BERNER
the safety system

Manufacturer's information
Cytostatic wipe sampling set
PharmaMonitor

PharmaMonitor
Analysis-Cleaning-Training

Z+ PLUS

1. Read user guide carefully before commencing work!

2. Application, properties, different types and disposal

- **Area of application:** Analysis - tool for wipe samples on a single or a group of cytostatic substances[1)]
  [1)] Cytostatic agents belong to the group of CMR drugs (Carcinogenic, mutagenic, toxic to reproduction)

Substances which can be analysed: 5-Fluorouracil, 6-Mercaptopurin, Acemetacine, Azathioprine, Busulfane, Capecitabine, Carboplatin, Carmustine, Chlorambucil, Cisplatin, Clomiphene, Cyclophosphamide, Cytarabine, Etoposide, Flutamide, Gemcitabine, Ifosfamide, Methotrexate, Mitomycine, Oxaliplatin, Tamoxifene, Thalidomide, total platinum.
Available as single analysis after consultation: Docetaxel and Paclitaxel.

Use: The functionality compared to other substances cannot be guaranteed!
Analysis of other substances only after consultation with the testing institute IUTA e.V. .
For single use only!

- **Contents:** The wipe sample set (Item-no.: 4155) contains the following (for max. 5 wipe samples in one step):

- 5x Sample containers, each with 3 folded wipes (1 cloth for each wipe direction – also see instructions)
- 1x ca. 40 ml special wipe sampling solution (H_20 pH3)
- 5x Pipette
- 5x Pair of cytostatic protective gloves
- 4x Freezer packs (freeze before wipe sampling)
- 1x Adhesive tape for marking
- 1x Measuring tape
- 1x Permanent-marker pen for labelling the container
- Manufacturer's data and documentation for sending on to the test institute

- Further optional materials (not included):

  Protective gown, safety goggles, if necessary a digital camera for personal documentation of wipe sample surfaces

Area of application: The BERNER cytostatic wipe sample set **PharmaMonitor** is used for sampling and analysis of surface contaminations when handling CMR-pharmaceuticals (e.g. cytostatics, virustatics).

The analysis and presentation of potential contaminations, reveals errors in the handling of cytostatic substances as well as subsequent cleaning procedures so that the work instructions can be adjusted accordingly. Additionally, a validation of the cleaning procedures can be achieved with wipe sampling. Suitable surfaces are marked in accordance with the instructions. The wipe samples are then taken and sent, along with the required documentation to our business partner, the german Institute of Energy and Environmental Technology (IUTA e.V.) for analysis. You will receive the results of the analysis after about 4 weeks following receipt of the wipe sample at IUTA.

Examples for wipe sampling locations during production:

- Work surface inside and outside of Preparation (Size: e.g.: 30 cm x 30 cm)
- Storage areas
- Transport boxes and transport trolleys
- Floor in front of the safety cabinet
- Refrigerator door incl. handling
- Shrink wrap devices

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- Door handles
- Waste container
- Cleaned surfaces after use of SpillKits
  (e.g. for spilt cytostatics)
- …

Examples of wipe samples for transport and during application:

- To check cleaning results after transport damage
- Door handles
- Infusion stand
- Infusion tray
- Treatment chair
- Patient's bed
- Waste container
- Cleaned surfaces after SpillKit use (e.g. for spilt cytostatics)
- …

Attention: the total area per wipe sampling point should not exceed 2.500 cm².

Works instructions for carrying out wipe samples: see 2. Document (Description wipe samples).

Disposal: **Substance:** 	**Origin**			
	Human		**Animal**	
	Risk potential			
	low	**high**	**low**	**high**
CMR drugs	180101	180108*	180203	180207*

- For Germany: Dispose of the non-contaminated residual materials via the German Green Dot system or as part of the normal household waste!

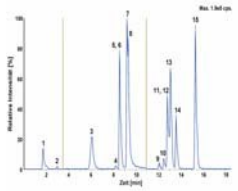
  ➔ "Grüner Punkt" = „Duales System Deutschland GmbH"

4. Queries on the results of the analysis:

You will receive the results of the samples with 4 weeks via e-mail or post. In case of any queries in respect of the analysis, please get in direct touch with:

Institute for Energy and Environmental Technology e.V.
Herrn Dr. Türk
Bliersheimer Straße 60
D-47229 Duisburg
Germany

Tel: +49 (0)2065 / 418 - 179
E-Mail: analysis@iuta.de



5. Quality management system

The Berner quality management system in tested and certified in accordance with DIN EN ISO 9001:2008 by the TÜV Management Service GmbH.

6. Storage and transport requirements

Wipe sample set:

- Dark (protect from direct UV- and sunlight)
- Store in a cool (+5 to +40°C) and dry place.
- Freeze ice packs before transport

Samples:

- Transport only with frozen ice packs.
- If required the samples -18˚Celsius can be frozen for up to 4 days

7. Date of manufacture
Digit 1-4: year, digit 5+6: month, code 39 readable

8. Expiry date
Digit 1-4: year, digit 5+6: month, code 39 readable

9. LOT - Number
Lot number, Code 39 readable

10. Copyright and industrial property laws

BERNER INTERNATIONAL GMBH shall not accept liability for any errors / damage arising from the improper use of the wipe sample sets. The contract partner for the customer is BERNER INTERNATIONAL GMBH. The analysis part is subcontracted to the Institute for Energy and Environmental Technology e.V. (IUTA).

The wipe sample set may be subject to technical and production-related changes without prior notice.
The German version of this manufacturer's information is binding.

Z+® PLUS is a registered trademark of BERNER INTERNATIONAL GMBH.

PharmaMonitor Analysis-Cleaning-Training PharmaMonitor is a registered trademark of the Institute for Energy and Environmental Technology e.V. (IUTA)

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