

Pre-Analytcs



The cornerstone of effective analytics



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◦ Our goal with this brochure is to improve the collaboration with our customers and **the quality of the results** we provide by helping you to avoid “laboratory errors” as reliable pre-analytical processes are crucial for obtaining conclusive results. While we ensure **high quality** on our end, your contribution is of equal importance. By sticking to the guidelines laid out here, we can assure you that **our results** truly reflect what you intended to investigate.

General Information

Pre-analytics encompasses all steps **preceding** the actual laboratory measurements (i.e., at the doctor's office or at the patient's home):

- Laboratory request or correct selection of analytes
- Proper completion of the request form
- Special patient preparation (e.g. fasting, medication status)
- Unambiguous sample labelling and precise sample collection
- Sample preparation (e.g. centrifugation, freezing)
- Correct sample storage (e.g. refrigerated, frozen, protected from light)
- Sample transportation

At each of these steps, disturbances and errors can occur that influence the results in a diagnostically relevant manner, thereby posing the risk of inaccurate evaluations of laboratory tests. Essentially, disturbances occurring in pre-analytics can be categorized into patient-related factors (in vivo) and other factors (in vitro).

Patient-Related Factors

■ Unmodifiable Factors:

- Age (some parameters are not applicable in children, for example)
- Sex (e.g. hormonal effects)
- Pregnancy
- Genetic factors
- Ethnicity

■ Variable Factors:

- Time of sample collection
- Body position
- General nutrition (e.g. protein-rich diet → ↑ urea, fasting → ↑ uric acid)
- Fasting at the time of sample collection
- Body weight
- Physical exertion (e.g. stress → ↑ cholesterol, leukocytes)
- Consumption of stimulants (e.g. smoking → ↑ cholesterol, leukocytes, ↓ uric acid or alcohol → ↑ triglycerides, γGT, MCV, ↓ magnesium)
- Medication (plenty of interactions, e.g. cortisone → ↑ blood sugar, ↓ eosinophils)
- Interfering factors such as lipaemia, hyperbilirubinaemia, in vivo haemolysis

Other Influencing Factors Include

■ Sample Collection:

- Selection of the correct sample tube (addition of anticoagulants)
- Collection technique (order of collection, venous pressure, aspiration suction)
- Contamination of samples with infusions or disinfection solutions
- Incorrect filling of the tube (too much/too little)

■ Storage and Transportation:

- Failure to adhere to transport and storage conditions (temperature, light protection)
- Time elapsed between sample collection and arrival at the laboratory
- Pre-treatment of the material (centrifugation)
- Not considering in vivo influences (lipaemia, hyperbilirubinaemia, haemolysis)

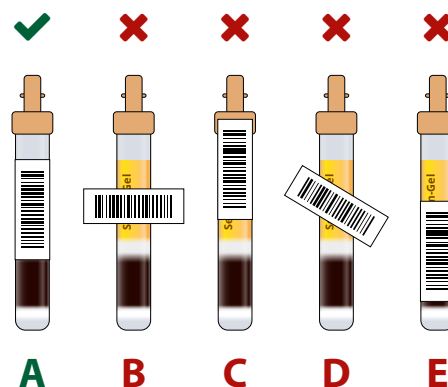
Labelling Sample Collection Containers and Request Forms

The correct association of patient, sample, and request form is essential for all subsequent processes, as organizational and administrative errors are the most significant cause of incorrect laboratory results. The labelling of the sample tube should be done before collection and checked again during collection. Ideally, you should use the barcode labels provided by us to ensure unambiguous sample identification. The corresponding barcode label must be found on the accompanying request form.



Important: A separate set of barcodes must be used for each individual patient.

The barcode labels should be placed vertically on the upper area of the tube.



