

Imagine that the complex **68Ga PSMA** labeling process has just turned into a simple **1 vial, 5-minute** preparation kit



Multi patient vial

isoPROtrace-11 Kit for PSMA-11 labeling

A dedicated kit for **68Ga PSMA-11** labeling to use as a PET CT tracer for prostate cancer imaging and diagnosis.

- The **isoPROtrace-11 Kit** we have developed is a safe, ready-to-use, single vial for producing multi-doses and dispensing them within 5 short minutes.
- Unique patented formula
- Eliminates the need for costly modules and consumables
- Enhances efficiency, saves time and money
- Minimizes the technician's exposure to isotopes

Method	isoPROtrace-11 Kit	Conventional Semiautomated synthesis
Additional reagents added	Not needed	Needed
pH adjustments	Not needed	Requires adjustment
Heating step	Not needed	Needed
Purification	Not needed	Needed
Time to final product	5 min	30 min



5 minutes incubation time

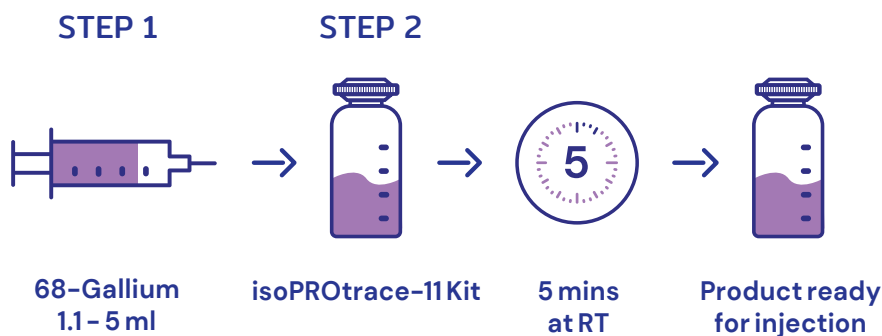


No heating steps necessary



Multi patient vial

1 vial- 2 simple preparation steps



isoPROtrace-11 kit

STEP 1 – Inject 1.1 – 5 ml 0.1M ^{68}Ga or 2.2 – 4 ml 0.05M ^{68}Ga into the kit vial

STEP 2 – Shake the vial and let it incubate for 5 minutes at room temperature

At the end of this brief process, the product is ready for use.

Compatible with the three major generators, and accelerator produced ^{68}Ga .

Radiolabeled Kit Specifications	
Appearance	Clear and colorless solution, free of visible particles
pH after radiolabeling	4.0-8.0
Radio-Chemical Purity	$\geq 95\%$
Radio-Chemical Yield	$\geq 99\%$
Sterility	Sterile
Bacterial Endotoxins	$< 175/V$ V being the maximum recommended dose in milliliters



*Any use of this product is on an investigational basis or for use in approved clinical trials only.

This product has not received marketing authorization in any jurisdiction to date.



References

- " ^{68}Ga -PSMA-11: The First FDA-Approved ^{68}Ga -Radiopharmaceutical for PET Imaging of Prostate Cancer"
U. Hennrich. 2021 MDPI journal.
- " ^{68}Ga -labeled PSMA-11 (^{68}Ga isoPROtrace-11) synthesized with ready to use kit: normal biodistribution and uptake characteristics of tumour lesions"
M. Muchnik Kurash. 2020 Scientific Reports.
- "Enhancing capacity and synthesis of ^{68}Ga -PSMAHBED- CC with the lyophilized ready-to-use kit for nuclear pharmacy applications"
H. Golan. 2020 Nuclear Medicine Communications.
- "Performance of a Prostate-Specific Membrane Antigen Positron Emission Tomography/Computed Tomography-Derived Risk-Stratification Tool for High-risk and Very High-risk Prostate Cancer"
M. Xiang. 2021 JAMA Network Open.

