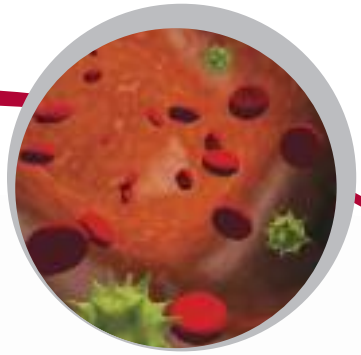
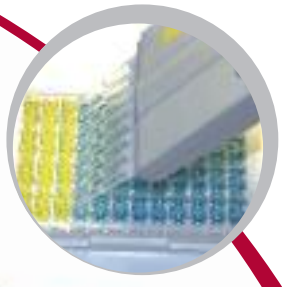
ASTRA BIOTECH

Catalogue 2012

Quality reagents and assays for life





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About Astra Biotech GmbH

A reputation for quality

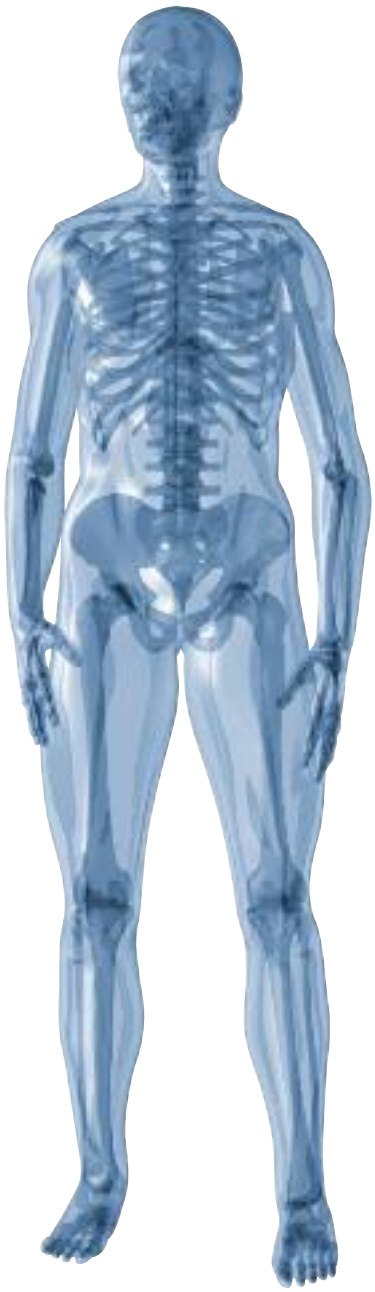
Astra Biotech GmbH offers high quality reagents, allergens, antibodies, recombinant proteins, and assays for the determination of hormones, allergies, tumour markers and infectious diseases. Quality is one of the key cornerstones on which Astra Biotech maintains its reputation and with which we strive to increase customer satisfaction and gain growing customer loyalty.

We take great pride in our highest quality assays, which are all IVD compliant and therefore suitable for direct, accurate and reproducible diagnostic purposes, as well as for research.

Optimising patient healthcare

Our target is to offer laboratories, hospitals and diagnostic centres excellent quality, affordable reagents and assays which meet and even exceed the standards set by leading international laboratories.

For example, an important product group within Astra Biotech's portfolio is PCR test kits for the identification of genetically influenced diseases and sensitivities to specific drugs. By developing these innovative assays we contribute to optimising patient healthcare around the world through early diagnosis of potential risks to individuals.



Research and development

Astra Biotech's high-quality diagnostic kits and component reagents are supported by the breadth of skills and experience of our research and development specialists.

Creating new products and bringing them successfully to market are vital for future health and well-being. If you aim to grow your business by developing new diagnostic solutions, the expertise within our team can help you use your resources more efficiently, achieve regulatory compliance, and reduce the time to market and associated costs.

Further information

If you have any questions about our products, or you would like to arrange a meeting to discuss details of your applications, please contact us. We look forward to assisting you with your project.

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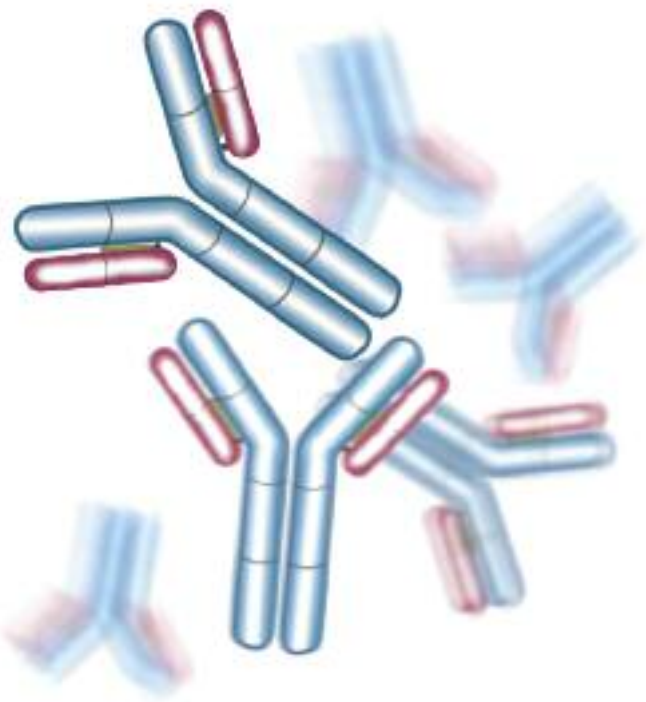
Reagents and semi-products

We offer high-quality kit components, reagents and semi-products for OEM as well as for developing in-house clinical research and diagnostic assays. High sensitivity, specificity and stability ensure excellent results and reproducibility.

Astra Biotech's diagnostic portfolio contains a broad selection of antibodies, antigens, recombinant proteins, conjugates (ready to use or concentrated), calibrators, microplates and slides. Allergens are also available – see pages 25–26.

