

# ONE STEP RAPID TESTS

SELF-TESTING  
PROFESSIONAL USE



**BIOGEMA**





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# Biogema, production cooperative, Košice

## A stable partner in diagnostics

Company Biogema, production cooperative, Košice **builds on strong foundations** of long-term partnership in the field of production and distribution of in vitro diagnostics. As the only Slovak manufacturer of ELISA diagnostic kits, we have been striving to exceed client expectations and needs for more than 35 years. We use the knowledge, that we have acquired through many years of experience and try to make use of it in our daily practice.

We are aware of the responsibility of being a strong and stable partner in medical diagnostics and therefore offer a **strong pro-client approach** combined with high flexibility. Our expert team of employees solves everyday challenges in the production and innovation of diagnostics and their implementation in the dynamic environment of modern laboratories.

We understand the need for quality, which is why we offer our clients **only certified diagnostics**, that meet all the strictest standards and legislative requirements. Since 2004 we have had a **quality management system** in place according to STN EN ISO 9001 and STN EN ISO 13485 in the current version, which, together with internal and external control forms a process quality guarantee.



# Rapid diagnosis of Fecal Occult Bleeding

## Hemoglobín FOB test



Hemoglobin FOB test is a rapid, qualitative, immunochromatographic test device, that combines selectivity of monoclonal and polyclonal antibodies for highly sensitive identification of human hemoglobin in tested sample - human feces. This test is intended for self-testing.

Detection of occult bleeding with a rapid screening Hemoglobin FOB test is used as an initial preventive examination of various cancers of digestive tract, especially colorectal cancer. Performing of these test is simple, fast and produce a reliable result with high accuracy.

REF	Product name	$\Sigma$	Sensitivity
1037	Hemoglobín FOB test	1	50ng hHb.ml <sup>-1</sup>
1030	Hemoglobín FOB test 3 v 1	3	50ng hHb.ml <sup>-1</sup>



# Rapid diagnosis of stomach and duodenal infection

## Helicobacter Pylori test



Helicobacter Pylori test is intended for rapid, qualitative immunochromatographic determination of H.Pylori antigen in a tested sample - human feces. H. Pylori is spiral gram-negative bacterium, that colonizes the epithelium of the stomach and proximal duodenum. Her expansion causes gastrointestinal difficulties such as pain in abdominal area, stomach ulcers and in the case of a long-term untreated form of infection, it can even lead to stomach cancer. This test is intended for self-testing.


Infection with the bacterium with Latin name Helicobacter Pylori is the second most common infection of the upper digestive tract, primary mucous membrane of stomach and duodenum, where it disrupts its integrity and thus allows acidic environment to contact with unprotected epithelium, which subsequently leads to health problems. Treatment of this infection is very complicated, but early diagnosis greatly contributes to shortening treatment time.

REF	Product name		Sensitivity
1025	Helicobacter Pylori test	1	150ng HP antigen/ml

# Drug of abuse tests



Drug of abuse test are designed to determine drug or its metabolite in tested sample in equal or higher concentration, than is sensitivity of individual test. High sensitivity is ensured by competitive immunoanalysis on a solid phase. Drug of abuse tests can provide a rapid preliminary result about consumption of individual drug. Advantage of these tests is their simple execution and relatively long detection time after using of drug.

REF	Product name	
1014	Cocaine test	1
1015	Marijuana - THC test	1
1013	Metamphetamine - meth test	1
1021	Multidrug test - 5 parameters MDMA, METH, BZO, MOR, THC	5
1041	Multidrug test - 10 parameters MDMA, METH, BZO, MOR, THC, AMP, BAR, COC, PCP, TCA	10
1051	Multidrug test - 6 parameters from saliva MDMA, METH, BZO, MOR, THC, COC	6

# Drug of abuse tests

## Technical parameters

### Tests performed from a human urine sample

Drug type	Sample	Sensitivity	Detection time
Ecstasy (MDMA)	urine	500 ng.ml <sup>-1</sup>	up to 4 days
Meth (METH)	urine	1000 ng.ml <sup>-1</sup>	up to 5 days
Benzodiazepine (BZO)	urine	300 ng.ml <sup>-1</sup>	up to 7 days
Morphine (MOR)	urine	300 ng.ml <sup>-1</sup>	up to 5 days
Marijuana (THC)	urine	50 ng.ml <sup>-1</sup>	up to 7 days
Cocaine (COC)	urine	300 ng.ml <sup>-1</sup>	up to 2 days
Amphetamine (AMP)	urine	1000 ng.ml <sup>-1</sup>	up to 2 days
Barbiturates (BAR)	urine	300 ng.ml <sup>-1</sup>	up to 4 days
Phencyclidine (PCP)	urine	25 ng.ml <sup>-1</sup>	up to 14 days
Tricyclic antidepressant (TCA)	urine	1000 ng.ml <sup>-1</sup>	up to 10 days