If the sample tubes are labelled manually, the following data must be noted:

- Patient's name (first name, last name)
- Patient's date of birth
- Description of the sample material after centrifugation: serum, EDTA plasma, or citrate plasma

Infectious materials (e.g. blood from an HIV or hepatitis patient) must be labelled! If samples are being resent at a later point in time (e.g. frozen material), this should be noted on the sample. Additionally, a remark that frozen material will follow should be added to the original request form.

Proper Completion of the Request Form

■ Indispensable Information on the Request Form:

- Sender (medical practice, address, telephone/fax)
- Patient's name, first name, date of birth, sex, address, and purchaser
- Test request (correct marking of the parameters to be examined)
- Patient's height and body weight
- Identity verification or confirmation (patient's signature on the request form)
- Type of primary sample, date, exact time of sample collection
- Medication
- Labelling of infectious material
- Additional information for special analyses
- Collection volume and time for urine collection
- Clinically relevant diagnostic information (e.g. date of last menstrual period for hormone tests)





The request form should be filled out clearly and **legibly** using a computer or block letters. The **patient's data** should be entered into the left upper field, and the free field on the right should contain the **practice stamp** and/or **barcode**.

Krankenkasse bzw. Kostenträger
Name, Vorname und Adresse des Versicherten
Mustermann, Peter
Musterweg 11
00000 Musterort
Geburtsdatum: / / Datum

CORRECT ✓

Krankenkasse bzw. Kostenträger
Name, Vorname und Adresse des Versicherten
MUSTERMANN, PETER
MUSTERWEG 11
00000 MUSTERORT
Geburtsdatum: / / Datum

CORRECT ✓

Krankenkasse bzw. Kostenträger
Name, Vorname und Adresse des Versicherten
Mustermann Peter
Musterweg 11
0000 Musterort
Geburtsdatum: / / Datum

WRONG ✗

Practice stamp or barcode

CORRECT ✓
CORRECT ✗
WRONG ✗

All requested examinations **must be clearly marked** as otherwise it cannot be ensured that all information will be captured.

Anamnesis Form

If possible, the brief anamnesis form on the back of the request form should be filled out. However, some information such as height and body weight as well as current medication is mandatory. If **genetic tests** are being performed, the patient must fill out and sign the **consent form for genetic testing** in accordance with the German Genetic Diagnostics Act, as these types of test can't be performed otherwise. **It is also mandatory for the patient's physician to fill out and sign this section!** The corresponding parameters are marked on the request form with a red pen.

Furthermore, it is important to ensure that the patient fills out and signs the declaration. Should the patient fail to do so, the request cannot be processed by us.

I agree to my personal data being transmitted for the provision of services (name, address, payer, insurance number, date of birth and gender, if applicable, information on body height and weight, medical history and medication), insofar as this is necessary for requested analyses. (Regulation (EU) 2016/679 Art. 6 para. 1 lit. B). I give this consent voluntarily and can revoke it informally at any time with immediate effect for the future without giving reasons. My doctor has also informed me about this.

I agree that remaining sample material may be stored for scientific purposes (e.g. method development) until revoked.

Musterstadt, 28.06.2018
Place and Date

Dr. Peter Mustermann
Signature/Legal Representative

Furthermore, make sure that the **patient completes and signs the declaration**, otherwise we will not be able to process the order.

Please, always complete when requesting hormone tests:

Date of Blood Sampling: / /

Last Menstruation: / /

Menstrual Cycle Phases:

- Follicle Phase
- Luteal Phase
- Ovulation Phase
- Menopause
- Post-Menopause

For hormone tests in women, it is mandatory that the corresponding menstrual history is also filled out to allow for correct interpretation of the respective test results.

Blood - Sample Collection

The collection of blood causes a disruption of blood vessels (arteries, veins, and capillaries). Therefore, only flawless and sterile materials should be used. Suitable disposable items are available for blood collection. For puncturing, needles that are not too fine should be used. Venous blood collection should be performed at a suitable site in the elbow, forearm, or back of the hand. Existing influencing factors must be taken into account.