High grade of purity is guaranteed in all components and rigorous quality control procedures in Astra Biotech's facilities enable clear tracking of all component materials.

If the reagent or component you require is not listed, please contact our Sales Department for further information.



Antibodies

High-affinity murine monoclonal antibodies (Mabs) against human hormones and proteins. Our antibodies are used in the manufacturing of our own ELISA kits, guaranteeing superior performance.

- All Mabs are ELISA-tested.
- Supplied either as protein G-affinity-purified or as ascites.
- In addition to use in ELISA kit manufacturing, the table below indicates suggested pairs for sandwich immunoassays.

Ref	Antibody	Clone	Suggested use
10-01	Anti-AFP-mouse-mAb (IgG1)	3G6	As detection antibody with Mab 3H3
10-02	Anti-AFP-mouse-mAb (IgG1)	3H3	As solid-phase antibody with Mab 3G6
10-03	Anti-Testosterone-mouse-mAb (IgG1)	3F6	
10-04	Anti-Progesterone-mouse-mAb	4G7	
10-05	Anti-L-thyroxin-mouse-mAb	3F3	
10-06	Anti-hCG-mouse-mAb	11C9	As detection antibody with Mab 4B4
10-07	Anti-hCG-mouse-mAb	4B4	As solid-phase antibody with Mab 11C9
10-08	Anti-Prolactin-mouse-mAb	3C5	As solid-phase antibody with Mab 3P10
10-09	Anti-Prolactin-mouse-mAb	3P10	As detection antibody with Mab 3C5
10-10	Anti-Cortisol-mouse Mab	7C12	Suggested Use
10-11	Anti-CA 125	3C81	As a conjugated tracer together with Mab 2B6
10-12	Anti-CA 125	2B6	As a solid-phase antibody together with Mab 3C81

Antigens

Antigens are isolated from culture supernatants and purified by gel filtration, dialysis or affinity chromatography.

- Quantified using ELISA.
- For use in calibration probes, as immunogens or in other applications.

Ref	Antigen	Concentration	Format
11-01	Thyroglobulin	≥1 mg/ml	Highly purified, liquid
11-02	CA125	≥100.000 IU/ml	Purified Affinity chromatography
11-03	CA19-9	≥50.000 IU/ml	Purified Ammonium sulfate precipitation, gel filtration chromatography
11-04	IgE	≥10.000 IU/ml	Purified, liquid

Recombinant proteins

Our recombinant proteins are manufactured in liquid format with high purity above 90%.

- Storage: up to 3 years at –20°C; short-term at +4°C for convenience.
- For use in ELISA and Western Blot applications.

Ref	Recombinant protein	Additional information
17-01	HIV-1	Contains immunodominant region of HIV-1 gp41 protein
17-02	HIV-2	Contains immunodominant region of HIV-2 gp36 protein
17-03	HSV-2	Contains immunodominant HSV gG2 region (525-578 aa)
17-04	HSV-2	Contains immunodominant Herpes Simplex Virus gG2 region (525-578 aa), GST
17-05	hProlactin	Human Prolactin
17-06	HCV core	Contains immunodominant region of Hepatitis C Virus (type 1b) Core protein (2-120 aa)
17-07	HCV NS5	Contains immunodominant region of Hepatitis C Virus (type 1b) NS5 protein (2006-2313 aa)
17-08	Rubella E1 mosaic	Contains immunodominant fragments of Rubella Virus glycoprotein E1, amino acids: 157-176, 213-239, and 374-390
17-09	Rubella E2 mosaic	Contains Rubella Virus glycoprotein E2 immunodominant region (31-105 aa)
17-10	PAPP-A	Human Pregnancy-associated protein A (PAPPA)
17-11	Rubella C	Contains immunodominant region of Rubella Virus Capsid, amino acids 1-123
17-100	Betv 1a	Recombinant Birch pollen (Betula verrucosa), PR-10 protein

Steroid and Thyroid Conjugates (concentrated)

HRP-conjugates of steroid and thyroid hormones are produced by binding hormones and HRP amino groups, resulting in stable covalent bonds. All steps of the synthesis are strictly controlled.

- High lot-to-lot reproducibility.
- For use in competitive ELISA for quantitative detection of some hormones in blood serum.

Ref	Conjugate	Description	Titre
12-01	Cortisol-HRP Conjugate	Cortisol-3-O-carboxymethyloxime-HRP conjugate	1:10 000
12-02	Progesterone-HRP Conjugate	Progesterone-11α-hemisuccinate-HRP conjugate	1:10 000
12-03	Testosterone-HRP Conjugate	Testosterone-3-O-carboxymethyloxime-HRP conjugate	1:10 000
12-04	DHEA-HRP Conjugate	DHEA-3ß hemisuccinate-HRP conjugate	1:10 000
12-05	T3-HRP Conjugate	Triiodothyronine-aminocaproate-HRP conjugate	1:10 000
12-06	T4-HRP Conjugate	L-thyroxin-aminocaproate-HRP conjugate	1:10 000
12-07	17-OH-Progesterone Conjugate	17-OH-Progesterone-3-O-carboxymethyloxime-HRP conjugate	1:10 000

Mab- and Protein-HRP Conjugates (concentrated)

Conjugates of antibodies and antigens with HRP. The conjugate buffer contains substances that reduce occurrence of false positive and false negative reactions.

- High lot-to-lot reproducibility.
- High activity and specificity.
- For use in ELISA or Western blot assays. Stable also when diluted.
- Shelf life: 1 year; stable for 1 month after opening.

