

# ELISA and PCR kits

## CATALOG



Hormonal  
Diagnostics



Infection  
Diagnostics



Tumor  
Markers



Allergy  
Diagnostics



Molecular-Genetic  
Diagnostics



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## HORMONAL DIAGNOSTICS

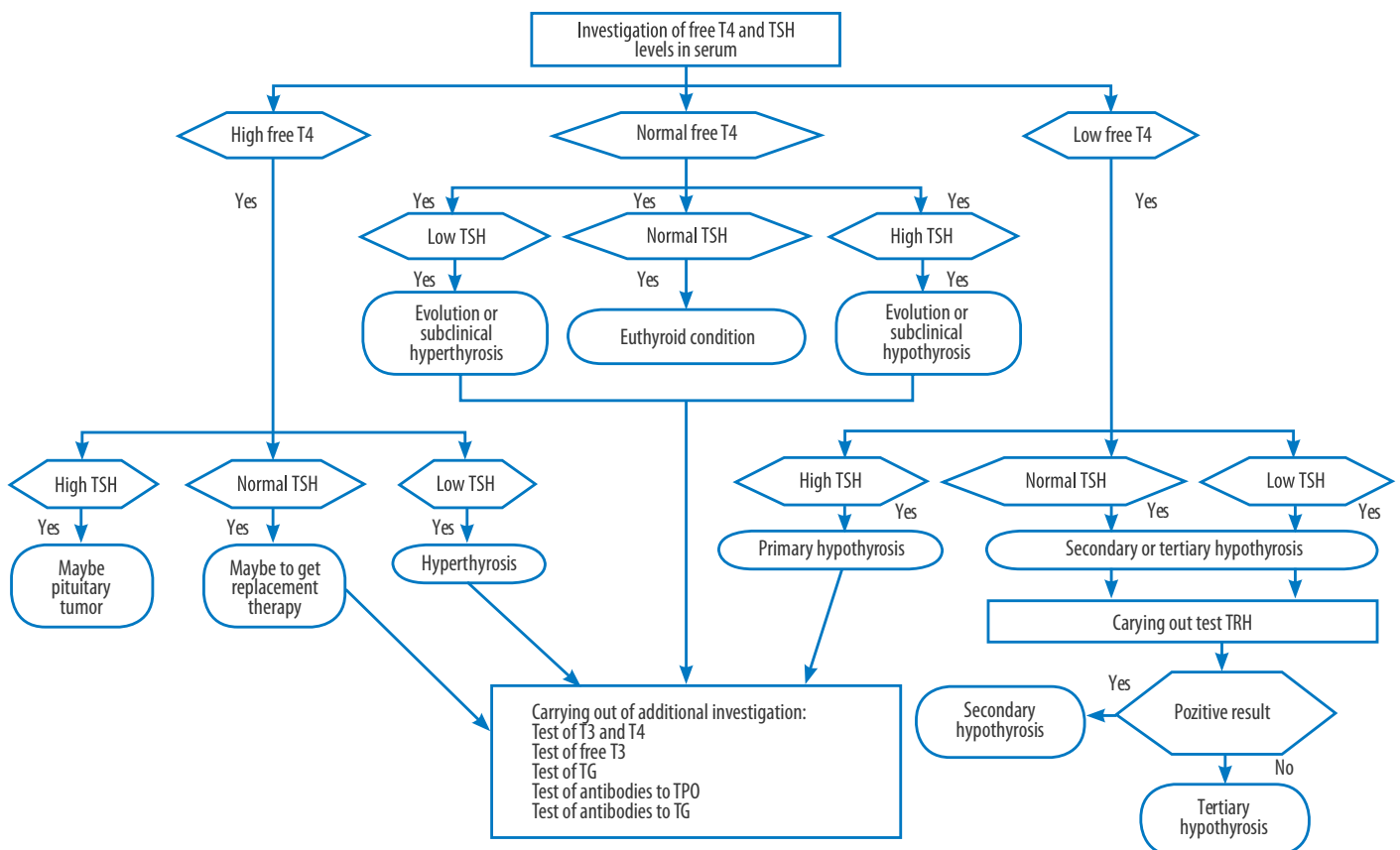
### Thyroid

The thyroid gland develops such hormones as thyroxin (T4) and triiodthyronine (T3). In blood the most part of hormones of the thyroid gland is in the connected condition with carrier protein. They are inactive, during too time the small free fraction of hormones is active and carries out their functions. Thyroid gland function is under the control of hypothalamo- pituitary systems. Thyreotropin-riizing hormone is synthesized in hypotalamus (TRH). This hormone in pituitary stimulates formation of thyreotrophin hormone (TSH), which stimulates activity of a thyroid gland and formation T4 and T3.

Practically, thyroid gland's hormones participate in all processes of organism, regulate the metabolism, synthesis of vitamins (vitamin A in the hepar), and also take part in realization of other hormones' function in all organism. Thyroid gland diseases are accompanied both decrease and increase of its function.

Diagnostics of thyroid gland's diseases is based on research of its functions by special laboratory methods, basic of which is ELISA. The first stage of laboratory diagnostics of thyroid gland's function is definition of thyreotrophin hormone (TSH) and free thyroxin (T4) level. At low TSH level and normal free T4 level specialists define quantity of free triiodthyronine (free T3). It is necessary to define autoantibodies for thyroglobulin (abTG) and autoantibodies for thyroid peroxidase (abTPO) in addition to definition of thyroid gland's hormones' level for exception of autoimmune pathologies. In the diagnostic purposes specialists recommend to investigate these markers in a complex: abTG + abTPO. Other laboratory tests are carried out on orders for differential diagnostics of thyroid gland's diseases.

### Algorithm of results rating TSH and free T4 definifon\*



\* Kishkun A.A. Hormonal and genetic investigations in clinical practice. - Moscow, Labora. - 2007. - 400 p.

## ThyroidEIA-TSH

**Nº 100-11**  
Page 32

Thyroid-stimulating hormone (TSH) is a glycoprotein with a molecular weight of about 30 000 Da, that consists of two subunits – alpha and beta. TSH is secreted by frontal lobe of pituitary gland and stimulates thyroxin and triiodothyronine synthesis in thyroid gland. TSH assay is important in evaluation for thyroid status.

ThyroidEIA-TSH kit is intended for the quantitative determination of thyroid stimulating hormone in human serum.

## ThyroidEIA-TSH (third generation)

**Nº 100-23**  
Page 32

This kit has high sensitivity. It is recommended to use for definition of low concentration TSH.

ThyroidEIA-TSH (third generation) kit is intended for the quantitative determination of low concentrations of thyroid stimulating hormone in human serum.

## ThyroidEIA-free T4

**Nº 100-09**  
Page 33

Thyroxin (T4) is one of the thyroid gland hormones with a molecular weight of 777 Da. Quantitative determination of serum free thyroxin is significant for evaluation of thyroid gland function.

The bulk of serum T4 persists in protein-bound form. The main T4-binding proteins are thyroxin-binding globulin (TBG), thyroxin-binding pre-albumin and albumin. Concentration of non-bound form of T4 (freeT4) is very low, approximately 0,03% of the total concentration of circulating hormone. Namely free T4 is considered to be responsible for biological activity of the hormone. Free T4 concentration does not depend on the concentration of binding proteins and remains

normal when TBG levels are either increased (e.g. due to congenital pathology, pregnancy, intake of estrogens and oral contraceptives) or decreased (e.g. due to congenital pathology, administration of androgens and salicylates, renal insufficiency) and when the binding capacity of the proteins is diminished due to salicylates treatment. So, free T4 level adequately reflects the actual thyroid status. Concentration of free T4 is above normal in patients with thyroid hyperfunction or after intake of thyroxin preparations; it is below normal in the case of thyroid hypofunction.

ThyroidEIA-free T4 kit is intended for the quantitative determination of free thyroxin in human serum.

## ThyroidEIA-free T3

**Nº 100-36**  
Page 33

Triiodothyronine (T3) is one of the thyroid gland hormones with a molecular weight of 651 Da. Quantitative determination of serum T3 is significant for evaluation of thyroid gland function.

Concentration of non-bound form of T3 (free T3) is very low, approximately 0,1-0,3% of the total concentration

of circulating hormone. Free T3 concentration does not depend on the concentration of binding proteins.

ThyroidEIA-free T3 kit is intended for the quantitative determination of free triiodothyronine in human serum and plasma .

## ThyroidEIA-Triiodothyronine

**Nº 100-08**  
Page 33

Triiodothyronine (T3) is one of the thyroid gland hormones with a molecular weight of 651 Da. Quantitative determination of serum triiodothyronine is significant for evaluation of thyroid gland function.

ThyroidEIA-Triiodothyronine kit is intended for the quantitative determination of triiodothyronine in human serum.

## ThyroidEIA-Thyroxin

**Nº 100-10**  
Page 34

Thyroxin (T4) is one of the thyroid gland hormones with a molecular weight of 777 Da. In overwhelming majority of cases at clinically expressed hyperthyroidism maintenance T4 in blood is raised, and at hypothyroidism is lowered.

ThyroidEIA-Thyroxin kit is intended for the quantitative determination of total thyroxin in human serum.

## ThyroidEIA-Anti-TPO

**Nº 100-13**  
Page 34

Autoimmune antibodies against thyroid peroxidase (Anti-TPO) are mainly IgG and, in less extent, IgM. TPO is a key enzyme in the biosynthesis of thyroid hormones. In healthy individuals, concentrations of Anti-TPO in serum may reach 30 U/ml.

Quantitatively, exceeding this limit is the sign of an autoimmune process that usually leads to thyroid dysfunction, mainly due to reduced thyroxin secretion.

Quantitative determination of Anti-TPO antibodies in serum is used for diagnosis of autoimmune thyroid diseases, such as idiopathic myxoedema, Hashimoto's thyroiditis and Graves's syndrome.

ThyroidEIA-Anti-TPO kit is intended for the quantitative determination of autoimmune antibodies against thyroid peroxidase in human serum.

## ThyroidEIA-Anti-TG

**Nº 100-12**  
Page 34

Autoantibodies against thyroglobulin (Anti-TG) are mainly IgG and, less frequently, IgA and IgM. Anti-TG concentration in serum of healthy people may reach 65 U/ml. Level exceeding this threshold is a symptom of the autoimmune disorder that usually leads to the thyroid gland dysfunction. Quantitative determination

of Anti-TG in human serum is useful in the diagnostics of autoimmune thyroid diseases (Hashimoto thyroiditis, idiopathic myxoedema, Graves disease).

ThyroidEIA-Anti-TG kit is intended for the quantitative determination of autoantibodies against thyroglobulin in human serum.

## ThyroidEIA-TG

**100-29**

Page 35

Thyroglobulin (TG) is the main protein produced by thyroid gland. It is the precursor and the deposit form of thyroid hormones thyroxin (T4) and triiodothyronine (T3). TG is an iodinated glycoprotein with a molecular weight of 660 KDa that consists of two subunits.

TG concentration in serum depends on mass of thyroid gland, its functional status and degree of inflammation. In healthy people TG concentration varies from 2 to 50 ng/ml and may increase about twofold during the pregnancy. After surgical operation or treatment with radioactive iodine TG concentration remains increased for several weeks. In the population suffering from environmental iodine deficiency mean TG concentration in blood is increased. Since 1994 TG has been regarded by WHO as one of the indicators of endemic goiter.

Serum TG measurement is performed mostly for monitoring of thyroid carcinoma patients. Dynamics of TG concentration is used as a marker for evaluation of treatment efficiency, revealing of possible recurrence and metastases in patients after thyrectomia. This parameter is not used for primary diagnostics of thyroid cancer.

TG concentration in serum may be useful for exact diagnostics in the case of congenital hypothyroidism. Increased TG concentration permits to differentiate subacute thyroiditis from pharmacological thyrotoxicosis (when TG level remains stable). In patients with Grave's disease increase in TG concentration is a preliminary sign of recurrence after canceling of suppressive therapy.

TG measurement may be affected by presence of anti-TG autoantibodies in the serum sample. In this case the results may be false-negative. To obtain the reliable results it is recommended always to combine TG and anti-TG autoantibodies determination.

Serial TG determinations for patient monitoring should be always done by the same method. The physician should be always informed not only of the results of TG determination but also of the type of assay used. When the type of diagnostic kit is changed, the laboratory must perform the appropriate clinical evaluation and compare the range of the results obtained with two types of kits.

ThyroidEIA-TG kit is intended for the quantitative determination of thyroglobulin in human serum.

## Neonatal Screening

Neonatal screening is mass inspection of newborn children for the purpose of early diagnosis of congenital diseases. It allows to define these diseases and to spend a number of medical actions to stop the development of serious disorders during the time. Neonatal screening includes investigation for congenital hypothyroidism. The level of TSH (thyrotropin) is used for diagnosis of hypothyroidism.

## NeonatalEIA-TSH

**100-15**Page 35  
192 tests

Thyroid-stimulating hormone (TSH) is a glycoprotein hormone with a molecular weight of about 30 000 Da, that consists of two subunits – alpha and beta. TSH is secreted by the frontal lobe of the hypophysis and stimulates the thyroxin and triiodothyronine synthesis in the thyroid gland.

concentration decreases in several days after birth and then remains stable at the normal level ( $< 20 \mu\text{IU/ml}$  of blood). The increased TSH concentration in the blood of newborn on 3rd-5th day of life is the earliest diagnostic indicator of the congenital primary hypothyroidism.

**100-16**Page 35  
960 tests

A sharp increase of TSH concentration in blood is detected in the newborns just after the birth. If a thyroid gland function of the newborn is normal, TSH

NeonatalEIA-TSH kit is intended for the quantitative determination of thyroid-stimulating hormone in dry spots of blood of newborns.

## Fertility

Analysis of reproductive function consists of estimation of level of sex and hypophysis hormones. The hormones of hypophysis are responsible for regulation of synthesis of sex hormones. Sex hormones are produced by the sex glands and adrenal cortex. They can be divided into three groups: androgens (testosterone), estrogens (estradiol) and gestogens (progesterone). The hormones of hypophysis are luteinizing hormone (LH), follicles-stimulating hormone (FSH) and prolactin.

### SteroidEIA-Progesterone

**Nº 100-02**  
Page 36

Progesterone is a steroid hormone with a molecular weight of 314 Da. The quantitative measurement of serum progesterone is a valuable tool for evaluation of corpus luteus functional status. It is also used in pregnancy surveillance and may be performed for investigational purposes.

SteroidEIA-Progesterone kit is intended for the quantitative determination of progesterone in human serum.

### SteroidEIA-Testosterone

**Nº 100-03**  
Page 36

Testosterone is a steroid hormone with a molecular weight of 288,4 Da. Testosterone is synthesized mainly in testicles and, in sufficiently less extent, in ovaries and adrenal cortex. The determination of serum testosterone is a valuable tool for investigation of testis function and diagnostics of some adrenal, ovary and testicle tumors as well as female hirsutism.

SteroidEIA-Testosterone kit is intended for the quantitative determination of testosterone in human serum.

### SteroidEIA-SHBG

**Nº 100-30**  
Page 36

Sex hormones binding globulin (SHBG) (also known as sex steroids binding globulin – SSBG) is a serum protein that binds to steroid sex hormones. SHBG is synthesized in the liver. It is a dimeric glycoprotein with a molecular weight of 80 to 100 kDa (depending on the degree of glycosilation).

Steroid hormones circulate in blood partly in their free form and partly as a complex with albumin and corresponding specific protein (SHBG in the case of sex steroids). Fraction of sex steroid hormone that is not bound to SHBG (so-called bioavailable hormone) can perform the regulatory function in the target cells. Steroids that bound to albumin are also bioavailable, because in this case the bound is weak and does not block the diffusion of the hormone into target cells.

SHBG shows maximal affinity to androgens and less – to estrogens. The synthesis of SHBG is affected by sex steroids. Estrogens show stimulating effect, whereas androgens inhibit the synthesis.

In healthy individuals SHBG concentration may vary over a wide range. In general, its concentration in

women is higher than in men. SHBG concentration increases in the case of hyperthyroidism or hyperestrogenia (luteal phase of the cycle, pregnancy, intake of estrogencontaining oral contraceptives, cyrrhosis etc.). In adult men the concentration of bioavailable testosterone decreases with age due to increased concentration of SHBG. In women decreased concentration of SHBG correlates with hyperandrogenic status (polycystic ovary syndrome, congenital dysfunctions of adrenal cortex, hirsutism). Moderate decrease in SHBG concentration is also observed in the case of hypothyroidism, Cushing disease, hyperprolactinemia, acromegalia and after the treatment with androgens or progestins that have androgenic effect.

SHBG concentration is used for calculation of free androgen index (ratio between concentrations of total testosterone and SHBG).

SteroidEIA-SHBG kit is intended for the quantitative determination of sex hormones binding globulin (SHBG) in human serum.



## EIA-Prolactin

№ 100-04

Page 37

Prolactin is a single-chain protein hormone with a molecular weight of about 23 000 Da. It is synthesized in the frontal lobe of pituitary gland. The determination of prolactin is a valuable tool in diagnostics of testicular and ovarian dysfunctions. Hyperprolactinemia in women may lead to galactorrhea, amenorrhea and other distortions in menstrual cycle. In men it may result in impotence or loss of libido. Measurement of circulating prolactin is used as a primary test for barrenness.

Pathological hyperprolactinemia takes place in the case of hypothyroidism, renal insufficiency and in patients with a pituitary gland tumor - prolactinoma. Physiological increase of prolactin level takes place during the gestation, lactation, in sleep and after physical and emotional stress.

EIA-Prolactin kit is intended for the quantitative determination of prolactin in human serum.

## GonadotropinEIA-LH

№ 100-05

Page 37

Luteinizing hormone (LH) is a glycoprotein with a molecular weight of about 30 000 Da that consists of two subunits –  $\alpha$  and  $\beta$ . LH is secreted by frontal lobe of pituitary gland and stimulates testosterone synthesis in testicles. Together with other hormones, LH regulates the menstrual cycle in females.

Increased LH levels are observed in patients with different forms of hypogonadism (primary ovary or testicle insufficiency, polycystic ovary, menopause etc), renal insufficiency and cirrhosis. Decreased LH levels, that may lead to sterility in both sexes, are observed in the case of dysfunctions in hypothalamus or frontal lobe of pituitary gland.

LH measurement is useful for the diagnosis of menopause, exact determination of ovulation time and for endocrine therapy monitoring.

GonadotropinEIA-LH kit is intended for the quantitative determination of luteinizing hormone in human serum.

## GonadotropinEIA-FSH

№ 100-06

Page 37

Follicle-stimulating hormone (FSH) is a glycoprotein with a molecular weight of about 30 000 Da, that consists of two subunits – alpha and beta. FSH is secreted by frontal lobe of pituitary gland.

Together with LH and testosterone, FSH is necessary for spermatogenesis in spermatid ducts of testicles. In pubescent females FSH induces follicle growth and maturation in ovaries. Increased FSH levels are observed in patients with different forms of hypogonadism (primary ovary or testicle insufficiency, polycystic ovaries, menopause etc), renal insufficiency, cirrhosis and also as a result of castration. As a rule, decreased FSH levels are observed in the case of testicle malignancies.

FSH measurement is useful for the diagnosis of menopause, exact determination of ovulation time and for endocrine therapy monitoring.

