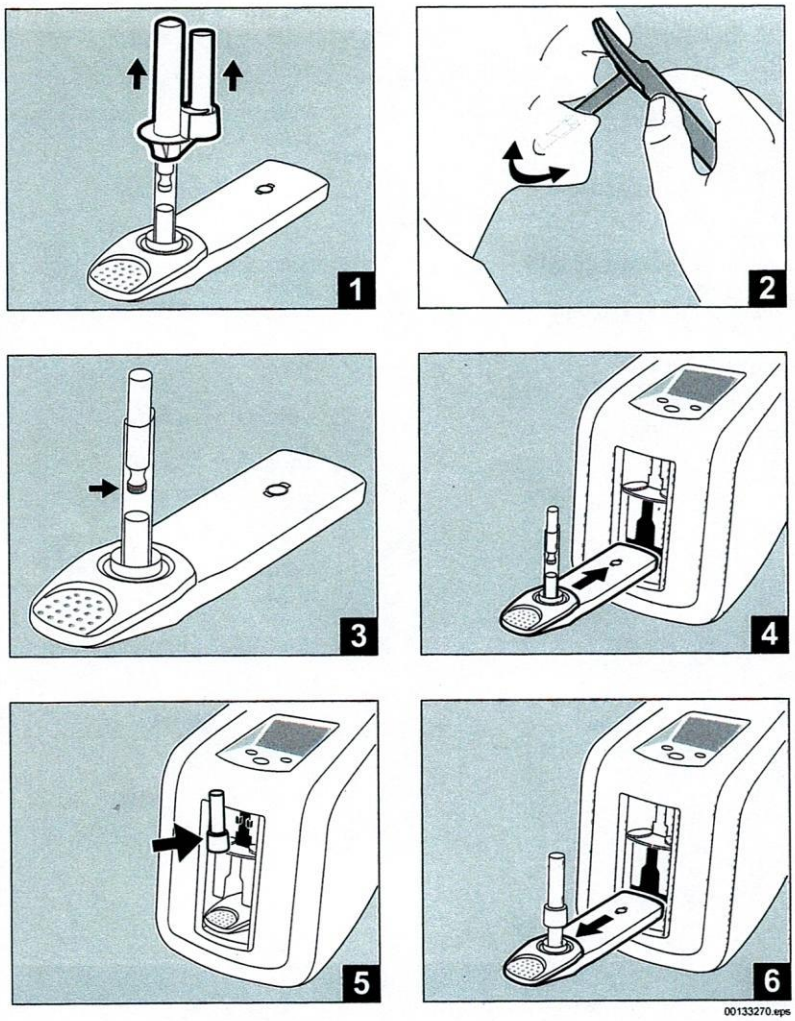
Dräger

Not for sale in the US market

Dräger DrugTest® 5000 STK
IVD

Dräger. Technology for Life®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1 For your safety

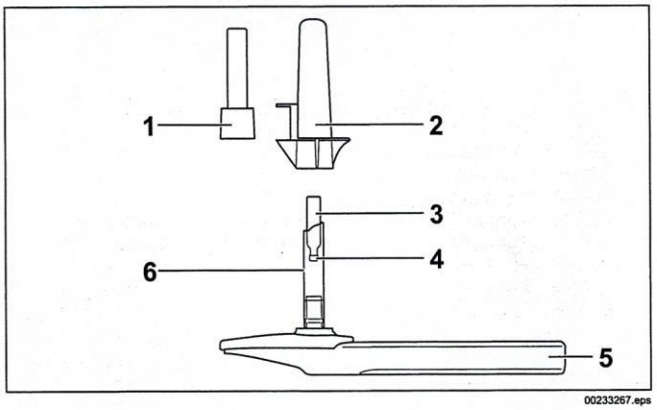
1.1 Strictly follow the Instructions for Use

Any use of the Dräger DrugTest® 5000 STK[1)] requires full understanding and strict observation of these Instructions for Use.

The components of the Dräger DrugTest 5000 STK are intended for the prescribed use only.

2 Description

2.1 Product overview



1 Cartridge
2 Safety cap
3 Sampler
4 Sample volume indicator
5 Housing with test strip
6 Sampler holder

Each packing unit contains:

- Dräger DrugTest 5000 STK, each packed in a sealed foil pouch.. The exact number is illustrated on the label on the packing unit. Every foil pouch contains a pouch with desiccant and a Dräger DrugTest 5000 STK, consisting of:
  a. a test cassette with integrated sampler
  b. a safety cap with cartridge
- Instructions for Use

2.1.1 Required materials that are not included

- Dräger DrugTest 5000 Analyzer (order no. 83 19 900) for processing and analysis of the test cassettes.