Ref	Conjugate	Titre
13-01	Anti-TSH-HRP Conjugate	1:10 000
13-03	Anti-AFP-HRP Conjugate	1:10 000
13-04	Anti-hCG-HRP Conjugate	1:10 000
13-05	Anti-Prolactin-HRP Conjugate	1:10 000
13-06	Protein-A-HRP Conjugate	1:10 000
13-07	Anti-FSH-HRP Conjugate	1:10 000
13-08	Anti-Ferritin-HRP Conjugate	1:10 000
13-09	Anti-hIgG-HRP Conjugate	1:10 000
13-10	Anti CA-125	1:10 000
13-11	Anti-hIgE	1:10 000
13-12	Anti-SHBG	1:10 000
13-13	Anti-LH	1:10 000
13-14	Anti-TG	1:10 000
13-15	Anti-Proinsulin	1:10 000

Conjugates (ready for use)

Conjugates of antibodies and antigens with HRP.

Ref	Conjugate	Note
14-01	Anti-IgE-HRP Conjugate	
14-02	Anti-hIgG-HRP Conjugate	
14-04	Anti-AFP-HRP Conjugate	
14-05	DHEA-HRP Conjugate	DHEA-S conjugated with HRP
14-06	Cortisol-HRP Conjugate	
14-07	Anti-LH-HRP Conjugate	
14-08	Anti-Prolactin-HRP Conjugate	
14-09	Progesterone-HRP Conjugate	
14-10	Anti-CA-125-HRP Conjugate	
14-11	Anti-SHBG-HRP Conjugate	
14-13	T3-HRP Conjugate	Human T3 conjugated with HRP
14-14	T4-HRP Conjugate	
14-15	Anti-TG-HRP Conjugate	
14-16	Testosterone-HRP Conjugate	
14-17	Anti-TSH-HRP Conjugate	
14-18	Anti-Ferritin-HRP Conjugate	
14-19	Anti-Proinsulin-HRP Conjugate	
14-20	Anti-FSH-HRP Conjugate	
14-21	Anti-hCG-HRP Conjugate	
14-22	17-OH-Progesterone-HRP Conjugate	

Calibrators

Calibrator sets include serum-based calibrators containing highly purified antigens. The presence of serum reduces matrix effects and ensures quality of the reagents.

- Controlled using international standards.
- Standardised with reference assays regarded as well-established gold standards.
- Shelf life: 1 year; stable for 1 month after opening.

Ref	Calibrators	Ready for use	Lyophilized
15-01	IgE Calibrators	•	
15-02	Anti-TG Calibrators	•	
15-03	Anti-TPO Calibrators	•	
15-04	AFP Calibrators	•	
15-05	DHEA Calibrators	•	
15-06	Cortisol Calibrators	•	•
15-07	LH Calibrators	•	•
15-08	Neo-TSH Calibrators (Dried spots of blood with known TSH concentration)	•	
15-09	Prolactin Calibrators	•	
15-10	Progesterone Calibrators	•	
15-11	CA-125 Calibrators	•	•
15-12	SHBG Calibrators	•	
15-13	Free-T4 Calibrators	•	
15-14	T3 Calibrators	•	•
15-15	T4 Calibrators	•	•
15-16	TG Calibrators	•	
15-17	Testosterone Calibrators	•	
15-18	TSH Calibrators	•	
15-19	Ferritin Calibrators	•	•
15-20	Proinsulin Calibrators	•	•
15-21	FSH Calibrators	•	
15-22	hCG Calibrators	•	
15-23	17-OH-Progesterone Calibrators	•	•

Microplates (ready for use)

Microplates with immobilised antibodies and antigens.

- Antigens and antibodies manufactured in-house using pure and highly specific raw materials to prevent cross-reactions.
- Post-coating reagents covering micro-wells prevent possible interference.
- 12 breakable strips of 8 wells each: 96-well plate format fits into all workflows.
- Shelf life: 2 years.

Ref	Microplates	Coating
16-01	IgE Plate	Anti-IgE monoclonal antibodies
16-02	Ab-TG Plate	Purified TG
16-03	Ab-TPO Plate	Human TPO
16-04	AFP Plate	Anti-AFP monoclonal antibodies
16-05	DHEA Plate	Goat polyclonal antibodies against rabbit IgG
16-06	Cortisol Plate	Anti-cortisol monoclonal antibodies
16-07	LH Plate	Anti-LH monoclonal antibodies
16-08	Neo-TSH Plate	Anti-TSH monoclonal antibodies
16-09	Prolactin Plate	Anti-prolactin monoclonal antibodies
16-10	Progesterone Plate	Anti-progesterone monoclonal antibodies
16-11	CA-125 Plate	Anti-CA 125 monoclonal antibodies
16-12	SHBG Plate	Anti-SHBG monoclonal antibodies
16-13	Free-T4 Plate	Anti-T4 monoclonal antibodies
16-14	T3 Plate	Anti-T3 monoclonal antibodies
16-15	T4 Plate	Anti-T4 monoclonal antibodies
16-16	TG Plate	Anti-TG monoclonal antibodies
16-17	Testosterone Plate	Anti-testosterone monoclonal antibodies
16-18	TSH Plate	Anti-TSH monoclonal antibodies
16-19	Ferritin Plate	Anti-ferritin monoclonal antibodies
16-20	Proinsulin Plate	Anti-proinsulin monoclonal antibodies
16-21	FSH Plate	Anti-FSH monoclonal antibodies
16-22	hCG Plate	Anti-hCG monoclonal antibodies
16-23	17-OH-Progesterone Plate	Anti-17-OH-Progesterone monoclonal antibodies

Slides

Ready-to-use slides manufactured from extra-white microscope glass.

- Low intrinsic fluorescence and background noise.
- High quality immobilizing surface compatible with most appropriate buffers.
- Shelf life: at least 3 months at room temperature in original packaging.

