PRISMAP+

Medical-Radionuclides.eu

Nuklearmedizin Klinikum rechts der Isar der TUM/TUM-MED Münich, Germany

Hot and cold chemistry labs, small animal imaging facility and GMP radiopharmacy for the development of innovative theranostic tools

PRISMAP+ Biomedical Facility TUM-MED

The Nuclear Medicine department at the Klinikum rechts der Isar of the Technical University of Munich is one of the main centres of preclinical and clinical research in Germany. It is located in Munich, (Bayern, Germany) at ~590 km from CERN and ~460 km from HZDR; which are the two closest PRISMAP+ productions centres.

The radionuclides from the PRISMAP+ portfolio that are already approved in the Nuklearmedizin/TUM-MED biomedical facility are listed in Table 1. Additional radionuclides can be made available upon request.

Table 1. Radionuclides from the PRISMAP+ portfolio that can be used at the Nuklearmedizin/TUM-MED facility.

Radionuclide	Max. Activity, MBq	Remarks
Sc-44	10	
Sc-47	10	
Cu-61	10	
Cu-64	10	
Cu-67	10	
Ga-67	10	
La-135		
Sm-153		
Tb-155	1	
Er-165	0.4	
Ac-225	0.15	

Infrastructure and experiments available

The Nuklearmedizin/TUM-MED facility offers radiolabelling studies, as well as animal biodistribution, imaging and therapy studies.

Our department is fully equipped to support guest researchers in the chemical and radiochemical development on new tools for SPECT and PET imaging. Furthermore, we conduct preclinical research with novel radionuclides and radiotracers. Three premises are available:

- The chemical and biological research labs consist in cold and hot chemistry labs, cell culture rooms and rooms dedicated for biodistributions. The cold chemistry labs are equipped for the synthesis of small molecules such as chelators or peptides as well as for the production of protein-based molecules such as for example, antibody fragments. Here two rotary evaporators, a lyophiliser, analytical and preparative HPLC systems (Shimadzu), a mass spectrometer (Shimadzu) and small lab equipment can support your research in the very early stage. On the same floor, the two hot labs include a radio-HPLC (Shimadzu with a Gabi radiodetector; Raytest), a radio-TLC scanner, a gamma counter (PerkinElmer), a scintillation counter (Perkin Elmer), an autoradiography scanner, dose calibrators, two automatic/semi-automatic synthesis modules (Scintomics and Eckert & Ziegler). Several fume hoods and laminar flow hoods are available in the labs.
- The imaging core facility (PICTUM) is located in the control area of the animal facility of TranslaTUM building inside the Klinikum rechts der Isar. The facility currently consists of a Mediso PET/MRI and Mediso SPECT/CT scanner and also contains equipment to aid in nuclear medicine research, such as a Perkin Elmer gamma counter, two dose calibrators and appropriate spaces to perform biodistribution studies. The facility is fully equipped to safely work with radiation according to local radiation protection regulations. To facilitate the workflow a pneumatic tube transport system is available to send radioactivity from the production site at the -2 floor of the nuclear medicine department GMP hot labs to the imaging facility in less than 1 minute. Consult the PICTUM website for more information.

- The GMP accredited radiopharmacy is equipped with high and low energy hot cells (Comecer, Von Galen), modules for automated synthesis (Scintomics, FastLab and Eckert&Ziegler), QC laboratory with radio-iTLC (miniGita; Raytest) and radioHPLC (Shimatzu; radiodetector Raytest). Gamma counter (PerkinElmer). Gas chromatography system (6850, Agilent Technologies).

The Nuclear Medicine department and the PICTUM imaging facility can offer support for the advancement of your radiotracers into first in human clinical trials.

To get further information about all the specifications of the small animal nanoScan PET/MRI1 and nanoScan SPECT/CT2, visit the Mediso website.

Details regarding the equipment available for imaging at the Nuklearmedizin/TUM-MED biomedical facility can be found in Table 2.

Table 2. Imaging equipment details.

Equipment	Modality	Remarks
nanoScan® PET/MR Mediso	PET	
nanoScan® SPECT/CT Mediso	SPECT	

Animal models available

- healthy mice, including commonly used immunocompetent strains such as BALB/c and C57BL/6;
- immunodeficient mice, including BALB/c nude and NSG mice;
- healthy rats, including Wistar rats;
- tumour-bearing mouse models, including subcutaneous xenograft models;
- selected models for biodistribution, pharmacokinetics, imaging and therapy studies.

Support available

The support available to the users before, during and after their visit at the Nuklearmedizin/TUM-MED biomedical facility can be found in Table 3.

Table 3. Support available at the Nuklearmedizin/TUM-MED biomedical facility.

Support	Remarks
Assistance to apply for experiment permission	
Assistance with project writing	
Help/supervision with radiolabeling	
Help/supervision with radiolabeling quality control	
Help/supervision with labeled compound stability studies	
Help/supervision during cell studies setup	
Help/supervision during cell studies follow-up and results reading	
Help/supervision with animal handling	
Help/supervision with animal scanning	
Help/supervision with image generation and analysis	
Help with results processing and interpretation	
Help with publication writing	

TUM-MED may provide support in experimental design, selection of appropriate radiolabelling strategies, selection of animal models, planning of biodistribution studies, pharmacokinetic, imaging and therapy

studies, dosimetry analysis, radiation safety instruction, preparation of study reports, graphical presentation of results and scientific interpretation, publication and dissemination of the results.

Services available

The services available at the Nuklearmedizin/TUM-MED biomedical facility (without the presence of the user) can be found in Table 4.

Table 4. Services available at the Nuklearmedizin/TUM-MED biomedical facility.

Service	Remarks
Activity measurement, dose calibrator	
Activity measurement, gamma spectrometry	
Radiolabeling according to protocol provided by / decided with the user	
Formulation of radiolabeled compound for cell tests or animal tests	
Radiolabeling quality control TLC	
Radiolabeling quality control HPLC	
Growing cell lines available in house	
Growing cell lines provided by user	
Radiopharmaceutical stability in non-biological media	
Radiopharmaceutical stability in biological media	
Cell studies setup	
Cell studies follow up (after setting up with user)	
Animal preparation (healthy animals)	
Animal preparation (tumor-bearing animals, in house model)	
Animal handling (injection, scanning process, sacrifice)	
Animal studies follow-up	

Additional services may include biodistribution studies, pharmacokinetic studies, ex vivo gamma counting of organs and biological samples, preparation of samples for further analysis, small-animal imaging, tissue section autoradiography imaging, image reconstruction and analysis, tumour growth monitoring, toxicity monitoring, dosimetry-related data preparation and preparation of study reports.

Manufacturing Infrastructure & Clinical Supply Capabilities: The facility is equipped with a certified GMP facility dedicated to the formulation and manufacturing of radioactive products. Processing operations are executed within qualified cleanroom environments operated in strict conformity with cGMP standards. This infrastructure is utilized for R&D activities and the formal manufacturing, compounding, and filling of Investigational Medicinal Products (IMPs) destined for clinical trials.