■ Standardizing Blood Sample Collection:

- Blood collection between 7 am and 9 am (which is also the time frame for reference values)
- No extreme physical activity within the last three days before sample collection
- Avoid excessive alcohol consumption several days before blood collection
- Fasted state: patients should abstain from food consumption for 12 to 14 hours (24 hours for alcohol)
- Blood collection should always be done in the same position (sitting or lying down)
- Rest for at least ten minutes before blood collection
- Avoid opening and closing the fist as this can lead to haemolysis
- Avoid prolonged stasis: Maximum of one minute (preferably 30 seconds) of stasis, release the tourniquet, then collect blood
- Draw blood gently, without interrupting the suction
- Immediately after sample collection, gently invert tubes containing anticoagulants several times. However, the tubes must not be shaken!

Order of tubes during blood collection:

1. Blood cultures
2. Serum
3. Citrate blood (coagulation)
4. Homocysteine
5. EDTA / Heparin / BSG Citrate
6. Fluoride



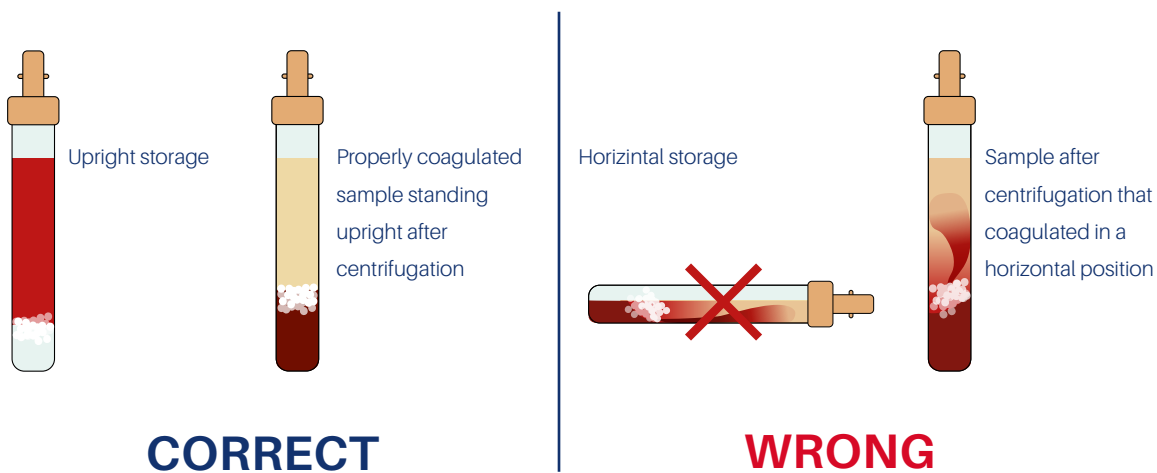
Centrifugation of Tubes

■ Serum

For some parameters, centrifugation is mandatory. This is indicated on our request forms with the abbreviation "Sz". For this purpose, serum and serum gel tubes should be stored upright for at least 30 minutes and subsequently centrifugated for 10 minutes at 3000-4000 rpm. Then, decant the supernatant (serum) into empty tubes.



Important: Blood must undergo centrifugation within 1 hour to prevent haemolysis!



■ EDTA Plasma etc.

In contrast to serum, which must first coagulate completely, EDTA should be centrifugated immediately after blood collection. Here too, centrifugation should be performed for 10 minutes at 3000–4000 rpm, followed by transferring the supernatant into an empty tube.



Important: Do not pipette any red components into the tubes!



