
Diagnostic kits

# PRODUCT CATALOGUE

*LLC «Sivital» - quality and validity from the manufacturer.*

2016 / 2017

**CONTENT:**

**DESCRIPTION:**

# Diagnostic kits based on spectrophotometry

*Test system «BioLaktam»*

Antibiotic-resistance of bacteria is one of the most important and topical issues nowadays. Almost all known to science bacteria, which cause infectious diseases (with few exceptions) are more or less resistant to the various anti-infective preparations.


The most extensive and practically used group of anti-infective drugs is beta-lactam antibiotics, which are chosen in most infectious diseases: skin and soft tissue, bones and articulations, upper and lower airways, central nervous system, ENT-organs infections and other. In addition to, beta-lactams are included into treatment patterns of infective endocarditis, sepsis, neutropenic fever. They are also used to prevent bacterial complications in surgery and oncology.

Lack of impact in prescribing of beta-lactam antibiotics at bacterial infections can be connected with natural or acquired resistance of infectious agents to the medical products, that in 80% of cases is due to the antibiotic inactivation through synthesis of ferments (beta-lactamases) by bacteria. Apart from beta-lactamases of bacteria influence, destruction of beta-lactam antibiotics may occur by influencing blood plasma components (albumin, globulins). Albumin, globulin factions of human blood have their own beta-lactam activity, which can cause significant quantity of really used in clinical practice beta-lactam preparations decomposition, decreasing their clinical effectiveness thereby. This kind of resistance belongs to a biological one.

Optimum pH of beta-lactam blood activity is about 9,0. Herewith takes place anomalous rapid increase of the level of this activity at pH increase within the range 7,0 up to 8,0, creating the preconditions for sharp change of the level of beta-lactam blood activity at pathological states, accompanied by severe acidosis or alkali disease. In addition, beta-lactam activity of human blood increases fast with the body temperature growth and by patients with a high fever it can be significantly (up to 44,6%) higher, than by persons with a normal body temperature, that may lead to decrease of the clinical efficiency of beta-lactam antibiotics as well.

Test system allows to quantify the level of the «total» beta-lactam activity in biological fluids (blood serum, spinal fluid, urine, saliva, pleural and peritoneal fluids), an in biotic substrates as well, which can be used for transparent filtrate preparation (including phlegm and bacterial suspension), regardless of the fact of pure culture of disease agent extraction from the given biological material. The methodology of beta-lactam activity detecting with the test system «BioLaktam» is characterized by high sensitivity (70%), specificity (90%) and reproducibility. It is easy to use and based on the change of color of a synthetic antibiotic (chromogen substrate) from yellow to red-orange at breaking of its beta-lactam connection. Necessary for reaction equipment is only plate reader (from any manufacturers) and thermostate. All procedure of beta-lactam activity detection takes from 45 (at blood serum testing) up to 135 (for other substrates) minutes.

Test system «BioLaktam» is widely used in medical practice. Detection and quantifying of beta-lactam activity of blood serum, spinal fluid, saliva, phlegm, urine, pleural and peritoneal fluids using test system «BioLaktam» are necessary for prescription tactics identifying and also antibacterial therapy correction, which is conducted patients with various diseases of bacterial etiology (inflammation of the lungs, external pyocephalus, acutus quinsy, erysipelas etc.).

Test system «BioLaktam» allows to introduce an element of objectivity in the empirical causal treatment. Reasonable antibiotics prescription at the beginning phase of the treatment of severe bacterial infections makes possible to lessen the severity, to make prognosis better, to reduce complications, and also to decrease the cost of medicamentous therapy generally and significant money savings within 20-30%. In addition, rational prescribing of antibiotics prevents the appearance or increasing of antibiotic resistance in bacteria — agents of infectious diseases.

**Test system *BioLaktam allows*:**

- to define the cause of lack of impact of antibacterial therapy
- to change the tratment
- to choose an antibacterial preparation reasonable

**As a result:**
- decreases a possibility of complications
- shortens the duration of the treatment.
- decreases the frequency of unreasonable antibiotics change
- reduction of value of the therapy
- decrease of antibiotic resistance of bacteria

**Advantages of the test system BioLaktam:**
- Simplicity of performance
- Possibility to use in any laboratory of health facilities
- Minimal financial and time expenditures
- There are no analogs to this test system.

Test system is produced for 4 and 20 examinations.

# *Test system «D-Laktam»*

Test system D-Laktam is aimed to determine the level of D-2-hydroxypropanoic acid – dextrorotatory isomer of lactic acid. Production D-2- hydroxypropanoic acid in the human organism is on a very low level, its concentration in blood serum is measured in mcM in liter, while concentration of sinistrorotatory isomer (L-laktat) is measured in mmol in liter. Large increases in D-2- hydroxypropanoic acid concentration in sterile body fluids means total or local bacterial infection or absorption from the places, contaminated with copious amounts of bacterial pathogens.