Ref	Slide substrate	Use	Immobilization capacity
18-01	Aldehyde	Amino modified oligos and cDNAs; proteins	$>0.5\times10^{-18}$ mol/µm^2
18-02	Aminosilane	Long lengths of DNA (more than 200 bp)	$500–600\times10^{-15}$ mol/μm^2
18-03	Epoxy	Amino specific covalent bindingof DNA (preferably longer than100bp) and proteins	0.35×10^{-18} mol/µm^2

ELISA test kits

Astra Biotech ELISA test kits are manufactured by incorporating only certified high purity reagents and in accordance with stringent internal quality control procedures. All the assays are IVD-compliant and therefore suitable for direct diagnostic purposes. The standard 96-well plate format fits into all work flows and the assays' high specificity and sensitivity parameters allow consistently accurate results and guarantee high reproducibility.

Kit characteristics

Except where noted, all ELISA test kits share the following characteristics:

- Number of tests: 96 (Neonatal TSH, Toxo-IgG-avidity and Hepatitis-HBsAg confirmation kits differ)
- Precision: Intra-assay variation <8% (Neonatal TSH kit differs)
- Shelf life: 12 months (Specific IgE kit –18 months)

Adrenal

DHEA-Sulphate (Ref 20-01)

Quantitative assay of DHEA-S is required for differential diagnostics of ovariopathies, assessing adrenal function in pubescence, and for differential diagnostics of Cushing's syndrome and Cushing's disease.

• Analytical sensitivity:	0,04 µg/ml
• Range of evaluated concentrations:	0–10 µg/ml
• Incubation:	60 minutes at 37°C

Cortisol (Ref 20-02)

The serum cortisol assay is used in assessing the functional status of the 'hypothalamus–pituitary gland–adrenal cortex' system. Quantifying cortisol concentration is especially significant when diagnosing Addison's and Cushing's diseases.

• Analytical sensitivity:	10 nmol/L
• Range of evaluated concentrations:	0–2000 nmol/L
• Incubation:	60 minutes at 37°C

17-OH-Progesterone (Ref 20-03)

Measurement of 17-OHP in serum can be used to monitor the activity of 21-hydroxylase in the adrenal cortex and plays a significant role in the differential diagnosis of congenital adrenal hyperplasia.

• Analytical sensitivity:	0,3 nmol/L
• Range of evaluated concentrations:	0–60 nmol/L
• Incubation:	30 minutes at 37°C

Fertility

SHBG (Ref 21-01)

The concentration of SHBG increases with hyperthyroidism or hyperestrogenia. In women a decrease in SHBG concentration correlates with its hyperandrogenic status (polycystic ovary syndrome, congenital dysfunctions of adrenal cortex, hirsutism). A moderate decrease in SHBG concentration is also observed in cases of hypothyroidism, Cushing's disease, hyperprolactinemia, acromegalia and after administering androgens or progestins possessing an androgenic effect. SHBG concentration is used to calculate the free androgen index.

• Analytical sensitivity:	2 nmol/L
• Range of evaluated concentrations:	0–200 nmol/L
• Incubation:	60 minutes at 37°C

Testosterone (Ref 21-02)

Serum testosterone assays are of great value in investigating the function of the testes and in the diagnostics of certain adrenal, ovarian and testicular tumours, as well as female hirsutism.

• Analytical sensitivity:	0,2 nmol/L
• Range of evaluated concentrations:	0–50 nmol/L
• Incubation:	90 minutes at 18–25°C

Progesterone (Ref 21-03)

The serum progesterone assay is a valuable tool for evaluating the functional status of the corpus luteus. The test is also used in pregnancy monitoring and may be carried out for research purposes.

• Analytical sensitivity:	0,7 nmol/L
• Range of evaluated concentrations:	0–100 nmol/L
• Incubation:	60 minutes at 37°C

Fertility

Prolactin (Ref 21-04)

Prolactin assays are used in diagnosing testicular and ovarian dysfunctions. Circulating prolactin is measured as a primary test for barrenness. Pathological hyperprolactinemia takes place in hypothyroidism, renal insufficiency and in patients with a pituitary tumour – prolactinoma.

• Analytical sensitivity:	50 mIU/L
• Range of evaluated concentrations:	0–4500 mIU/L
• Incubation:	60 minutes at 37°C

Gonadotropin LH (Ref 21-05)

Increased LH levels are observed in patients with different forms of hypogonadism, renal insufficiency and with cirrhosis. Decreased LH levels that can result in sterility in either sex are observed with dysfunctions of the hypothalamus or the frontal lobe of the pituitary gland. LH quantification is useful for diagnosing menopause, the exact ovulation time definition and for endocrine therapy monitoring.

• Analytical sensitivity:	0,25 mIU/ml
• Range of evaluated concentrations:	0–100 mIU/ml
• Incubation:	60 minutes at 37°C

Gonadotropin FSH (Ref 21-06)

Increased FSH levels are observed in patients with different forms of hypogonadism, renal insufficiency, cirrhosis or as an after-effect of male sterilisation. As a rule, decreased FSH levels are observed in cases of testicular malignancies. FSH measurement is useful for diagnosing menopause, determining exact ovulation time and for endocrine therapy monitoring.

• Analytical sensitivity:	0,25 mIU/ml
• Range of evaluated concentrations:	0–100 mIU/ml
• Incubation:	60 minutes at 37°C

Fertility

Estradiol (Ref 21-07)

The monitoring of estradiol levels is important in evaluating amenorrhea, the onset of menopause, foetal-placental competence during early stages of pregnancy, and infertility in women. It is also essential during ovarian hyperstimulation for IVF.

• Analytical sensitivity:	30 pmol/L
• Range of evaluated concentrations:	0–7500 pmol/L
• Incubation:	60 minutes at 37°C

Prenatal screening

Astra Biotech presents the DS line of test kits, which are designed to detect and assess the presence of trisomy-21 risk (Down's syndrome).

