

- ✓ 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 solid 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 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 compliment your internal GLP training records.

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



Certificate No: 10926
ISO 9001

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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: 1535
ISO 9001



Related Products

Scan-RAM™

PET/SPECT radio-TLC Scanner



Flow-RAM™

PET/SPECT radio-HPLC Detector



PET LIMS Software



PET/SPECT Radiochromatography Instrument Control, Data Collection and Analysis Software



Radiochromatography Data Collection and Analysis Software



The Complete PET Quality Control Service

Tracer-QC™

Automated optical testing for PET-QC



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 three simple-to-handle consumables.

Ease of Compliance

- No room for missing a process, record or signature.
- Objective measurements with reference to standards and without any human interaction.
- Data flow from measurement to batch record.
 - Automated.
 - Uncompromised.
 - Completely traceable.
- Regular automated suitability testing with a permanent record.
- FDA 21 CFR part 11 and 212 compliant software.
- No cross-contamination as the sample never leaves the disposable kit.
- Ease of (FDA or internal) audits with instantaneous data retrieval.

Cost Reduction

- Cumulative QC cost reduction of around 30% or more.
- Fewer and less skilled personnel.
- Faster and cheaper training.
- Faster and cheaper audits.
- Remote record access/auditing.
- Minimize the cost of addressing 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 is written to enable GMP-compliance.
- FDA 21 CFR part 11 and 212 compliant.
 - Electronic signatures.
 - Audit trail.
 - 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, due to tracking individual expiry dates of multiple supplies/standards.
- Process standardization across sites and/or products.
- Single sample injection for 10 analyses.



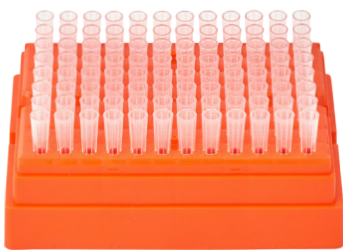
Kit B: Reagent Set



QC tests

- ✓ Color
- ✓ Clarity
- ✓ pH
- ✓ Kryptofix concentration
- ✓ Pyrogen concentration
- ✓ Residual ethanol
- ✓ Residual acetonitrile
- ✓ Radiochemical identity (T_{1/2})
- ✓ Radioactivity concentration
- ✓ Radiochemical identity & purity

38.5" (98cm)



Pipetting Tips



Kit A: Analysis Plate

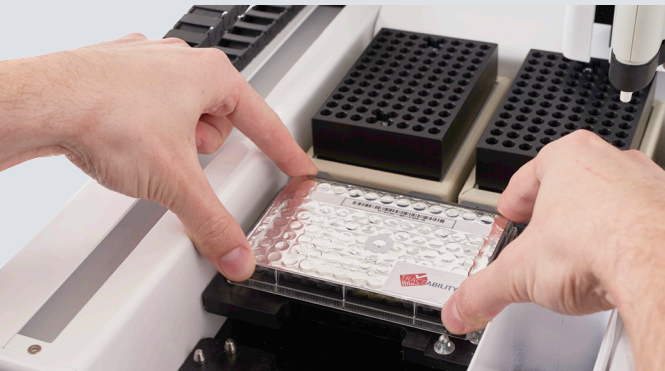
26.3" (67cm)

13" (34cm)

The Process

1. Add the sample and consumables

User installs three consumables and adds the product sample.



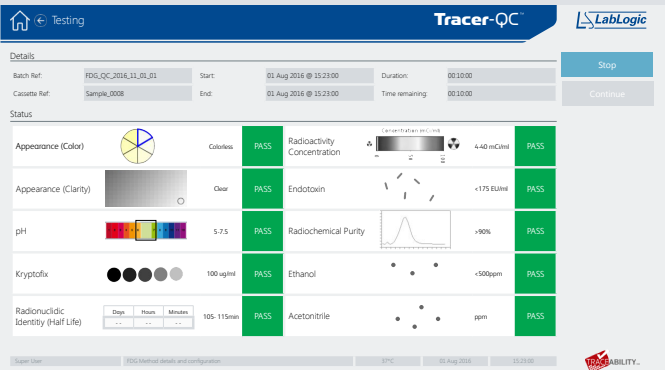
3. Tracer-QC Robot mixes and dispenses the sample

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



5. Analysis complete

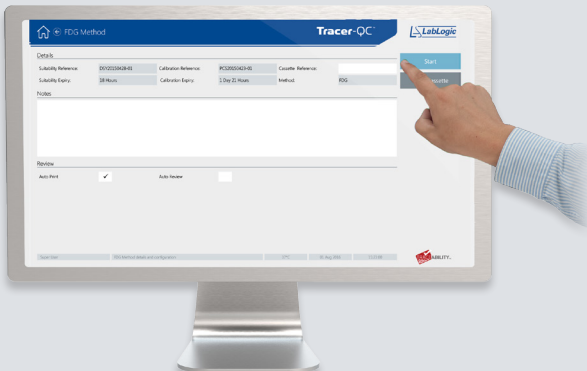
After approximately 30 minutes the analysis is complete.



Search Tracer-QC on YouTube to watch the video

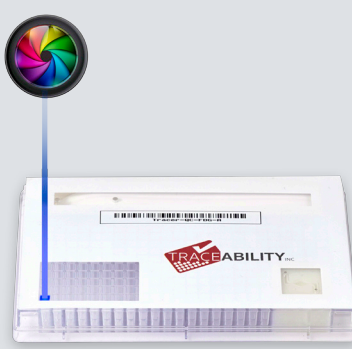
2. Initiate the analysis

User initiates the analysis using the software.



4. Tracer-QC Reader analyzes the optical signals

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



6. Collect the report

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