2.1.2 Additional recommended materials

- Dräger DCD® 5000 (order no. 83 19 910)
- Dräger Mobile Printer (order no. e.g. 83 19 310)
- Disposable gloves (e.g. latex or nitrile gloves)

2.2 Intended use

The Dräger DrugTest 5000 test system consists of the Dräger DrugTest 5000 Analyzer and the Dräger DrugTest 5000 STK. The test system is a point of collection test for the simultaneous, qualitative detection of up to 8 analytes in human oral samples for diagnostic purposes (in-vitro diagnostics) or for forensic use.

Depending on the version, the Dräger DrugTest 5000 STK is designed for the detection of influence by amphetamine, benzodiazepine, cocaine, ketamine, methadone, methamphetamine, opiates and THC/ cannabis. Designer amphetamines (e.g. MDMA/Ecstasy) are also detected by cross reactivities. The label on the packaging provides information about the present version of the Dräger DrugTest 5000 STK and the limit value (in ng/mL) for the specific substance. The meaning of the abbreviations can be found in the table.

Analyzers with firmware 2.0.0 or higher can process Dräger DrugTest 5000 STK with various evaluation times if this option is activated in the Analyzer. The evaluation time only influences the limit value of THC: a short evaluation time increases the limit value, a long evaluation time reduces it. All other analytes are evaluated with the same limit value regardless of the measurement mode.

If the Dräger DrugTest 5000 STK enables different evaluation times, the label on the packaging also shows the limit value for THC in the various measurement modes.

1) Dräger DrugTest is a registered trademark of Dräger.

The Dräger DrugTest 5000 test system is a qualitative measurement procedure. It provides information on the presence of the tested substances in the sample above or below a limit value (cut-off) and therefore only supplies a preliminary analytical result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. The preferred methods are GC/MS or LC/MS - see Section 3.3 "Confirmation of results".

All the results of the Dräger DrugTest 5000 test system require professional assessment with reference to further clinical assessment of the test subjects. This is particularly applicable for a preliminary positive result, see Table 1 (**T1**) auf page 72.

Depending on the configuration of the Dräger DrugTest 5000 STK, the Dräger DrugTest 5000 test system can be used to confirm the presence of the following drugs:

Drug (target analyte)	
AMP	Amphetamine (d-amphetamine sulfate)
BZO	Benzodiazepines (Diazepam)
COC	Cocaine (cocaine)
MET	Methamphetamines (D-methamphetamine)
MTD	Methadone (methadone)
KET	Ketamine (ketamine)
OPI	Opiates (morphine)
THC	Tetrahydrocannabinol (Δ9-THC)

2.3 Explanation of symbols

	Strictly follow the Instructions for Use!
	Manufacturer
IVD	In-vitro diagnostic medical product
LOT	Batch
	Temperature limitation
	Expiry date
Σ	Contents sufficient for <n> tests
	Measurement mode: fast (THC)
	Measurement mode: sensitive (THC)

2.4 Test principle

The Dräger DrugTest 5000 test system is based on the immunoassay principle of competitive inhibition. Drugs contained in the sample compete with drugs on the test membrane for the cohesion of microparticles coated with antibodies.

Sampling:
The Dräger DrugTest 5000 STK is designed for use with saliva samples, which are taken with the integrated sampler.

The sample does not require special treatment. The sample is taken directly by absorption into the sampler, which is integrated into the test cassette. After sampling, the analysis is started by inserting the test cassette and the cartridge into the Analyzer. The Analyzer transfers the sample to the test cassette, where the test development is started.

Test:
The sample interacts with microparticles coated with antibodies and with drug conjugates on the test membrane. If the sample is drug-free, the antibodies can react freely with the drug conjugates, which triggers a signal on the test membrane. If the sample contains drugs, they bond to the microparticles coated with antibodies, which weakens the generated signal. The Analyzer detects the signal generated by a specific sample and decides whether this signal originates from a preliminary positive (non-negative) sample.

Quality control:
An additional antibody and antigen reaction independent of the sample is integrated into every test membrane. When the sample has been successfully processed, antibodies on the reagent membrane bond to the antigens on the microparticles and generate a control signal. The Analyzer also detects this signal and it is used to decide whether the test is valid or not valid.

2.5 Precautions and warnings

NOTICE

For hygienic reasons, use gloves when handling the Dräger DrugTest 5000 test system and all samples. Do not touch the sampler with bare hands before and after sampling and observe current hygiene rules.