Further Processing of Blood Samples

■ Sample Storage

If the transport service picks up the samples shortly after they have been collected, it is sufficient for most parameters to store the samples at room temperature, unless they must be pipetted and sent frozen. These are marked on the sheet (see below). The following applies for longer storage periods of up to 24 hours:

Sample Material	Recommended Storage		
	Room temperature (15–25 °C)	Fridge (2–8 °C)	Freezer
S = Serum whole blood uncentrifuged	X		
Sz = centrifugated (and possibly pipetted) serum		X	
Szg = centrifugated, pipetted, and frozen serum			X
EDTA = whole blood EDTA	X*		
EDTA-PI = plasma EDTA (pipetted)			X
CPDA	X*		
Hep = heparin	X*		
HCY = homocysteine special tube		X	
NaF = sodium fluoride		X	
Citrate = whole blood citrate	X*		
CPg = frozen citrate plasma swabs			X
Smears		X	
Saliva		X	
Urine		X	
Stool		X	

* Express delivery is necessary for some parameters that are determined from these samples so that the samples can be processed in the laboratory within 24 hours.

■ Frozen Material (Marked With „g”)

After centrifugation, pipette off and freeze the sample at at least -10 °C (preferably approx. -20 °C) until sample transportation. The sample should be completely frozen by the time it is shipped. Please label the sample accordingly, e.g. **EDTA plasma**, **citrate plasma**, or **serum**.



Important: Always have shipping containers ready for the transportation of frozen samples. It is best to store these in the freezer some time in advance. Inform the transport service about the frozen sample the day before!

■ Light-Protected Materials

Some samples are highly susceptible to light. These should be protected from light exposure as quickly as possible, either by wrapping them with aluminum foil or by using suitable dark containers. Please pay particular attention (especially with centrifugated serum) to ensure appropriate protection during the resting period! All analytes that require a light-protected handling/transportation are marked with a sunglasses icon (🕶️) on our request form.

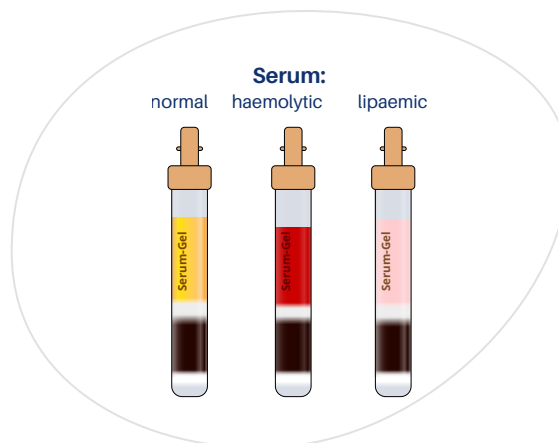
Material Peculiarities

■ Haemolytic Serum (Haemolysis)

Haemolysis occurs when the red blood cells (erythrocytes) in the blood are destroyed, thereby releasing the haemoglobin they contain. Depending on the degree of haemolysis, the serum or plasma of a haemolyzed blood sample may have a more or less intense orange/red colour. Haemolysis can occur intravascularly due to prolonged stasis or extravascularly due to excessive aspiration during blood collection. Contaminants, excessive cooling or warming, vigorous shaking of the sample, and exceeding storage times for whole blood are other factors that promote haemolysis. Haemolytic samples are a common problem in laboratory practice, leading to distorted analytics, especially in colour and turbidity measurements (incorrectly high/low values).

■ Lipaemic Serum (Hyperlipoproteinaemia)

Lipaemia refers to a milky-turbid discolouration of serum/plasma caused by neutral fats. A lipaemic sample may indicate a disorder of lipid metabolism. Certain fats (chylomicrons) form a creamy layer at the top of the sample after 24 hours of cooling, while others lead to a homogeneous turbidity of the plasma. The presence of excessive amounts of lipids in a sample, especially during photometric measurements, can lead to interferences.