### Tests performed from a human oral fluid sample

Drug type	Sample	Sensitivity	Detection time
Ecstasy (MDMA)	oral fluid	50 ng.ml <sup>-1</sup>	up to 72 hours
Meth (METH)	oral fluid	50 ng.ml <sup>-1</sup>	up to 72 hours
Benzodiazepine (BZO)	oral fluid	50 ng.ml <sup>-1</sup>	up to 72 hours
Morphine (MOR)	oral fluid	40 ng.ml <sup>-1</sup>	up to 48 hours
Marijuana (THC)	oral fluid	12 ng.ml <sup>-1</sup>	up to 14 hours
Cocaine (COC)	oral fluid	20 ng.ml <sup>-1</sup>	up to 24 hours




# Determination of pregnancy hormone - hCG

## Pregnancy test BABY



Baby pregnancy tests are a simple, fast and reliable tests for qualitative determination of human pregnancy choriogonadotropin (hCG) in sample of human urine in concentration higher than 25 mU/ml. It is based on immunochromatography analysis, which ensures high sensitivity and high specificity.

BABY pregnancy test can provide a quick and accurate answer of presenting an increased level of pregnancy hormone - hCG in body. A big advantage of these tests can be performed at any time during the day - it is not necessary to take only morning urine. It reliably confirms pregnancy after 7 days after conception. These tests are intended for self-testing.

REF	Product name		Sensitivity
1002	Pregnancy test - MONO	1	25 mU.ml <sup>-1</sup>
1010	Pregnancy test - DUO	2	25 mU.ml <sup>-1</sup>
1000	Pregnancy test - KOMFORT	1	25 mU.ml <sup>-1</sup>


# Determination of fertile days

## Ovulation test



Ovulation test is a simple rapid and reliable test for qualitative determination of luteinizing hormone (LH) in human urine sample. Test is based on immunochromatographic analysis, which uses a combination of conjugate and antibody for identification of LH hormone. LH hormone together with follicle-stimulating hormone (FSH) stimulates egg maturation.

Increasing of LH hormone concentration appears 48 hours before ovulation. This fact is used for the most accurate determination of the fertile period - ovulation, which lasts only 12-24 hours. Measuring of LH hormone in woman is one of the most accurate and reliable methods to increase probability of conception.

REF	Product name		Sensitivity
1009	Ovulation test 5 in 1	5	25 mU.ml <sup>-1</sup>
1039	Ovulation test 20 in 1	20	25 mU.ml <sup>-1</sup>

# Diagnosis of SARS-CoV-2


## Rapid antigen test AG Covid-19

## Covid-19 antibody test IgG - IgM



Rapid antigen Covid-19 AG test is an immunochromatographic test for qualitative detection of Covid-19 antigen in samples taken from swabs from throat, nose and tip of nose. This test reliably detect viral infection of all mutations of SARS-CoV-2 disease and provides good readable and accurate result in a short time.

Covid-19 IgG/IgM antibody test is an immunochromatographic test for qualitative detection and differentiation of IgG and IgM antibodies against SARS-CoV-2 disease from a sample of human blood, serum or plasma. This test reliably detects presence of antibodies against Covid-19 virus after overcoming the disease.

REF	Product name	
1035	Covid-19 antibody test IgG - IgM	1
1036	Rapid antigen test AG Covid-19	1

# Tests for professional use



Tests for professional use are intended for in vitro diagnostic use by professional medical workers in laboratories and medical clinics. These test are CE certified and feature high sensitivity and high specificity to guarantee a reliable result. Tests can be used for screening examination or preliminary diagnosis.

REF	Product name	Test type	$\Sigma$	Sensitivity
1034	Hemoglobin FOB test	Cassette	25	50ng hHb.ml <sup>-1</sup>
1052	H Pylori test	Cassette	25	150ng HP antigen.ml <sup>-1</sup>
1001	HCG test	Strip	50	25 mU.ml <sup>-1</sup>
1009	LH test	Strip	20	25 mU.ml <sup>-1</sup>
1013	Metamphetamine - meth test	Cassette	1	1000 ng.ml <sup>-1</sup>
1014	Cocaine test	Cassette	1	300 ng.ml <sup>-1</sup>
1015	THC Marijuana test	Cassette	1	50 ng.ml <sup>-1</sup>
1021	Multidrug test - 5 parameters MDMA, METH, BZO, MOR, THC	Dipcard	5	Individually
1041	Multidrug test - 10 parameters MDMA, METH, BZO, MOR, THC, AMP, BAR, COC, PCP, TCA	Dipcard	10	Individually
1051	Multidrug test - 6 parameters from saliva MDMA, METH, BZO, MOR, THC, COC	Test cup	6	Individually



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