- Follow proper handling and disposal procedures.
- Open the foil pouch only immediately before use to prevent contamination of the sampler.
- Do not use the Dräger DrugTest 5000 STK if the foil pouch is damaged.
- Do not use the Dräger DrugTest 5000 STK beyond the expiry date printed or embossed on the pouch. The expiry date is formatted as YYYY-MM, e.g. 2011-01 means the Dräger DrugTest 5000 STK should not be used after the end of January 2011.
- The Dräger DrugTest 5000 STK can be processed only with the Dräger DrugTest 5000 Analyzer.

3 Testing

3.1 Test preparation and sampling

- Ensure that the test subject has not had any substances like e.g. food, chewing gum or tobacco in the mouth for at least 10 minutes before sampling.
- Make sure that the ambient temperature is between +5 °C to + 40°C and the relative air humidity is between 5% and 95% relative humidity.
- Make sure that the packaged test cartridges are at ambient temperature (wait for 15 minutes to achieve temperature equalisation if necessary).

1. Remove the safety cap with cartridge from the sampler of the test cassette **(Fig. 1)** and give the test cassette to the test subject. Keep the safety cap with cartridge.
2. Instruct the test subject to place the sampler in the cheek and move it carefully from one side of the mouth to the other **(Fig. 2)**. The test subject must not chew or suck on the sampler. Watch the sampling process!

- A sufficient sample will be collected within 4 minutes. If the sample volume indicator shows blue before the 4 minutes have passed, the sampling can be ended **(Fig. 3)**.

If the sample is not analysed immediately after it has been taken, make sure to follow the instructions in Section 3.1.1 "Delayed analysis".

3.1.1 Delayed analysis

NOTICE

Results may be invalid or incorrect if maximum storage times are not observed.

If the saliva is not analysed immediately after the sample has been taken, the Dräger DrugTest 5000 STK can be stored at room temperature up to a max. of 4 hours (confirmation of THC) or 8 hours (confirmation of all other drugs). The safety cap must be placed back onto the sampler holder in this case. Remove the safety cap from the sampler holder again before analysis.

3.2 Test procedures

NOTICE

Observe the Instructions for use of the Dräger DrugTest 5000 Analyzer.

3. Take the test cassette with the sample from the test subject. Open the Analyzer door and insert the test cassette into the bottom slot of the Analyzer until it audibly clicks into position **(Fig. 4)**.
4. Remove the cartridge from the safety cap and insert the cartridge into the top slot of the Analyzer until it audibly clicks into position **(Fig. 5)**.
5. Close the door
   The Analyzer automatically starts the analysis.
   On completion of the analysis, the Analyzer displays the results for every tested substance on the screen.
   Note the display.
6. Remove the test cassette with the cartridge after the analysis and dispose of it **(Fig. 6)**.

3.3 Confirmation of results

The Dräger DrugTest 5000 test system is a qualitative measurement procedure. For a confirmed result, a second sample must be taken and analysed by an accredited laboratory.

Take the second sample with a collection system suitable for saliva samples (e.g. Dräger DCD® 5000 (order no. 83 19 910)).

4 Interpretation of results

On completion of the analysis, the Analyzer displays the results for every tested substance on the screen. See the Instructions for Use for additional details on the operation of the Analyzer.

Data management

After the analysis, the test results are shown on the Analyzer display and saved in the Analyzer memory. All data can be printed out with the Dräger Mobile Printer. For more information on the data management options of the Analyzer see the Technical Manual for the Dräger DrugTest 5000 test system[2)].

5 Quality control

Regular quality control is part of a good analytical practice and may be required by the responsible authority. Always contact the responsible authorising and accreditation bodies to ensure that the applied quality control programme corresponds to the applicable standards.

Internal control

An integrated process control is conducted with every analysis (see also Section 2.4 "Test principle"). If the analysis was run without errors and the result safe to interpret, a control signal is generated. If the control signal is not generated, the Analyzer does not interpret the analyses but shows "invalid" as the result. Depending on the configuration, the Analyzer display may differ if a result is invalid (e.g. "not interpretable").

External control

The properties of the test allow a quality control to be run on site by taking a drug-free sample and processing it. The result for all analyses of this sample must be "negative".

When using positive controls, ensure that they are suitable for the Dräger DrugTest 5000. For information on suitable positive controls, please contact DrägerService®.

2) The Technical Manual can be downloaded free of charge from the Dräger home page (www.draeger.com).

6 Limitations of procedure

Due to unspecific interactions (physiological deviation, state of health or sample contamination), false positive or false negative results may occur in rare cases.