Use of Blood Tubes (examples - this list is inchoate!)						
EDTA	Serum	Heparin	CPDA	Fluoride	HCY	Citrate
<ul style="list-style-type: none"> • All cellular examinations (blood counts, cellular immune profiles) • Nitrotyrosine • HbA1c • Special haematological tests (e.g. HLA B27) • All genetic examinations • Certain vitamins (folic acid, B1, B2, B6) • Amino acids, glutathione peroxidase 	<ul style="list-style-type: none"> • All enzymes (e.g. yGT, GOT, GPT, CK, AP, LDH, amylase) • Retention values (creatinine, urea) • Metabolic values (cholesterol, HDL, LDL, triglycerides, uric acid) • Serum electrolytes • CRP, sIL2R • Protein and electrophoresis • Hormones • Serological tests (antibodies) • and many more 	<ul style="list-style-type: none"> • Functional immunodiagnosics (e.g. cytokines) among others • Whole blood mineral analyses • Vitamin C • Intracellular glutathione 	<ul style="list-style-type: none"> • Special immunological tests on living cells (e.g. tumour killing test, LTT) • BHI and complementary biomarkers, mitochondrial activity • Glutathione metabolism 	<ul style="list-style-type: none"> • Glucose 	<ul style="list-style-type: none"> • Homocysteine 	<ul style="list-style-type: none"> • Standard coagulation diagnostics (INR / Quick, PTT, fibrinogen) • Almost all further coagulation tests • Lactate, pyruvate



Important: On the last page of this brochure, you will find an overview of the colour coding of the various blood collection tubes as well as additional shipping materials.

Urine - Sample Collection

When collecting urine for urine tests, it is important to consider which type of urine is needed: first or second morning urine, 24-hour urine collection, or urine for special test kits (e.g. cryptopyrrol, Sander's acid-base test, neurotransmitters). Typically, midstream urine is used.

Urine tubes with yellow caps: Urine tubes without stabilizer for examination of a native urine sample.

Urine tubes with green caps: Urine tubes with stabilizer. Contains a lyophilized bacteriostatic agent that stabilizes the urine for 48 hours. Please ensure that the tube is filled adequately. For bacterial examinations, the surroundings should be disinfected, and urine should be collected using a sterile container. In the case of special urine tubes with additives (depending on the test kit), please follow the respective test instructions!



■ Procedure:

Remove the small cap and attach the pipette tube to draw urine from a urine cup.

You can find detailed instructions for urine collection on our website.



Important: The first morning urine is the urine obtained after waking up in the morning (regardless of how many times urine was passed during the night)! The second morning urine is collected least 2-4 hours after the first morning urine in the morning. Disregarding this time frame can at lead to the distortion of test results.

Stool - Sample Collection

Please use the enclosed stool collector for collecting stool samples. The stool should not come into contact with the toilet bowl or the water inside the toilet.

Please unscrew the stool tube (brown cap) and take stool samples from different spots of the stool using the spoon. Please fill the tube with stool up to the marked line.

Screw the lid back onto the stool tube with the spoon. Please label the sticker with the name, date of birth, and collection date and place it in the enclosed transport tube (white).

Please put the transport tube and the completed (and signed) request form into the enclosed postal shipping bag and seal it properly. Preferably, the postal shipping bag should be dropped off at a post office or sent to us via courier service.





Important: Please do not send your samples on Fridays (weekend) or before public holidays!

Feel free to use our detailed, illustrated guide to stool sample collection on our website.

■ **Special Stool Examinations**

For the assessment of faecal histamine, tryptophan, serotonin, or GABA levels, as well as for our ColoAlert test, special stool samples are required, which must be appropriately stabilized. You can find the exact instructions for the collection of these special types of samples in the respective test kits and on our website.

Other Examinations

■ **Saliva**

For saliva examinations, a special test kit is provided which comes with detailed instructions. It is important to refrain from consuming foods such as meat, dairy products, soy, cucumbers, and legumes the day before taking the saliva sample. Alcohol, chocolate, and nicotine should also be avoided. The ideal time for women still having their menstrual cycle is on the 22nd day of the cycle (+/-2 days), but in any case, the test should be done in the second half of the cycle. If women no longer have a menstrual cycle, it does not matter on which day the test is performed. Men can perform the test on an empty stomach every morning. Until the samples are posted, the saliva samples should be stored in the refrigerator. However, they should be sent to us as soon as possible.

