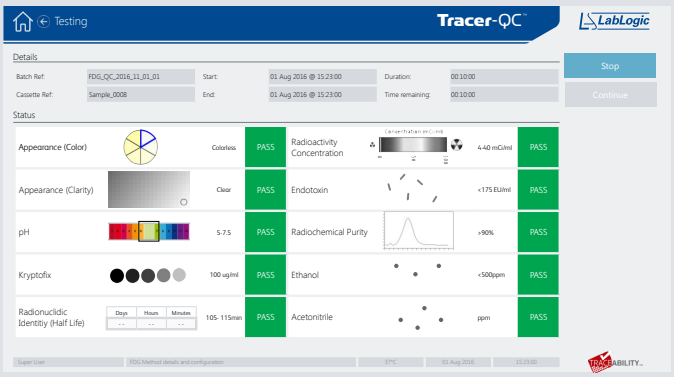
The pipetting robot mixes the sample with specific reagents and dispenses them to the analysis plate.

4. Tracer-QC Reader analyzes the optical signals

The reader then analyzes their optical characteristics against a set of predefined and validated reference specifications.

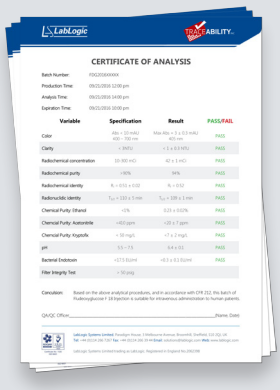
5. Analysis complete

After approximately 30 minutes the analysis is complete.



6. Collect the report

A single page report on up to 10 QC parameters is automatically printed or exported in the desired format.



Search Tracer-QC on YouTube

- ✓ 1 Sample
- ✓ 1 Analytical Instrument
- ✓ 10 Tests
- ✓ 1 Traceable & Objective Report

About Trace-Ability Inc.

Trace-Ability is a growing, California-based company that answered the FDA call for modernization of testing technologies in radiopharmaceutical production. Years of experience in PET industry allowed the founders to recognize the opportunity to revolutionize and simplify PET-QC testing using optical techniques. The FDA funding and collaboration have enabled optimization 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 create an intuitive software interface, built with FDA 21 CFR Part 11 (Electronic Signatures) and Part 212 (GMP) compliance in mind.

Commercialization of Tracer-QC is a joint effort.

Service and Support

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

We provide complete service and support for all of our customers to 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 incorporate years of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet your company's 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.

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

USA & Canada

LabLogic Systems, Inc.

East Pointe Park, 1040 East Brandon Blvd.
Brandon, FL 33511-5509, USA

E-mail: solutions@lablogic.com
Tel: +1-813-626-6848
Fax: +1-813-620-3708
Web: www.lablogic.com

Europe & Worldwide

LabLogic Systems Limited

Paradigm House, 3 Melbourne Avenue
Broomhill, Sheffield, S10 2QJ, UK

E-mail: solutions@lablogic.com
Tel: +44 (0)114 266 7267
Fax: +44 (0)114 266 3944
Web: www.lablogic.com

Certificate No: 10926
ISO 9001

Certificate No: 1535
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