Gonadotropin hCG (Ref 22-01-DS)

Quantitative measurement of hCG is considered the most reliable indicator for early diagnosis of pregnancy. With the Gonadotropin hCG kit it is possible to detect pregnancies as early as the 6th–9th day after conception.

Measurement of changes in the hCG serum level in pregnant women is an important method for prenatal diagnostics of some inborn diseases. This method is also widely used in obstetrics for diagnosing multiple pregnancies, ectopic pregnancies and an increased risk of miscarriage.

• Analytical sensitivity:	5 IU/L
• Range of evaluated concentrations:	0–500 IU/L
• Incubation:	60 minutes at 37°C

Prenatal screening

AFP (Ref 22-02-DS)

Serum AFP measurement in pregnant women is an important method for early diagnosis of certain genetic diseases. This method is also widely used in obstetrics to diagnose multiple pregnancies, prenatal death and risk of miscarriage.

• Analytical sensitivity:	0,9 IU/ml
• Range of evaluated concentrations:	0–300 IU/ml
• Incubation:	60 minutes at 37°C

PAPP-A (Ref 22-03-DS)

The measurement of Pregnancy-associated plasma protein A (PAPP-A) in the first trimester of pregnancy has been reported as a useful marker in antenatal screening for Down's syndrome and other foetal aneuploidies. Reduced PAPP-A values, in combination with maternal age, the measurement of free ß-hCG and the ultrasonic determination of nuchal translucency (NT) in pregnancy weeks 11 to 14, may detect up to 90% of pregnancies with Down's syndrome.

• Analytical sensitivity:	0,02 mU/ml
• Range of evaluated concentrations:	0–7 mU/ml
• Incubation:	90 minutes at 37°C

Gonadotropin free ß-hCG (Ref 22-04-DS)

Normally, free ß-hCG concentration in foetal serum increases and reaches its maximum in the tenth week of pregnancy, then starts to decrease. A foetus with Down's syndrome increases the free beta-subunits in the maternal serum by a factor of two compared with the median value for unaffected pregnancies at each foetal phase.

• Analytical sensitivity:	2 ng/ml
• Range of evaluated concentrations:	0–200 ng/ml
• Incubation:	45+15 minutes at 37°C

Prenatal screening

Prenatal Risk Assessment Software (Ref 22-100)

This software package is designed to increase the effectiveness of complex risk assessments in maternal screening for foetal anomalies such as Down's syndrome, Edwards' syndrome, neural tube defects, and foetal growth retardation.

Group data input enhances efficiency, minimises the time required to process results and reduces user errors arising from manual data input.

Screening protocols supported

- 1st trimester double test (PAPP-A, free ß-hCG) in combination with nuchal translucency (NT).
- 2nd trimester quadruple test (AFP, hCG, uE3, Inhibin-A).
- Complex risk definition using combined test data from both trimesters.

Software features

- Risk assessment protocols support not only biochemical and ultrasound marker data but also a woman's age, weight and type 1 diabetes mellitus status.
- For the first time, chromosomal abnormalities during previous pregnancy and a woman's ethnicity are also considered in the risk calculation.
- Information about individual patients is saved in an editable database.
- Various reports can be created and printed, including individual results of prenatal screening.

Neonatal screening

Neonatal TSH (Ref 23-01)

An increased TSH concentration in dry spots of newborns' blood between the 3rd–5th day of life provides the earliest diagnostic indicator of congenital primary hypothyroidism.

• Kit volume:	192/960
• Analytical sensitivity:	3 µIU/ml
• Intra-assay variation:	<15%
• Range of evaluated concentrations:	0–250 µIU/ml
• Incubation:	overnight at 18…25, 2…8°C

Thyroid

The following kits cover a range of assays which are significant in the evaluation of thyroid function and diagnosis of autoimmune thyroid diseases, such as idiopathic myxoedema, Hashimoto's thyroiditis and Graves' disease.

TSH (Ref 24-01)

• Analytical sensitivity:	0,05 µIU/ml
• Range of evaluated concentrations:	0–15 µIU/ml
• Incubation:	60 minutes at 37°C

TSH 3rd generation (Ref 24-02)

• Analytical sensitivity:	0,01 µIU/ml
• Range of evaluated concentrations:	0–2,5 µIU/ml
• Incubation:	60 minutes at 37°C

Free T4 (Ref 24-03)

• Analytical sensitivity:	1 pmol/L
• Range of evaluated concentrations:	0–100 pmol/L
• Incubation:	60 minutes at 37°C

Triiodothyronine (Ref 24-04)

• Analytical sensitivity:	0,25 nmol/L
• Range of evaluated concentrations:	0–12 nmol/L
• Incubation:	60 minutes at 37°C

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Thyroid

Thyroxin (Ref 24-05)

• Analytical sensitivity:	10 nmol/L
• Range of evaluated concentrations:	0–400 nmol/L
• Incubation:	60 minutes at 37°C

Anti-TPO (Ref 24-06)

• Analytical sensitivity:	4 U/ml
• Range of evaluated concentrations:	0–500 U/ml
• Incubation:	30+30 minutes at 37°C

Anti-TG (Ref 24-07)

• Analytical sensitivity:	7,5 U/ml
• Range of evaluated concentrations:	0–1200 U/ml
• Incubation:	30+30 minutes at 37°C

TG (Ref 24-08)

• Analytical sensitivity:	1 ng/ml
• Range of evaluated concentrations:	0–300 ng/ml
• Incubation:	60 minutes at 37°C

Free T3 (Ref 24-09)

• Analytical sensitivity:	0,5 pmol/L
• Range of evaluated concentration:	0–60 pmol/L
• Incubation:	45+15 minutes at 37°C

Tumour markers

CA-125 (Ref 30-01)

Increased concentration of serum CA-125 is a sign of ovarian pathology (either benign or malignant). Serum CA-125 assays are used to monitor patients with ovarian cancer in order to determine treatment efficacy, and achieve early identification of recurrences and the asymptomatic dissemination of residual tumours.

