



# Radiopharmaceuticals



Distributeur exclusif



Spécialisé en Médecine Nucléaire et Imagerie Médicale

# Radionuclide generator $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$

*Natrii pertechnetatis ( $^{99\text{m}}\text{Tc}$ ) fissione formati solutio iniectionabilis*

code: MTcG-4

## Qualitative and quantitative composition:

Sodium pertechnetate ( $^{99\text{m}}\text{Tc}$ ) injection is produced by means of a ( $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ ) generator. Technetium ( $^{99\text{m}}\text{Tc}$ ) decays with the emission of gamma radiation with a mean energy of 140 keV and a half-life of 6.01 hours to technetium-99 which, in view of its long half-life of  $2.13 \times 10^5$  years, can be regarded as quasi stable.

The radionuclide generator containing the parent isotope  $^{99}\text{Mo}$ , adsorbed on a chromatographic

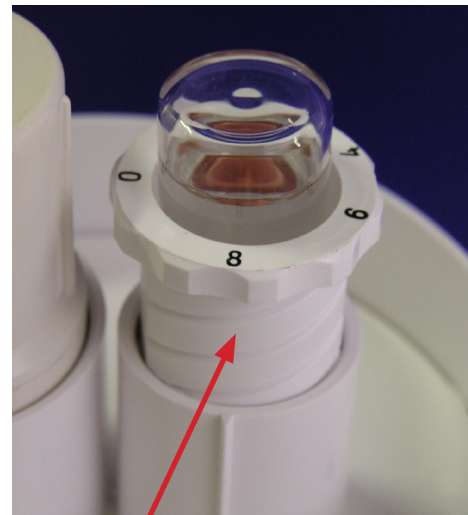
column delivers sodium pertechnetate- $^{99\text{m}}\text{Tc}$  injection in sterile solution.

The  $^{99}\text{Mo}$  on the column is in equilibrium with the formed daughter isotope  $^{99\text{m}}\text{Tc}$ . The generators are supplied with the following  $^{99}\text{Mo}$  activity amounts at activity reference time which deliver the following technetium-99m amounts, assuming a 100% theoretical yield and 24 hours time from previous elution and taking into account that branching ratio of  $^{99}\text{Mo}$  is about 87%.

## Examples of activities of radionuclide generators:

$^{99\text{m}}\text{Tc}/^{99}\text{Mo}$ activity [GBq] at production date	8.0 9.1	14 16	21 24	28 32	35 40	42 48	53 60.6	64 73.1	69 78.9	88 100.6	125 142.9	141 161.1	175 200
$^{99\text{m}}\text{Tc}$ activity (maximal theoretical eluable activity at calibration date, 5 days after production, at 12 a.m. CET) [GBq]	2.3	4.0	6.0	8.0	10	12	15	18	20	25	35	40	50
$^{99}\text{Mo}$ activity (at calibration date, 5 days after production, at 12 a.m. CET) [GBq]	2.6	4.5	6.8	9.2	11	14	17	21	22	29	41	46	57

The technetium ( $^{99\text{m}}\text{Tc}$ ) amounts available by a single elution depend on the real elution yield of generator itself declared by manufacturer and approved by National Competent Authority (NCA).



Eluate volume control from 4 ml to 8 ml

### Expected radioactivity of eluted <sup>99m</sup>Tc on each exploitation day from the generators within standard range of nominal activities:

GBq	2.00	4.00	5.00	6.00	7.50	8.00	10.00	12.00	13.00	15.00	17.00	18.50	20.00	23.00	25.00	30.00	35.00	40.00	50.00	82.00	
Day																					
-5	7.1	14.1	17.6	21.2	26.4	28.2	35.3	42.3	45.8	52.9	59.9	65.2	70.5	81.1	88.2	105.8	123.4	141.1	176.3		
-4	5.5	11.0	13.7	16.4	20.6	21.9	27.4	32.9	35.6	41.1	46.6	50.7	54.8	63.0	68.5	82.2	95.9	109.6	137.0	175.0	
-3	4.3	8.5	10.7	12.8	16.0	17.0	21.3	25.6	27.7	32.0	36.2	39.4	42.6	49.0	53.3	63.9	74.6	85.2	106.5	136.0	
-2	3.3	6.6	8.3	9.9	12.4	13.2	16.6	19.9	21.5	24.8	28.1	30.6	33.1	38.1	41.4	49.7	57.9	66.2	82.8	105.6	
-1	2.6	5.1	6.4	7.7	9.6	10.3	12.9	15.4	16.7	19.3	21.9	23.8	25.7	29.6	32.2	38.6	45.0	51.5	64.3	81.6	
0	2.00	4.00	5.00	6.00	7.50	8.00	10.00	12.00	13.00	15.00	17.00	18.50	20.00	23.00	25.00	30.00	35.00	40.00	50.00	82.00	
1	1.55	3.11	3.89	4.66	5.83	6.22	7.77	9.33	10.10	11.66	13.21	14.38	15.54	17.88	19.43	23.32	27.20	31.09	38.86	63.73	
2	1.21	2.42	3.02	3.62	4.53	4.83	6.04	7.25	7.85	9.06	10.27	11.17	12.08	13.89	15.10	18.12	21.14	24.16	30.20	49.53	
3	0.94	1.88	2.35	2.82	3.52	3.76	4.69	5.63	6.10	7.04	7.98	8.69	9.39	10.80	11.74	14.08	16.43	18.78	23.47	38.50	
4	0.73	1.46	1.82	2.19	2.74	2.92	3.65	4.38	4.74	5.47	6.20	6.75	7.30	8.39	9.12	10.95	12.77	14.59	18.24	29.92	
5	0.57	1.13	1.42	1.70	2.13	2.27	2.84	3.40	3.69	4.25	4.82	5.25	5.67	6.52	7.09	8.51	9.93	11.34	14.18	23.25	
6	0.44	0.88	1.10	1.32	1.65	1.76	2.20	2.64	2.87	3.31	3.75	4.08	4.41	5.07	5.51	6.61	7.71	8.82	11.02	18.07	
7	0.34	0.69	0.86	1.03	1.28	1.37	1.71	2.06	2.23	2.57	2.91	3.17	3.43	3.94	4.28	5.14	6.00	6.85	8.56	14.05	
8	0.27	0.53	0.67	0.80	1.00	1.07	1.33	1.60	1.73	2.00	2.26	2.46	2.66	3.06	3.33	3.99	4.66	5.33	6.66	10.92	
9	0.21	0.41	0.52	0.62	0.78	0.83	1.03	1.24	1.35	1.55	1.76	1.91	2.07	2.38	2.59	3.10	3.62	4.14	5.17	8.48	
10	0.16	0.32	0.40	0.48	0.60	0.64	0.80	0.96	1.05	1.21	1.37	1.49	1.61	1.85	2.01	2.41	2.81	3.22	4.02	6.59	
11	0.13	0.25	0.31	0.38	0.47	0.50	0.63	0.75	0.81	0.94	1.06	1.16	1.25	1.44	1.56	1.88	2.19	2.50	3.13	5.12	
12	0.10	0.19	0.24	0.29	0.36	0.39	0.49	0.58	0.63	0.73	0.83	0.90	0.97	1.12	1.21	1.46	1.70	1.94	2.43	3.98	
13	0.08	0.15	0.19	0.23	0.28	0.30	0.38	0.45	0.49	0.57	0.64	0.70	0.76	0.87	0.94	1.13	1.32	1.51	1.89	3.10	
14	0.06	0.12	0.15	0.18	0.22	0.23	0.29	0.35	0.38	0.44	0.50	0.54	0.59	0.67	0.73	0.88	1.03	1.17	1.47	2.41	
15	0.05	0.09	0.12	0.14	0.17	0.18	0.22	0.27	0.30	0.34	0.39	0.42	0.46	0.52	0.57	0.68	0.80	0.91	1.14	1.87	