The antibodies used in the Dräger DrugTest 5000 test system are specifically adjusted to drugs. Nevertheless, structurally similar prescribed and over-the-counter drugs can react with the antibody reagents and cause false positive results. To achieve a confirmed analytical result, a more exact, alternative chemical method like GC/MS or LC/MS/MS has to be used. All the results of the Dräger DrugTest 5000 test system require professional assessment with reference to further clinical assessment of the test subjects. This is particularly important for a preliminary positive result.

The sampling process can be closely monitored. This means that faking the sample is improbable. However, if faking or substitution of a sample is suspected, dispose of the sample and repeat the test with a new Dräger DrugTest 5000 STK.

7 Performance features

7.1 Influence of food and beverages

Saliva may be contaminated immediately after consuming food, beverages or stimulants. To determine any influence of such contamination on the results of the Dräger DrugTest 5000, saliva samples were taken and interpreted immediately after consuming the following sample preparations:

Coke, toothpaste, American cranberry juice, aseptic mouthwash, orange juice, water, cough syrup (without codeine), coffee, chewing gum, chocolate, fruit tea, herb tea and cigarettes.

None of the evaluations yielded incorrect results.

As it is impossible to detect the possible influence of any food on the test absolutely, comply with a waiting time of 10 minutes before sampling.

7.2 Analytical performance

7.2.1 Analytical specificity

Most of the immunochemical detection reactions are not monospecific for a single analyte, but they react to a group of analytes with a similar chemical structure (e.g. the benzodiazepine test of the Dräger DrugTest 5000 test system detects several different benzodiazepines).
Therefore, it is not recommend that you use the results of a Dräger DrugTest 5000 test system as a basis for (semi) quantitative statements on the concentrations of one single analyte of a group of analytes.
Data on the analytes which can be detected with the corresponding test of the Dräger DrugTest 5000 test system, as well as data on the individual concentrations which separately generate a positive result, can be found in Table 1 (**T1**) on page 72.

The analytes listed in Table 2 (**T2**) on page 72 are not detected by the Dräger DrugTest 5000 STK at concentrations below 10,000 ng/mL.

7.2.2 Repeatability

Reproducibility studies were conducted with commercially available reference standards and negative saliva samples. Every saliva sample was enriched with corresponding standards to maintain the desired concentration of the analyte to be tested (no drugs, 250% limit value, 400% limit value. Every sample was tested at every analyte concentration ten times on 3 different days with the same batch of the Dräger DrugTest 5000 STK 6-Panel (8319830).

See Table 4 (**T4**) on page 73 for the results of the study.

7.3 Diagnostic performance

To test the diagnostic performance of the DrugTest 5000 test system, saliva samples were collected and analysed with the Dräger DrugTest 5000 test system in a clinical environment. A second sample was taken at the same time and tested by GC/MS or LC/MS. The diagnostic performance of the Dräger DrugTest 5000 test system is summarised in Table 3 (**T3**) on page 73.

The specified clinical performance is based on tests with the specified limit values.

8 Storage

Store the Dräger DrugTest 5000 STK between +4 and +30°C. Do not use the Dräger DrugTest 5000 STK if the foil pouch is damaged (e.g. has a hole or is torn). Use the Dräger DrugTest 5000 STK immediately after opening the foil pouch.
Do not use the Dräger DrugTest 5000 STK any more if the embossed expiry date has passed.

9 Disposal

The Dräger DrugTest 5000 STK can be disposed of with normal household rubbish.

10 Bibliography

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T1 – Specificity

Cocaine related compounds	[ng/mL]
Benzoylecgonine	200
Cocaethylene	500
Cocaine	20
Ecgoninemethylester	>10000
Norcocaine	400
Procaine	30000

Opiates related compounds	[ng/mL]
6-Monoacetylmorphine	35
Codeine	25
Dihydrocodeine	20
Hydrocodone	20
Hydromorphone	30
Morphine	20
Morphine-3ß-D-glucuronide	35
Nalorphine	35
Naloxone	1000
Norcodeine	4000
Normorphine	8000
Oxycodone	1000

Benzodiazepine related compounds	[ng/mL]
7-Aminoflunitrazepam	50
Alprazolam	10
Bromazepam	70
Chlordiazepoxide	3000
Clonazepam	15
Desalkylflurazepam	10
Desmethylflunitrazepam	10
Diazepam	15
Flunitrazepam	20
Flurazepam	3500
Lorazepam	200
Midazolam	40
Nitrazepam	30
Nordiazepam	45
Oxazepam	40
Prazepam	9000
Temazepam	20
Triazolam	40

THC related compounds	[ng/mL]
Cannabidiol	90000
Cannabinol	350
delta8-THC	25
THC (delta9-THC)	5
THC-COOH (11-Nor-9-Carboxy-delta9-THC)	2
THC-OH (11-Hydroyx-delta9-THC)	10
CP 47,797	>100000
JWH-18	>100000