• Analytical sensitivity:	3 U/ml
• Range of evaluated concentrations:	0–500 U/ml
• Incubation:	60 minutes at 37°C

Gonadotropin hCG (Ref 22-01)

Increased levels of hCG may be detected in patients with teratogenic carcinomas or trophoblastic neoplasias. Less frequently, hCG concentration can increase through ectopic synthesis due to cancer of the testes, breast, intestine, lung or prostate. Measuring hCG provides an important method for diagnosing and monitoring such diseases.

• Analytical sensitivity:	5 IU/L
• Range of evaluated concentrations:	0–500 IU/L
• Incubation:	60 minutes at 37°C

AFP (Ref 22-02)

AFP measurement can be used for diagnosing and monitoring different forms of cancer. For example, high and maintained AFP levels (800–80 000 IU/ml) are often directly connected to primary hepatomas, testicular teratomas and ovarian tumours.

• Analytical sensitivity:	0,9 IU/ml
• Range of evaluated concentrations:	0–300 IU/ml
• Incubation:	60 minutes at 37°C

Anaemia

Ferritin (Ref 40-01)

Ferritin concentration is used to differentiate asiderotic anaemia from other types of anaemia and also helps monitor the iron reserves in pregnant women, donors and patients subjected to regular haemodialysis. The concentration of ferritin in the serum increases with infection, inflammatory processes, acute and chronic liver disorders, leukaemia, Hodgkin's lymphoma, breast cancer and other oncopathologies.

• Analytical sensitivity:	5 ng/ml
• Range of evaluated concentrations:	0–1000 ng/ml
• Incubation:	30 minutes at 37°C

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Allergy

Total IgE (Ref 50-01)

IgE production is essential to anti-helminthic immunity. Detection of high IgE concentrations in serum is an important tool for differentiating between allergic diseases and other pathologies with similar clinical manifestations, such as asthma, frequent respiratory diseases, chronic rhinitis and dermatitis. Increased concentration of total IgE in serum has also been reported in patients with lymphosarcoma and hyper-IgE syndrome.

• Analytical sensitivity:	2,3 IU/ml
• Assay dynamic range:	0–500 IU/ml
• Incubation:	90 minutes at 37°C

Specific IgE (Ref 50-02)

A feature of this test-system is the application of liquid allergens binding to monoclonal antibodies against human IgE immobilized on the inner surface of the wells. This technique has a number of advantages in comparison with systems based on solid-phase allergens, particularly as it avoids cross-reactions of anti-IgE antibodies with the immunoglobulins A, G, M and D.

A different range of allergens can be used for each patient.

• Analytical sensitivity:	0,15 IU/ml
• Specificity:	no cross-reaction with human IgA, IgM, IgG or IgD
• Results are obtained quantitatively and in classes from 0 to 5.	
• Incubation:	60 + 30 +15 minutes at 37°C

Allergens

- Liquid biotinylated allergens for use with the Specific IgE test kit.
- Vial volume: 26 determinations
- Shelf life: 18 months

Ref	Code	Description
		ALLERGEN MIXES
50-11	dm1	Environment mix (d1-d2-e1-e2)
51-04	em1	Feather mix (e70-e85-e86)
51-14	fm1	Infancy food mix (f1-f2-f3-f4-f14-f25-f75)
51-40	fm3	Starches mix (f4-f6-f7-f8-f9)
51-30	fm4	Food mix (seafood: f3-f41-f205-f206-f254)
51-59	fm6	Food mix (nuts: f17+f18-f20-f36-f256)
51-53	fm7	Food mix (vegetable: f12-f15-f25-f31-f35)
50-12	gm1	Grass mix (g3-g4-g5-g6-g8)
51-01	mm1	Mould mix (m1-m2-m3-m4-m6)
50-13	tm2	Tree mix (t2-t3-t4-t15))
50-15	wm2	Weed mix (w1-w6-w7-w8-w9)
		FOOD
50-41	f1	Egg white
50-42	f2	Milk
50-43	f3	Fish (cod)
50-44	f4	Wheat
51-07	f5	Rye
51-18	f7	Oat
51-16	f9	Rice
51-17	f13	Peanut
51-12	f14	Soybean
51-25	f24	Shrimp
51-15	f25	Tomato
51-08	f26	Pork
51-03	f31	Carrot
51-13	f33	Orange
50-45	f35	Potato
51-51	f41	Salmon
51-34	f44	Strawberry
51-56	f45	Yeast
51-09	f49	Apple

Allergens

		FOOD (continued)
50-46	f75	Egg yolk
51-58	f76	Alpha-lactalbumin
51-27	f78	Casein
51-02	f83	Chicken meat
51-21	f82	Cheese, mould type
51-20	f92	Banana
51-49	f94	Pear
51-47	f259	Grape
		MITES
50-21	d1	*Dermatophagoides pteronyssinus*
50-22	d2	*Dermatophagoides farinae*
		EPITHELIA – ANIMAL PROTEINS
50-31	e1	Cat epithelium
50-32	e2	Dog epithelium
51-26	e81	Sheep epithelium
		GRASSES
51-43	g3	Orchard grass (*Dactylis glomerata*)
51-52	g4	Meadow fescue (*Festuca elatior*)
		HOUSE DUSTS
50-51	h1	House dust (Greer Labs, Inc.)
		INSECTS
51-57	i1	Honey bee venom (*Apis mellifera*)
51-11	i6	Cockroach (*Blatella germanica*)
		MOULDS, YEASTS AND MICROORGANISMS
51-38	m1	*Penicillium notatum*
51-45	m2	*Cladosporium herbarum*
51-33	m3	*Aspergillus fumigatus*
51-10	m6	*Alternaria tenuis* (alternata)
		TREES
51-50	t2	Alder (*Alnus incana*)
		WEEDS
51-22	w1	Ragweed, common (*Ambrosia elatior*)
51-35	w204	Sunflower

We are constantly expanding our portfolio of antigens.

