

IDK Extract®

Prefilled stool sample preparation system

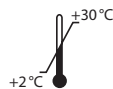
For laboratory professional use only

Valid from 2023-02-23

REF

K 6999.US
K 6999.17.US
K 6999.20.US

Σ 100
Σ 17x 100
Σ 20x 100



IVD

Rx Only



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1. INTENDED USE

The stool sample preparation system **IDK Extract®**, is a collection and storage device for stool samples, prefilled with a buffer for preservation. The device serves as a simplified method for the collection of a defined amount of stool, the storage and preservation of the stool sample and the preparation for further use in diagnostic examinations.

For *in vitro* diagnostic use only. For laboratory professional use only.

2. MATERIAL SUPPLIED

Cat. No.	Label	Kit components	Quantity
K 6999.US	IDK Extract®	Stool sample tube filled with 1.5 ml IDK Extract®	100 units
K 6999.17.US	IDK Extract®	Stool sample tube filled with 1.5 ml IDK Extract®	17 x 100 units
K 6999.20.US	IDK Extract®	Stool sample tube filled with 1.5 ml IDK Extract®	20 x 100 units

3. STORAGE AND PREPARATION OF REAGENTS

The device is stable until the expiry date when stored at **2–30 °C**.

4. SAMPLE PREPARATION

- Raw stool specimen is used.
- The stool sample has to be thawed. In case of very inhomogeneous samples, please homogenise mechanically, using an applicator, inoculation loop or similar device.
- 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 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 **barely changes colour**. Repeated insertion of sample into the tube will falsify results!
- Open the complete cap of the tube including the **lower blue cone-shaped insert**. The stool-buffer solution is now ready for further use in diagnostic examinations.












5. TECHNICAL HINTS

- The stool sample tubes must not be used after the expiration date.
- The stool sample tubes are intended for single use only.
- Do not interchange caps and lids of different sample tubes.

6. GENERAL NOTES

- Warranty claims and complaints regarding deficiencies must be logged within 14 days after receipt of the product. The product should be send to Immun-diagnostik 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.
- IDK® and *IDKExtract*® are trademarks of Immundiagnostik AG.

Used symbols:

	Temperature limitation		Catalogue number
	In Vitro Diagnostic Medical Device		Do not re-use
	Manufacturer		Contains sufficient for <n> tests
	Lot number		Use by
	Unique Device Identification		Consult instructions for use
	Prescription use only		

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