mCi	54.05	108.11	135.14	162.16	202.70	216.22	270.27	324.32	351.35	405.41	459.46	500.00	540.54	621.62	675.68	810.81	945.95	1081.08	1351.35	2216.21	
Day																					
-5	190.62	381.08	475.68	572.97	713.51	762.16	954.05	1143.24	1237.84	1429.73	1618.92	1762.16	1905.40	2191.89	2383.78	2859.46	3335.13	3813.51	4764.86	7722.43	
-4	148.13	297.30	370.27	443.24	556.76	591.89	740.54	899.19	962.16	1110.81	1259.46	1370.27	1481.08	1702.70	1851.35	2221.62	2591.89	2962.16	3702.70	5954.05	
-3	115.14	229.73	289.19	345.95	432.43	459.46	575.68	691.89	748.65	864.86	978.38	1064.86	1151.35	1324.32	1440.54	1727.03	2016.21	2302.70	2876.38	4729.73	
-2	89.46	178.38	224.32	267.57	335.13	356.76	448.65	537.84	581.08	670.27	759.46	827.03	894.59	1029.73	1118.92	1343.24	1564.86	1789.19	2237.84	3675.67	
-1	69.54	137.84	172.97	208.11	259.46	278.38	348.65	416.22	451.35	521.62	591.89	643.24	694.59	800.00	870.27	1043.24	1216.22	1391.89	1737.84	2854.05	
0	54.05	108.11	135.14	162.16	202.70	216.22	270.27	324.32	351.35	405.41	459.46	500.00	540.54	621.62	675.68	810.81	945.95	1081.08	1351.35	2216.21	
1	42.00	84.05	105.14	125.95	157.57	168.11	210.00	252.16	272.97	315.13	357.03	388.65	420.00	483.24	525.13	630.27	735.13	840.27	1050.27	1722.43	
2	32.65	65.41	81.62	97.84	122.43	130.54	163.24	195.95	212.16	244.86	277.57	301.89	326.49	375.41	408.11	489.73	571.35	652.97	816.22	1338.65	
3	25.36	50.81	63.51	76.22	95.14	101.62	126.76	152.16	164.86	190.27	215.68	234.86	253.78	291.89	317.30	380.54	444.05	507.57	634.32	1040.54	
4	19.73	39.46	49.19	59.19	74.05	78.92	98.65	118.38	128.11	147.84	167.57	182.43	197.30	226.76	246.49	295.95	345.13	394.32	492.97	808.65	
5	15.32	30.54	38.38	45.95	57.57	61.35	76.76	91.89	99.73	114.86	130.27	141.89	153.24	176.22	191.62	230.00	268.38	306.49	383.24	628.38	
6	11.92	23.78	29.73	35.68	44.59	47.57	59.46	71.35	77.57	89.46	101.35	110.27	119.19	137.03	148.92	178.65	208.38	238.38	297.84	488.38	
7	9.27	18.65	23.24	27.84	34.59	37.03	46.22	55.68	60.27	69.46	78.65	85.68	92.70	106.49	115.68	138.92	162.16	185.13	231.35	379.73	
8	7.19	14.32	18.11	21.62	27.03	28.92	35.95	43.24	46.76	54.05	61.08	66.49	71.89	82.70	90.00	107.84	125.95	144.05	180.00	295.13	
9	5.59	11.08	14.05	16.76	21.08	22.43	27.84	33.51	36.49	41.89	47.57	51.62	55.95	64.32	70.00	83.78	97.84	111.89	139.73	229.19	
10	4.35	8.65	10.81	12.97	16.22	17.30	21.62	25.95	28.38	32.70	37.03	40.27	43.51	50.00	54.32	65.14	75.95	87.03	108.65	178.11	
11	3.38	6.76	8.38	10.27	12.70	13.51	17.03	20.27	21.89	25.41	28.65	31.35	33.78	38.92	42.16	50.81	59.19	67.57	84.59	136.38	
12	2.62	5.14	6.49	7.84	9.73	10.54	13.24	15.68	17.03	19.73	22.43	24.32	26.22	30.27	32.70	39.46	45.95	52.43	65.68	107.57	
13	2.05	4.05	5.14	6.22	7.57	8.11	10.27	12.16	13.24	15.41	17.30	18.92	20.54	23.51	25.41	30.54	35.68	40.81	51.08	83.78	
14	1.59	3.24	4.05	4.86	5.95	6.22	7.84	9.46	10.27	11.89	13.51	14.59	15.95	18.11	19.73	23.78	27.84	31.62	39.73	65.14	
15	1.26	2.43	3.24	3.78	4.59	4.86	5.95	7.30	8.11	9.19	10.54	11.35	12.43	14.05	15.41	18.38	21.62	24.59	30.81	50.54	