Infectious diseases

Herpes Simplex Type 1 IgG (Ref 61-01)

Quantitative definition of HSV 1 specific IgG allows monitoring of antibody concentration and estimation of therapy effectiveness.

• Analytical sensitivity:	2 U/ml
• Sensitivity:	100%
• Specificity:	98,8%
• Range of evaluated concentrations:	0–200 U/ml
• Incubation:	45+30 minutes at 37°C (shaker)

Toxoplasma IgG (Ref 62-01)

An increase in specific antibodies for *Toxoplasma gondii* indicates the acute phase of the disease. Quantitative detection of specific IgG levels also allows indirect estimation of the dynamics of the recovery process.

• Analytical sensitivity:	1,3 IU/ml
• Sensitivity:	97%
• Specificity:	98%
• Range of evaluated concentrations:	0–100 IU/ml
• Incubation:	45+30 minutes at 37°C (shaker)

Toxoplasma-IgG-Avidity (62-02)

The initial IgG antibody response to infection is characterised by antibodies with low avidity. Therefore measuring the avidity of specific IgG is particularly useful for diagnosing a recently acquired, primary *Toxoplasma* infection.

• Number of tests (including controls):	48
• Sensitivity:	97%
• Specificity:	98%
• Incubation:	30+15+30 minutes at 37°C (shaker)

Infectious diseases

Hepatitis-HBsAg (Ref 63-01)

This assay is designed to detect all dominant HBsAg subtypes using a mixture of monoclonal antibodies to capture HBsAg.

• Analytical sensitivity:	0,05 IU/ml
• Sensitivity:	100%
• Specificity:	99,5%
• Range of evaluated concentrations:	0–5 IU/ml
• Incubation:	30+30 minutes at 37°C

Hepatitis-HBsAg confirmation (Ref 63-02)

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

• Kit volume:	48
• Incubation:	30+30+30 minutes at 18…25°C, 37°C

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HIV-anti-HIV-1,2 (Ref 64-01)

Two types, HIV-1 and HIV-2, are detected. Antibodies to HIV appear in 90–95% of infected people within 3 months after contamination, in 5–9% of cases 6 months after contamination and in 0,5–1% more than 6 months after contamination.

• Sensitivity:	100%
• Specificity:	100%
• Incubation:	60 minutes at 37°C

HIV-HIV-Ag/At (Ref 64-02)

Antibodies to HIV-1,2 and p24 antigen are detected. P24 appears in blood as early as 1–3 weeks after contamination and therefore allows for very early detection of HIV when the marker is present.

• Detection limit of HIV p24:	25 pg/ml
• Sensitivity:	100%
• Specificity:	100%
• Incubation:	60 minutes at 37°C

Molecular genetic test kits

Astra Biotech's PCR-based diagnostic kits are used to detect gene polymorphisms associated with life-threatening diseases and individual sensitivities to specific drugs. The test kits simultaneously detect several SNPs and ensure high reliability and diagnostic efficacy.

PCR remains the gold standard for analysis, while real-time PCR is highly accurate, powerful and sensitive. Our real-time PCR assays are validated on multiple commonly-used PCR instruments from leading biotechnology vendors.

Real-time PCR kits

• Requirements for the analysed DNA-sample:	concentration 1–500 ng/μl
• Analysis total time:	2 hours
• Kit size:	50 reactions
• Storage conditions:	–20°C

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Standard PCR kits

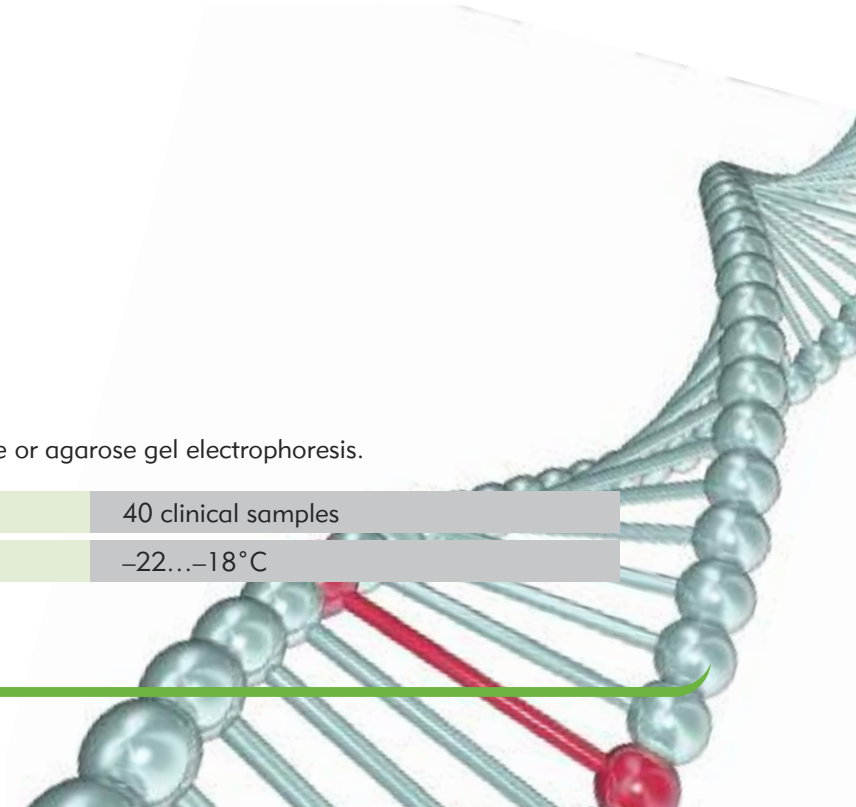
Kit contents

- PCR mixes
- Positive control for PCR and restriction
- DNA-polymerase
- Restriction enzymes
- Buffers for restriction enzymes.