GonadotropinEIA-FSH kit is intended for the quantitative determination of follicle-stimulating hormone in human serum.

## Adrenal

The adrenal cortex secretes three basic groups of hormones: Mineralocorticoids, glucocorticoids and sex steroid hormones (androgens and estrogens). Mineralocorticoids include aldosterone and deoxycorticosterone. Their mechanism of action is mainly connected with maintenance of salt balance. Glucocorticoids influence metabolism of carbohydrates, proteins, fats, and also on host protective mechanisms. The most important members of Glucocorticoids are cortisol and corticosterone. The sex steroids such as dehydroepiandrosterone sulphate (DHEAS), D4-androstendione, dehydroepiandrosterone and some estrogens have ancillary role.

### SteroidEIA-17-OH-Progesterone

**Nº 100-31**  
Page 38

The steroid hormone 17-OH-progesterone (17-OHP) is produced in the adrenal cortex and in the gonads. The measurement of 17 OHP in serum can be used to monitor the activity of 21-hydroxylase in the adrenal cortex. Deficiencies in 21-hydroxylase, most commonly found in congenital adrenal hyperplasia, result in excessive secretion of 17-OHP and consequently in elevated blood levels. Deficiencies in 11-hydroxylase, however, merely lead to moderately increased values of 17-OHP. The analysis of this steroid hormone, therefore, plays a significant role in the differential diagnosis of congenital adrenal hyperplasia.

In adult non-pregnant women, 17-OHP levels in the blood depend on the phase of the menstrual cycle. Like

progesterone, 17-OHP is secreted by the mature follicle and the corpus luteum. Concentrations are generally higher after ovulation. In addition, levels of 17-OHP are influenced by daytime rhythms which correlate with the adrenal secretion of cortisol. Maximal levels are found in samples collected between midnight and 8.00 a.m. In adult men, there are few indications of similar fluctuations of 17-OHP levels. During pregnancy, large amounts of 17-OHP are produced by the foetus, the placenta and the adrenal cortex.

SteroidEIA-17-OH-Progesterone kit is intended for the quantitative determination of 17-OH-progesterone in human serum and plasma.

### SteroidEIA-DHEA-sulfate

**Nº 100-20**  
Page 38

Dehydroepiandrosterone sulfate (DHEA-S) is a steroid hormone produced mainly by adrenal cortex. The function of DHEA-S in the organism is not definitely specified. The hormone has a weak androgenic effect. In peripheral tissues it can be converted into testosterone – a very strong androgen. DHEA-S does not bind to special transport proteins in blood stream. There is no circadian rhythm in DHEA-S secretion. Quantitative determination

of DHEA-S is necessary for differential diagnostics of ovariopathies as well as for evaluation of adrenal function in pubescence and for differential diagnostics of Cushing syndrome and disease.

SteroidEIA-DHEA-sulfate kit is intended for the quantitative determination of dehydroepiandrosterone sulfate in human serum.

### SteroidEIA-Cortisol

**Nº 100-01**  
Page 38

Cortisol is a steroid hormone with a molecular weight of 362 Da. The quantitative determination of serum cortisol is a valuable tool for evaluation of functional status of «hypothalamus – pituitary gland – adrenal cortex» system. Determination of cortisol

concentration is especially significant in Addison and Cushing disease diagnostics.

SteroidEIA-Cortisol kit is intended for the quantitative determination of cortisol in human serum.

## Prenatal screening

The purpose of prenatal screening is inspection of pregnant women for estimation of health's state of fetus about absence of congenital defects. They are Down's syndrome (trisomy in 21 steam of chromosomes), Edwards's syndrome (trisomy in 18 steam of chromosomes) and Neural Tube Defects.

The basic methods of prenatal diagnostics are Ultrasonic scanning and biochemical analysis for some seromarkers. Whereby number of biochemical indicators for different pregnancy terms will be various. PAPP-A (Pregnancy Associated) Plasma Protein of A) and  $\beta$ -free subunit of chorionic gonadotrophic hormone (hCG) are used in the first pregnancy trimester. Free estriol (unconjugated),  $\alpha$ -fetoprotein (AFP) and general hCG or  $\beta$ -free subunit of hCG are used in the second pregnancy trimester.

### 1<sup>st</sup> trimester

#### EIA-PAPP-A

**Nº 100-37**  
Page 39

PAPP-A is a large heterotetrameric glycoprotein of approximately 500 kDa, which was first discovered in serum from pregnant women. The hetretotetramer consists of two PAPP-A subunits and two proMBP subunits. The measurement of PAPP-A in the first trimester of pregnancy has been reported as a useful marker in antenatal screening for Down Syndrome and other fetal aneuploidies. Reduced PAPP-A values in combination

with maternal age, the measurement of free  $\beta$ -HCG and the ultrasonic determination of nuchal translucency (NT) in pregnancy weeks 11 to 14 may detect up to 90 % of pregnancies with Down syndrom.

EIA-PAPP-A kit is intended for the quantitative determination of Pregnancy associated plasma protein A in human serum.

#### GonadotropinEIA-free $\beta$ -hCG

**Nº 100-38**  
Page 39

Human Chorionic Gonadotropin (HCG) is a glycoprotein hormone normally produced by placenta during pregnancy. Structurally intact HCG molecule is consists of two non-covalently linked polypeptide subunits, the alpha and beta chain subunits. Measurements of intact HCG and of the alpha subunit of HCG appear to give similar results in blood and urine but not the levels of beta subunit. Normally Free  $\beta$ -HCG concentration in fetal serum increases and reaches its maximum on

the tenth week of pregnancy then it starts to decrease. Fetus with Down Syndrome increase maintenances free beta-subunits in the maternal serum in 2 times in comparison with value median line for each fetal phase.

GonadotropinEIA-free  $\beta$ -hCG kit is intended for the quantitative determination of free beta subunit of human chorionic gonadotropin in human serum.

### 2<sup>nd</sup> trimester

#### GonadotropinEIA-hCG

**Nº 100-07**  
Page 39

Human chorionic gonadotropin (hCG) is a glycoprotein hormone that consists of two subunits ( $\alpha$  and  $\beta$ ). Quantitative measurement of hCG is regarded as the most reliable indicator for early diagnostics of pregnancy. With GonadotropineEIA-hCG-1 kit it is possible to detect a pregnancy on 6th-9th day after conception.

Alteration in serum level of hCG in pregnant women is an important method for prenatal diagnostics of some inborn diseases (such as Down syndrome). Besides, this method is widely used in obstetrics for diagnostics of multiple pregnancy, ectopic pregnancy and the threatening abortion. Though hCG presence in serum

is usually associated with normal pregnancy, increased level of hCG may be also detected in patients with teratogenic carcinomas or throphoblastic neoplasias. Less frequently hCG concentration is increased in the case of ectopic synthesis due to testis, breast, intestinal, lung or prostate cancer. hCG concentration in patients with some particular forms of cancer may exceed 100 000 IU/ml. Measurement of hCG is an important method for diagnostics and monitoring of such diseases.

GonadotropinEIA-hCG kit is intended for the quantitative determination of human chorionic gonadotropin in human serum.

## EIA-AFP

**Nº 100-14**  
Page 40

Alfa-fetoprotein (AFP) is a glycoprotein with a molecular weight of about 70 000 Da. During the ontogenesis AFP is produced mostly in yolk-sac and embryonic liver and, in less extent, in gastrointestinal tract. AFP is the main serum protein of early fetus. AFP concentration in fetal serum reaches its pick point of up to 240 000 IU/ml between 12 and 15 weeks of gestation. Then its concentration decreases and at the end of second year reaches the normal level (0-16 IU/ml). Normally AFP concentration remains at this level for rest of the life.

AFP is excreted from fetus's kidneys into the amniotic fluid. From there it penetrates into maternal blood through placenta and umbilical cord. AFP level in serum of pregnant women continuously increases and reaches

the maximum (up to 400 IU/ml) at the middle of the third trimester. The serum level of AFP measurement in pregnant women is an important method of early diagnosis of some inborn diseases (such as Down's syndrome). Besides, this method is widely used in obstetrics for diagnosis of multiple pregnancy, prenatal death and risk of abortion.

AFP measurement can be also used for the diagnosis and monitoring of different forms of cancer. For instance, high and persistent AFP level (800...80 000 IU/ ml) is often connected with primary hepatomas, testis teratomas and ovary tumors.

EIA-AFP kit is intended for the quantitative determination of alpha-fetoprotein in human serum.

## Prenatal Risk Assessment Software «Isida™»

**Nº SP-02**  
Page 26

## Anemia Diagnostics

### EIA-Ferritin

**Nº 100-22**  
Page 40

Ferritin is an intracellular protein. It makes soluble iron pool that is necessary for successful erythropoiesis. At the same time ferritin protects the organism from the toxic effect of iron (connected with catalysis of free radicals production).

Ferritin molecule consists of iron-containing core and protein shell (apoferritin) with a molecular weight of about 450 kDa. Apoferritin consists of 24 subunits of «light»(L) and «heavy»(H) types. Each ferritin molecule can bind up to 4500 iron atoms in hydroxide and phosphate complexes.

Ferritin is located mainly in spleen, liver and red bone marrow cells; in small quantities it is also present in plasma. Ferritin concentration in plasma usually permits to estimate total iron reserve in the organism adequately.

Ferritin concentration at the moment of birth is high (up to 600 ng/ml). In the first months of life it falls and remains at the level of about 30 ng/ml till pubescence. Then ferritin concentration slowly begins to grow, the level reached at the age of 24–25 remains for life. Normal concentration of ferritin in serum is 50–250 ng/ml for men and 20–150 ng/ml for women.

Ferritin concentrations below 10 ng/ml is a sign of asiderotic anemia. This parameter permits successfully differentiate asiderotic anemia from another types of anemia. Measurement of serum ferritin is also useful for monitoring of iron reserve in pregnant women, donors and patients subjected to regular hemodialysis. In the case of iron overloading ferritin concentration exceeds 400–500 ng/ml. It may reach several thousands ng/ml in the case of distinct hemochromathosis.

Concentration of serum ferritin increases in the case of infection, inflammatory processes (such as osteomyelitis and rheumatoid arthritis), acute and chronic liver disorders, leukemia, Hodgkin disease, breast cancer and some other oncopathologies.

EIA-Ferritin kit is intended for the quantitative determination of ferritin in human serum.

## TUMOR MARKERS

Tumor markers are complete protein substances which are produced by the body in response to cancer growth or by the cancer tissue itself. Some tumor markers are specific, while others are seen in several cancer types.

Tumor markers can be used to examine clinically relevant questions:

- Revealing groups which are under high risk of cancer development;
- Localization of a tumor before more detailed investigation;
- Prediction of the diseases remission after the termination of treatment;
- Estimation of operative treatment effectiveness;
- Control of the treatment process.

### OncoEIA-total PSA

**No 100-17**  
Page 41

Prostate-specific antigen (PSA) is a single-chain glycoprotein with a molecular weight of about 32 000 Da. It is a serine protease that is produced only by human prostate epithelium. Normally PSA is secreted into seminal fluid in high concentrations, where it exhibits its enzymatic activity and is directly involved into liquefaction of seminal clot. In serum, PSA persists in low concentration. Increase of PSA concentration in serum is a sign of prostate malfunction, such as benign hyperplasia or malignant degeneration of prostate tissues. PSA level determination is widely used for the revealing and monitoring of prostate cancer patients.

It was demonstrated that PSA makes stable complexes with different protease inhibitors. The main part of the serum PSA is a complex with  $\alpha$ 1-antichymotrypsine (PSA-ACT). But there is a great difference in free PSA/PSA-ACT ratio in different groups of patients. In the case of benign hyperplasia the part of free PSA is higher than in the case of prostate cancer.

OncoEIA-total PSA kit is intended for the quantitative determination of prostate-specific antigen in human serum.

### OncoEIA-free PSA

**No 100-18**  
Page 41

Prostate-specific antigen (PSA) is a glycoprotein with a molecular weight of about 32 000 Da, that consists of one polypeptide chain.

In the serum the PSA contains in two forms. It is the free form and connected with various fibers of blood. The main part of the serum PSA is a complex with  $\alpha$ 1-antichymotrypsine (PSA-ACT). But there is a great

difference in free PSA/PSA-ACT ratio in different groups of patients. In the case of benign hyperplasia the part of free PSA is higher than in the case of prostate cancer.

OncoEIA-free PSA kit is intended for the quantitative determination of free fraction of the prostate-specific antigen in human serum.

### OncoEIA-CA 125

**No 100-211**  
Page 41

CA 125 is an oncofetal protein. It is a mucoglycoprotein with a molecular weight of over 200 000 Da. Normally in adults CA 125 exists in two forms: free and membranebound. Membrane-bound antigen can be identified on the surface of epithelial cells of fallopian tubes, cervix, endometrium, bronchi, mammary gland and sudoriferous gland. High concentrations of free form can be detected in seminal liquid, breast milk, vaginal secretions, saliva, bronchoalveolar and intraperitoneal liquids. In bloodstream CA 125 persists in low concentrations. Increased concentration of serum CA 125 is a sign of ovarian pathology (either benign or malignant).

Quantitative determination of serum CA 125 is used for monitoring of patients with ovarian cancer for estimation of treatment efficiency, early identification of recurrences and asymptomatic dissemination of residual tumor. Diagnostic value of method depends on histological type of tumor: it is the highest in the case of serous ovarian carcinomas in comparison with other types of carcinoma (e.g. mucinous carcinoma).

OncoEIA-CA 125 kit is intended for the quantitative determination of cancer antigen CA 125 in human serum.

### Poly KM-Onco

**No 500-05**  
Page 42

The certified control materials kit «PolyKM-Onco» is intended for use for control serum to control the correctness and reproducibility the results in laboratory researches of the tumor markers quantitative determination and other substances determined by immunoanalytical methods. The kit is intended to determine 12 analytes:

- Total PSA
- Free PSA
- CA 125
- CA 15-3
- CA 19-9
- CEA
- AFP
- HCG
- Prolactin
- Ferritin
- TG
- CYFRA 21-1

**The main characteristics of the kit:**

- 2 levels of certified control materials.
- Matrix of human origin.

- Lyophilized form of release.
- The vials of each level measure up to a certain color of the cap.

The shelf life of the kit is 2 years at a temperature of + 2 ... + 8 °C. Package: two-level set 2 x 2.5 ml. The ability to purchase bottles of each level separately.

Nowadays, for the successful operation in the modern clinical diagnostic laboratory, it is necessary to quickly execute a wide range of studies with a guarantee of high quality. Evaluation of the quality of research using the set of «PolyKM-Onco», this is a guarantee of reliability of each result!

## INFECTION DIAGNOSTICS

### ToRCH-complex

World Health Organization has identified a number of congenital infections causing persistent structural changes in fetal intrauterine infection in a single complex, which included viral, fungal, protozoal and bacterial infections, and merged them in ToRCH-complex.

Prenatal infections remain a serious problem of the modern medicine, despite the obvious successes reached last decades. Pathogens capable to cause such an infection widely circulate among the human population. Serious after-effects for obstetric anamnesis and the long-term effects for the development of the child were shown.

Similar clinical symptoms of the fetal infections at newborns practically exclude the possibility to arrive at diagnosis only on the basis of a clinical picture. In this connection the role of the laboratory researches, especially specific laboratory diagnostics for the purpose of as much as possible fast statement of the diagnosis increases.

In laboratory diagnostics of the fetal infections all spectrum of diagnostic methods is applied: from various variants of microscopy and pathogen isolation on cell culture, up to enzyme immunoassay testing and molecular-biological diagnostic methods (PCR, NASBA, etc.).

But only diagnostics based on serological blood markers detection is simple enough and extremely important for fetal infections precaution at pregnant women. These methods include enzyme immunoassay (EIA) and other immunological analyses. Only the results of a comprehensive serum research on specific IgG and IgM antibodies and antibody avidity determination of class G, we can establish the woman immune status concerning fetal infections and to predict group and degree of risk. Nowadays ELISA is a unique screening method, allowing to survey large population groups for definition the risk of contamination by fetal infections and after vaccination immune status.

### Toxoplasma gondii

*Toxoplasma gondii* is an intracellular protozoan parasite which causes infections in both man and animals. Its primary host are cats, in whose intestine it accomplishes the sexual phase of its life cycle. In man, infection occurs mainly by ingestion of infected raw or underdone meat, or by strict contact with infected material, especially small cats. In man, toxoplasmosis is a rather widespread infection. Most infections, both in adults and adolescents, have a subclinical or extremely mild course. Acquired infections of *Toxoplasma gondii* are often accompanied by lymphadenitis and occasionally by temperature, lymphocytosis and myalgia. Chorioretinitis is a well known manifestation of acquired infections, but could also be a delayed, relapsed congenital infection. Encephalitis caused by toxoplasmosis is a quite common disease in patients affected by AIDS.

The most vulnerable subjects to *Toxoplasma gondii* infections are immunodepressed patients and fetuses, mainly during the first six months of pregnancy. In fact, during this period in which the central nervous system is still developing, the course of the infection has generally a negative outcome. Congenital infections generally lead to dreadful clinical consequences. They are often responsible for abortions, chorioretinitis, cerebral calcifications, psychomotor retardation, hydrocephalus and microcephalus. The antibody titer in adults is quite variable, depending upon various factors such as age, geographical background and assay method.

### ToxoplasmaEIA-IgG

**Nº 200-18**  
96 tests  
Page 42  
"Alkor Bio"

Quantitative detection of specific IgG level allows to conduct monitoring of specific antibodies for toxoplasma. IgG increase indicates acute phase of disease and also allows to estimate dynamics of process of recover indirectly.

ToxoplasmaEIA-IgG kit is designed for qualitative and quantitative detection of class G antibodies for *Toxoplasma gondii* in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

### Toxoplasma IgG

**Nº K1TG**  
96 tests  
Page 42  
"Radim"

**Nº K1TGB**  
192 tests  
Page 42  
"Radim"

Toxoplasma IgG kit is designed for qualitative and quantitative detection of class G antibodies for *Toxoplasma gondii* in human serum or plasma by enzyme immunoassay method - ELISA (Sandwich assay).

## Toxoplasma IgM

**Nº** K1TM  
96 tests  
Page 42  
"Radim"

Specific IgM revealing without dependence from their level allows to assume a primary infection.

Toxoplasma IgM kit is designed for qualitative detection of class M antibodies for *Toxoplasma gondii* in human serum or plasma by enzyme immunoassay method - ELISA (Capture assay).

## ToxoplasmaEIA-IgG-Avidity

**Nº** 200-19  
48 tests  
Page 43  
"Alkor Bio"

Diagnosing a recently acquired, primary *Toxoplasma* infection is not easy, in that the IgM antibodies (a typical marker for recent infections) developed during toxoplasmosis may persist for many months and even for years. Measuring the avidity of specific IgG was demonstrated to be particularly useful for this purpose. As a matter of fact, the initial IgG antibody response to infection is characterized by antibodies with low avidity, in which binding to the specific antigen sites is easily dissociated.