Determination the concentration D-2-hydroxypropanoic acid in ascitic, pleural, cerebrospinal and synovial fluids can serve as a very specific and sensitive method for early bacterial infection detection, especially in comparison with bacterioscopic and culture research techniques.

An original design of test system D-Laktam for determination the existence and level of D-laktat in biotic fluids. The content of each matrass, which is part of this test system is optimized taking into account physical and chemical properties of the components, technological process of preparation and chemical and analytical format of tests execution phases. Linearity (value of accurate approximation) of the test system is 0,9992. QL (quantification limit, calculated on the criterion 3-σ is 0,0143 mM. Reproducibility of the test system for D-lactat detection is less than 10. Necessary for reaction equipment is plate reader (from any manufacturers) and thermostate.

Test system can be used in practical work of therapeutists, infection disease doctors, pulmonologists, gastroenterologists, pediatricians, urologists, nephrologists, in surgery practice.

**D-laktam can be used for:**
• Express diagnostics of bacterial and viral injuries of the central nervous system;
• Express identification of presence of bacteria in blood, pleural space fluid and ascetic fluid; in urina;
• Fast detection of bacteria in sterile solutions;
• Determination of optimal duration of antibiotics usage in surgical, gynecological, infectious bacterial disorders.

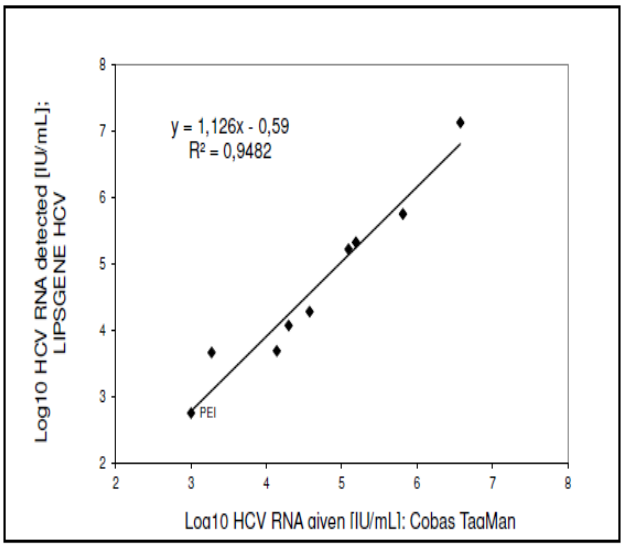
**As a result:**
• decreases a possibility of complications, shortens the duration of the treatment, decreases the frequency of unreasonable antibiotics prescription.
Advantages of test system *D-Laktam*:
• Simplicity of performance, high sensitivity and specificity;
• Possibility to use in any laboratory of health facilities, minimal financial and time expenditures.

Test system is produced for 1, 4 and 8 examinations.

# Diagnostic kits on the basis of PCR for genetic material of infectious agents detection

## *Test system for qualitative and quantitative determination of Hepatitis C Virus RNA*

The kit is intended for qualitative and quantitative determination of Hepatitis C Virus RNA detection (VHC) in human plasma or serum with EDTA or citrate in real time mode. VHC infection is the cause of most posttransfusion and sporadic hepatitis cases. A high frequency of progressive run of chronic hepatitis is observed.




The level of RNA VHC in blood serum or plasma can be used in combination with other markers and clinical data to differentiate acute and chronical infection HCV and response evaluation to the antiviral therapy.

Specificity of test system in VHC genotypes

| *Genotypes* | *HCV RNA (IU/mL)* | *HCV (FAM)* | *RC (ROX)* |
|---|---|---|---|
| 1a | $1.98 \times 10^5$ | + | + |
| 1b | $9.9 \times 10^4$ | + | + |
| 2a | $7.52 \times 10^4$ | + | + |
| 2b | $7.38 \times 10^4$ | + | + |
| 2c | $4.35 \times 10^4$ | + | + |
| 2i | $4.77 \times 10^4$ | + | + |
| 3a | $2.3 \times 10^4$ | + | + |
| 4 | $1.73 \times 10^5$ | + | + |
| 5a | $8.9 \times 10^4$ | + | + |
| 6 | $1.09 \times 10^5$ | + | + |

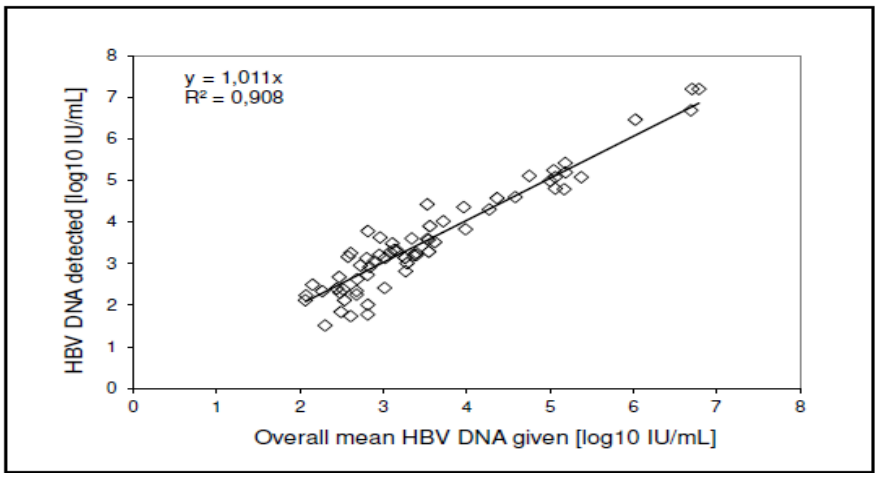
Test system can be used in any molecular genetic laboratories that perform investigations in real time mode.