Amphetamine related compounds	[ng/mL]
Dopamine	40000
MBDB	>10000
MDA	100
MDEA	>10000
MDMA	>10000
Phentermine	>100000
S(+)-Amphetamine	50
S(+)-Methamphetamine	>100000
Tyramine	5000

Methamphetamine related compounds	[ng/mL]
Chloroquine sulphate	1000
Ephedrine	50000
Fenfluoramine	300
MBDB	35
MDA	10000
MDEA	1000
MDMA	75
Procain	4000
Propylhexedrine	12
Pseudoephedrine	100000
R-(+)-Methcatinone	2000
Ranitidine	7000
S-(-)-Methcatinone	4500
S(+)-Amphetamine	100000
S(+)-Methamphetamine	35

Methadone related compounds	[ng/mL]
Diphenhydramine	12000
EDDP	7000
LAAM	1000
Methadone	20
Pheniramine	1000

Ketamin related compounds	[ng/mL]
none	

T2 – Interferents

Substance		
Acetaminophen	Acetylsalicylic acid	Ascorbic acid
Buprenorphine	Caffeine	Cotinine
Ephedrine	GHB	Ibuprofen
Imipramine	Naproxen	Nicotine
Phenobarbital	PCP	Tetracycline
Tramadol		

T3 – Clinical Performance

Cocaine

Cocaine-Equivalents

Dräger DrugTest 5000	Reference Sample contains [ng/mL]			
	<14	14 – 20	20 – 26	>26
positive	0	1	0	20
negative	98	1	0	2

Agreement: 97.5 % GC-MS Cut-off: 14.0 ng/mL

Opiates

Morphin-Equivalents

Dräger DrugTest 5000	Reference Sample contains [ng/mL]			
	<14	14 – 20	20 – 26	>26
positive	3	4	0	27
negative	89	2	0	1

Agreement: 95.2 % GC-MS Cut-off: 14.0 ng/mL

Benzodiazepine

Diazepam-Equivalents

Dräger DrugTest 5000	Reference Sample contains [ng/mL]			
	<10.5	10.5 – 15	15 – 19.5	>19.5
positive	2	1	1	16
negative	86	2	0	1

Agreement: 95.4 % GC-MS Cut-off: 10.5 ng/mL

Tetrahydrocannabinol

Delta-9-Tetrahydrocannabinol

Dräger DrugTest 5000	Reference Sample contains [ng/mL]			
	<3.5	3.5 – 5	5 – 6.5	>6.5
positive	0	0	0	25
negative	63	1	0	6

Agreement: 92.6 % GC-MS Cut-off: 3.5 ng/mL

Amphetamine

Amphetamine-Equivalents

Dräger DrugTest 5000	Reference Sample contains [ng/mL]*			
	<35	35 – 50	50 – 65	>65
positive	1	1	10	9
negative	93	5	0	0

* data comprise clinical and spiked samples

Agreement: 95.0 % GC-MS Cut-off: 35.0 ng/mL

Methamphetamine

Methamphetamine-Equivalents

Dräger DrugTest 5000	Reference Sample contains [ng/mL]*			
	<24.5	24.5 – 35	35 – 45.5	>45.5
positive	0	8	10	13
negative	90	2	0	0

* data comprise clinical and spiked samples

Agreement: 98.4 % GC-MS Cut-off: 24.5 ng/mL

Methadone

Methadone-Equivalents

Dräger DrugTest 5000	Reference Sample contains [ng/mL]			
	<14	14 – 20	20 – 26	>26
positive	3	1	0	71
negative	60	0	0	1

Agreement: 97.1 % GC-MS Cut-off: 14.0 ng/mL

Ketamin

Katamin-Equivalents

Dräger DrugTest 5000	Reference Sample contains [ng/mL]*			
	<210	210 – 300	300 – 390	>390
positive	2	9	4	22
negative	68	10	3	0

* data comprise clinical and spiked samples

Agreement: 87.3 % GC-MS Cut-off: 210.0 ng/mL

This Test-Kit is manufactured using proprietary technology created by Epitomics Inc. USA.

T4 - Reproducibility

Date	Batch/Result
08/08/2008	ARZH-0061: No positives at 0 %, no negatives at 250 % and 400 %.
18/08/2008	ARZH-0061: No positives at 0 %, no negatives at 250 % and 400 %
21/08/2008	ARZH-0061: No positives at 0 %, no negatives at 250 % and 400 %.

CE Directive 98/79/EC

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