itG Ge-68/Ga-68 Generator

Information for Use

1. General Description

The itG Ge-68/Ga-68 Generator is intended for the production of a [^{68}Ga]gallium chloride solution for radiolabeling, which is not suitable for direct use in patients.

An organic molecule is attached to the silica-based adsorbent efficiently retaining germanium-68 (Ge-68). The daughter nuclide gallium-68 (Ga-68) is selectively eluted from the column with 0.05 M HCl. The generator column is metal-free providing high chemical purity of the eluted Ga-68. The high purity of the eluate and its low acid concentration enable direct utilization of the obtained Ga-68 for radiolabeling.

ITG Isotope Technologies Garching GmbH holds a manufacturing license by the government of Upper Bavaria and is responsible for the GMP compliant production of the generator.

2. Physical characteristics

Long-lived Ge-68 decays with a half-life ($t_{1/2}$) of 270.95 days by electron capture to Ga-68 (Table 1). Ga-68 itself decays with a half-life of 68 minutes to stable Zn-68.

Time (d)	0	5	10	25	50	75
Activity (%)	100	98.7	97.5	93.8	88.0	82.5

Time (d)	100	150	200	250	300	350
Activity (%)	77.4	68.1	59.9	52.7	46.4	40.8

Table 1: Decay of Ge-68

The total amount of Ga-68 available is dependent on the time interval since the last elution. After one hour more than 45 % of maximum Gallium-68 is already available (Table 2).

Time (h)	1	2	3	4	5	6
Equilibrium (%)	45.7	70.6	84.0	91.3	95.3	97.4

Time (h)	7	8	9	10	11	12
Equilibrium (%)	98.6	99.2	99.6	99.8	99.9	99.93

Table 2: Equilibrium in the system Ge-68/Ga-68

3. Warning

Use of the itG Ge-68/Ga-68 Generator requires the application of radiation protection measures. Per GBq the surface dose rate is < 120 µSv/h, measured at the bottom of the generator.

For the elution of the generator please use the elution medium specified by ITG Isotope Technologies Garching GmbH exclusively. The use of other elution media can substantially influence the performance of the generator and lead to severe damage.

4. Precautions

The eluted [^{68}Ga]gallium chloride solution is solely intended for radiolabeling and is not suitable for direct use in patients.

The itG Ge-68/Ga-68 Generator contains a sterile solution of Ga-68 at the time of shipment. In order to maintain sterility aseptic techniques must be performed during the use of the generator.

The generator must not be disassembled for any reason. Disassembly may damage the generator column or sterile fluidic path.

5. How supplied

The shipment consists of:

- Lead-shielded itG Ge-68/Ga-68 Generator in type A outer packaging **(please retain carefully for return shipment)**
- Set of preassembled FEP connection tubing:
  - Inlet (white): 35 cm, Luer(f) / UNF 1/4-28
  - Outlet (brown): 35 cm, Luer(m) / UNF 5/16-24

Three (3) boxes with 5x4 ml vials of elution medium (sterile ultrapure 0.05 M HCl solution) are shipped separately.

6. Storage

The generator needs to be stored at -10 °C to +40 °C, taking into account radiation protection guidelines.

7. Preparation

For optimal adhering to the production of [^{68}Ga]gallium chloride solution read the present information for use carefully and follow them consequently.

Installation of the generator:

Lift the generator out of the packaging by its upper handle and position it on the working surface in front of you.

Pull up the locking pin on the generator top cover (1), rotate the cover 30° counterclockwise (2) and lift it up to remove (figure 1).