Characteristics of test system for RNA of hepatitis C detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic RNA VHC<br>Plasma with VHC | ≥5 copies for a run<br>250 ME/ml |
| Linear response range | Synthetic RNA VHC | >8 logarithms |
| Repair frequency | Synthetic RNA VHC | 100% above 6 logarithms |
| Genotypes identification | Reference samples | 1a 1b 2a 2b 2c 2i 3a 4 5a 6 |
| Analytical specificity | Different RNA and DNA viruses | 100% |
| Diagnostic specificity | VHC negative plasma | 100% |
| Stability: frequency of system mistakes | VHS plasma | 0% |
| Equivalency of plasma and serum | VHS positive samples | 100% |

Test system is produced for 50 examinations.

# *Test system for qualitative and quantitative determination of Hepatitis B Virus DNA*




The kit is intended for qualitative and quantitative determination of Hepatitis B (VHB) Virus DNA in human plasma with EDTA or serum in real time mode. Chronic carriers of hepatitis B virus face a high risk of development of complications, including hepatic cirrhosis and cancer. The level of VHB DNA in plasma or serum can be used in combination with other clinical data and markers to differentiate acute and chronical VHB infection and response evaluation to the antiviral therapy.
It is accepted that viral load ≥ 2000 ME in ml potentially requires treatment.

Test system can be used in any molecular genetic laboratories that perform investigations in real time mode.

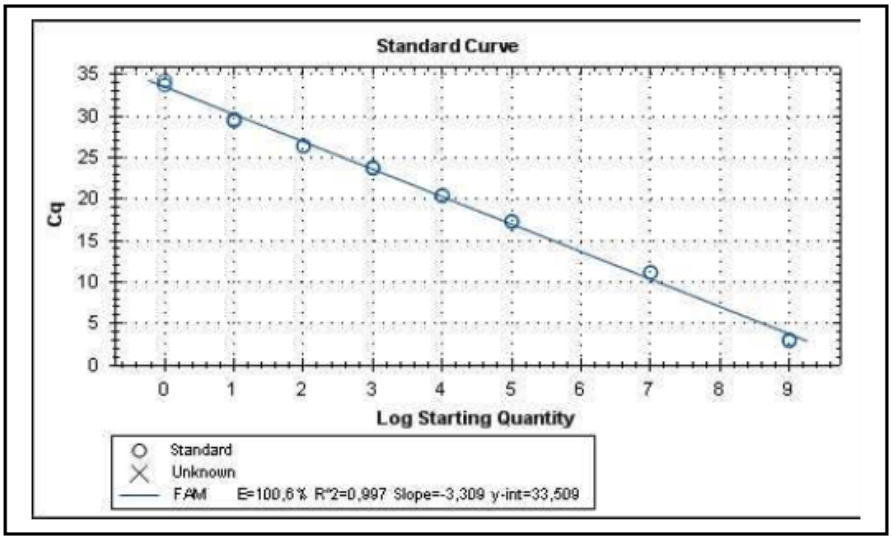
Characteristics of test system for DNA of hepatitis B virus detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic DNA VHB<br>Plasma with c VHB | ≥5 copies for a run<br>78 ME/ml |
| Linear response range | Synthetic DNA VHB<br>Plasma with VHB | 9 logarithms<br>6 logarithms |
| Repair frequency | Synthetic DNA VHB | 100% above 6 logarithms |
| Analytical specificity | Different RNA and DNA viruses | 100% |
| Diagnostic specificity | VHB negative plasma | 100% |
| Stability: frequency of system mistakes | VHB plasma | 0% |

Test system is produced for 50 examinations.

## *Test system for qualitative and quantitative determination of Hepatitis D Virus RNA*

The kit is intended for qualitative and quantitative determination of Hepatitis D Virus (VHD) RNA in serum, plasma, amniotic or synovial fluid in real time mode. Discovered by Mario Rizzetto in the late 1970s hepatitis delta virus consists of round single-stranded RNA ranging from 1672 up to 1697 nucleotides and, consequently,




it is one of the smallest from all known human pathogen viruses.