■ **Swabs**

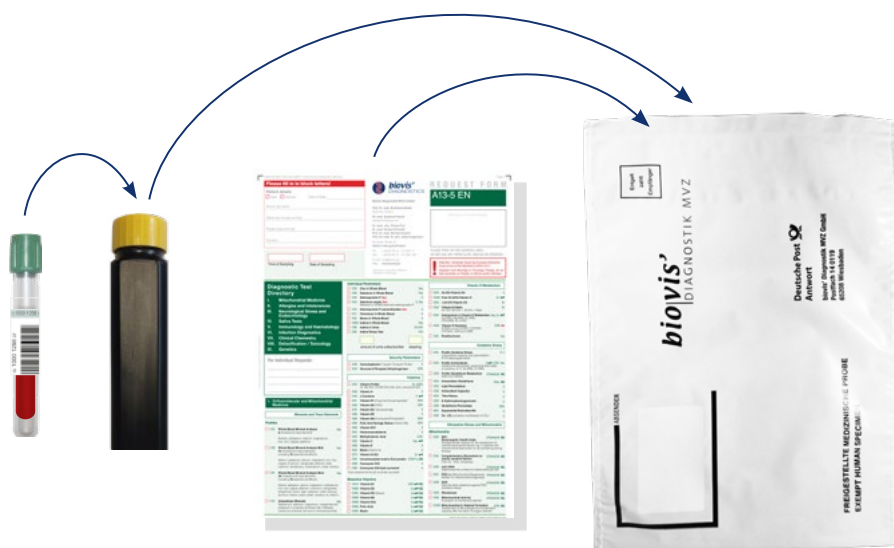
Swabs are needed for microbiological examinations and can be taken practically anywhere (please consult with our laboratory regarding the collection and transportation of the material). Generally, no disinfection should be performed before swabbing (however, there are exceptions, such as with skin fungus).

■ **Special Test Sets**

Special test kits are required for some of our tests. The corresponding instructions are included with these test kits but can also be viewed and downloaded from our website.

Preparing Samples for Transportation

For various laboratory tests, it is essential that special transport conditions are being adhered to to ensure reliable results (immediate centrifugation of the sample, separation of the serum/plasma from the blood clot, freezing of the sample, storage or transport at a specified temperature, protection from light, etc.). Corresponding information can be found on our request forms. A detailed material key can be found on the last page of our request forms.



■ Heatpacks

To prevent functional cellular tests from being affected by very low ambient temperatures, you can obtain heat packs from us. Using heat packs is advised for all functional and cell-based assays between October and Easter, or in case there is a risk of freezing during transportation. However, we do not recommend the use of heatpacks when outside temperatures reach more than 15-20 °C, as excessively high temperatures can also have a negative effect on the accuracy of the test results.



Important: The heat packs are not suitable for despatch via German post! If you are not yet using a transport service, please contact our head office. They will be happy to help you with the appropriate set-up. Please use the heat packs exclusively for functional cellular tests (please refer to the list on the back of the instructions for details). All other samples must not be heated!

Shipping Samples by Post

You can send samples via mail or by using our transport service. Make sure to use the transport envelopes we provide for this purpose. If you opt for our transport service, use the safety bags provided. Double-check to see if the sample tube is labelled with patient data or a barcode. Then, place the sample tube in a padded transport tube and put it in the envelope along with the filled-out request form.



Important: Please remember to use a separate envelope for every individual patient! If there are two request forms for one patient, use one envelope for each form! Also, always use a separate request form for stool tubes and a separate envelope for stool samples!

Only sera or plasma samples that have already been centrifuged are suitable for shipping by post. Whole blood is not suitable for transport over several days. Please ensure that the stability of the analytes is not compromised, especially when sending samples by post over the weekend.

