

# **IDK<sup>®</sup> TurbiTube<sup>®</sup>**

***Stool sample preparation system filled with extraction buffer  
for use in latex turbidimetric assays***

Gültig ab / Valid from 2021-08-10

**REF** TU0091.A

$\Sigma$   
100

+2°C ±30°C

**IVD** **CE**



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## 1. INTENDED USE

This stool sample preparation system **IDK®TurbiTUBE®** is intended for the sample preparation of stool samples to be used in the following Immundiagnostik latex turbidimetric assays:

- TU1011 - **IDK®TurbiPEL®** (Pancreatic Elastase)
- TU1021 - **IDK®TurbiCAL®** (Calprotectin)
- TU1031 - **IDK®TurbiFIT®** (Hemoglobin)

## 2. MATERIAL SUPPLIED

Cat. No.	Label	Kit components	Quantity
TU0091.A	<b>IDK®TurbiTUBE®</b>	Stool sample tube filled with extraction buffer	100 units

## 3. STORAGE AND PREPARATION OF REAGENTS

- The stool sample preparation system **IDK®TurbiTUBE®** (TU0091.A) is stable until the expiry date when stored at **2–30°C**.

## 4. TECHNICAL HINTS AND PRECAUTIONS

- The stool sample tubes should not be used after the expiry of the best-before date.
- The stool sample tubes are intended for single use only.
- The stool sample tubes are intended exclusively for the use of the above-mentioned Immundiagnostik latex turbidimetric assays.
- Avoid foaming when mixing reagents.
- The assay used should always be performed according the enclosed manual.
- Closures and lids of various sample tubes must not be swapped.

## 5. PREPARATIONS FOR STOOL SAMPLING

Raw stool specimen is used.

### *Processing of faecal material*

- The stool sample has to be thawed. For particularly heterogeneous samples, we recommend a mechanical homogenisation using an applicator, inoculation loop or similar device.
- **IDK®TurbiTUBE®** (TU0091.A): The sample tube is already filled with the needed extraction buffer volume, it is not necessary to add any more buffer.

Dilution table

<b>Dilution with 1.5 ml buffer:</b>	
Applied amount of stool:	15 mg
Extraction buffer volume:	1,5 ml
Total dilution factor:	1:100
Please note: for fluid stool samples,	15 mg = 15 µl

### *Application of the stool sample tube*

#### 1. Remove dipstick

Open the **upper yellow part** of the cap and remove the attached dipstick.

The blue cone-shaped insert remains on the tube!

#### 2. Obtain stool sample

Insert the dipstick into the stool at 3 different sites. Make sure that the notches at the lower part of the stick are covered completely with stool.

#### 3. Place dipstick back into the tube

Stick the dipstick with the attached stool **only once** back into the sample tube. Excess material will be stripped off by the cone-shaped insert, letting 15 mg of sample into the tube.

## Prepare stool sample suspension

Close the tube properly by turning until you hear the yellow shutter click. 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). For details about dilutions and volumes, please refer to the dilution table.

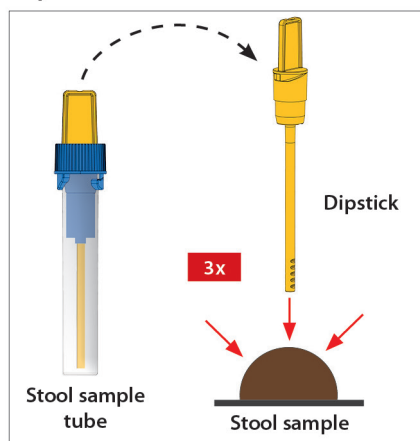
**Attention:** The **stool dilution** in the sample tube **hardly changes colour**. Repeated insertion of sample into the tube will falsify the results!

Samples should be centrifuged for ~ 10 minutes at 3 000 g to obtain a sediment-free sample. Floating material such as grain shells can be neglected.

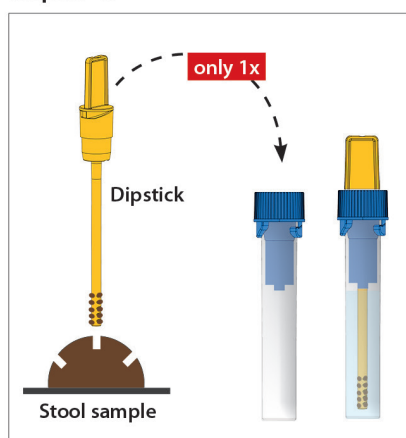
## Apply stool sample solution

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 turbidimetric assay manual.

Steps 1.–2.



Steps 3.–4.











## 6. PRECAUTIONS

- All reagents in the kit package are for in vitro diagnostic use only.
- A trained person in turbidimetric technique and autoanalyser use is required.
- The analyser should be ready before performing any assay.
- Read and follow the instructions for use provided with the kit.
- Reagents should not be used beyond the expiration date stated on the kit label.
- Reagents should not be used if the primary packaging is damaged or opened.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The solutions should be discarded in a proper container after testing following local regulations.

## 7. 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 sent to Immundiagnostik AG along with a written complaint.

### Used symbols:

	Temperature limitation		Catalogue Number
	In Vitro Diagnostic Medical Device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Lot number		European Conformity

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