Viroid codes a single nuclear phosphoprotein, delta antigen (HDAg), which is useful for virus replication while presence of surface antigen of hepatitis B virus (HBsAg) is necessary for its assemble and transmission. There are two main ways of VHD infection transmission: simultaneous hepatitis B and D virus infection, and superinfection in carriers HBsAg. Superinfection VHD of carriers HBsAg usually has chronical run with more significant and rapid progression of hepatic diseases, than in case of VHB monoinfection. The virus is endemical all over the world and therefore about 5% hepatitis B virus carriers are anti-VHD positive. Believe that about 10 - 15 million people are affected by $VHD_3$. At the level VHD RNA>1-2x$10^5$ copies / ml can be predicted treatment failure.

Characteristics of test system for RNA of hepatitis D virus detection

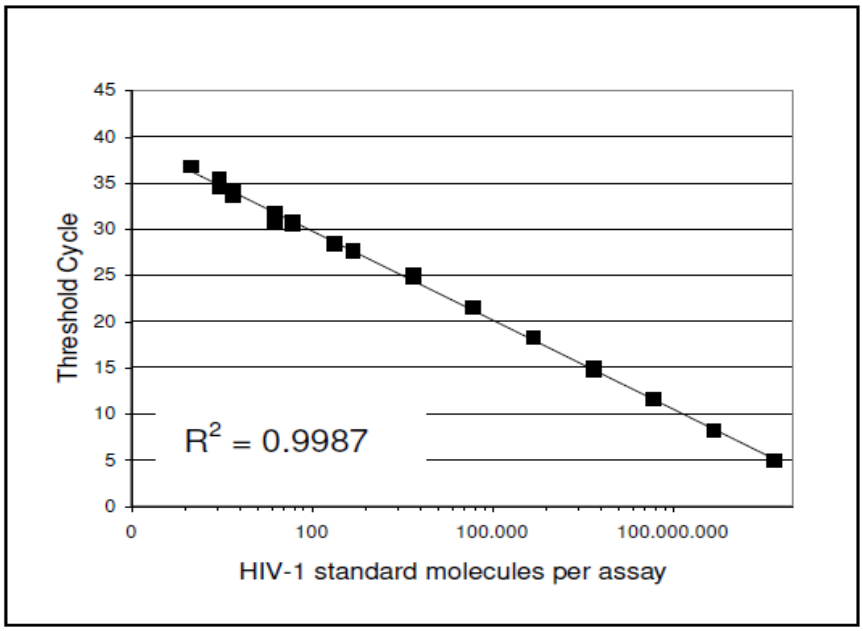
| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic RNA VHD<br>Plasma with VHD | ≥10 copies for a run<br>500 ME/ml |
| Linear response range | Synthetic RNA VHD | >8 logarithms |
| Genotypes identification | Reference samples | 1-8 |
| Analytical specificity | Different RNA and DNA viruses | 100% |
| Diagnostic specificity | VHD negative plasma | 100% |

Test system can be used in any molecular genetic laboratories that perform investigations in real time mode.

Test system is produced for 50 examinations.

## *Test system for qualitative and quantitative determination immunodeficiency virus RNA*

The kit is intended for qualitative and quantitative determination of human immunodeficiency virus 1 RNA detection (HIV-1) in samples of human plasma or serum with EDTA.
HIV is RNA virus and belongs to the retrovirus family in real time mode.
During replication of its genom HIV is integrated into genom of host cell as provirus DNA. It mutates intensively and shows a high level of gene variety. HIV-1 of subtype B prevails in Western countries. Level RNU HIV-1 in serum and plasma can be used in combination with other markers and clinical data to differentiate acute and chronical HIV-1 infection and response evaluation to the antiviral therapy.




Characteristics of test system for immunodeficiency virus RNA detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic RNA HIV<br>Plasma with HIV | ≥10 copies for a run<br>300 ME/ml |
| Linear response range | Synthetic RNA HIV | >8 logarithms |
| Genotypes identification | Reference samples | A B C D1 D2 D3 E1 G H |
| Analytical specificity | HIV negative samples | 100% |
| Diagnostic specificity | HIV negative plasma | 100% |

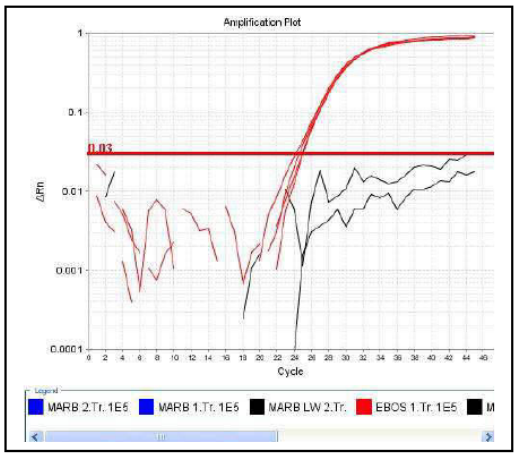
Test system is produced for 50 examinations.