■ Express Shipping

If an analyte is equipped with an annotation reading “**EXP**”, send the respective sample to us via express mail and make sure to direct it to our house address (not the PO box address!) or send it to us through our transport service.



Important: Express samples must arrive at the laboratory within 24 hours and may only be sent from Monday to Thursday and not on Fridays or before public holidays.

Sample Shipping

To ensure stable transport, we're happy to provide our transport service. This requires prior registration and can be requested for the following day as needed. Frozen samples are transported to the laboratory by our service in suitable refrigerated containers, maintaining the cold chain. So, please let us know in advance if you want to ship samples that require refrigeration!



Important: You can call us to arrange sample pick-ups and service set-up at: +49 6431-21248-0

Ordering Supplies:

All containers required for the collection and shipping of samples are provided free of charge by biovis. Please use the special order form for shipping materials to place your order. You can conveniently fill it out online and send it to us using the integrated send button.

Alternatively, save the document and email it to our ordering service at: **bestellung@biovis.de**

Some tests require specific test kits. You can request these using the order form available at:



<https://www.biovis.eu/en/order-shipping-material/>

biovis SAMPLE COLLECTION AND SHIPPING MATERIALS

VACUETTES	MONOVETS	CAPILLARY BLOOD	MISCELLANEOUS
 <p>EDTA Art. No. 454020 Violet cap / 3 ml</p>	 <p>EDTA Art. No. 04.1901 Pink cap / 2,6 ml</p>	 <p>CapiSave Art. No. 365968 Yellow cap / 0,5 ml</p>	 <p>Urine tubes Art. No. 10.252.001 without stabiliser / 10 ml</p>
 <p>Heparin Art. No. 368886 Green cap / 6 ml</p>	 <p>NH₄-Heparin Art. No. 02.1064 Blue cap / 9 ml</p>	 <p>Capillary heparin Art. No. 365966 Green cap / 0,5 ml</p>	 <p>Urine tubes Art. No. 10.253.001 with stabiliser / 10 ml</p>
 <p>Serum Art. No. 455071 Red cap / 8 ml</p>	 <p>Serum Art. No. 01.1602.001 Brown cap / 7,5 ml</p>	 <p>Capillary serum Art. No. 365964 Red cap / 0,5 ml</p>	 <p>Urine tube with stabiliser Test kit 908/928</p>
 <p>CPDA Art. No. 455056 Light yellow cap / 9 ml</p>	 <p>CPDA Art. No. 01.1610.001 Light yellow cap / 8,8 ml</p>	 <p>Lancet Art. No. 366594</p>	 <p>Saliva tube Art. No. 62.558.201 White closure</p>
 <p>Citrate Art. No. 455322 Blue cap / 9 ml</p>	 <p>Citrate Art. No. 04.1922.001 Light green cap / 4,3 ml</p>	 <p>Transport medium CapiSave Art. No. TH050</p>	 <p>Histamin in the stool Test kit 909 Yellow label / 1,5 ml</p>
 <p>HCY Art. No. 454421 White cap / 2 ml</p>	 <p>HCY Art. No. 04.1908.001 Light grey cap / 2,7 ml</p>	 <p>Dryspot filter card Art. No. DZ9027BV</p>	 <p>Occult blood test Test kit 910 White label/ 1,5 ml</p>
 <p>NaF Art. No. 454033 Grey cap / 5 ml</p>	 <p>NaF Art. No. 04.1903.001 Yellow cap / 2,6 ml</p>	 <p>Dryspot epigenetics</p>	 <p>Centrifugation tube Art. No. 60.610.100 White closure</p>
 <p>OmicSnap Art. No. KV10021CP with stabilisation buffer and matrix</p>	 <p>Stool-tube Art. No. HT8115 Outer tubes for tubes with brown lid and small spoon</p>	 <p>Transport tube protected from light Art. No. HT1011 Suitable for vacuettes, monovettes, urine tubes and among others</p>	



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