■ **Excipients:**

Sodium chloride  
Water for injection

■ **Indications**

This medicinal product is for diagnostic use only.  
The eluate from the generator (sodium pertechnetate <sup>99m</sup>Tc injection) is indicated for:

- ▶ labelling of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such solution,
- ▶ thyroid scintigraphy: direct imaging and measurement of thyroid uptake to give information on the size, position, nodularity and function of the gland in case of thyroid disease,
- ▶ salivary gland scintigraphy: diagnosis of chronic sialadenitis (e.g. Sjögren's Syndrom) as well as assessment of salivary gland function and duct patency in salivary glands disorders and monitoring of the response to therapeutic interventions (in particular radioiodine therapy),
- ▶ location of ectopic gastric mucosa (Meckel's diverticulum),
- ▶ lacrimal duct scintigraphy: to assess functional disorders of lacrimation and monitoring of the response to therapeutic interventions.

■ **Technical parameters**

Elution time varies from 2 minutes for eluate volume 4.0±0.5 ml, up to 4 minutes for eluate volume 8.0±0.5 ml. Generator is a „dry column” system.

elution yield: 90 - 110% of nominal activity  
radiochemical purity of the eluate: > 98%  
assay of <sup>99</sup>Mo in the eluate: < 0.1%  
assay of Al<sup>3+</sup> in the eluate: < 5 ug/ml  
pH of the eluate: 5.5 - 7.5  
weight of the generator: 16 kg

■ **Posology and method of administration:**

If sodium pertechnetate-<sup>99m</sup>Tc is administered intravenously, activities may vary widely according to

the clinical information required and the equipment employed. The injection of activities greater than local DRLs (Diagnostic Reference Levels) should be justified for certain indications.

The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group.

(for detailed information see SmPC)

■ **Expiration**

21 days from manufacturing date.

The calibration date and the expiry date are stated on the label.

Sodium pertechnetate-<sup>99m</sup>Tc eluate: after elution, use within 12 hours. This medicinal product does not require any special storage conditions.

■ **Special precautions for storage**

Generator: do not freeze.



**Marketing Authorizations:**

Austria:	Poltechnet
Belarus:	Polgentec 2-120 GBq
Bulgaria:	Poltechnet
Columbia:	Polgentec 2-120 GBq
Czech Republic:	Poltechnet
Denmark:	Poltechnet
Georgia:	Polgentec 2-120 GBq
Greece:	Technegen 2-120 GBq
Germany:	Pertector
Lithuania:	Poltechgen 8,0-175 GBq, radionuklidų generatorius
Poland:	Poltechnet
Portugal:	Poltechnet
Romania:	Poltechnet 8.0-175 GBq generator de radionuclizi
Russia:	Polgentek
Slovenia:	Poltechnet 8-175 GBq, radionuklidni generator
Spain:	Poltechnet 8,0-175 GBq generador de radionúclido
Sweden:	Poltechnet
Switzerland:	Pertector Radionuklidgenerator
Ukraine:	Poltechnet
United Kingdom:	Pertector

**Contact:**

Export Department +48 22 273 1820  
email: export@polatom.pl

# Accessories for radionuclide generator

## Kit for Poltechnet elution

code: MTcG-01

### ■ Content:

- ▶ 16 vials with eluent of 10 ml volume containing 9 mg/ml (0.9%) sodium chloride solution
- ▶ 16 evacuated vials of 10 ml volume

■ Expiration:  
12 months

■ Storage:  
< 25°C



**Lead shield for eluate vial** code: MTcG-02  
*Supplied f.o.c. with the first ordered generator*