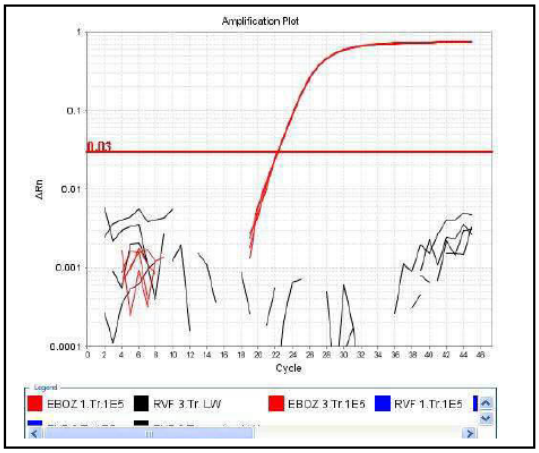
# *Test system for qualitative and quantitative Ebolavirus RNA determination*

The kit is intended for qualitative and quantitative determination of Ebolavirus RNA in serum, plasma, amniotic or synovial fluids in real time mode. Ebola haemorrhagic fever is one of the most virulent diseases known to humankind. Ebolavirus was first identified in Western Equatoria state of Sudan and in adjacent area of Zaire (nowadays Democratic Republic of the Congo) in 1976 after major epidemics in southern Sudan and in northern Zaire. There are five different kinds of Ebolavirus: Bundibujo, Côte d'Ivoire, Reston, Sudan and Zaire. Kinds Bundibujo, Sudan and Zaire were connected with major outbreaks in Africa that led to death 25-90 % of all persons with clinical symptoms, in contrast to the kinds Côte d'Ivoire and Reston. Ebolavirus is directly contagious on contact with blood, fluids and tissues of the body of infected persons. Transmission of Ebolavirus also occurs via contact with ill or dead contaminated wild animals (chimpanzees, gorillas, monkeys, bushbucks, fruit bats). Main treatment is disease-management therapy.

Characteristics of test system for Ebolavirus RNA detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic RNA | ≥10 copies for a run |
| Linear response range | Synthetic RNA | >8 logarithms |

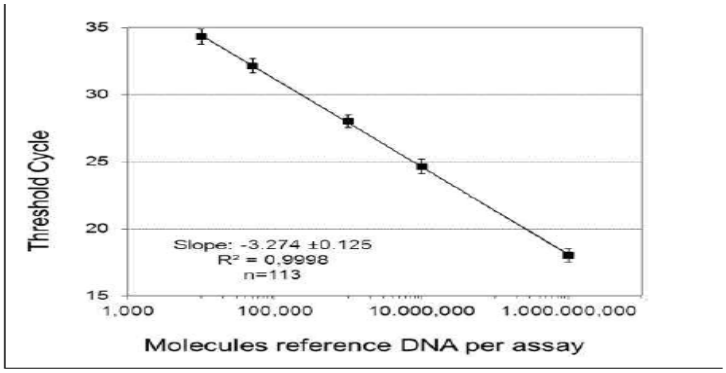



Test system is produced for 50 examinations.

# *Test system for qualitative and quantitative determination of Epstein-Barr virus DNA*

The kit is intended for qualitative and quantitative determination Epstein-Barr virus DNA (EBV) in human blood or tissue specimen in real time mode.



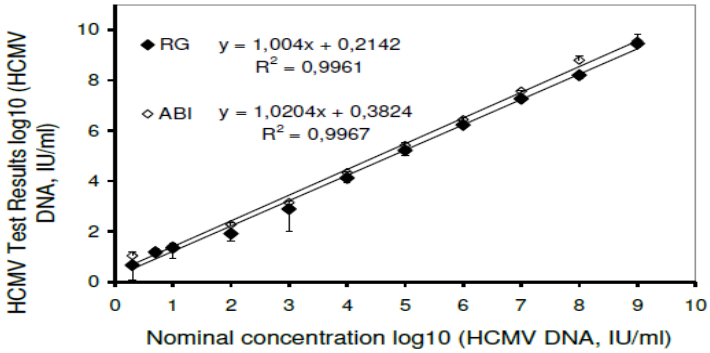

EBV is involved in aetiopathogenesis of large number of tumors, including non-Hodgkin B-cell lymphoma and Burkitt lymphoma. Detection / quantitation EBV in samples is relevant, as its high prevalence in some tumors makes the virus a prospective monitoring object for successful specific therapy. Teat system can be used in any molecular genetic laboratories that perform investigations in real time mode. Test system is produced for 50 examinations.

Characteristics of test system for DNA of Epstein-Barr virus detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic DNA EBV<br>Reference plasma | ≥10 copies for a run<br>5000 copies/ml |
| Linear response range | Synthetic DNA EBV | >6 logarithms |
| Analytical specificity | EBV negative samples | 100% |

# *Test system for qualitative and quantitative determination of cytomegalovirus DNA*

The kit is intended for qualitative and quantitative determination of human cytomegalovirus (CMV) DNA in human plasma with EDTA or serum in real time mode.




Quantifying of the virus covers a diversity of diagnostic purposes. Besides its usage as a diagnostic instrument it is a CMV infection prognostic marker, a therapeutic marker for antiviral therapy successfulness monitoring and for contagiosity evaluation.

