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Short manual

Stool preparation system SAS

For sampling of stool samples

Valid from 2022-05-25



1. INTENDED USE

The stool preparation system SAS is an extraction device for stool samples. The device is an *in vitro* diagnostic tool and intended to be used by professional users in a laboratory environment and for self-application by laypersons. It can be performed manually. The extraction device serves as a simplified method for the collection of a defined amount of stool, the storage of the stool and the preparation of stool samples for further use in diagnostic methods in laboratory environments.

2. MATERIAL SUPPLIED

Cat. No.	Kit components	Quantity
K 6998SAS	Stool sample tube	100 units

3. PREPARATIONS FOR STOOL SAMPLING

- The stool sample has to be thawed. In case of very inhomogeneous samples, please homogenise mechanicall using an applicator, inoculation loop or similar device.
- Add the specified amount of extraction buffer into the unfilled stool tube according to the instructions.
- Open the **upper yellow part** of the cap and remove the attached dipstick. The blue cone insert remains on the tube!
- Insert the dipstick into the stool at 3 different sites. Make sure that all notches are covered completely with stool.
- Stick the dipstick with the attached stool **only once** back into the sample tube. Excess material will be stripped off by the blue cone-shaped insert, letting 15 mg of sample into the tube.
- Close the tube so that the yellow cap audibly clicks into place. Then shake well until no stool sample remains in the notches and the stool is completely suspended in the extraction buffer. The suspension now contains 15 mg of stool (if the stool sample is fluid, pipet 15 µl into the tube).
- **Attention**: The stool dilution in the sample tube **hardly changes colour**. Repeated insertion of sample into the tube will falsify the results!
- Open the complete cap of the tube including the **lower blue cone-shaped insert**. The stool-buffer solution is now ready for use according to the corresponding ELISA manual.

Used symbols:

4. TECHNICAL HINTS

- The stool sample tubes are intended for single use only.
- Do not mix plugs and caps from different tubes.

5. GENERAL NOTES ON THE TEST AND TEST PROCEDURE

- Warranty claims and complaints regarding deficiencies must be logged within 14 days after receipt of the product. The product should be send to Immundiagnostik AG along with a written complaint.
- Serious incidents are to be reported to Immundiagnostik AG and the national regulatory authorities.
- As a precaution, it is recommended that the human material used is always considered potentially infectious.
- This product has been produced and placed on the market in accordance with the regulation (EU) 2017/746 (IVDR).

X	Temperature limitation	REF	Catalogue Number	LOT	Lot number
IVD	In Vitro Diagnostic Medical Device	8	Do not re-use	l	Consult instructions for use
***	Manufacturer	\sum	Contains sufficient for <n> tests</n>		
UDI	Unique Device Identification	\square	Use by		