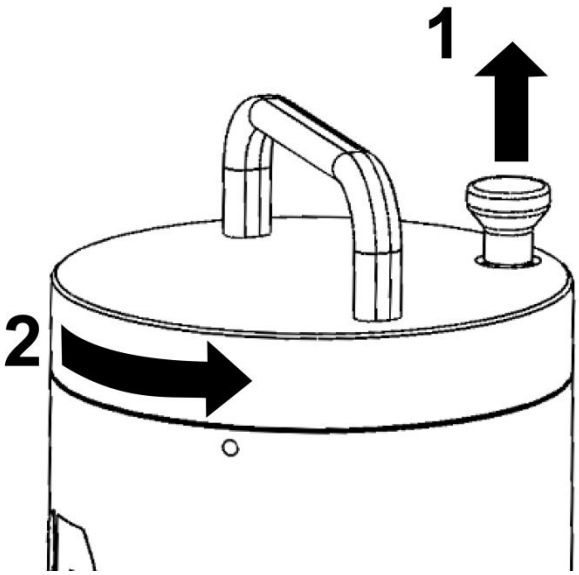

Figure 1: Removal of generator top cover

Remove plugs from ports (**please retain carefully for return shipment**) and attach inlet tubing (white) with UNF 1/4-28 finger-tight fitting at the right-side port and outlet tubing (brown) with UNF 5/16-26 finger-tight fitting at the left-side port (figure 2).

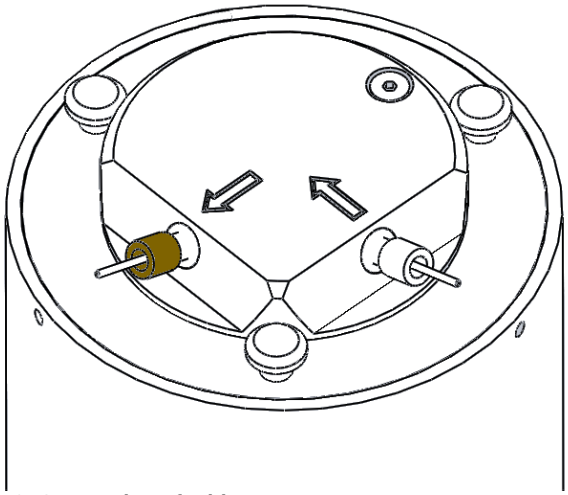

Figure 2: Connection of tubings

8. First Elution

After installation, the generator has to be eluted with a total of 20 ml elution medium. Only use elution medium specified for use by ITG Isotope Technologies Garching GmbH.

Connect a vial with sufficient capacity to accept the eluate volume to the outlet of the generator.

Afterwards elute the generator at the rate of 4 ml/min.

9. Subsequent elutions

The itG Ge-68/Ga-68 Generator has to be eluted with 4 ml elution medium.

Connect a vial with sufficient capacity to accept the eluate volume to the outlet line of the generator.

Elute the generator with 4 ml elution medium at the rate of 4 ml/min.

ATTENTION:

After an elution break of more than three (3) days or after delivery, the generator has to be rinsed with 20 ml of elution medium. After shorter elution breaks, e.g. over the weekend, one elution with 10 ml is sufficient to rinse the generator.

The shelf life of the itG Ge68/Ga68 generator is 12 months or a maximum of 250 elutions (not more than 1000 ml in total), whatever endpoint reached first.

10. Ge-68 breakthrough measurement

Measure Ge-68 activity in eluate at least weekly in order to determine Ge-68 breakthrough, but at the earliest after a decay time of 36 h after elution. After the generator was rinsed, the elution solution might contain an increased Ge-68 content. This value is therefore not representative for breakthrough determination.

11. Disposal of Generator

Remove and dispose of connection tubing. Insert and tighten plugs into in- and outlet port. Place generator top cover onto generator and rotate 30° clockwise until locking pin locks.

CAUTION:

Always send the generator back to ITG Isotope Technologies Garching GmbH. Use the packaging used for delivery for return shipment. Otherwise follow local regulations for disposal.

12. Customer Information

For further information please contact our customer service:

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13. Revision Index

- Version 2 (01/2015): Correction of tubing material in section 5
- Version 1 (08/2014): Initial Version