ToxoplasmaEIA-IgG-Avidity kit is designed for detection of IgG antibodies avidity for *Toxoplasma gondii* in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

## Toxoplasma IgG Avidity

**Nº** K1TGA  
48 tests  
Page 43  
"Radim"

Toxoplasma IgG Avidity kit is designed for detection of IgG antibodies avidity for *Toxoplasma gondii* in human

serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

## Rubella Virus

Rubella (RNA Togavirus) usually causes a mild disease, leaving the patient totally immunized. When acquired during pregnancy however, it may cause tremendous effects on the fetus, especially in the first term of pregnancy. Cardio-vascular injuries, deafness, chorioretinitis, brain and growth retardation are some of the damages caused by the virus on the fetus. Rubella is less infectious than the Measles virus, which explains why a significant amount of women in age of puberty does not contract this disease: about 10-20 % of fertile women not subjected to vaccination, are susceptible to the Rubella virus.

## Rubella IgG

**Nº** K2RG  
96 tests  
Page 43  
"Radim"

Quantitative detection of specific IgG level in the range from 0 to 240 IU/ml can indicate:

- current infection;
- presence of protective immunity as a result of the disease in past (anamnestic antibodies);
- successfully passed vaccination.

Rubella IgG kit is designed for qualitative and quantitative detection of class G antibodies for Rubella virus in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

**Nº** K2RGB  
192 tests  
Page 43  
"Radim"

## Rubella IgM

**Nº** K2RM  
96 tests  
Page 43  
"Radim"

Specific IgM revealing irrespectively their level indicate acute Rubella virus infection.

Rubella IgM kit is designed for qualitative detection of class M antibodies for Rubella virus in human serum or plasma by enzyme immunoassay method – ELISA (Capture assay).



## Rubella IgG Avidity

### Nº K2RGA

48 tests  
Page 44  
"Radim"

A significant amount of women (about 10-20%), if not subjected to vaccination, will reach fertile age without having acquired immunity against the Rubella virus. The diagnosis of Rubella infection in its acute stage is therefore particularly important in pregnant women. It is usually performed by testing for the presence of IgM antibodies. Identifying the acute phase of the disease, based upon a single sample however may turn out difficult, either due to IgM persistence (often protracted) or else to the presence of IgM in cases of asymptomatic Rubella infection, which is not threatening for the fetus.

Measuring the avidity of specific IgG was demonstrated to be particularly useful in identifying primary infection. As a matter of fact, the initial IgG antibody response to infection is characterized by antibodies with low avidity, in which binding to the specific antigen sites is easily dissociated.

Rubella IgG Avidity kit is designed for determination of IgG antibodies avidity for Rubella virus in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

## Cytomegalovirus

Cytomegalovirus (CMV) is a virus of icosahedral shape, 180-250 nm in diameter, belonging to the Herpes Viruses family. The Virus has a cytopathological effect, with enlargement of the host cells and evidence of cytoplasmic as well as nuclear inclusions.

Currently CMV is considered the major biological agent which causes congenital anomalies in consequence of intrauterine infections. About 2% of pregnant women contract primary infection or reinfection, whereas 10-20% of new-born babies with CMV congenital infections show significant injuries to the central nervous system.

These congenital infections can also occur as a consequence of endogenous viral reactivations in the mother. Recently, great importance has been ascribed to CMV as a cause of complications in organ transplantation, particularly in kidney transplantation. The incidence of CMV infection in consequence of kidney transplantation from a CMV positive donor to a CMV negative subject has been estimated to be around 52-100%. CMV infection is widely spread: anti-CMV antibodies have been found in 50-70% of individuals beyond 35. Furthermore, CMV can be isolated from the uterine cervix in 10% of healthy women. Usually CMV infection is asymptomatic. As a consequence of CMV primary infection, anti-CMV antibodies of the IgM class, in immunocompetent subjects persist from 2 up to 9 months; they persist even over two years in individuals exposed to transplantation and in immunodepressed subjects.

## Cytomegalovirus IgG

### Nº K3CG

96 tests  
Page 44  
"Radim"

Specific IgG revealing indicates the latent or chronic form of infection. IgG antibodies are present at:

- primary infected patients on a late stage of infection development;
- patients with reactivation of latent infection.

For differentiation the basic development stages of the CMV-infection it is necessary to detect specific IgG in a quantitative variant.

Cytomegalovirus IgG kit is designed for qualitative and quantitative determination of class G antibodies for Cytomegalovirus in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

### Nº K3CGB

192 tests  
Page 44  
"Radim"

Therefore it is not enough qualitative detection IgG antibodies for CMV for the appropriate diagnostics, especially given high contaminated population.

## Cytomegalovirus IgM

### Nº K4CM

96 tests  
Page 44  
"Radim"

Specific IgM revealing indicates acute infection or its reactivation.

Cytomegalovirus IgM kit is designed for qualitative detection of class M antibodies for Cytomegalovirus in human serum or plasma by enzyme immunoassay method – ELISA (Capture assay).



## Cytomegalovirus IgG Avidity

**Nº K3CGA**  
48 tests  
Page 46  
"Radim"

Fetal damage is now thought to be mainly due to primary infection, rather than to a re-infection. CMV is also an important cause of complications in organ transplantation, particularly in kidney transplantation. Again in these cases, primary infection is more harmful than a re-infection.

The diagnosis of recently acquired primary infection by means of specific IgM antibodies can be difficult, due to the IgM presence even in recurring infections. In addition, circulating IgM antibodies may persist for a lot of months and even for two years in

immunodepressed subjects. Measuring the avidity of specific IgG was demonstrated to be particularly useful in identifying primary infection. As a matter of fact, the initial IgG antibody response to infection is characterized by antibodies with low avidity, in which binding to the specific antigen sites is easily dissociated.

Cytomegalovirus IgG Avidity kit is designed for detection of IgG antibodies avidity for Cytomegalovirus in human serum or plasma by enzyme immunoassay method - EIA (Sandwich assay).

## Herpes Simplex Virus

Two kinds of Herpes Simplex are known, with some common and some specific antigenic characteristics.

- Herpes simplex virus type 1 (HSV-1): localized on the orbital and labial regions.
- Herpes simplex virus type 2 (HSV-2): responsible for pathologies of male and female reproductive organs.

This Virus has a considerable pathogenic capacity; transmission occurs by direct or indirect contact and by venereal transmission. Clinical manifestations are Herpes labialis, herpetic eczema up to the most serious forms of Herpes genitalis and congenital diseases, contracted by the fetus during pregnancy (mainly caused by type 2 Virus).

Anti-HSV IgM antibodies appear within 1 week from the disease onset, persisting for several months. IgG class antibodies appear about ten days from the infection and may be evidenced for years thereafter, sometimes with titer fluctuations due to re-infections or re-activation of the latent virus.

## HerpesEIA-1IgG

**Nº 200-20**  
96 tests  
Page 45  
"Alkor Bio"

Quantitative determination of HSV 1 specific IgG allows monitoring antibodies concentration and estimation therapy effectiveness.

HerpesEIA-1IgG kit is designed for qualitative and quantitative determination of class G antibodies for Herpes virus type 1 in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

**Nº 200-46**  
192 tests  
Page 46  
"Alkor Bio"

## HSV 1 IgG

**Nº KH1G**  
96 tests  
Page 45  
"Radim"

**Nº KH1GB**  
192 tests  
Page 45  
"Radim"

Specific IgG revealing indicates infection in past and can become apparent within the whole life.

HSV 1 IgG kit is designed for qualitative detection of class G antibodies for Herpes virus in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

## HerpesEIA-2IgG

**Nº** 200-21

96 tests  
Page 47

"Alkor Bio"

Detection of circulating in the serum of specific antibodies is an important criteria for the diagnosis. At the same time using a two-fold determination of antibody titer in the blood, which allows you to identify and determine - whether it is primary or a recurrence of the disease. At the same diagnosis of a primary viral infection is based on identifying fourfold increment of specific IgG antibodies in paired serum samples with an interval 3-4 weeks.

HerpesEIA-2IgG kit is designed for qualitative and quantitative determination of class G antibodies for Herpes virus type 2 in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

## HSV IgM

**Nº** KHM

96 tests  
Page 46

"Radim"

Specific IgM revealing indicates acute infection or its reactivation.

HSV IgM kit is designed for qualitative detection of class M antibodies for Herpes virus in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

## HerpesEIA-1,2 IgG (96 tests)

## HerpesEIA-1,2 IgG (192 tests)

**Nº** 200-62

96 tests  
Page 46

"Alkor Bio"

The "HerpesEIA-1,2 IgG" kit is designed for qualitative definition of class G antibodies for Herpes virus in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

**Nº** 200-63

192 tests  
Page 46

"Alkor Bio"

## Diagnostics of Viral Hepatitis

### Hepatitis C Virus Diagnostics

HCV is a major cause of acute hepatitis and chronic liver disease, including cirrhosis and liver cancer. Globally, an estimated 170 million persons are chronically infected with HCV and 3 to 4 million persons are newly infected each year. HCV is spread primarily by direct contact with human blood. The major causes of HCV infection worldwide are use of unscreened blood transfusions, and re-use of needles and syringes that have not been adequately sterilized.

## HepatitisEIA-anti-HCV

**Nº** 200-25

96 tests  
Page 47

"Alkor Bio"

**Nº** 200-29

192 tests  
Page 47

"Alkor Bio"

HepatitisEIA-anti-HCV kit is designed for qualitative detection of immunoglobulin G and M to the hepatitis C virus (HCV) in human serum or plasma by enzyme immunoassay method – ELISA (Sandwich assay).

## Hepatitis B Virus Diagnostics

Hepatitis B Virus infections are a serious health problem in the world. In high endemic areas the main route of infection is mother-to-child transmission while sexual transmission and blood transfusion are more frequent in low endemic parts of the world.

### HepatitisEIA-HBsAg

**Nº 200-16**  
96 tests  
Page 47  
"Alkor Bio"

Surface antigen (HBsAg) is a glycosylated envelope protein of HBV and is an important marker of infection. HBsAg contains a determinant «a» is common to all subtypes and additional subdeterminant (d and y), causing differences in immunologic subgroups (ad and ay).

asymptomatic carriers of HBsAg, has established its role as the main reservoir of infection, defined risk groups. In the service of blood transfusion exclusion of persons with the presence of HBsAg from donation resulted in a significant reduction in post-transfusion hepatitis. Blood samples from the presence of HBsAg should not be used for transfusion or for production of these blood products.

**Nº 200-26**  
192 tests  
Page 47  
"Alkor Bio"

HBsAg as the main serological marker of hepatitis B virus plays a key role in the diagnosis and study of the etiology, pathogenesis, clinical and prevention of this infection. Thus, in establishing the etiologic diagnosis of hepatitis B HBsAg may be the first marker of infection and serve as one of the main indicators for the diagnosis (Fig. 1). Detection of HBsAg in patients with chronic hepatitis and cirrhosis of the liver shows the etiology of the disease (Fig. 2). Identification HBsAg population demonstrated the presence of

In terms of clinical practice seems appropriate quantification of HBsAg in the blood, as this information will help to correct diagnosis and adequate treatment to choose to follow the dynamics of infectious the process.

The purpose of this reagent kit is a qualitative or quantitative determination of serum surface antigen (HBsAg) of hepatitis B virus.

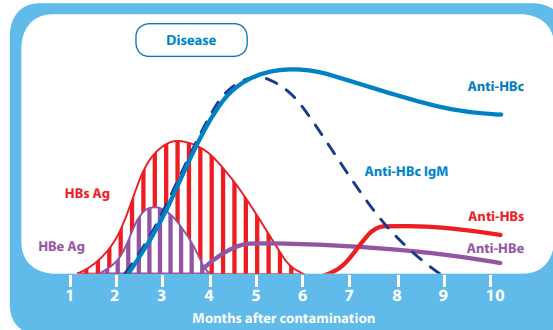


Fig. 1. Serological marker's spectrum of changes in acute hepatitis B with permission's stage.

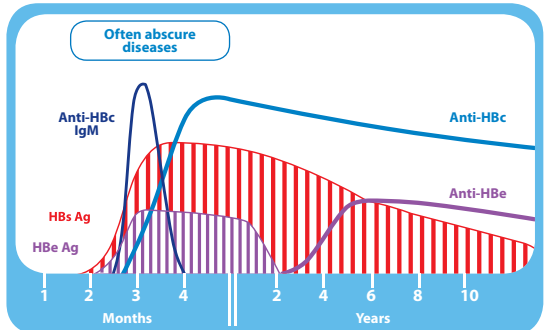


Fig. 2. Serological marker's spectrum of changes in chronic hepatitis B.

### HepatitisEIA-HBsAg confirmatory

**Nº 200-17**  
48 tests  
Page 47  
"Alkor Bio"

Alkor Bio HBsAg confirmatory assay is designed to confirm presence of HBsAg by neutralizing the positive response found within the Alkor Bio HBsAg assay.

## HIV Diagnostics

HIV-infection it is a slowly progressing infection disease which appeared as a result of the infection by immunodeficiency virus of human. Immunodeficiency virus of human belong to retrovirus with RNK. Two types of HIV-1 and HIV-2 is described here. The source of the infection are AIDS diseased people and virus carrier. Virus contamination is passed on sexual contacts, pouring of infect blood, repeated using the infect medicine equipment and transplacental mode is possible to.

Antibodies to HIV of infect people appeared in 90-95% in 3 months after contamination, in 5-9% cases in 6 months after contamination and in 0,5-1% - more than in 6 months.

### EIA-HIV-anti-1,2

<b>Nº</b> 200-23 96 tests Page 48 "Alkor Bio"	<b>Nº</b> 200-27 192 tests Page 48 "Alkor Bio"
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EIA-HIV-anti-1,2 kit destined for qualitative HIV-1,2 antibodies detection in serum or plasma by enzyme immunoassay method ELISA.

### EIA-HIV-Ab/Ag

<b>Nº</b> 200-24 96 tests Page 48 "Alkor Bio"	<b>Nº</b> 200-32 480 tests Page 48 "Alkor Bio"
<b>Nº</b> 200-28 192 tests Page 48 "Alkor Bio"	<b>Nº</b> 200-33 960 tests Page 48 "Alkor Bio"

Kits which define antibodies to HIV and antigens HIV-1 p-24 are used for earlier HIV infect diagnostic. P24 appeared in the blood in 1-3 weeks after contamination and used as early marker of it.

EIA-HIV-Ab/Ag kit destined for qualitative detection p24 antigens and antibodies to HIV-1,2 in serum or plasma by enzyme immunoassay method ELISA.

## STD Diagnostics:

Sexually transmitted infections like syphilis are illnesses that have a significant probability of transmission between humans by means of human sexual behavior.

### TreponemaEIA-Total Antibodies (IgG+ IgA+IgM)

**NEW**

<b>Nº</b> 200-50 96 tests Page 48 "Alkor Bio"	<b>Nº</b> 200-52 480 tests Page 48 "Alkor Bio"
<b>Nº</b> 200-51 192 tests Page 48 "Alkor Bio"	<b>Nº</b> 200-53 960 tests Page 48 "Alkor Bio"

TreponemaEIA-Total Antibodies kit is provided for the qualitative determination of IgG, IgA and IgM (total Ab) to Treponema pallidum (T. pallidum) in human serum, plasma and liquor. The same recombinant antigens TpN15, TpN17, TpN47 conjugated with horseradish peroxidase (HRP) bind to the "antigen-antibody" complex.

Antibodies to Borrelia burgdorferi, Trichomonas vaginalis, Herpes Simplex Virus, Chlamydia trachomatis and Rheumatoid Factor do not have cross-reactivity in the analysis with the set of "Syphilis-total antibodies".

# ALLERGY DIAGNOSTICS

The importance as well as the mechanism of action of IgE antibodies in allergic response have been known for some time IgE antibodies, which are bound to the surface of basophile leukocytes, react with the allergens by means of their Fab fragment. This binding process stimulates basophiles to release several vasoactive

substances which account for allergic symptomatology. Detection as well as quantification of allergen-specific IgE is of great importance for both diagnostic and therapeutic (de-sensitizing) purposes, in the study of allergic diseases.

## AllergoEIA-Total IgE

**№ 300-19**  
96 tests

Page 49

AllergoEIA-Total IgE kit is intended for the quantitative determination of immunoglobulin E (IgE) in human serum.

Normally IgE concentration in serum is very low. It increases gradually from birth to teen-age. In adults normal concentration of IgE may reach 100 IU/ml. In elderly people IgE level sometimes decreases.

IgE production is essential in anti-helminthic immunity. 15-20-fold increase in IgE concentration (up to 1500 – 2000 IU/ml) is observed in the case of ascariasis. But in industrialized countries detection of high IgE concentrations is mainly connected with allergic diseases. Quantitative determination of total

IgE has a great prognostic value. In 75% of children born from parents with allergic diseases serum IgE concentration is >95% from superior limit of normal range for corresponding age group. Detection of high IgE concentrations in serum by enzyme immunoassay is an important tool for differentiation between allergic diseases and other pathologies with similar clinical manifestations (such as asthma, frequent respiratory diseases, chronic rhinites and dermatites).

Increased concentration of total IgE in serum was also reported in patients with lymphosarcoma and Hyper-IgE syndrome.



AllergoEIA-Total IgE

Allergy Diagnostics

## AllergoELISA-specific IgE

**№ 300-29**  
96 tests  
Page 49

**№ 300-25**  
192 tests  
Page 49

**№ 300-26**  
480 tests  
Page 49

**№ 300-27**  
960 tests  
Page 49

The new method for quantitative determination of specIgE – capture-ELISA is implemented in the AllergoELISA-specific IgE kit. The test system contains a die with adsorbed specific to IgE antibodies and liquid biotinylated allergens. These characteristics ensure a high biological accessibility for connection with allergen-specific IgE in a human serum. Moreover it gives flexibility and an ability to format a wide assortment

of allergens to the analysis. Also due to the features of the kit a number of nonspecific reactions with Ig other classes decreases. The obtained results can be presented in IU/mL or classes (from 0 to 5). Any vertical plan-table photometer can be used for the analyses. The design of the kit also gives the ability for the analysis to be made on the automatic EIA-analyzer "Alisei Q.S."



AllergoELISA-specific IgE

### Allergens

**№ 300-30**  
Page 49, 52

### Allergen mixes

**№ 300-33**  
Page 49, 50

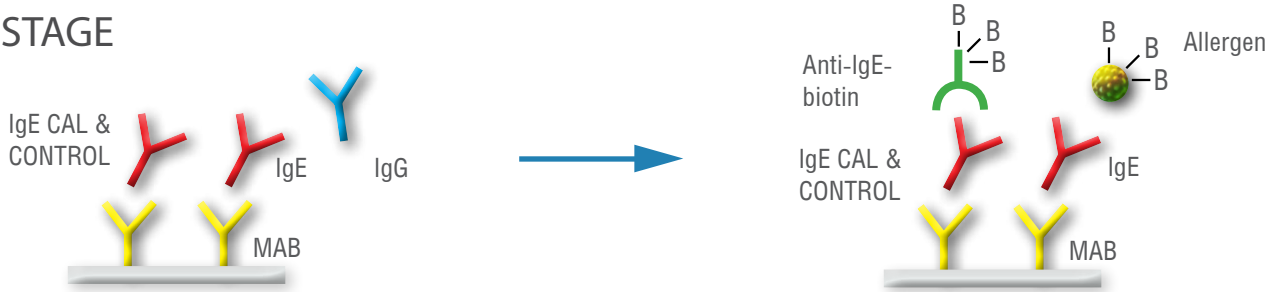
### Allergen components

**№ 300-34**  
Page 49, 50

Principle of the assay

The kit allows quantitative detection of specific IgE in human serum by means of a two-step «capture» assay.

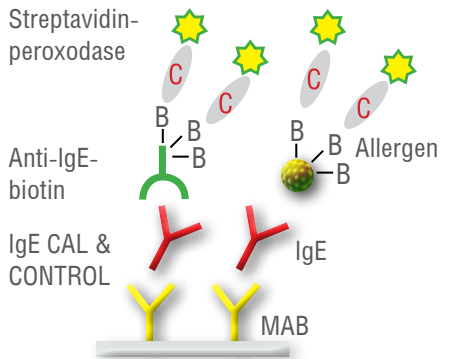
1 STAGE



In the first step, samples are incubated with a biotinylated allergen solution in a monoclonal anti-human IgE (MAB) coated microplate. During this first incubation, the sample IgE antibodies are bound to the solid phase. At the same time, the biotinylated allergen is bound to the sample IgE, specific for that allergen, if present.

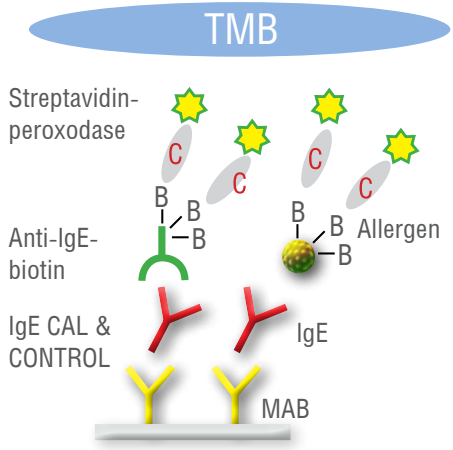
In order to quantify specific IgE, a calibration curve with known amounts of total IgE antibodies is incubated in the same coated microplate with a biotinylated anti-IgE antibody. The second incubation with the enzyme conjugate (streptavidin-HRP) will be the same for both calibrators and samples. In comparing the sample absorbances with the calibration curve, it is possible to express the sample concentrations of specific IgE in terms of International units of total IgE.

2 STAGE



After removing the unbound material by an aspiration/washing cycle, the enzyme conjugate (streptavidin-HRP) is added to the wells, where it binds to the biotinylated allergen.

3 STAGE



450 nm  
405 nm  
620 nm

After a further aspiration/washing cycle, the enzyme activity bound to the solid phase will be directly proportional to the concentration of allergen-specific IgE present in calibrators and samples and evidenced by incubating the wells with a Chromogen solution (Tetramethylbenzidine, TMB) in a Substrate-Buffer. Colorimetric reading will be performed by using a spectrophotometer at 450 and 405 nm.

## SOFTWARE

### Program «EIA-Master»\*

№ SP-03

This modern and convenient program for experiment's results processing was received with use of ELISA method.

Mathematical data processing EIA methods play not less important role, than quality of analysis carrying out. Mainly result's reliability depends on the robustness of calibration curve calculation method. Incorrect data processing method can lead both to false rejection of entire analysis because of erroneous evaluation of control serum concentration, and to incorrect diagnostics on the basis of erroneous calculation of analyte concentrations which lie near guideline's points.

Empirical estimation of standard curves (piecewise linear or cubic spline) are realised in the majority ELISA-analysers, but can be used only under high measurements precision conditions and demand the rigorous control. Considerable variability of results is found out by comparison different empirical methods. At any range over/understatement of detectable concentrations can be probably observed. Accordingly there is an opportunity to consider given curve estimation methods questionable.

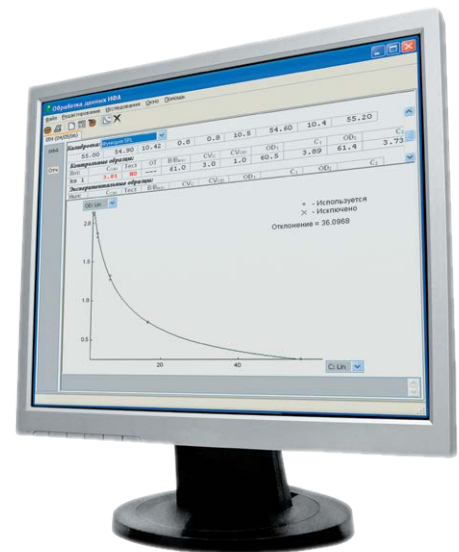
Four and five parameter logistic (4PL / 5PL) equations show the closest matching for EIA signal-concentration dependences. The results assisted by these methods of curve calculation, are characterized by the least variability and high reproducibility. Now models «4PL» and «5PL» are considered optimum for both competitive and «sandwich» ELISA variant.

These every curve calculation methods are realized in the program «EIA-Master».

Key program benefits:

- graphic interface;
- simple information input;
- operations with the data received on any ELISA-equipment;
- possibility to transfer automatically to the program data from photometer Multiskan EX and Multiskan RC with the subsequent calculations;
- import experimental results from the files program Genesis.
- curve calculation a with use 4 and 5 parametrical logistical models, construction of evident schedules;
- calculation of samples concentration and statistical value;
- printable results;
- saving calculation results.

Calibration curve calculated  
by «EIA-Master» programme





## Prenatal Screening

The main idea of pregnant women prenatal screening is defining the women risk level of giving birth to a child with Down's syndrome, Edwards's syndrome, Neural Tube Defect, and fetal growth retardation.

These factors include weight of the woman, her age, occurrence of some diseases, ultrasound examination data, etc. Defining the risk in such circumstances requires complicated calculation algorithms. Therefore the modern prenatal screening concepts require using special software. The «Alkor Bio» company offers software complex for prenatal screening allowing making of fetal abnormalities risks calculations automatically.

### Prenatal Risk Assessment Software «Isida™»\*

#### № SP-02

The «Isida™» program complex is intended for the effective-ness increase of risk assessments in maternal screening for fetal anomalies. «Isida™» software allows to calculate risk of Down's syndrome, Edwards's syndrome, neural tube defects, and fetal growth retardation. Three variants of screening protocols are possible: only for the 1st pregnancy trimester, for the 2nd pregnancy trimester, and also by results of both trimesters estimation.

«Isida™» supports several types of screening protocols:

1st trimester double test (PAPP-A, free  $\beta$ -HCG) in combination with nuchal translucency (NT);

2nd trimester quadruple test (AFP, hCG, uE3, Inhibin-A) complex risk definition by combined date of both trimesters estimation.

Complex risk definition by combined date of both trimesters estimation.

The software maintains PAPP-A, free  $\beta$ -HCG, AFP and hCG medians received with the use of «Alkor Bio» kits and uE3 medians - «DRG International Inc».

It is possible for your own laboratory to carry out calculation of biochemical markers regional medians.

The group data input realized in «Isida™» software facilitates the users work minimizes time of processing results, reduces errors probability.

Protocols of risk assessments support not only biochemical and ultrasound markers data but also woman's age, her weight, type 1 diabetes mellitus incidence. For the first time chromosomal abnormalities during previous pregnancy and woman's ethnicity are consider wile risk calculation.

«Isida™» software saves the individual information about patients in data base, supports editings.

Patients can be described by entering demographics, ultrasound and biochemical results.

It makes possible to draw up and print out different report variants including individual results prenatal screening. Also it allows to summarize done work for the definite period of time.

«Isida™» software is comparable with software of automatic EIA-analyzer «Alisei Q.S.». Results got by «Alisei» analyzer transfer to «Isida™» and then assessed in automatic manner. Such an approach to prenatal screening minimizes routine laboratory work, allows to exclude a numerous number of errors during manual data input, leads to reliability increase of the received results, is convenient at work with a considerable patients number.

Time-saving «Isida™» is a prenatal risk assessment software, helps to increases the number of specific diagnostic tests and to understand deeply their relationships having improved the effectiveness of risk assessment for maternal screening. «Isida™» calculate complex risk of chromosomal diseases and fetal growth abnormalities, support 's databases, form and print reports.

#### Software «Isida™»

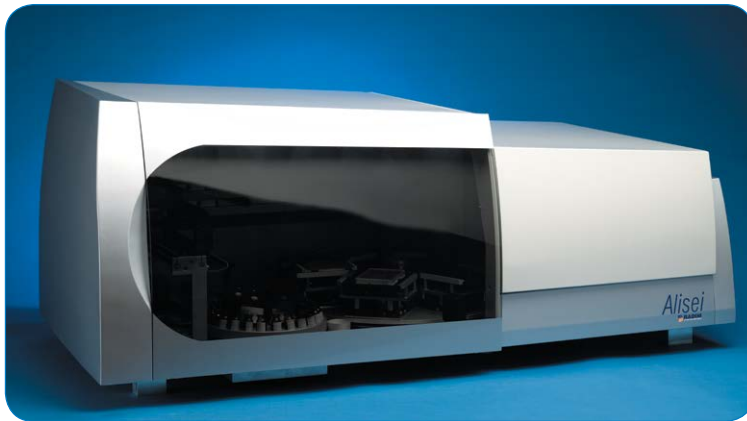


\* Only in Russian

## EIA EQUIPMENT

### Automatic Analyzer «Alisei Q.S.»

«Alisei Q.S.» is a high-speed completely automatic open system which allows performing various immunoassays in 96-well format produced by SEAC Group (Italy). This successful model of the EIA-automatic analyzer is available for laboratories with both large assay streams and mid-level ones.



#### The basic characteristics:

- Allows making large-scale screening as well as single assays.
- The total testing capacity is 540 samples running on 6 microplates.
- 12 kinds of tests on line at once.
- Combines up to 2 kinds of assays on one microplate.
- Handless assay results.
- Support of laboratory informational system.

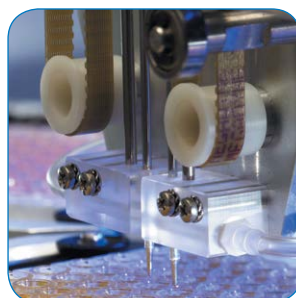
#### Main blocks:

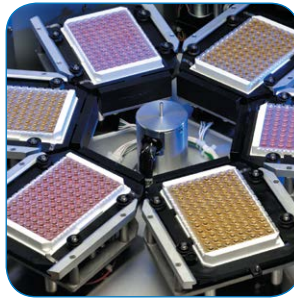
##### 1. Sample and Reagent Loading Group:

- 2 rotating serum plates than can hold different primary tubes. Maximum capacity: 240 tubes in line, are possible use of samples in primary test tubes.
- Movable, flexible and cooled reagent holder, consisting of 2 rotating plates for reagents (simultaneous loading up to 12 sets of reagents).
- Cooling of the reagents support makes the instrument always ready for the user, by reducing preliminary manual operations to a minimum.

##### 2. Block of Dispensing and Dilution:

- The dispensing system includes two independent needles, which are able to aspirate from two adjacent samples, or else, from the same reagent, to be dispensed into two separate wells at once.
- Two dilutors one for each needle, with two syringes.
- Speed of serums entering is 700 samples in hour.
- Speed of reagents entering is 1500 wells in hour.





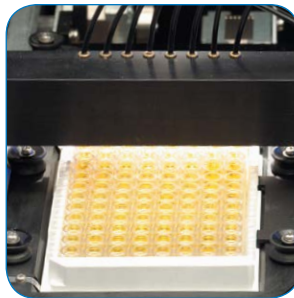
### 3. Incubation and Mixing Block:

- The Rotating table is designed for study from 1 to 6 microplates.
- Carries out up to 12 kinds of assays at the same time.
- Independent temperature (RT or 30-40°C) and shaking modes for each microplate.
- Incubation and can be set by program.



### 4. Washing System:

- 8-channel washer.
- Up to 4 different washing solutions.
- Washing both of «U» and flat bottomed microwells.
- Software-mediated.



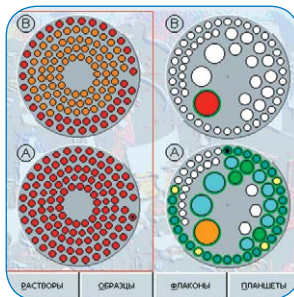
### 5. Reading Station:

- 8-channel optical fiber photometer.
- Holding up to 8 interferential filters.
- Measurements can be carried out with single, double or multiple wavelengths.
- Reading range: 0-3 OD in bichromatism; 0-9 OD in polychromatism.



### 6. Bar-code Reader:

- For easy identification of samples and reagents.
- Prevents possible user's errors.



### 7. Software:

Includes:

- Operating program (on external PC).
- Self-testing program.
- Quality control program.
- Time management system to minimize the assay time.
- Automatic switching off when the assay is finished.

The program is made of different modules which allow the user:

- to insert and modify tests and their features;
- to insert the work-list along with all relevant patient data;
- to monitor the entire test-run;
- to display and manage the final results;
- to personalize and print the patient report.

The software also includes a Service module for checking instrument mechanical functioning.

- «Alisei Q.S.» is exclusive distributed by «Alkor Bio» company.
- After-sales service is provided by «Alkor Bio» service office, based in St.-Petersburg.

## THE MOLECULAR GENETIC DIAGNOSTICS

### Reagents for PCR



#### F polymerase

№ 768

High-processional and high-precise DNA polymerase, having high resistance to inhibiting.

№ 777

Enzyme suits for paragraphs amplification till 20 kb and with higher speed and accuracy. So, for amplification of 1 kb elongation duration equals to 15-30 sec only. F polymerase can be used for carrying out of mutagenesis and creating of gene libraries.

№ 775

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##### Scopes of application:

- High-precise PCR;
- Long-range PCR (>10 kbp);
- «Direct-PCR» with using of EDTA-stabilized blood (up to 15%) as a matrix

##### Enzyme characteristics:

- exhibits 5'→3' polymerase activity;
- has corrective 3'→5' exonucleolytic activity, providing high precision of amplification (in 50 times more precise than Taq polymerases).
- 5'→3' exonucleolytic activity is absent
- Gives high yield of amplification products
- Is resistant to presence of inhibitors: up to 15% of whole blood can be added directly to PCR.
- allows to receive blunt-ended DNA, i.e. it doesn't suit for A/T cloning
- Doesn't have hot-start.

#### Taq polymerase

№ 750

Taq polymerase is a highly purified recombinant enzyme, it perfectly suits for wide range of routine analytical studies — DNA amplification, carrying out of PCR-screenings, inclusion of labeled nucleotides, nick-translation etc.

№ 754

№ 755

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#### Hot-start polymerases

№ 751

Taq AB polymerase — Taq DNA polymerase with hot-start on the base of blocking of enzyme active site by two antibodies. Using of two antibodies for enzyme blocking provides reliable hot-start, which begins to come off after heating up till 60°C only, herewith full enzyme activity while exposing at specified temperature is reached in 5 hours only. For full enzyme unblocking heating up within 3 min at 95°C is enough. Along with antibodies enzyme has high stability — it stands storage at +37°C within not less than a month without changing of properties!

№ 756

№ 757

№ 752

№ 763

№ 776

Page 63

Taq M polymerase is a highly purified recombinant enzyme Taq DNA polymerase with chemical modification in active site, providing high-efficient hot-start.

In the process of reaction Taq M keeps optimum activity till the last cycles of amplification. Length of paragraph, which is possible to amplify with the help of Taq M DNA polymerase depends on nature and quality of DNA nanomatrix. In optimum conditions it can reach 5 000 base pairs.

Polymerases are completed with a transparent buffer for «real-time» PCR and Mg2 + solution.

For the PCR, followed by electro-phoretic detection polymerases are Taq M (green / red buffer) and Taq AB polymerase (green / red buffer).

## Uracil-DNA-glycosylase (UDG)

**Nº 753**  
Page 64

An enzyme that catalyzes the release of uracil from uracil-containing single- or double-stranded DNA, but does not affect dTTP. The resulting abasic site blocks the work of DNA polymerases and undergoes hydrolytic cleavage at elevated temperature and high pH. Enzyme itself is also sensitive to heat and can be inactivated at temperatures above 70°C.

UDG can be used in the system of combating contamination with products of previously conducted PCR, which reduces the risk of false positive results.

## Proteinase K

**Nº 770**  
Page 64

Freeze-dried serine proteinase of a broad spectrum of activity with dilution buffers and a buffer for pre-treatment of samples.

Most actively hydrolyses the peptide bond adjacent to the carboxyl group of aliphatic and aromatic amino acids.

Used for the hydrolysis of protein contaminants of various natures and inactivating nucleases in preparations of nucleic acids, as well as to improve the efficiency of lysis of cells and tissues in the procedures of extraction of nucleic acids.

Used for the hydrolysis of protein contaminants of various natures and inactivating nucleases in preparations NC, and to improve the efficiency of lysis of cells in tissues and NK extraction procedures.

## DBS pretreatment buffer

**Nº 771-01**  
Page 64

Buffer for pre-treatment of dry blood spots.

DBS after pretreatment can be used as samples for DNA extraction using any commercial kit, but we recommend using the kit Extra-DNA-Bio.

DBS pretreatment buffer together with proteinase K is designed for pre-treatment of dry blood spots (DBS), which provides high lysis efficiency.

## Ready Mixtures for PCR and Back Reverse PCR

**Nº 758**

### Master mixes for PCR with the detection in real time (Real-Time PCR)

**Nº 759**

Taq M master-mix

**Nº 764**

Taq AB master-mix

**Nº 765**

### Master mixes for systems for electrophoretic detection

**Nº 767**

Taq M master-mix (green)

**Nº 769**

Taq AB master-mix (green)

**Nº 772-774**

Contain yellow and blue tracer dyes, is best suited for conducting PCR followed by electrophoretic analysis.

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## Master mixes for lyophilization

Taq M master-mix Lyo

Taq AB master-mix Lyo

Suitable for Real-Time PCR, it has the optimum composition for the preparation of lyophilized dried reaction mixtures.

## Master mixes for reverse transcription and PCR

MMLV Taq AB master-mix Lyo

MMLV Taq M master-mix Lyo

Master mixes 2 in 1, designed for sequential reverse transcription and PCR in one tube. They have the optimum composition for the preparation of freeze-dried reaction mixtures

## KITS FOR DNA EXTRACTION

### Multi-DNA-Extraction

№ 400-20

Page 64

Isopropanol DNA extraction is a widely spread method of sample preparation based on the nucleic acid aggregation with salt and spirit. This method is notable for its easiness, rapidity and purity of the obtained DNA.

Diagnostic kit Multi-DNA-Extraction is aimed for quick and effective DNA extraction from blood serum/plasma, whole blood, dried blood, saliva, urine, epithelial cell scrapes from cervical canal and urethra for further examination including Real-Time PCR.

Multi-DNA-Extraction is the only registered diagnostic kit in Russia which allows to extract DNA from dried blood samples!

#### Test destination:

- DNA extraction before carrying out molecular-genetic diagnostics;
- DNA extraction before infectious agents detection.

#### Principle of the analysis:

- Processing of a sample with a lysis buffer and following spirit precipitation.

### Rapid-DNA-Bio

№ 400-22

Page 64

DNA extraction method based on thermic lysis let us get a suitable for PCR-analysis nucleic acid sample. The main advantage of this method is velocity of the procedure.

Diagnostic kit «Rapid-DNA-Bio» is aimed for quick and effective DNA extraction from saliva, urine, cerebrospinal fluid, prostate gland secretion, epithelial cell scrapes from cervical canal and urethra, oropharyngeal surface, bulbar conjunctiva for further examination including Real-Time PCR.

«Rapid-DNA-Bio» includes a subsidiary component – coprecipitator of inhibitors. Due to this fact the DNA samples extracted with «Rapid-DNA-Bio» are notable for its purity in comparison with samples extracted with other manufacturer's kits based on the same extraction method.

#### Test destination:

- DNA extraction before carrying out molecular-genetic diagnostics.

#### Principle of the analysis:

- Processing of a sample with a lysis buffer and following centrifugation for precipitation of insoluble components. For further PCR analysis processing a supernatant from probe is used.



## The Molecular Genetic diagnostics by means of Real-Time PCR

### TromboGENE

№ 400-05  
Page 64

Diagnostic kit «TromboGENE» is aimed for genetic diagnostics of hereditary thrombophilia as well as the evaluation of a risk of a deep vein thrombosis and pulmonary artery thromboembolism.

The most important risk factors of hereditary thrombophilia development are single nucleotide polymorphism (SNP) +1691G/A in *F5* gene (Leiden mutation), which leads to fibrin accumulation and development of a blood clot, and SNP + 20210G/A in *F2* (prothrombin) gene, that enhances the gene expression, which by-turn leads to a prothrombin concentration extension in blood as well as blood clots active development.

Analysis of SNPs in *F5* and *F2* genes is made by means of Real-Time PCR.

#### Analysis is intended for:

- Patients with family anamnesis of thrombosis;
- Women planning pregnancy;
- Patients before operative surgical intervention;
- Patients who had been diagnosed with thrombosis or embolism at the age under 50;
- Patients who had first episode of thrombosis localized non-typically;
- Repeatable episodes of thrombosis and embolism in anamnesis;
- Patients who had first episode of thrombosis associated with pregnancy, childbirth, taking oral contraceptives, hormonal substitution therapy;
- Women who had spontaneous abortion in second or third trimester of pregnancy for unknown reasons;
- Prevention of thrombotic complications in case of oral contraceptives taking or hormonal substitution therapy planning;
- Prevention of thrombotic complications in case of continuous immobilization.

### PharmacoGENE-CYP2C9

№ 400-06  
Page 64

Diagnostic kit «PharmacoGENE-CYP2C9» is aimed for genetic diagnostics of individual susceptibility for indirect anticoagulants (warfarin).

Presence of allelic polymorphisms *CYP2C9\*2* (+430C/T) and *CYP2C9\*3* (+1075A/C) in *CYP2C9* gene leads to a significant decrease of a cytochrome isoenzyme activity. It by-turn increases an expected anticoagulating effect up to seven times and can be the reason for complications development, for example extensive internal bleeding.

Analysis of allelic polymorphisms in *CYP2C9* gene is made by means of Real-Time PCR.

It is recommended to use «PharmacoGENE-CYP2C9» diagnostic kit together with «PharmacoGENE-VKORC1».

#### Analysis is intended for:

- Adjustment of primary indirect anticoagulants dosage for patients with high risk of thrombosis, thrombotic complications or ischemic stroke development;
- Adjustment of drug dosage for patients diagnosed with ciliary arrhythmia, those who went through heart valve replacement surgery;
- Adjustment of drug dosage for postexposure prophylaxis of cardiovascular episodes at patients who had acute coronary syndrome;
- Adjustment of drug dosage for patients with unwanted reactions for medication in family or personal anamnesis.

### PharmacoGENE-VKORC1

№ 400-07  
Page 64

Diagnostic kit «PharmacoGENE-VKORC1» is aimed for genetic diagnostics of individual susceptibility for indirect anticoagulants (warfarin).

Allelic polymorphism -1639G/A in *VKORC1* gene, which encodes vitamin K enzyme – epoxide reductase complex, an aim for indirect anticoagulants, significantly influences gene expression level and increases an anticoagulant effect.

Analysis of allelic polymorphisms in *VKORC1* gene is made by means of Real-Time PCR.

It is recommended to use «PharmacoGENE-VKORC1» diagnostic kit together with «PharmacoGENE-CYP2C9».

#### Analysis is intended for:

- Adjustment of primary indirect anticoagulants dosage for patients with high risk of thrombosis, thrombotic complications or ischemic stroke development;
- Adjustment of drug dosage for patients diagnosed with ciliary arrhythmia, those who went through heart valve replacement surgery;
- Adjustment of drug dosage for postexposure prophylaxis of cardiovascular episodes at patients who had acute coronary syndrome;
- Adjustment of drug dosage for patients with unwanted reactions for medication in family or personal anamnesis.

## Diagnosics of Sexually Transmitted Diseases

### Intifica *Neisseria gonorrhoeae* Intifica *Trichomonas vaginalis*



№ 440-01

**Gonococcal infection** is a human infectious disease caused by gonococci (*Neisseria gonorrhoeae*) – gram-negative diplococci, which are bean-shaped, non-controversial pyogenic bacteria. Currently, gonococcal infection is one of the most common sexually transmitted infections (STIs).

Qualitative determination of ***Neisseria gonorrhoeae* and *Trichomonas vaginalis*** DNA in the scraped-off mucous membranes of the urogenital tract, urine samples, secretion of the prostate and other biological materials by the PCR method with hybridization-fluorescent detection in real time.

№ 440-02

№ 442-01

№ 442-02

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Infection of adult men and women occurs during sexual contact, children – through the passage of the birth canal of a sick mother, sexual contact, contact and domestic way.

To increase the sensitivity and specificity of the analysis, Taq polymerases with «hot start» are used, and the inclusion of uracil-DNA glycosylase (UDG) and deoxyuridine triphosphate (dUTP) in the reaction mixture reduces the risk of cross contamination.

**Urogenital trichomoniasis** is a sexually transmitted infection, the causative agent of which is the simplest unicellular parasite – *Trichomonas vaginalis*. In the structure of all STDs, trichomoniasis is one of the first places and leads in terms of the frequency of detection in persons who have applied for specialized dermatovenereological, obstetric-gynecological and urological help for infectious and inflammatory diseases of the urogenital tract.

Infection of adult men and women occurs during sexual contact, children - through the passage of the birth canal of a sick mother, sexual contact or contact and domestic way.

## Microarray Diagnostics

### Cystic Fibrosis-BioChip

№ 600-01

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Cystic fibrosis (CF) is one of the most common autosomal recessive diseases with multisystem manifestation. This monogenic disease is caused by mutations in the Cystic fibrosis transmembrane conductance regulator (CFTR) gene which lead to malfunction of the protein. An abnormal CFTR protein results in defective electrolyte transport and defective chloride ion transport in the apical membrane epithelial cells of the sweat gland, lung, pancreas, and intestine.

Over 1700 mutations have been identified in the *CFTR* gene. However, the vast majority of mutations are at frequencies of <0.01% or associated with mild CF phenotype. Only few most frequent mutations associated with an aggressive clinical behavior have an actual diagnostic value. The major mutation, ΔF508, accounts for 31% to 72% of CF patients, depending upon ethnicity/race. This diagnostic is designed to detect 25 mutations that are found at high frequency in European populations (including Slavic populations) and cause severe disease phenotype.

#### Indications for analysis:

- Neonatal screening;
- The disease confirmation, diagnosed in adulthood;
- Prenatal diagnostics in case of family history of the disease;
- Risk evaluation in case of family planning;
- Male sterility diagnostics.

#### Intended use:

- The diagnostic kit “Cystic Fibrosis-BioChip” provides a DNA test for the simultaneous mutation detection in the *CFTR* gene.



## HORMONAL DIAGNOSTICS

### Thyroid

#### № 100-11 ThyroidEIA-TSH CE

Kit volume, tests (including controls)	96
Analytical sensitivity, $\mu\text{U/ml}$	0,05
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, $\mu\text{U/ml}$	0-15
Range of normal concentrations of TSH for healthy people, $\mu\text{U/ml}$	0,23-3,4
Incubation time, minutes	60
Incubation temperature, $^{\circ}\text{C}$	37 (shaking)
Sample size, $\mu\text{l}$	50
Shelf-life, month	12

#### № 100-23 ThyroidEIA-TSH (third generation) CE

Kit volume, tests (including controls)	96
Analytical sensitivity, $\mu\text{U/ml}$	0,01
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, $\mu\text{U/ml}$	0-2,5
Range of normal concentrations of TSH for healthy people, $\mu\text{U/ml}$	0,23-3,4
Incubation time, minutes	60
Incubation temperature, $^{\circ}\text{C}$	37 (shaking)
Sample size, $\mu\text{l}$	50
Shelf-life, month	12

Nº	100-09	ThyroidEIA-free T4	CE
	Kit volume, tests (including controls)		96
	Analytical sensitivity, pmol/l		1,0
	Precision: Intra Assay Variation , %		8
	Range of evaluated concentrations, pmol/l		0-100
	Range of normal concentrations of free T4 for healthy people, pmol/l		10,0-23,2
	Incubation time, minutes		60
	Incubation temperature, °C		37 (shaking)
	Sample size, µl		20
	Shelf-life, month		12

Nº	100-36	ThyroidEIA-free T3	CE
	Kit volume, tests (including controls)		96
	Analytical sensitivity, pmol/L		0,5
	Precision: Intra Assay Variation , %		8
	Range of evaluated concentrations, pmol/L		0-60
	Range of normal concentrations of free T3 for healthy people, pmol/L		2,5-7,5
	Incubation time, minutes		45+15
	Incubation temperature, °C		37 (shaking)
	Sample size, µl		20
	Shelf-life, month		12

Nº	100-08	ThyroidEIA-Triiodothyronine	CE
	Kit volume, tests (including controls)		96
	Analytical sensitivity, nmol/l		0,25
	Precision: Intra Assay Variation , %		8
	Range of evaluated concentrations, nmol/l		0-12
	Range of normal concentrations of triiodothyronine for healthy people, nmol/l		1,0-2,8
	Incubation time, minutes		60
	Incubation temperature, °C		37 (shaking)
	Sample size, µl		50
	Shelf-life, month		12

**Nº 100-10 ThyroidEIA-Thyroxin**

**CE**

Kit volume, tests (including controls)	96
Analitical sensitivity, nmol/l	10
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, nmol/l	0-400
Range of normal concentrations of thyroxine for healthy people, nmol/l	53-158
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	20
Shelf-life, month	12

**Nº 100-13 ThyroidEIA-Anti-TPO**

**CE**

Kit volume, tests (including controls)	96
Analitical sensitivity, U/ml	4
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, U/ml	0-500
Range of normal concentrations of Anti-TPO for healthy people, U/ml	<30
Incubation time, minutes	30 + 30
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

**Nº 100-12 ThyroidEIA-Anti-TG**

**CE**

Kit volume, tests (including controls)	96
Analitical sensitivity, U/ml	7,5
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, U/ml	0-1200
Range of normal concentrations of Anti-TG for healthy people, U/ml	<65
Incubation time, minutes	30 + 30
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

**№ 100-29 ThyroidEIA-TG** **CE**

Kit volume, tests (including controls)	96
Analytical sensitivity, ng/ml	1
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, ng/ml	0-300
Range of normal concentrations of TG for healthy people, ng/ml	< 55
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

## Neonatal Screening

**№ 100-15 NeonatalEIA-TSH (192 tests)** **CE**  
**№ 100-16 NeonatalEIA-TSH (960 tests)**

Kit volume, tests (including controls)	192/960
Analytical sensitivity, µIU/ml	2,0
Precision: Intra Assay Variation , %	15
Range of evaluated concentrations, µIU/ml	0-250

The usage of TSH determination in the spots of dry blood as a method for diagnostics of congenital hypothyroidism is based on the concept of «cut-off» value, that allows to divide the newborns to euthyroid and hypothyroid groups. The commonly used «cut-off» value is 20 µIU/ml of blood (that is equivalent to 40 µIU/ml in serum for the blood with 50–55% hematokrit). This «cut-off» value is adequate for the assay of dry spots of blood collected from the heel of newborns on 3rd – 5th day of life.

Incubation time, minutes night	night
Incubation temperature, °C	18...25 (shaking) 2...8
Sample size	disc from the dry spots
Shelf-life, month	12

## Fertility

### Nº 100-02 SteroidEIA-Progesterone CE

Kit volume, tests (including controls)	96
Analitical sensitivity, nmol/l	0,5
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, nmol/l	0-100
Range of normal concentrations of progesterone for healthy people, nmol/l	Males: <0,5-5,2 Females: follicular phase <0,5-6 luteal phase 10-89
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	20
Shelf-life, month	12

### Nº 100-03 SteroidEIA-Testosterone CE

Kit volume, tests (including controls)	96
Analitical sensitivity, nmol/l	0,2
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, nmol/l	0-50
Range of normal concentrations of testosterone for healthy people, nmol/l	Males: 12,1-38,3 Females: 0,5-4,3
Incubation time, minutes	90
Incubation temperature, °C	18...25 / RT (shaking)
Sample size, µl	50
Shelf-life, month	12

### Nº 100-30 SteroidEIA-SHBG CE

Kit volume, tests (including controls)	96
Analitical sensitivity, nmol/l	2
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, nmol/l	0-200
Range of normal concentrations of SHBG for healthy people, nmol/l	Males: 12,4-78,4 Females: 14,1-129
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	20
Shelf-life, month	12

**Nº 100-04 EIA-Prolactin CE**

Kit volume, tests (including controls)	96
Analitical sensitivity, mIU/l	50
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, mIU/l	0-4500
Range of normal concentrations of prolactin for healthy people, mIU/l	Males: 105-540 Females: 67-726
Incubation time, minutes	60 min, 37°C (shaking) 180 min, (18...25)°C RT
Incubation temperature, °C	37 or 18...25
Sample size, µl	20
Shelf-life, month	18

**Nº 100-05 GonadotropinEIA-LH CE**

Kit volume, tests (including controls)	96
Analitical sensitivity, mIU/ml	0,25
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, mIU/ml	0-100
Range of normal concentrations of LH for healthy people, mIU/ml	Males: 0,8-8,4 Females: follicular phase 1,1-8,7 midcycle peak 13,2-72 luteal phase <0,9-14,4 postmenopausal 18,6-72
Incubation time, minutes	60 min, 37°C (shaking) 120 min, (18...25)°C RT
Incubation temperature, °C	37 or 18...25
Sample size, µl	20
Shelf-life, month	18

**Nº 100-06 GonadotropinEIA-FSH CE**

Kit volume, tests (including controls)	96
Analitical sensitivity, mIU/ml	0,25
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, mIU/ml	0-100
Range of normal concentrations of FSG for healthy people, mIU/ml	Males: 1,0-11,8 Females: follicular phase 1,8-11,3 midcycle peak 4,9-20,4 luteal phase 1,1-9,5 postmenopausal 31-130
Incubation time, minutes	60 min, 37°C (shaking) 120 min, (18...25)°C RT
Incubation temperature, °C	37 or 18...25
Sample size, µl	50
Shelf-life, month	18

## Adrenal

### Nº 100-31 SteroidEIA-17-OH-Progesterone CE

Kit volume, tests (including controls)	96
Analitical sensitivity, nmol/L	0,3
Precision: Intra Assay Variation, %	8
Range of evaluated concentrations, nmol/L	0-60
Range of normal concentrations of 17-OHP for healthy people, nmol/L	Males: 0,4-8,3 Females: follicular phase <0,3-2,06 luteal phase 1,42-6,91
Incubation time, minutes	30
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

### Nº 100-20 SteroidEIA-DHEA-sulfate CE

Kit volume, tests (including controls)	96
Analitical sensitivity, µg/ml	0,04
Precision: Intra Assay Variation, %	8
Range of evaluated concentrations, µg/ml	0-10
Range of normal concentrations of DHEA-sulfate for healthy people, µg/ml	Males: 1,0-4,2 Females: 0,8-3,9 Females postmenopausal: 0,1-2,5 Pregnant women: 0,2-1,2
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

### Nº 100-01 SteroidEIA-Cortisol CE

Kit volume, tests (including controls)	96
Analitical sensitivity, nmol/l	10
Precision: Intra Assay Variation, %	8
Range of evaluated concentrations, nmol/l	0-2000
Range of normal concentrations of cortisol for healthy people, nmol/l	150-660
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

## Prenatal Screening

### 1<sup>st</sup> trimester

Nº	100-37	EIA-PAPP-A	CE
Kit volume, tests (including controls)			96
Analytical sensitivity, mIU/mL			0,02
Precision: Intra Assay Variation , %			8
Range of evaluated concentrations, mIU/mL			0-7,0
Incubation time, minutes			90
Incubation temperature, °C			37 (shaking)
Sample size, µl			20
Shelf-life, month			12

Nº	100-38	GonadotropinEIA-free-hCG	CE
Kit volume, tests (including controls)			96
Analytical sensitivity, ng/mL			2
Precision: Intra Assay Variation , %			8
Range of evaluated concentrations, ng/mL			0-200
Incubation time, minutes			45+15
Incubation temperature, °C			37 (shaking)
Sample size, µl			20
Shelf-life, month			12

### 2<sup>nd</sup> trimester

Nº	100-07	GonadotropinEIA-hCG	CE
Kit volume, tests (including controls)			96
Analytical sensitivity, IU/l			5
Precision: Intra Assay Variation , %			8
Range of evaluated concentrations, IU/l			0-500
Range of normal concentrations of hCG for healthy people, IU/l			<10
Incubation time, minutes			60
Incubation temperature, °C			37 (shaking)
Sample size, µl			50
Shelf-life, month			12



**Nº 100-14 EIA-AFP**



Kit volume, tests (including controls)	96
Analitical sensitivity, IU/ml	0,9
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, IU/ml	0-300
Range of normal concentrations of AFP for healthy people, IU/ml	0-14,4
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	20
Shelf-life, month	12

**Nº SP-02 Prenatal Risk Assessment Software «Isida™»**  
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**Anemia Diagnostics**

**Nº 100-22 EIA-Ferritin**



Kit volume, tests (including controls)	96
Analitical sensitivity, ng/ml	5
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, ng/ml	0-1000
Range of normal concentrations of ferritin for healthy people, ng/ml	Males: 22-346 Females: 10-147 Pregnant women (I trimester) 55-90 Pregnant women (II trimester) 25-74 Pregnant women (III trimester) 10-16
Incubation time, minutes	30
Incubation temperature, °C	37 (shaking)
Sample size, µl	20
Shelf-life, month	12

## TUMOR MARKERS

### Nº 100-17 OncoEIA-total PSA

Kit volume, tests (including controls)	96
Analytical sensitivity, ng/ml	0,2
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, ng/ml	0-30
Range of normal concentrations of total PSA for healthy people, ng/ml	<4
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	20
Shelf-life, month	12

### Nº 100-18 OncoEIA-free PSA

Kit volume, tests (including controls)	96
Analytical sensitivity, ng/ml	0,08
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, ng/ml	0-10

The ratio of free PSA concentration to total PSA concentration can be used for differentiation between benign prostate hyperplasia and prostate malignancies in the patients with moderately increased total PSA level. The ratio is calculated as follows:

$$\frac{\text{Free PSA concentration}}{\text{Total PSA concentration}} \times 100\%$$

Ratio below certain threshold limit (14-16%, according to most publications), indicates the high probability of prostate malignancy.

Incubation time, minutes	60 + 60
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

### Nº 100-211 OncoEIA-CA 125



Kit volume, tests (including controls)	96
Analytical sensitivity, U/ml	1,6
Precision: Intra Assay Variation , %	8
Range of evaluated concentrations, U/ml	0-1200
Range of normal concentrations of CA 125 for healthy people, U/ml	<35
Incubation time and temperature	60 min, 37°C (shaking) 120 min, (18...25)°C RT
Sample size, µl	50
Shelf-life, month	12

### Nº 500-05 PolyKM-onco

Number of levels	2 levels × 1 vial × 2,5 ml
Characteristic of levels	1. normal significance 2. increased significance (pathology)
Number of detectable analytes	12
Detectable analytes	CA 15-3, CA 19-9, Ferritin, AFP, Prolactin, TG, free PSA, total PSA, CEA, CA 125, hCG, Cyfra-21-1
Form of issue	Lyophilized
Shelf life, month	24

## INFECTION DIAGNOSTICS

### ToRCH-panel

#### Toxoplasma gondii

**№ 200-18 ToxoplasmaEIA-IgG (96 tests)**

"Alkor Bio"

Kit volume, tests (including controls)	96
Analytical sensitivity, IU/ml	1.3
Sensitivity, %	97
Specificity, %	98
Range of evaluated concentrations, IU/ml	0-100
Incubation time, minutes	45 + 30
Incubation temperature, °C	37 (shaking)
Sample size, µl	10
Shelf-life, month	12

**№ K1TG Toxoplasma IgG (96 tests) CE**

**№ K1TGB Toxoplasma IgG (192 tests)**

"Radim"

Kit volume, tests (including controls)	96, 192
Analytical sensitivity, IU/ml	0.6
Sensitivity, %	97.1
Specificity, %	99.1
Range of evaluated concentrations, IU/ml	0-240
Incubation time, minutes	60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

**№ K1TM Toxoplasma IgM CE**

"Radim"

Kit volume, tests (including controls)	96
Sensitivity, %	98.1
Specificity, %	98.2
Incubation time, minutes	60 + 60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

**Nº 200-19 ToxoplasmaEIA-IgG-Avidity (48 tests)**

"Alkor Bio"

Kit volume, tests (including controls)	48
Sensitivity, %	97
Specificity, %	98
Incubation time, minutes	30 + 15 + 30
Incubation temperature, °C	37 (shaking)
Sample size, µl	20
Shelf-life, month	12

**Nº K1TGA Toxoplasma IgG Avidity**

**CE**

"Radim"

Kit volume, tests (including controls)	48
Sensitivity, %	89.0
Specificity, %	90.0
Incubation time, minutes	60 + 60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

**Rubella Virus**

**Nº K2RG Rubella IgG (96 tests)**

**CE**

**Nº K2RGB Rubella IgG (192 tests)**

"Radim"

Kit volume, tests (including controls)	96, 192
Analytical sensitivity, IU/ml	0.4
Sensitivity, %	100
Specificity, %	97.2
Range of evaluated concentrations, IU/ml	0-240
Incubation time, minutes	60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

**Nº K2RM Rubella IgM**

**CE**

"Radim"

Kit volume, tests (including controls)	96
Sensitivity, %	96.4
Specificity, %	100
Incubation time, minutes	60 + 60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

**Nº** K2RGA **Rubella IgG Avidity**

**CE**

"Radim"

Kit volume, tests (including controls)	48
Sensitivity, %	87.8
Specificity, %	100
Incubation time, minutes	60+30+30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

## Cytomegalovirus

**Nº** K3CG **Cytomegalovirus IgG (96 tests)**

**CE**

**Nº** K3CGB **Cytomegalovirus IgG (192 tests)**

"Radim"

Kit volume, tests (including controls)	96, 192
Analytical sensitivity, RU/ml	0.07
Sensitivity, %	98.7
Specificity, %	97.5
Range of evaluated concentrations, RU/ml	0-240
Incubation time, minutes	60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

**Nº** K4CM **Cytomegalovirus IgM**

**CE**

"Radim"

Kit volume, tests (including controls)	96
Sensitivity, %	93.4
Specificity, %	100
Incubation time, minutes	60 + 60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

**Nº** K3CGA **Cytomegalovirus IgG Avidity**

**CE**

"Radim"

Kit volume, tests (including controls)	48
Sensitivity, %	93.9
Specificity, %	97.4
Incubation time, minutes	60+30+30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	12

## Herpes Simplex Virus

**Nº** 200-20 **HerpesEIA-1IgG**

"Alkor Bio"

Kit volume, tests (including controls)	96, 192
Analytical sensitivity, U/ml	2
Sensitivity, %	100
Specificity, %	98.8
Range of evaluated concentrations, U/ml	0-200
Incubation time, minutes	45 + 30
Incubation temperature, °C	37 (shaking)
Sample size, µl	20
Shelf-life, month	12

**Nº** KH1G **HSV 1 IgG (96 tests)**

**CE**

**Nº** KH1GB **HSV 1 IgG (192 tests)**

"Radim"

Kit volume, tests (including controls)	96, 192
Sensitivity, %	97,6
Specificity, %	100
Incubation time, minutes	60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	18

**Nº 200-21 HerpesEIA-2IgG**

"Alkor Bio"

Kit volume, tests (including controls)	96
Analitical sensitivity, U/ml	3,0
Sensitivity, %	100
Specificity, %	100
Range of evaluated concentrations, U/ml	0-200
Incubation time, minutes	45 + 30
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

**Nº KHM HSV IgM**

**CE**

"Radim"

Kit volume, tests (including controls)	96
Diagnostic Sensitivity, %	100
Diagnostic Specificity, %	100
Incubation time, minutes	60 + 30
Incubation temperature, °C	37
Sample size, µl	10
Shelf-life, month	6

**Nº 200-62 HerpesEIA-1,2 IgG (96 tests)**

**Nº 200-63 HerpesEIA-1,2 IgG (192 tests)**

"Alkor Bio"

Kit volume, tests (including controls)	96, 192
Sensitivity, %	99,4-100
Specificity, %	97-100
Incubation time, minutes	45+30
Incubation temperature, °C	37 (shaking)
Sample volume, µl	10
Shelf-life, month	18

## Diagnosics of Viral Hepatitis

### Hepatitis C Virus

- Nº 200-25 HepatitisEIA-anti-HCV (96 tests)**
- Nº 200-29 HepatitisEIA-anti-HCV (192 tests)**

"Alkor Bio"

Kit volume, tests (including controls)	96, 192
Sensitivity, %	100
Specificity, %	100
Incubation time, minutes	30 + 30
Incubation temperature, °C	37 (shaking)
Sample size, µl	40
Shelf-life, month	12

### Hepatitis B Virus

- Nº 200-16 HepatitisEIA-HBsAg (96 tests)**
- Nº 200-26 HepatitisEIA-HBsAg (192 tests)**

"Alkor Bio"

Kit volume, tests (including controls)	96, 192
Analytical sensitivity, IU/ml	0.05
Sensitivity, %	100
Specificity, %	99.5
Range of evaluated concentrations, IU/ml	0 - 5
Incubation time, minutes	30+30/60+60
Incubation temperature, °C	37(shaking)/ 37(no shaking)
Sample size, µl	100
Shelf-life, month	12

- Nº 200-17 HepatitisEIA-HBsAg confirmatory**

"Alkor Bio"

Kit volume, tests (including controls)	48
Incubation time, minutes	30+30+30
Incubation temperature, °C	18...25, 37 (shaking)
Sample size, µl	100
Shelf-life, month	12



## HIV Diagnostics

- (Nº) 200-23 EIA-HIV-anti-1,2 (96 tests)  
 (Nº) 200-27 EIA-HIV-anti-1,2 (192 tests)

Kit volume, tests (including controls)	96, 192
Sensitivity, %	100
Specificity, %	100
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	12

- (Nº) 200-24 EIA-HIV-Ab/Ag (96 tests)  
 (Nº) 200-28 EIA-HIV-Ab/Ag (192 tests)  
 (Nº) 200-32 EIA-HIV-Ab/Ag (480 tests)  
 (Nº) 200-33 EIA-HIV-Ab/Ag (960 tests)

Kit volume, tests (including controls)	96, 192, 480, 960
Sensitivity, %	100
Specificity, %	100
Detection limit of HIV p24, pg/ml	25
Incubation time, minutes	60
Incubation temperature, °C	37 (shaking)
Sample size, µl	50
Shelf-life, month	15

## STD Diagnostics

- (Nº) 200-50 TreponemaEIA-Total Antibodies (IgG+ IgA+IgM)  
 (Nº) 200-51 TreponemaEIA-Total Antibodies (IgG+ IgA+IgM)  
 (Nº) 200-52 TreponemaEIA-Total Antibodies (IgG+ IgA+IgM)  
 (Nº) 200-53 TreponemaEIA-Total Antibodies (IgG+ IgA+IgM)



Kit volume, tests (including controls)	96, 192, 480, 960
Diagnostic sensitivity, %	100
Diagnostic specificity, %	99,1
Incubation time, minutes	30
Incubation temperature, °C	37 (shaking)/ 37 (no shaking)
Sample size µL	10
Shelf-life, month	12

## ALLERGY DIAGNOSTICS

<b>Nº</b> 300-19	<b>AllergoEIA-Total IgE</b>	<b>CE</b>
Tests number (including Calibrators and control serum)		96
Analytical Sensitivity, IU/mL		2,3
Precision: Intra Assa Variation, %		not more 8%
Range of evaluated concentrations, IU/mL		0-500
Incubation times, min		90
Incubation temperature, °C		37 (shaking)
Sample size, µl		20
Shelf-life, month		12

<b>Nº</b> 300-29	<b>AllergoELISA-specific IgE (96 tests)</b>	<b>CE</b>
<b>Nº</b> 300-25	<b>AllergoELISA-specific IgE (192 tests)</b>	
<b>Nº</b> 300-26	<b>AllergoELISA-specific IgE (480 tests)</b>	
<b>Nº</b> 300-27	<b>AllergoELISA-specific IgE (960 tests)</b>	
Tests number (including Calibrators and control serum)		96, 192, 480, 960
Analytical Sensitivity, IU/mL		0,15
Precision: Intra Assay Variation 8%		not more 8%
Specificity: cross-react with other human Ig classes: IgA, IgM, IgG and IgD		none
Incubation times, min		60 + 30
Incubation temperature, °C		37 (shaking)
Sample size, µl		50
Read the OD at, nm		450/405/620
Results		Quantitatively in IU/mL and classes from 0 to 5
Kit includes calibrators and control sera		
Shelf-life, month		18

<b>Nº</b> 300-30	<b>Allergens</b>	<b>CE</b>
<b>Nº</b> 300-33	<b>Allergen mixes</b>	
<b>Nº</b> 300-34	<b>Allergen components</b>	
1 Vial, tests number		26
Liquid biotinylated allergens		
Flexible choice of allergens		
Shelf-life, month		18

## Allergens List

### Nº 300-34 Allergen components (recombinant & native)

NEW

e204	nBos d 6 BSA (Bovine serum albumin)	g215	rPhl p 5 Timothy (Phleum pratense)
e220	nFel d 2 Cat serum albumin	g210	rPhl p 7 Timothy (Phleum pratense)
e221	nCan f 3 Dog serum albumin	g212	rPhl p 12 Timothy (Phleum pratense)
f67	nGal d 2 Ovalbumin	t215	rBet v 1 Birch (Betula verrucosa)
f68	nGal d 1 Ovomucoid	t216	rBet v 2 Birch (Betula verrucosa)
f69	nGal d 3 Conalbumin (ovotransferrin)	t220	rBet v 4 Birch (Betula verrucosa)
f76	nBos d 4 α-lactalbumin	w211	rPar j 2 Wall pellitory (Parietaria judaica)
f77	nBos d 5 β-lactoglobulin	w230	nAmb a 1 Common ragweed (Ambrosia elatior)
f78	nBos d 8 Casein	w231	nArt v 1 Mugwort (Artemisia vulgaris)
f311	rDau c 1 Carrot	w233	nArt v 3 Mugwort (Artemisia vulgaris)
f352	rAra h 8 Peanut	i12	nApi m 4 Melittin
f353	rGly m 4 Soya bean	k201	nCar p 1 Papain (from papaya)
f417	rApi g 1 Celery	k202	nAna c 2 Bromelain (from pineapple)
f434	rMal d 1 Apple	k203	nApi m 1 Phospholipase A2 (from honey bee)
g205	rPhl p1 Timothy (Phleum pratense)	k208	nGal d 4 Lysozyme (from egg)

### Nº 300-33 Allergen mixes

fm1	Infant food mix (f1-f2-f3-f4-f14-f25-f75) (egg white, cow milk, codfish, wheat flour, soya bean, tomato, egg yolk)
fm2	Food mix (seafood) (f3-f23-f24-f37) (codfish, crab, shrimp, mussel)
fm3	Food mix (cereals) (f4-f6-f7-f8-f9) (wheat, barley, oats, maize, rice)
fm4	Food mix (fish) (f3-f41-f205-f206-f254) (codfish, salmon, herring, mackerel, plaice)
fm5	Food mix (paediatric) (f1-f2-f3-f4-f13-f14) (egg white, cow milk, codfish, wheat, peanut, soya bean)
fm6	Food mix (nuts) (f17-f18-f20-f36-f256) (hazelnut, brazil nut, almond, coconut, walnut)
fm7	Food mix (vegetables: f12-f15-f25-f31-f35) (pea, white bean, tomato, carrot, potato)
fm9	Fruit mix (f20-f84-f87-f92-f259) (almond, kiwi, melon, banana, grape)
fm10	Food mix (f4-f5-f7-f79) (wheat, rye, oats, gluten)
fm11	Food mix (cereals) (f4-f7-f8-f10-f11) (wheat, oats, maize, sesame seed, buckwheat)
fm14	Food mix (f25-f214-f216-f218) (tomato, spinach, cabbage, sweet pepper)
fm15	Food mix (f33-f49-f92-f95) (orange, apple, banana, peach)
fm16	Food mix (f44-f94-f208-f210) (strawberry, pear, lemon, pineapple)
fm17	Fruit mix (f49-f92-f94-f95) (apple, banana, pear, peach)
fm18	Food mix (citrus) (f33-f208-f209-f302) (orange, lemon, grapefruit, mandarin)
fm19	Food mix (f26-f27-f88) (pork, beef, mutton)
fm20	Food mix (f57-f83-f284) (duck meat, chicken meat, turkey)
fm21	Fruit mix (f84-f87-f92-f95-f210) (kiwi, melon, banana, peach, pineapple)
fm22	Food mix (cheese) (f70-f81-f82-f150-f198) (swiss cheese, cheese cheddar type, cheese mould type, edam cheese, gouda cheese)
fm23	Food mix (meat) (f26-f27-f83-f284) (pork, beef, chicken meat, turkey)
fm24	Food mix (seafood) (f3-f24-f37-f40-f41) (codfish, shrimp, mussel, tuna, salmon)
fm61	Food mix (nuts) (f13-f17-f20-f36-f256) (peanut, hazelnut, almond, coconut, walnut)
fm70	Spice mix (f272-f273-f274-f275) (tarragon, thyme, majoran, lovage)
fm71	Spice mix (f265-f267-f268-f282) (caraway, cardamon, cloves, nutmeg)
fm72	Spice mix (f219-f269-f270-f271) (fennel seed, basil, ginger, anise)

fm101	Food mix (f1-f2-f4-f5-f8-f75-f76-f77-f78-f79-f81) (egg white, cow milk, wheat, rye, maize, egg yolk, alpha-lactalbumin, beta-lactoglobulin, casein, gluten, cheese Cheddar type)
fm102	Food mix (f13-f14-f256-f17-f26-f45-f48-f83) (peanut, soya bean, walnut, hazelnut, pork, yeast, onion, chicken meat)
fm103	Food mix (f20-f25-f33-f44-f84-f87-f92-f95) (almond, tomato, strawberry, kiwi, melon, banana, peach)
fm104	Stone fruits mix (f242-f95-f237-f255) (cherry, peach, apricot, plum)
fm105	Food mix (f10-f12-f36-f84-f85-f93-f105-f221-f300) (sesame seed, pea, coconut, kiwi, celery, cocoa, chocolate, coffee, goat milk)
fm201	Foodscreen №1 (f2-f3-f4-f13-f14-f17-f24-f25-f31-f33-f44-f245) cow milk, codfish, wheat flour, peanut, soya bean, hazelnut, shrimp, tomato, carrot, orange, strawberry, whole egg
fm202	Foodscreen №2 (f5-f7-f9-f26-f27-f35-f41-f49-f83-f85-f92-f105-f216) rye, oats, rice, pork, beef, potato, salmon, apple, chicken meat, celery, banana, chocolate, cabbage
dam	Allerscreen inhalants mix (d1-d2-e1-e2-e3-g2-g8-m3-m6-t4-t9-t11-w1-w6-w9-w21) (Dermatophagoides pteronyssinus, Dermatophagoides farinae, cat epithelium, dog epithelium, horse dander, bermuda grass, common meadow grass, Aspergillus fumigatus, Alternaria alternata (tenuis), common hazel, olive, london plane, common ragweed, mugwort, ribwort plantain, wall pellitory)
dam1	Inhalants mix (d1-e1-e5-g6-g12-m2-t3-w6) (Dermatophagoides pteronyssinus, cat epithelium, dog dander, timothy grass, cultivated rye, Cladosporium herbarum, birch, mugwort)
dam2	Inhalants mix №2 (d1-d2-e1-e2-g3-g6-i6-m3-m5-m6-t3-w1-w6-w8) Dermatophagoides farinae, Dermatophagoides pteronyssinus, cat epithelium, dog epithelium, cocksfoot, timothy grass, cockroach, Aspergillus fumigatus, Candida albicans, Alternaria alternata (tenuis), silver birch, common ragweed, mugwort, dandelion
dam3	Inhalants mix №3 (e6-e82-e84-e85-e87-g12-h1-m1-m2-t4-t7-w10-w20) dog epithelium, rabbit epithelium, hamster epithelium, chicken feathers, rat epithelium+serum-urine proteins, cultivated rye, house dust (Greer labs inc.), Penicillium notatum, Cladosporium herbarum, common hazel, oak, goosefoot, common nettle
dm1	Environment mix (d1-d2-e1-e2) (Dermatophagoides pteronyssinus, Dermatophagoides farinae, cat epithelium, dog epithelium)
dm2	Mite mix (d1-d2-d3-d70-d71-d72-d73-d74) (Dermatophagoides pteronyssinus, Dermatophagoides farinae, Dermatophagoides microceras, Acarus siro, Lepidoglyphus destructor, Tyrophagus putrescentiae, Glycyphagus domesticus, Euroglyphus maynei)
drm2	Perennial mix (d2-e1-e3-e5-m6) (Dermatophagoides farinae, cat epithelium, horse dander, dog dander, Alternaria alternata (tenuis))
drm5	Indoor mix (d1-e1-m3-i6) (Dermatophagoides pteronyssinus, cat epithelium, Aspergillus fumigatus, cockroach)
mm1	Mould mix (m1-m2-m3-m4-m6) (Penicillium notatum, Cladosporium herbarum, Aspergillus fumigatus, Mucor racemosus, Alternaria alternata (tenuis))
mm2	Mould mix (m1-m2-m3-m5-m6-m8) (Penicillium notatum, Cladosporium herbarum, Aspergillus fumigatus, Candida albicans, Alternaria alternata (tenuis), Helminthosporium halodes)
hm1	House dust mix (h1-d1-d2-i6) (house dust, Dermatophagoides pteronyssinus, Dermatophagoides farinae, cockroach)
hm100	House dust mix (m1-m3-m5-m6-d1-d2-h1) (Penicillium notatum, Aspergillus fumigatus, Candida albicans, Alternaria alternata (tenuis), Dermatophagoides pteronyssinus, Dermatophagoides farinae, house dust)
em1	Feather mix (e70-e85-e86-e89) (goose feathers, chicken feathers, duck feathers, turkey feathers)
em2	Epithelia mix (e1-e5-e6-e87-e88) (cat epithelium, dog dander, guinea pig epithelium, rat epith.+serum-urine prot., mouse epith.+serum-urine prot.)
em4	Epithelia mix (e1-e2-e3-e4) (cat epithelium, dog epithelium, horse dander, cow dander)
em70	Rodent mix (e6-e82-e84-e87-e88) (guinea pig epithelium, rabbit epithelium, hamster epithelium, rat epith.+serum-urine prot., mouse epith.+serum-urine prot.)
em72	Domestic bird feathers (e78-e93-e201-e213) (budgerigar feathers, parakeet feathers, canarian feathers, parrot feathers)
em100	Epithelia mix (e1-e2-e3-e4-e5-e70-e81-e85-e86-e100) (cat epithelium, dog epithelium, horse dander, cow dander, dog dander, goose feathers, sheep epithelium, chicken feathers, duck feathers, cat dander)
im100	Insect-venom mix (i1-i3-i6-i75) (honey bee, common wasp (yellow jacket), cockroach, european hornet)
gm1	Grass mix (g3-g4-g5-g6-g8) (cocksfoot, meadow fescue, rye grass, timothy, meadow grass)
gm2	Grass mix (early flowering) (g2-g5-g6-g8-g10-g17) (bermuda grass, rye grass, timothy grass, common meadow grass, johnson grass, bahia grass)
gm3	Grass mix (late flowering) (g1-g5-g6-g12-g13) (sweet vernall grass, rye grass, timothy grass, cultivated rye, velvet grass)
gm100	Grass mix (g2-g3-g5-g6-g8-g10-g12-g13-g14-g15-g16) (bermuda grass, cocksfoot, rye grass, timothy grass, common meadow grass, johnson grass, cultivated rye, velvet grass, cultivated oat, cultivated wheat, meadow foxtail)
tm1	Tree mix (t1-t3-t7-t8-t9-t10) (maple ash, birch, oak, elm, olive, walnut)
tm2	Tree mix (early flowering) (t2-t3-t4-t15) (grey alder, birch, common hazel, white ash)

tm3	Tree mix (late flowering) (t1-t7-t12-t14) (maple ash, oak, willow, cottonwood)
tm4	Tree mix (t7-t8-t11-t12-t14) (oak, elm, london plane, willow, eastern cottonwood)
tm5	Tree mix (early flowering) (t2-t4-t8-t12-t14) (grey alder, common hazel, elm, willow, eastern cottonwood)
tm6	Tree mix (late flowering) (t1-t3-t5-t7-t10) (maple ash, birch, american beech, oak, walnut)
tm100	Tree mix (t1-t2-t3-t4-t7-t11-t12-t14) (maple ash, grey alder, birch, common hazel, oak, london plane, willow, eastern cottonwood)
wrm1	Seasonal mix (g6-w6-w9-w21-t3) (timothy grass, mugwort, ribwort plantain, wall pellitory, birch)
wm1	Weed mix (w1-w6-w7-w10-w19) (common ragweed, mugwort, ox eye daisy, lamb's quarters, wall pellitory)
wm2	Weed mix (w1-w6-w7-w8-w9) (common ragweed, mugwort, ox eye daisy, dandelion, ribwort plantain)
wm3	Weed mix (w6-w9-w10-w12-w20) (mugwort, ribwort plantain, goosefoot (lamb`s quarters), golden rod, common nettle)
wm4	Weed mix (w1-w6-w10-w11) (common ragweed, mugwort, goosefoot (lamb`s quarters), salwort)
wm5	Weed mix (w1-w6-w7-w8-w12) (common ragweed, mugwort, ox eye daisy (marguerite), dandelion, golden rod)
wm6	Weed mix (w9-w10-w11-w18) (ribwort plantain, goosefoot (lamb`s quarters), salwort, sheep sorrel)
wm7	Weed mix (w1-w9-w10-w12-w20) common ragweed, Ribwort plantain, Goosefoot, Golden rod, Common nettle
wm100	Weed mix (w1-w6-w9-w12-w14) (common ragweed, mugwort, ribwort plantain, golden rod, common pigweed)
om1	Wood mix (o32, o33, o36, o49) (beech, oak, pine, elm)

**Nº 300-30 Allergens**

**FOODS**

FRUITS, VEGETABLES & BERRIES			
f49	Apple	f262	Eggplant/aubergine
f237	Apricot	f296	Feijoa
f172	Artichoke	f276	Fennel
f261	Asparagus	f328	Fig
f96	Avocado	f47	Garlic
f92	Banana	f327	Gooseberry
f107	Barberry	f259	Grape
f319	Beet	f209	Grapefruit
f109	Black chokeberry	f292	Guava
f211	Blackberry	f346	Haskap berry
f321	Blackcurrant	f102	Horseradish
f288	Blueberry	f257	Iceberg (crisphead) lettuce
f260	Broccoli	f103	Jerusalem artichoke
f217	Brussel sprout	f84	Kiwi
f216	Cabbage	f170	Kohlrabi (cabbage turnip)
f31	Carrot	f310	Kumquat (cumquat)
f291	Cauliflower	f66	Leek
f236	Chard	f208	Lemon
f242	Cherry	f215	Lettuce
f106	Cherry plum	f306	Lime
f227	Chinese green radish	f348	Lychee
f118	Corn salad	f91	Mango
f182	Cowberry	f87	Melon
f341	Cranberry	f228	Napa cabbage
f244	Cucumber	f343	Nectarine
f289	Date	f183	Northern bilberry

f342	Olive
f48	Onion
f33	Orange
f293	Papaya
f294	Passionfruit
f95	Peach
f94	Pear
f301	Persimmon (Kaki)
f347	Physalis (cape gooseberry)
f210	Pineapple
f298	Pitahaya (pitaya)
f255	Plum
f295	Pomegranate
f305	Pomelo
f35	Potato
f238	Potato starch (amylum)
f225	Pumpkin
f339	Quince
f119	Radicchio (Italian chicory)
f112	Raisin
f111	Raspberry
f116	Red cabbage
f322	Red currant
f226	Red radish
f223	Rhubarb

f340	Rose hips
f171	Ruccola
f115	Sauerkraut
f117	Savoy cabbage
f108	Sea buckthorn
f243	Serviceberry
f65	Shallot
f316	Sorrel
f214	Spinach
f44	Strawberry
f73	Sweet cherry
f218	Sweet pepper
f104	Sweet potato
f302	Tangerine
f25	Tomato
f229	Turnip
f181	Viburnum berries
f329	Watermelon
f320	White currant
f156	Witloof
f113	Zucchini
f311	rDau c 1 Carrot (ref. Nº300-34)
f417	rApi g 1 Celery (ref. Nº300-34)
f434	rMal d 1 Apple (ref. Nº300-34)

## SEEDS, LEGUMES, NUTS

f20	Almond
f6	Barley
f190	Bran (Wheat)
f18	Brazil nut
f11	Buckwheat
f202	Cashew nut
f299	Chestnut
f309	Chick pea
f36	Coconut
f315	French bean
f233	Gliadin
f79	Gluten
f17	Hazelnut
f235	Lentil
f98	Linseed
f345	Macadamia nut
f8	Maize
f55	Millet
f7	Oats
f12	Pea

f13	Peanut
f145	Pearl barley
f201	Pecan nut
f253	Pine-seeds
f203	Pistachio nut
f224	Poppy (seed)
f125	Pumpkin seed
f287	Red bean
f9	Rice
f5	Rye
f146	Semolina
f10	Sesame seed
f14	Soya bean
f124	Spelt
f384	Sunflower seed
f256	Walnut
f4	Wheat
f15	White bean
f352	rAra h 8 Peanut (ref. Nº300-34)
f353	rGly m 4 Soya bean (ref. Nº300-34)

## MEAT

f27	Beef	f26	Pork
f241	Beef liver	f213	Rabbit meat
f184	Horse meat	f165	Veal
f88	Mutton		

## MILK, DAIRY PRODUCTS

f158	Bryndza cheese	f154	Maasdam cheese
f151	Camembert cheese	f54	Mare milk
f81	Cheese Cheddar type	f168	Milk powder
f82	Cheese mould type	f252	Mozzarella cheese
f251	Cheese Parmesan type	f152	Roquefort cheese
f231	Cooked milk	f159	Ryazhenka
f2	Cow milk	f160	Smetana (Sour cream)
f232	Curd	f157	Sulguni cheese
f153	Dutch cheese	f70	Swiss cheese
f150	Edam cheese	f161	Whey
f325	Ewe's cheese	f250	Yogurt
f326	Goat cheese	f76	nBos d 4 $\alpha$ -lactalbumin (ref. N°300-34)
f300	Goat milk	f77	nBos d 5 $\beta$ -lactoglobulin (ref. N°300-34)
f198	Gouda cheese	f78	nBos d 8 Casein (ref. N°300-34)
f63	Kefir		

## EGGS & POULTRY

f83	Chicken meat	f192	Quail meat
f57	Duck meat	f284	Turkey
f58	Goose meat	f245	Whole egg
f1	Egg white	f67	nGal d 2 Ovalbumin (ref. N°300-34)
f75	Egg yolk	f68	nGal d 1 Ovomucoid (ref. N°300-34)
f193	Quail egg	f69	nGal d 3 Conalbumin (ovotransferrin) (ref. N°300-34)

## FISH & SEAFOOD

f62	Alaska pollock	f42	Haddock
f313	Anchovy	f307	Hake
f37	Blue mussel	f303	Halibut
f185	Bream	f205	Herring
f365	Butterfish	f411	Hunchback salmon
f357	Capelin	f80	Lobster
f180	Carp	f206	Mackerel
f364	Chum salmon	f59	Octopus
f207	Clam	f290	Oyster
f3	Codfish	f248	Pacific saury
f23	Crab	f362	Pangasius (swai)
f239	Cuttlefish	f163	Pike
f355	Dorada	f254	Plaice
f264	Eel	f323	Red caviar
f360	Grouper	f249	Saithe

f41	Salmon
f61	Sardine
f308	Sardine (Pilchard)
f338	Scallop
f359	Seabass
f24	Shrimp
f179	Shrimp tiger
f363	Smelt
f337	Sole

f304	Spiny lobster
f366	Sprat
f258	Squid
f358	Sturgeon
f354	Tilapia
f204	Trout
f40	Tuna
f356	Wolffish
f415	Zander

## SPICES

f333	Allspice (pimento, allspice)
f271	Anise
f269	Basil
f278	Bay leaf
f280	Black pepper
f265	Caraway
f267	Cardamon
f85	Celery
f279	Chili pepper
f318	Cilantro
f220	Cinnamon
f268	Cloves
f317	Coriander
f283	Curcuma
f281	Curry
f277	Dill
f219	Fennel seed
f270	Ginger

f263	Green pepper
f285	Lemon balm (Melissa)
f275	Lovage
f274	Majoram
f126	Mint
f89	Mustard
f282	Nutmeg
f334	Oregano
f46	Paprika
f86	Parsley
f335	Rosemary
f331	Saffron
f344	Sage
f272	Tarragon
f273	Thyme
f234	Vanilla
f332	White pepper

## OTHERS

f120	Aspartame (E951)
f286	Bamboo shoot
f200	Cep (Boletus edulis)
f330	Chamomile tea
f199	Chanterelle
f155	Chicory
f105	Chocolate
f93	Cocoa
f361	Coconut milk
f221	Coffee
f383	Fireweed tea (Ivan Chai)
f194	Forest mushrooms
f266	Green tea
f246	Guar gum (E412)
f297	Gum arabic
f147	Hibiscus tea

f247	Honey
f197	Honey mushrooms (armillaria)
f324	Hops
f169	Lactose
f123	Lecithin
f90	Malt
f336	Mate
f212	Mushrooms (champignon)
f195	Oyster mushroom
f148	Rooibos tea
f173	Seaweed (Laminaria)
f314	Snail
f121	Sugarcane
f222	Tea
f230	Tofu (bean curd)
f45	Yeast (Saccharomyces cerevisiae)



## DRUGS

### LOCAL ANESTHETICS

c86	Benzocaine	c83	Novocaine (Procaine)
c89	Bupivacaine (Marcaïne)	c100	Prilocaine
c82	Lidocaine	c210	Tetracaine
c88	Mepivacaine	c68	Ultracaine (Articaïne)

### ANALGESICS & NSAIDS

c51	Aspirin	c110	Naproxen
c209	Chymopapain	c20	Paracetamol
c281	Diclofenac	c65	Phenylbutazone
c286	Ibuprofen	c77	Piroxycam
c93	Indometacin	c90	Propyphenazone
c172	Ketoprofen	c52	Pyrazolon (4-aminoantipyrine)
c91	Metamizol		

### ANTIBIOTICS

c204	Amoxicillin	c207	Gentamycin
c203	Ampicillin	c153	Metronidazole
c194	Azithromycin	c95	Neomycin
c119	Bacampicillin	c175	Norfloxacin
c69	Cephalexin	c118	Ofloxacin
c7	Cefaclor	c116	Oxacillin
c206	Cephalosporin	c1	Penicilloyl G
c54	Cephalothin	c2	Penicilloyl V
c152	Chloramphenicol	c63	Phosphomycin
c108	Ciprofloxacin	c301	Rifampicin
c170	Clarithromycin	c436	Spiramycin
c67	Cloxacillin	c295	Streptomycin
c59	Co-trimoxazole	c205	Tetracycline
c62	Doxycycline	c162	Vancomycin
c212	Erythromycin		

### ANTIINFECTIVES

c111	Resorcin	c57	Trimethoprim
c58	Sulfamethoxazole		

### HORMONAL TREATMENTS

c3	ACTH	c73	Insulin human
c155	Cortisone	c70	Insulin porcine
c196	Epinephrine	c424	Prednisolone
c71	Insulin bovine	c99	Thyroxine

### CONTRAST AGENTS

c121	Amidotrizoate meglumine	c120	Diatrizoate
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## OTHERS

c105	4-Aminobenzoic acid (Vitamin B10)	c138	Ginkgo biloba
c320	Acetylcysteine	c282	Penicillamine
c96	Ambroxol	c208	Protamine
c181	Ascorbic acid (Vitamin C)	c109	Pyridoxamine (Vitamin B6)
c103	Atropine	c101	Pyridoxine
c97	Bromhexine	c81	Theophylline
c107	Captopril	c106	Thiamine (Vitamin B1)
c133	Cobalamin (Vitamin B12)	c114	Tryptophan
c104	Folinic acid	c113	Tyramine
c74	Gelatin		

## EPITHELIA

e77	Budgerigar droppings	e84	Hamster epithelium
e78	Budgerigar feathers	e3	Horse dander
e79	Budgerigar serum proteins	e31	Horse epithelium
e201	Canarian feathers	e71	Mouse epithelium
e100	Cat dander	e88	Mouse epithelium+serum-urine proteins
e1	Cat epithelium	e93	Parakeet feathers
e218	Chicken droppings	e213	Parrot feathers
e85	Chicken feathers	e83	Pig epithelium
e208	Chinchilla epithelium	e7	Pigeon droppings
e4	Cow dander	e215	Pigeon feathers
e41	Cow epithelium	e82	Rabbit epithelium
e5	Dog dander	e87	Rat epithelium+serum-urine proteins
e2	Dog epithelium	e74	Rat urine proteins
e86	Duck feathers	e81	Sheep epithelium and wool
e214	Finch feathers	e89	Turkey feathers
e209	Gerbil epithelium	e204	nBos d 6 BSA (Bovine serum albumin) (ref. Nº300-34)
e80	Goat epithelium	e220	nCan f 3 Dog serum albumin (ref. Nº300-34)
e70	Goose feathers	e221	nFel d 2 Cat serum albumin (ref. Nº300-34)
e6	Guinea pig epithelium		

## OCCUPATIONAL

k73	Acrylic	k95	Cochineal (natural)
k87a	Alpha-amylase (from Aspergillus oryzae)	k98	Collagen
k87b	Alpha-amylase (from barley malt)	k83	Cotton seed
k99	Amaranth (dye)	k78	Ethylene oxide
k97	Azorubine (carmoisine)	k302	Ethylparaben (E214)
k300	Benzoic acid	k81	Ficus benjamina
k92	Brilliant green (dye)	k80	Formaldehyde
k96	Chinoline yellow	k91	Henna
k85	Chloramine-T	k93	Indigocarmine

k77	Isocyanate HDI	k20	Sheep wool (treated)
k76	Isocyanate MDI	k74	Silk
k75	Isocyanate TDI	k301	Sorbic acid
k13	Jute	k84	Sunflower seed
k82	Latex	k94	Tartrazine
k100	Maleic anhydride	k86	Trimellitic anhydride
k213	Pepsin	k202	nAna c 2 Bromelain (from pineapple) (ref. Nº300-34)
k79	Phthalic anhydride	k203	nApi m 1 Phospholipase A2 (from honey bee) (ref. Nº300-34)
k71	Ricinus bean (Castor bean)	k201	nCar p 1 Papain (from papaya) (ref. Nº300-34)
k72	Safflower Seed	k208	nGal d 4 Lysozyme (from egg) (ref. Nº300-34)

## MOULDS

m6	<i>Alternaria alternata</i> (tenuis)	m24	<i>Paecilomyces variotii</i>
m17	<i>Aspergillus amstelodami</i>	m25	<i>Penicillium brevi-compactum</i>
m228	<i>Aspergillus flavus</i>	m55	<i>Penicillium digitatum</i> (Green mold of citrus)
m3	<i>Aspergillus fumigatus</i>	m1	<i>Penicillium notatum</i>
m33	<i>Aspergillus niger</i>	m30	<i>Penicillium roquefortii</i> (Blue mold cheese)
m48	<i>Aspergillus oryzae</i>	m28	<i>Penicillium expansum</i>
m36	<i>Aspergillus terreus</i>	m13	<i>Phoma betae</i>
m12	<i>Aureobasidium pullulans</i>	m11	<i>Rhizopus nigricans</i>
m7	<i>Botrytis cinerea</i>	m52	<i>Rhodothorula rubra</i>
m5	<i>Candida albicans</i>	m43	<i>Saccharomyces carlsbergiensis</i> (Barm)
m41	<i>Cephalosporium acremonium</i>	m44	<i>Saccharomyces cerevisiae</i>
m2	<i>Cladosporium herbarum</i>	m34	<i>Serpula lacrymans</i>
m16	<i>Curvularia lunata</i>	m65	<i>Sporisorium cruentum</i>
m57	<i>Epidermophyton floccosum</i>	m10	<i>Stemphylium botryosum</i>
m9	<i>Fusarium moniliforme</i>	m53	<i>Streptomyces griseus</i>
m49	<i>Fusarium solani</i>	m15	<i>Trichoderma viride</i>
m51	<i>Fusarium solani</i>	m205	<i>Trichophyton rubrum</i>
m8	<i>Helminthosporium halodes</i>	m60	<i>Ustilago avenae</i>
m227	<i>Malassezia spp</i>	m61	<i>Ustilago cynodontis</i>
m56	<i>Microsporum canis</i>	m62	<i>Ustilago maydis</i>
m20	<i>Mucor mucedo</i>	m63	<i>Ustilago nuda</i>
m4	<i>Mucor racemosus</i>	m64	<i>Ustilago tritici</i>
m23	<i>Neurospora sitophila</i>		

## MITES

d70	<i>Acarus siro</i>	d74	<i>Euroglyphus maynei</i>
d201	<i>Blomia tropicalis</i>	d73	<i>Glycyphagus domesticus</i>
d2	<i>Dermatophagoides farinae</i>	d71	<i>Lepidoglyphus destructor</i>
d1	<i>Dermatophagoides pteronyssinus</i>	d72	<i>Tyrophagus putrescentiae</i>
d3	<i>Dermatophagoides microceras</i>		

## DUST

h0	House dust (Mites - Moulds - Epithelia)	h2	House dust (Mites - Moulds - Epithelia - Insects - Textiles)
h1	House dust - Greer labs inc.	h3	Books dust

## PARASITES

p4	Anisakis simplex	p3	Toxocara canis
p1	Ascaris lumbricoides		

## INSECTS – VENOMS

i206	American cockroach ( <i>Periplaneta americana</i> )	i14	House cricket ( <i>Acheta domestica</i> )
i67	Aphids ( <i>Aphididae</i> )	i15	Housefly ( <i>Musca domestica</i> )
i68	Black fly ( <i>Simulium venustum</i> )	i71	Mosquito ( <i>Aedes communis</i> )
i73	Bloodworm ( <i>Chironomus spp.</i> )	i74	Mosquito ( <i>Culex pipiens</i> )
i66	Cat flea ( <i>Ctenocephalides felis</i> )	i8	Moth ( <i>Heterocera mix</i> )
i6	Cockroach ( <i>Blatella germanica</i> )	i4	Paper wasp ( <i>Polistes spp.</i> )
i3	Common wasp (yellow jacket) ( <i>Vespa spp.</i> )	i69	Red wood ant ( <i>Formica spp.</i> )
i75	European hornet ( <i>Vespa crabro</i> )	i2	White-faced hornet ( <i>Dolichovespula maculata</i> )
i70	Fire ant ( <i>Solenopsis invicta</i> )	i5	Yellow hornet ( <i>Dolichovespula arenaria</i> )
i1	Honey bee ( <i>Apis mellifera</i> )	i12	nApi m 4 Melittin (ref. Nº300-34)
i204	Horse fly ( <i>Tabanus spp.</i> )		

## GRASSES

g17	Bahia grass ( <i>Paspalum notatum</i> )	g10	Johnson grass ( <i>Sorghum halepense</i> )
g201	Barley ( <i>Hordeum vulgare</i> )	g202	Maize ( <i>Zea mays</i> )
g9	Bentgrass ( <i>Agrostis stolonifera</i> )	g4	Meadow fescue ( <i>Festuca elatior</i> )
g2	Bermuda grass ( <i>Cynodon dactylon</i> )	g16	Meadow foxtail ( <i>Alopercurus pratensis</i> )
g11	Bromegrass ( <i>Bromus inermis</i> )	g5	Rye grass ( <i>Lolium perenne</i> )
g71	Canary grass ( <i>Phalaris arundinacea</i> )	g1	Sweet vernall grass ( <i>Anthoxanthum odoratum</i> )
g3	Cocksfoot ( <i>Dactylis glomerata</i> )	g6	Timothy grass ( <i>Phleum pratense</i> )
g200	Common cattail ( <i>Typha latifolia</i> )	g13	Velvet Grass ( <i>Holcus lanatus</i> )
g8	Common meadow grass ( <i>Poa pratensis</i> )	g70	Wild rye grass ( <i>Elymus triticoides</i> )
g7	Common reed ( <i>Phragmites communis</i> )	g205	rPhl p 1 Timothy ( <i>Phleum pratense</i> ) (ref. Nº300-34)
g21	Couch (Quack) Grass ( <i>Agropyron repens</i> )	g206	rPhl p 2 Timothy ( <i>Phleum pratense</i> ) (ref. Nº300-34)
g14	Cultivated oat ( <i>Avena sativa</i> )	g212	rPhl p 12 Timothy ( <i>Phleum pratense</i> ) (ref. Nº300-34)
g12	Cultivated rye ( <i>Secale cereale</i> )	g215	rPhl p 5 Timothy ( <i>Phleum pratense</i> ) (ref. Nº300-34)
g15	Cultivated wheat ( <i>Triticum aestivum</i> )		

## WEEDS

w45	Alfalfa ( <i>Medicago sativa</i> )	w55	Lily of the valley ( <i>Convallaria majalis</i> )
w210	Beet ( <i>Beta vulgaris</i> )	w44	Madonna lily ( <i>Lilium candidum</i> )
w206	Camomile ( <i>Matricaria chamomilla</i> )	w6	Mugwort ( <i>Artemisia vulgaris</i> )
w24	China aster ( <i>Callistephus chinensis</i> )	w7	Ox eye daisy (Marguerite) ( <i>Chrysanthemum leucanthemum</i> )
w13	Cocklebur ( <i>Xanthium commune</i> )	w39	Peony ( <i>Paeonia</i> spp.)
w38	Coltsfoot ( <i>Tussilago farfara</i> )	w36	Primerose ( <i>Primula variabilis</i> )
w20	Common nettle ( <i>Urtica dioica</i> )	w203	Rape ( <i>Brassica napus</i> )
w14	Common pigweed ( <i>Amaranthus retroflexus</i> )	w34	Red clover ( <i>Trifolium pratense</i> )
w1	Common ragweed ( <i>Ambrosia elatior</i> )	w9	Ribwort plantain ( <i>Plantago lanceolata</i> )
w53	Common Saint John's wort ( <i>Hypericum perforatum</i> )	w16	Rough marshelder ( <i>Iva ciliata</i> )
w41	Curly dock ( <i>Rumex crispus</i> )	w11	Salwort ( <i>Salsola kali</i> )
w23	Dahlia ( <i>Dahlia pinnata</i> )	w15	Scale ( <i>Atriplex lentiformis</i> )
w8	Dandelion ( <i>Taraxacum vulgare</i> )	w18	Sheep sorrel ( <i>Rumex acetosella</i> )
w46	Dog fennel ( <i>Eupatorium capillifolium</i> )	w204	Sunflower ( <i>Helianthus annuus</i> )
w52	Dwarf everlast ( <i>Helichrysum arenarium</i> )	w30	Tulip ( <i>Tulipa</i> spp.)
w4	False ragweed ( <i>Franseria acanthicarpa</i> )	w21	Wall pellitory ( <i>Parietaria judaica</i> )
w17	Firebush ( <i>Kochia scoparia</i> )	w19	Wall pellitory ( <i>Parietaria officinalis</i> )
w16	Fireweed ( <i>Chamaenerion angustifolium</i> )	w2	Western ragweed ( <i>Ambrosia psilostachya</i> )
w37	Garden cosmos ( <i>Cosmos bipinnatus</i> )	w32	White sweet clover ( <i>Melilotus alba</i> )
w28	Garden rose ( <i>Rosa</i> spp.)	w5	Wormwood ( <i>Artemisia absinthium</i> )
w35	Geranium ( <i>Pelargonium</i> spp.)	w33	Yellow sweet clover ( <i>Melilotus officinalis</i> )
w3	Giant ragweed ( <i>Ambrosia trifida</i> )	w211	rPar j 2 Wall pellitory ( <i>Parietaria judaica</i> ) (ref. Nº300-34)
w12	Golden rod ( <i>Solidago virgaurea</i> )	w230	nAmb a 1 Common ragweed ( <i>Ambrosia elatior</i> ) (ref. Nº300-34)
w10	Goosefoot (Lamb's quarters) ( <i>Chenopodium album</i> )	w231	nArt v 1 Mugwort ( <i>Artemisia vulgaris</i> ) (ref. Nº300-34)
w65	Krantz aloe ( <i>Aloe arborescens</i> )	w233	nArt v 3 Mugwort ( <i>Artemisia vulgaris</i> ) (ref. Nº300-34)
w54	Lavender ( <i>Lavandula angustifolia</i> )		

## TREES

t19	Acacia ( <i>Acacia longifolia</i> )	t73	Australian pine ( <i>Casuarina equisetifolia</i> )
t34	Almond ( <i>Prunus dulcis</i> )	t223	Bald cypress ( <i>Taxodium distichum</i> )
t72	American sweetgum ( <i>Liquidambar styraciflua</i> )	t5	Beech ( <i>Fagus</i> spp.)
t25	Apple ( <i>Malus pumila</i> )	t3	Birch ( <i>Betula verrucosa</i> )
t30	Apricot ( <i>Prunus armeniacea</i> )	t21	Cajeput tree ( <i>Melaleuca leucadendron</i> )
t222	Arizona cypress ( <i>Cupressus arizonica</i> )	t80	Cedar elm ( <i>Ulmus crassifolia</i> )
t13	Aspen ( <i>Populus tremula</i> )	t31	Cherry ( <i>Prunus cerasus</i> )

t206	Chestnut ( <i>Castanea sativa</i> )	t39	Mango ( <i>Mangifera indica</i> )
t37	Chinese pear ( <i>Pyrus pyrifolia</i> )	t1	Maple ash ( <i>Acer negundo</i> )
t38	Coconut tree ( <i>Cocos nucifera</i> )	t20	Mesquite ( <i>Prosopis juliflora</i> )
t4	Common hazel ( <i>Corylus avellana</i> )	t112	Mock-orange ( <i>Philadelphus coronarius</i> )
t116	Common privet ( <i>Ligustrum vulgare</i> )	t7	Oak ( <i>Quercus alba</i> )
t214	Date palme ( <i>Phoenix dactylifera</i> )	t9	Olive ( <i>Olea europea</i> )
t114	Dog-rose ( <i>Rosa canina</i> )	t32	Orange tree ( <i>Citrus sinensis</i> )
t207	Douglas fir ( <i>Pseudotsuga taxifolia</i> )	t35	Peach ( <i>Prunus persica</i> )
t14	Eastern cottonwood ( <i>Populus deltoides</i> )	t36	Pear ( <i>Pyrus communis</i> )
t205	Elder ( <i>Sambucus nigra</i> )	t16	Pine ( <i>Pinus silvestris</i> )
t8	Elm ( <i>Ulmus americana</i> )	t33	Plum ( <i>Prunus domestica</i> )
t218	English oak ( <i>Quercus robur</i> )	t71	Red mulberry ( <i>Morus rubra</i> )
t209	European hornbeam ( <i>Carpinus betulus</i> )	t45	Rowan ( <i>Sorbus aucuparia</i> )
t42	European larch ( <i>Larix decidua</i> )	t115	Silver wattle (mimosa) ( <i>Acacia dealbata</i> )
t28	False acacia ( <i>Robinia pseudoacacia</i> )	t29	Sweet cherry ( <i>Prunus avium</i> )
t2	Grey alder ( <i>Alnus incana</i> )	t43	Thuja ( <i>Thuja orientalis</i> )
t18	Gum-tree ( <i>Eucalyptus</i> spp.)	t77	Virginia live oak ( <i>Quercus virginiana</i> )
t22	Hickory ( <i>Carya pecan</i> )	t10	Walnut ( <i>Juglans</i> spp.)
t203	Horse chestnut ( <i>Aesculus hippocastanum</i> )	t15	White ash ( <i>Fraxinus americana</i> )
t23	Italian cypress ( <i>Cupressus sempervirens</i> )	t70	White mulberry
t17	Japanese cedar ( <i>Cryptomeria japonica</i> )	t44	White poplar ( <i>Populus alba</i> )
t113	Jasmine ( <i>Jasminum</i> spp.)	t102	White willow ( <i>Salix alba</i> )
t6	Juniper ( <i>Juniperus sabinooides</i> )	t12	Willow ( <i>Salix caprea</i> )
t24	Lilac ( <i>Syringa vulgaris</i> )	t41	Yew ( <i>Taxus media</i> )
t208	Linden ( <i>Tilia cordata</i> )	t215	rBet v 1 Birch ( <i>Betula verrucosa</i> ) (ref. Nº300-34)
t11	London plane (Maple leaf sycamore) ( <i>Platanus acerifolia</i> )	t216	rBet v 2 Birch ( <i>Betula verrucosa</i> ) (ref. Nº300-34)
		t220	rBet v 4 Birch ( <i>Betula verrucosa</i> ) (ref. Nº300-34)

## OTHER ALLERGENS

o208	Artemia, Fish feed	o71	Human hair
o32	Beech wood	o33	Oak wood
o1	Cotton linters	o36	Pine wood
o207	Daphnia	o70	Seminal fluid
o49	Elm wood	o209	Tetramin, Fish feed
o100	Escherichia coli	o201	Tobacco leaf
o7	Hay dust		

## THE MOLECULAR GENETIC DIAGNOSTICS

### Reagents for PCR



768-01	F polymerase 100 U	758-10	Taq M master-mix 50 µl: 1000 reactions
768-05	F polymerase 500 U	758-12	Taq M master-mix 50 µl: 1200 reactions
777-05	F polymerase with master-mix buffer, 500 U	759-02	Taq M master-mix (green) 50 µl: 200 reactions
775-01	F polymerase Lyo, 100 U	759-10	Taq M master-mix (green) 50 µl: 1000 reactions
775-05	F polymerase Lyo, 500 U	759-12	Taq M master-mix (green) 50 µl: 1200 reactions
750-10	Taq polymerase 1000 U	764-02	Taq AB master-mix 50 µl: 200 reactions
750-50	Taq polymerase 5000 U	764-10	Taq AB master-mix 50 µl: 1000 reactions
754-10	Taq polymerase (Green) 1000 U	765-02	Taq AB master-mix (green) 50 µl: 200 reactions
754-50	Taq polymerase (Green) 5000 U	765-10	Taq AB master-mix (green) 50 µl: 1000 reactions
755-10	Taq polymerase (Red) 1000 U	767-10	Taq AB master-mix 2,5x 25 µl: 1000 reactions
755-50	Taq polymerase (Red) 5000 U	767-100	Taq AB master-mix 2,5x 26 µl: 10000 reactions
751-10	TaqM Polymerase 1000 U	769-10	TaqM master-mix Lyo. 30 µl: 1000 reactions
751-50	TaqM Polymerase 5000 U	769-25	TaqM master-mix Lyo. 30 µl: 2500 reactions
751-100	TaqM Polymerase 10000 U	773-10	TaqAB master-mix Lyo 30 µl: 1000 reactions
756-10	TaqM Polymerase (Green) 1000 U	773-25	TaqAB master-mix Lyo 30 µl: 2500 reactions
756-50	TaqM Polymerase (Green) 5000 U	774-10	MMLV TaqM master-mix Lyo. 30 µl: 1000 reactions
756-100	TaqM Polymerase (Green) 10000 U	774-25	MMLV TaqM master-mix Lyo. 30 µl: 2500 reactions
757-10	TaqM Polymerase (Red) 5000 U	772-10	MMLV TaqAB master-mix Lyo. 30 µl: 1000 reactions
757-50	TaqM Polymerase (Red) 1000 U	772-25	MMLV TaqAB master-mix Lyo 30 µl: 2500 reactions.
752-10	TaqAB Polymerase 1000 U	753-05	Uracil-DNA-Glycosylase 500 U
752-50	TaqAB Polymerase 5000 U	753-50	Uracil-DNA-Glycosylase 5000 U
763-10	TaqAB Polymerase (Green) 1000 U	770-01	Proteinase K, 10 mg
763-50	TaqAB Polymerase (Green) 5000 U	770-10	Proteinase K, 100 mg
776-10	Taq AB polymerase Lyo, 1000 U	771-01	DBS pretreatment buffer, 10 ml
776-50	Taq AB polymerase Lyo5000 U		Storage conditions: -18°C...-30°C
758-02	Taq M master-mix 50 µl: 200 reactions		Shelf life of the kit: 2 years

### DNA Extraction



400-20

Multi-DNA-Extraction



Analyzed bioassay

samples of blood serum/ plasma, whole blood, dried blood, saliva, urine, epithelial cell scrapes from cervical canal and urethra

Number of tests

96

Duration of the procedure

35-40 min

Storage conditions

+2°C...+8°C

Shelf-life, month

12

**Nº 400-22 Rapid-DNA-Bio**



Analyzed bioassay

samples of saliva, urine, cerebrospinal fluid, prostate gland secretion, epithelial cell scrapes from cervical canal and urethra, oropharyngeal surface, bulbar conjunctiva

Number of tests	100
Duration of the procedure	15 min
Storage conditions	(+2°C) – (+8°C)
Shelf-life, month	12

**The Molecular Genetic diagnostics by means of Real-Time PCR**

**Nº 400-05 TromboGENE**



Detection method	Real-Time PCR
SNPs detected	+1691G/A in <i>F5</i> gene, +20210G/A in <i>F2</i> gene
Specimen types	Whole blood, saliva
Number of tests	50
Equipment	CFX96, iCycler iQ5, Rotor-Gene 6000, DT-96
Detection channels	FAM, ROX
Shelf-life, month	12
Storage conditions	-20°C

**Nº 400-06 PharmacoGENE-CYP2C9**



Detection method	Real-Time PCR
SNPs detected	<i>CYP2C9</i> *2 (+430C/T) and <i>CYP2C9</i> *3 (+1075A/C) in <i>CYP2C9</i> gene
Specimen types	Whole blood, saliva
Number of tests	50
Equipment	CFX96, iCycler iQ5, Rotor-Gene 6000, DT-96
Detection channels	FAM, ROX
Shelf-life, month	12
Storage conditions	-20°C

**Nº 400-07 PharmacoGENE-VKORC1**



Detection method	Real-Time PCR
SNPs detected	-1639G/A in <i>VKORC1</i> gene
Specimen types	Whole blood, saliva
Number of tests	50
Equipment	CFX96, iCycler iQ5, Rotor-Gene 6000, DT-96
Detection channels	FAM, ROX
Shelf-life, month	12
Storage conditions	-20°C



## Diagnostics Of Sexually Transmitted Diseases

№ 440 **Intifica Neisseria gonorrhoeae**

№ 442 **Intifica Trichomonas vaginalis**



Form of issue	Form S №440-01 №442-01	Form T №440-02 №442-02
	strips	individual tubes
Number of tests	112	112
Method of detection	Real-Time PCR	Real-Time PCR
Equipment	CFX96, CFX96 Touch (Bio-Rad, USA), «DTprime», «DTlite» (DNA- Technology, Russia), LightCycler 96 (Roche, Germany) or similar	Rotor-Gene 3000/6000 (Corbett Research, Australia), Rotor-Gene Q (Qiagen, Germany) or similar
Storage conditions	+2°C...+8°C	+2°C...+8°C
Shelf life of the kit	12 months	12 months

## Microarray Diagnostics

№ 600-01 **Cystic Fibrosis-BioChip** **CE**

Analysis Method	reverse hybridization of fluorescent-labeled probes on the microarray
Analyzed bioassay	DNA sample
Analytical sensitivity	1ng/μl
Diagnostic sensitivity	≈95%
Specificity	≈97%
Repeatability	100%
Number of tests	5
Storage conditions	-18°C...-22°C
Shelf-life, month	6



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