Characteristics of test system for cytomegalovirus DNA detection

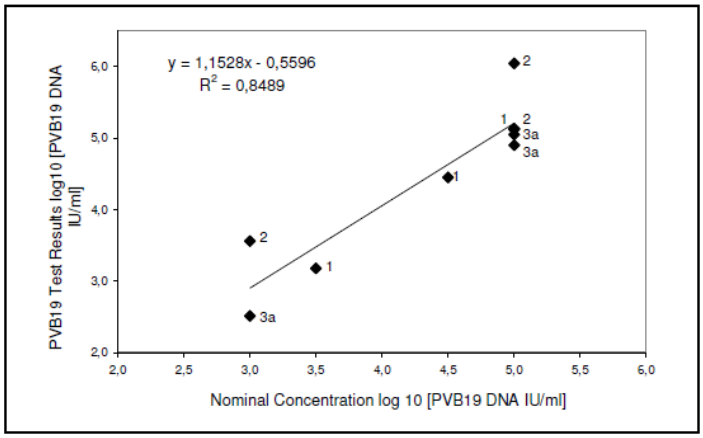
| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic DNA CMV<br>Control with CMV | ≥2 copies for a run<br>500 ME/ml |
| Linear response range | Synthetic DNA CMV | >8 logarithms |
| Analytical specificity | CMV negative samples | 100% |
| Diagnostic specificity | CMV negative samples | 100% |

Test system can be used in any molecular genetic laboratories that perform investigations in real time mode.

Test system is produced for 50 examinations.

# Test system for qualitative and quantitative determination of parvovirus B19 DNA

The kit is intended for qualitative and quantitative determination of parvovirus B19 (PVB19) DNA in serum, plasma, amniotic or synovial fluid in real time mode.




Over the last 10 years it has been determined that one of the causes of anemia, inflammatory arthropathy and nephropathy is the pre-existing parvovirus infection. Main target cells for PV B19 are erythroblasts and their differentiation into erythrocytes after virus contamination gets broken, that leads to decrease of erythrocytes in blood. Immune-compromised patients, who are not able to develop neutralizing antibodies, PV B19 can cause chronic anaemia.

In adults, unlike children, arthralgia and inflammatory arthropathy are often indicators of primary parvovirus B19 infection (60% of women and 30% of men are effected). Arthral symptoms occur as acutus peripheral polyarthritis, affecting metacarpophalangeal joints (75%); knees- (65%), wrists (55%) and ankles (40%), herewith arthral damage (erosion) is non-existent. In 50% patients, suffering from chronical parvovirus arthopathy, the disease meets the criteria of diagnostics of rheumatoid arthritis of the American Association of Rheumatology.

Detection of DNA PV B19 is recommended at suspicion on parvovirus infection in pregnantwomen, in patients with severe anaemia, cardiomyopathy, immunological suppression. Detection PV B19 DNA in synovial fluid is recommended in patients with arthritis. Detection PVB19 in clinical samples is important in monitoring of specific therapy successfulness.

Parvovirus B19 is thermoresistant, that is why infection contamination is possible also at transfusion of preparates, obtained in result of donated blood processing. It is

shown that degree of incidence PV B19 among donors worldwide varies between 0,003% and 1,3%.

Test system can be used in any molecular genetic laboratories that perform investigations in real time mode.

Characteristics of test system for parvovirus B19 DNA detection

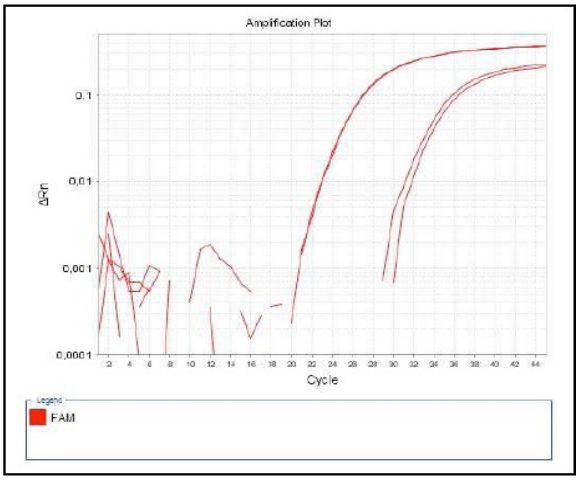
| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic DNA PVB19 | ≥10 copies for a run |
| Linear response range | Synthetic DNA PVB19 | >6 logarithms |
| Genotypes identification | Reference samples | 1 2 3a 3b |
| Analytical specificity специфичность | PVB19 negative samples | 100% |
| Diagnostic specificity | PVB19 negative plasma | 100% |

Test system is produced for 50 examinations.

# *Test system for qualitative and quantitative determination African swine fever DNA*

The kit is intended for qualitative and quantitative determination African swine fever DNA in serum, plasma, organs, long bones and pork products in real time mode.
Test system contains positive and inside controls.
Analytical sensitivity of the test system is not less than $10^{-4}$ of reference sample dilution, validated in SI Belgosvetcentr. Sensitivity of the test system is not less than 100% (for $10^{-4}$ of reference sample dilution, validated in SI Belgosvetcentr – not less than 5 samples). Slope of tenfold dilutions of reference sample, validated in SI Belgosvetcentr (not less than 4 dilutions) is within the range -3.00...-3,66 (optimum is -3,33). According to these specificity and sensitivity parameters the developed test system is far beyond the available in the world anologs, that allows to use it for solution of epizoology questions and evaluation of pork products quality as well.

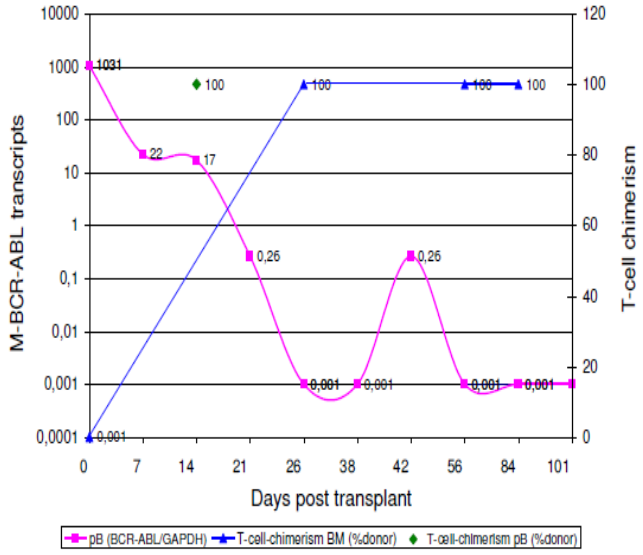
Test system is produced for 50 examinations.



# Diagnostic kits for detecting oncogenicity genes expression

## *Test system for detecting gene expression M-BCR/t(9;22)*

The kit is intended for quantitative detection of merge BCR-ABL and transcripts to DNA, containing (Ph+) of t translocation (9; 22) in main critical points of region




cluster (M-BCR) b2a2 and b3a2, respectively, in RNA or mRNA samples, prepared of native or cleaned human white blood cells, received from blood or bone marrow through aspiration.

BCR gene (Breakpoint Cluster Region) or false point cluster zone, also known as kidney cancer antigen NY-REN. BCR is one of two genes in the complex BCR-ABL that is connected with Ph chromosome. A normal gene BCR is localized in a long arm of the 22nd chromosome. These days is known, that the normal gene BCR, codes two main proteins. The proteins, coded by this gene, have serine-trenine kinase activity and are guanosine triphosphate activating proteins as well.

Recent studies led to a new appreciation of diffucult functions of a normal gene BCR and BCR-ABL chimaera organization that allowed to ground new treatment principles of patients with Ph chromosome-positive leukosis.

Quantitative detection using real time PCR M-BCR and m-BCR in whole blood samples and in cleaned leucocytes or bone marrow aspirate is one of diagnostic maneuvers for chronic myeloid leukemia associated with Ph chromosome and acute

B-lymphoblastic leukemia diagnosis for proof of necessity of treatment with imatinib and for treatment effectiveness control and minimal residual disease detection.

Characteristics of test system for M-BCR/t(9;22) detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic DNA M-BCR-ABL<br>K562 cDNA | ≥5 copies for a run<br>1 tumour cell for $10^6$ leucocytes |
| Linear response range | Synthetic DNA M-BCR-ABL | 5 logarithms |
| Diagnostic specificity | cytogenetics / cDNA of pacient with CML | Correlation between level Ph+ and BCR-ABL transcripts<br>BM 0.731, p<0.001<br>PB 0.7684, p<0.001 |
| Stability: frequency of system mistakes | K562 cDNA | 0% |

Test system can be used in any molecular genetic laboratories that perform investigations in real time mode.

Test system is produced for 50 examinations.

## *Test system for detecting gene expression HER2/NEU*

The kit is intended for quantitative determination of HER2/NEU transcripts. Oncogene originally named as NEU was obtained from cell line of neuro/ glioblastoma of rats and codes tumour antigen that is serologically similar to ecderonic growth factor receptor.

HER2 was named as such because it has an analogical structure of human receptor of ecderonic growth factor or HER1. Neu is so called because it was obtained from glioblastoma cells of gnawing animals neural tumor. ErbB-2 was so named as it has a similarity to ErbB (bird oncogene B erythroblastosis), oncogene that was found later

for EGFR coding. Genes cloning has shown that HER2-Neu and ErbB-2 are coded by one gene.

Hyperexpression HER2-NEU is diagnosed in 25–30% cases of breast cancer, moreover in 90–95% cases hyperexpression HER2-NEU is a direct result of gene ErbB–2 amplification. Preclinical and clinical studies demonstrate that amplification and/or Hyperexpression HER2 are of key value in oncotransformation and tumorigenesis of breast cancer. Hyperexpression HER2-NEU in a tumor cell correlates with a range of poor prognosis factors, and namely: size of tumour, high malignance level, decrease of estrogen and progesterone receptors in the tumor. As a result of a substantial range of studies was shown that hyperexpression HER2/neu is an independent predictor for breast cancer with N+ и N–.

Excess expression is also detected in ovarian cancer, stomach cancer, aggressive forms of uterine cancer, especially serosal endometrial cancer.

Nowadays are developed and widely used medicine remedies, which effect is based on inhibition of the signaling pathway triggered by HER2-NEU receptor. A monoclonal preparate trastuzumab works only in tumors with HER2 hyperexpression. An important impact of trastuzumab is protein p27 increase that stops cell proliferation. Another monoclonal preparate, pertuzumab, that inhibits HER2 and HER3 receptors dimerization, was approved by FDA for usage in combination with trastuzumab in June 2012.

HER2 testing is necessary to conduct in breast cancer patients in order to assess prognostication and determine the need for trastuzumab therapy. As a rule, the testing is made while examination tumor cores, obtained after needle core biopsy or surgical treatment and blood plasma examination, especially in dispensary observation of patients.

Characteristics of test system for HER2/NEU detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic DNA HER2/NEU | ≥5 copies for a run |
| Linear response range | Synthetic DNA HER2/NEU | >5 logarithms |

Test system is produced for 50 examinations. Test system can be used in any molecular genetic laboratories that perform investigations in real time mode.

# *Test system for detecting gene expression Survivin*

The kit is intended for quantitative overall estimate of survivin transcripts (IAPs), including all known splicing variants in RNA / mRNA samples.

Survivin is –family member of apoptosis inhibitors (IAP). IAP family members usually contain some baculovirus IAP repeats (BIR) domains, but this gene codes proteins with a single domain BIR. In this connection survivin is also named a baculovirus protein thaz is coded in human with BIRC5 gene. Expression of BIRC5 genes is high in utero and in most tumours. Survivin gene expression is regulated by cell cycle and expressed in phases G2–M.It is known that survivin can play the supportive role in regulating mitosis.

The main function of the survivin protein is to stop a caspase activity of cell apoptosis, thus inhibiting apoptosis. Survivin protein may be regarded as oncogene, since its overexpression in most cancer cells contributes to their resistance to apoptotic stimulations and chemotherapy treatment methods, thus contributing to their continuing survival and progressing.

Survivin is undetectable in terminally differentiated tissues of adults and in normal mononuclear cells of peripheral blood, while it is significantly expressed in transformed cell lines and in all most common oncological diseases of: lung, large bowel, pancreas, prostate, breast and T-cell leukemia in adults. It has been shown that survivin expression is an adverse prognostic factor in acute myelogenous leukemia and soft tissue sarcoma. Inverse correlation between mRNA Survivin level in soft tissue sarcoma is connected with 2,7 –fold increase of the risk of dying from tumour. It is determined that coexpression of survivin and reverse transcriptase of human telomerase (TERT) is a significant negative prognostic factor for patients with stage 1-4 soft tissue sarcoma leading to 20-fold increase of a relative risk of dying from tumour. An important moment in clinical practice of survivin expression determination is its synergistic activity with other oncoproteins. It is determined that cells of breast cancer – hyperexpressing ErbB2 – had higher level of survivin, that correlated with suppression via Taxol-triggered apoptosis. Combination of Taxolwith survivin leads to increased apoptosis in ErbB2-overexpressing breast cancer cells рака, than Taxol monotherapy.

Characteristics of test system for survivin detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic DNA Survivin | ≥5 copies for a run |
| Linear response range | Sznthetic DNA Survivin | >5 logarithms |

Test system is produced for 50 examinations.

## *Test system for c-ABL gene expression detecting*

The kit is intended for quantitative determination cDNA transcript C-ABL in RNA or mRNA samples, prepared of native or cleaned human white blood cells, received from blood or bone marrow through aspiration. It is determined that c-ABL gene expression has the highest correlation with some transcripts cDNA, for instance, including Ph+ translocations t(9, 22). When their quantity is measured in the same cDNA samples, this allows to confirm RNA integrity of the analyzed sample and to adjust RNA load, cDNA synthesis efficiency, PCR inhibition and possible loss of the sample during long storing as well. In accordance with the recommendations of the program Europe Against Cancer (EAC) c-ABL is a reference gene for metastasis process of leukemia diagnostics.

Characteristics of test system for c-ABL gene expression detection

| *Characteristics* | *Sample* | *Productiveness* |
|---|---|---|
| Analytical sensitivity | Synthetic DNA c-ABL | ≥5 copies for a run |
| Linear response range | Synthetic DNA c-ABL | 5 logarithms |
| Stability: frequency of system mistakes | K562 cDNA | 0% |

Test system can be used in any molecular genetic laboratories that perform investigations in real time mode.
Test system is produced for 50 examinations.