Equipment required

- PCR-workstation
- Thermocycler
- Minivortex, centrifuge
- Thermostat
- Set of pipettes with variable volume
- Standard equipment for polyacrylamide or agarose gel electrophoresis.

• Kit size:	40 clinical samples
• Storage conditions:	–22…–18°C



Thrombosis

Thrombosis, caused by blood coagulation in vessels and the heart cavity, is one of the most widespread causes of death in developed countries. The pathogenesis lies in the formation of a thrombus in the vein lumen and the disturbance of blood circulation in affected extremities. Approximately 95% of all venous thromboses occur in the lower extremities. The most dangerous complication of deep vein thrombosis is pulmonary embolism, often the first and only manifestation of venous thrombosis and ranking third among causes of sudden death.

The most understood markers of hereditary thrombosis are polymorphisms of several genes:

- *F5* (Leiden mutation) encoding factor V, a protein cofactor involved in transforming prothrombin into thrombin.
- *F2* encoding prothrombin, one of the main components of the blood coagulation system. Polymorphism +20210G>A intensifies the expression of *F2* gene, leading to a significant increase in the prothrombin concentration in blood (1.5–2 times). The frequency of the *F2* +20210G>A genotype reaches 1–4% in European populations.
- *MTHFR* – the most widespread polymorphism encoding the methylenetetrahydrofolate reductase enzyme which influences homocysteine levels in the blood and causes hyperhomocysteinemia.[1, 2]

A genetic predisposition to develop thrombosis, together with the moderate influence of adverse environmental factors, can trigger severe complications up to pulmonary embolism. Detecting high risk groups allows prevention of disease development in the presymptomatic period.

Indications for use of thrombosis test kits

- Following first occurrence of venous embolism in patients under 50 years.
- Patients with venous embolism after 50 years without apparent reasons.
- Repeated venous embolism.
- Patients with venous embolism during pregnancy, postnatal period, during use of contraceptives or hormone replacement therapy.
- Members of families with expressed hereditary thrombophilia.
- Women with unexplained prenatal abnormalities of a foetus in the second and third trimesters of pregnancy.
- Patients with a first occurrence of venous embolism in atypical locations.

1. Den Heijer M, Lewington S, Clarke R. 'Homocysteine, MTHFR and risk of venous thrombosis: a meta-analysis of published epidemiological studies'. *J Thromb Haemost*, 2005, 3(2), 292–9.
2. Joffe HV, Goldhaber SZ. 'Laboratory thrombophilias and venous thromboembolism'. *Vascular Medicine*, 2002, 7, 93–102.

Thrombosis

Thrombosis kit – F5, F2 (Ref 81-01)

Assay principle

Simultaneous detection of polymorphisms in the *F5* and *F2* genes by means of real-time PCR.

Polymorphisms detected

- *F5* +1691G>A (rs6025)
- *F2* +20210G>A (rs1799963)

Kit contents

- Buffers for restriction enzymes
- PCR mixes for analysis of polymorphisms *F5* +1691G>A and *F2* +20210G>A
- DNA-polymerase

Thrombosis kit (Ref 71-01)

Assay principle

Simultaneous detection of polymorphisms in the *F5*, *F2* and *MTHFR* genes by means of multiplex PCR with subsequent restriction and polyacrylamide or agarose gel electrophoresis.

Polymorphisms detected

- *F5* +1691G>A (rs6025)
- *F2* +20210G>A (rs1799963)
- *MTHFR* +677C>T (rs1801133)

Osteoporosis

According to the World Health Organization, osteoporosis ranks fourth among non-infectious pathologies after cardiovascular disorders, cancer and diabetes mellitus. It affects approximately 75 million people in Europe, the USA and Japan. In 2000 some 9 million new cases of osteoporotic fractures occurred, of which 1.6 million were hip fractures, 1.7 million forearm and 1.4 million clinical vertebral fractures. Europe and the Americas together accounted for 51% of all of these fractures, while most of the rest occurred in the Western Pacific area and Southeast Asia.

Osteoporosis is a typical multifactorial disease arising from the interaction of genetic factors and adverse environmental conditions. The disease is characterized by a progressive decrease in the bone mineral density (BMD), reduced bone weight and deteriorating micro-architecture of the trabeculae, accompanied by an increased risk of bone fractures. Osteoporosis is dangerous because it often remains latent for a long time and is only diagnosed after manifesting itself.

Polymorphic alleles of *VDR* and *COL1A1* genes are associated with osteoporosis development, risk of fracture and fast BMD loss in postmenopausal woman and in patients taking glucocorticoids.[1, 2]

Identifying patients at risk allows individuals to take preventive measures before the disease manifests itself. This may substantially reduce the risk of accidents leading to fractures which can severely affect quality of life and life expectancy.

Indications for use of osteoporosis test kit

- Pre- and postmenopausal woman; women with menopause caused by bilateral ovariectomy.
- Patients taking glucocorticoids or androgens.
- Close relatives of patients with osteoporosis.
- Patients suffering malabsorption, kidney disease, chronic respiratory diseases, rheumatoid artitis and diseases leading to nonmotility.

1. Gennari L, Becherini L, Masi L, Mansani R, Gonnelli S, Cepollaro C, Martini S, Montagnani A, Lentini G, Becorpi AM, Brandi ML. 'Vitamin D and estrogen receptor allelic variants in Italian postmenopausal women: evidence of multiple gene contribution to bone mineral density'. *J Clin Endocrinol Metab*. 1998;83(3):939–44.
2. Tracy L. