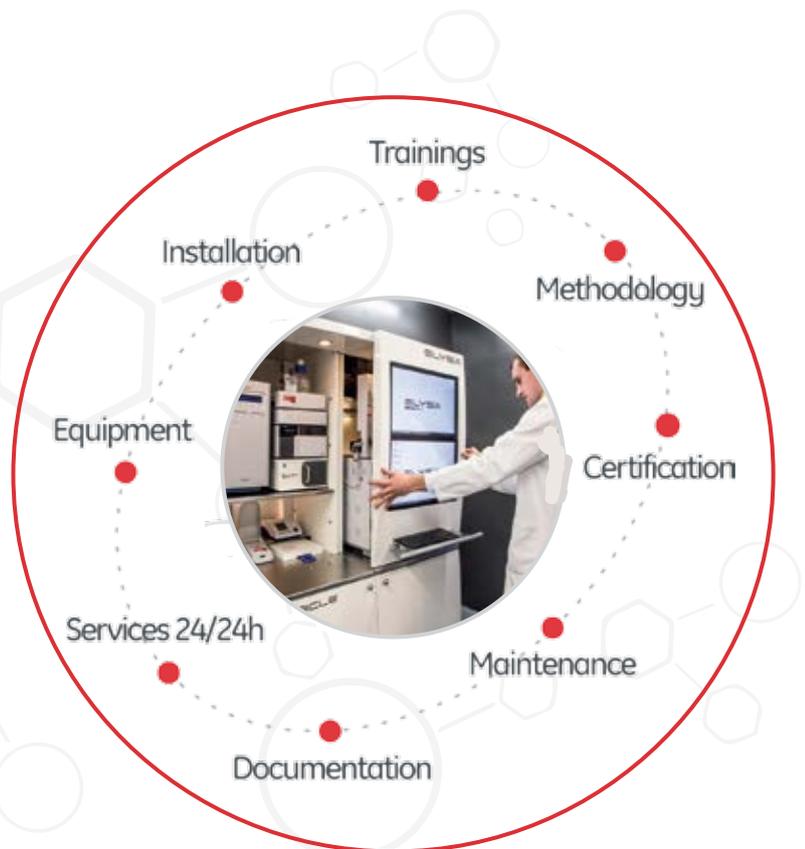


QC-CUBICLE

INTEGRATED QUALITY CONTROL LAB FOR RADIO-PHARMACEUTICALS

A FULLY INTEGRATED AND MODULAR QC SOLUTION ON 1,2M² LAB SPACE

- COMPACT
- FOLLOWING EU PHARMACOPOEIA QC STANDARDS
- REDUCES TIME FROM INSTALLATION TO ACCREDITATION
- PAPERLESS DOCUMENTATION FOR DATA SECURITY AND REDUCING HUMAN ERROR



The QC-Cubicle is an all-in-one solution for the Quality Control of Ga labelled radiopharmaceuticals. The basic system incorporates all the hardware needed for the Quality Control tests of ⁶⁸Ga according to the European Pharmacopoeia. It can be easily extended to other tracers. It has been designed to save space and to permit optimally efficient work flows. The complete QC system, including local shielding, can be fitted into 1m² lab space. In addition to the high end hardware, the QC-Cubicle comes with extensive software and service package enabling the setup of a complete QC lab in a very short time.

Hardware

The QC-Cubicle is modular and can be adapted to your personal needs and regional legislation. The core system contains all the hardware needed for the Quality Control of radiopharmaceuticals according to the European pharmacopeia. We propose 2 different extension modules, one for the preparation of the samples and one for additional tracers. The additional tracer module allows to integrate additional bench space, a shelf for a second HPLC and some more storage room.



Radiation protection and environmental control



One aim of the QC-Cubicle is to increase the safety of the users. To reach this goal we have increased the radiation protection with specific shielding and an improved environmental control. Additional lead shielding on sensitive parts and some small handling tools reduce the irradiation risk during the QC and the sample preparation. The ambient and internal temperature are monitored and registered to deliver additional information about the working conditions.

The active extraction of GC gases and the use of a hydrogen generator decrease the risk of using hydrogen and of radioactive gas evacuation during the QC. The inbuilt shielded waste systems offer an optimal waste management and user protection.

To ensure that your QC can be done even in case of a power failure, the QC is secured for 20 minutes by the built-in UPS battery pack.

Services



The QC-Cubicle is delivered with an extensive service package to support the customer both with the set-up of the facility and his daily routine work. Depending on the customer's needs, we can extend the service pack with additional training and service contracts.

Each system undergoes an extensive factory acceptance test as well as an installation test according to Elysia test procedures and guidelines to ensure a high end quality standard.

The standard package includes on-site training, covering the basic hardware and software functions, offering the user an optimal use of the different QC instruments.

Our included method training is dedicated to the QC of FDG or Gallium according to the pharmacopeia. It comes with a full digital SOP and includes the following tests: determination of PH, turbidity, radioactive concentration, radiochemical purity, radionuclide purity, specific activity, residual solvents and pyrogens.

The sterility determination and other methods are not included in the standard pack but are available on request.

IQ/OQ-service of the entire QC-Cubicle, with separated IQ/OQ modules of each QC instrument, is performed by trained and certified Elysia-raytest technicians.



Additional sample preparation module



The sample preparation module has been designed to optimize the work flow whilst increasing radiation protection for the user. It comes with built-in waste containers for the daily production and decontamination. The module is delivered with some special sample holders,

small shielding and working tools to facilitate the work and to minimize the hands-on time. The automatic door opener for the waste makes the work smooth and easy. The preparation module incorporates an integrated TLC plate dryer. This is a unique solution with a software controlled drying of your TLC plates and an active extraction of your solvent gases. This is a high end solution for a standardized drying process with increased user safety.



Instruments

GC with Flame Ionisation Detector (FID) + Injector

The GC has been designed and configured for the residual solvent control. The small size, the automatic sample injector for up to 12 samples and the adapted column allow highest quality and easy standardization. The GC is optional and can be taken out if not required by local regulations.



Dose calibrator

The calibrator is designed for the fast and accurate determination of the activity or volume activity of radiopharmaceuticals. It is PC controlled, calibrated for the PET nuclides (e.g. ^{18}F , ^{124}I) and comes with a large lead shielding. The included software is easy to handle and touchscreen based.



HPLC FDG

The HPLC is especially designed to achieve best performance in minimum space for the quality control of FDG or ^{68}Ga labelled peptides according to the pharmacopeia. It contains all the hardware you need, including the gas purge, manual injector, degasser, pump, column heating, radio detector and product specific detector.



CCD Camera

For a good digital recording of the kryptofix and other visual test, we deliver the QC-Cubicle with a CCD camera.



Multi Channel Analyser (MCA)

Our non-cooled fast MCA comes with a 3x3NaIcrystal, a 5 cm low radiation lead shielding and a sample holder.

High-end electronics enable the system to perform fast spectrum analysis of radiopharmaceuticals.

The system is delivered with a software package for the instrument control and data analysis.



Osmometer

The Semi-Micro Osmometer enables freezing point depression to be measured and determines the total osmolality of aqueous liquids. In our QC-Cubicle, the system is fully controlled by software and all data can be digitally transferred to the server. The system is delivered with a corresponding calibration buffer. As with the GC, the osmometer is optional and can be omitted if not required.



TLC scanner

The built-in TLC scanner has been designed for optimal space saving without decreasing the sample size. It can be used with TLC plates up to 20 cm and detector has been designed for PET applications to give a great sensitivity, a high resolution and to minimize background interference.



LAL test device + LAL test consumables

The bacterial endotoxin (LAL) detection system is FDA approved. In the QC-cubicle, the LAL test device is directly connected to the server and the signal / result transfer is fully digital.



Easy PH

The QC-Cubicle contains an automatic ph.-strip reader. The system allows rapid testing and high precision, eliminating the subjectivities of visual reading.



H₂ Generator

To avoid any potential problems with hydrogen supply or quality, the Cubicle is equipped with an integrated low maintenance hydrogen generator, installed in its own compartment and with air extraction to increase safety.



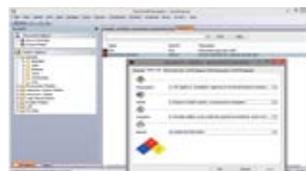
IT software

The QC-Cubicle high-end hardware is completed with an extensive software and service package which will help you to set up the new lab in a very short time. This will help you to fulfill highest GxP standards with optimal data transfer, documentation and storage. All instruments can be controlled and used in stand-alone mode to ensure a maximal flexibility. To fit your local regulations as well as your personal needs, we deliver two different LIMS solutions.

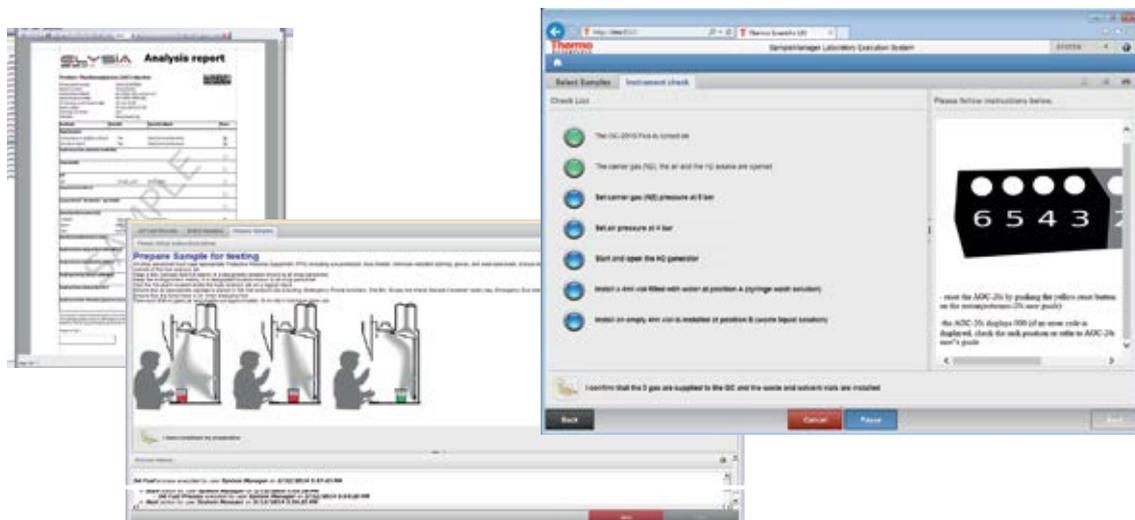


The ARGUS-RP software solution (RP = Radio Pharma) is an extensive software package covering the complete laboratory process, stock management, data visualization, lab management and the interactive digital SOPs.

Handling SOPs, instruments, data, results, consumables, work flows, documentation or resources becomes easy and safe. Acquire, record & report results out of the individual instruments according to newest GxP standards. Digital SOPs for different radiotracers and guidelines can be provided.



RAPHAELA-RS is a leaner and lighter LIMS solution. It is focused on essential information for the analysis certificate and designed for high simplicity, ease of use and fast handling. RAPHAELA-RS helps you to save time, ensure easy data transfer, allow safe data storage and simplify the data visualization. Handle the entire data transfer from the Cyclotron, the dispenser, the synthesis unit and QC equipment by a simple mouse click.



Simply generate QC analysis certificates on a single page containing all data from the AC and synthesis instruments required for the release of the product.

Bar codes will help you to introduce data, trace samples and minimize the risk of human errors.



Technical specifications

Radio HPLC for FDG	<ul style="list-style-type: none">• Manual injector, degasser, gas purge, solvent container, isocratic pump, active seal wash, thermostated column, Pulse Amperimetric Detector, Radioflow monitor• Columns for FDG• Pre-column and analytical column
Radio HPLC for ⁶⁸Ga	<ul style="list-style-type: none">• Manual injector, degasser, solvent container, quaternary pump, active seal wash, thermostatic column, UV Detector, Radio flow monitor• Columns for ⁶⁸Ga• Pre-column and analytical column
GC	Gas chromatograph, Split/Split less Injector, FID, Fast residual solvent GC column. Automatic Liquid Sampler for GC and Hydrogen generator
TLC for PET	TLC scanner
Ph-meter	Laboratory ph-measuring device
LAL test	LAL test system, suitable for the Charles River cartridges
Dose calibrator	Dose calibrator with lead shielding
Osmometer	Semi micro Osmometer
Camera	CCD camera
Multi Channel Analyser	Multi-channel analyser for gamma spectroscopy, 3x3" Scintillation detector and lead shielding
Printers & bar code reader	Laser printer, label printer, bar code reader
Radiation protection	Additional lead shielding on sensitive parts to reduce the irradiation risk and background interference during the QC
Environmental control	Ambient and internal temperature control and measurement
Gas extraction	Active extraction of Hydrogen and gases
Waste control	Lead shielded waste container with overflow control
FDG-QC starter kit	<p>Our QC starter kit contains nearly all consumables you need to set up the QC method for FDG and to make the first run. The kit is very helpful for the installation and the training.</p> <p>Besides some chemicals (like 2-chloro-2-deoxy-d-glucose, glucose, 2-fluoro-deoxy-glucose 2-fluoro-2-deoxy-mannose; 1,2,3,4-tetra-O-acetyl-beta-D-glucopyranose..), it also contains some consumables and small material needed for the kryptofix test and the TLC (kryptofix, DC plates, development chamber, Micropipette ...)</p>

Physical specifications

Dimensions	W130 x D80 x H190 cm
Weight	+/- 750 kg (fully equipped)



Email:
Website:
Headquarters:

info@elysia-raytest.com
www.elysia-raytest.com
Elysia s.a.
rue du Sart-Tilman 375
4031 Angleur - Belgium
Tel +32 (0)4 243 43 50
Elysia-raytest GmbH
Benzstraße 4
75334 Straubenhardt - Germany
Tel. +49 (0)7082 92 55 0

Production: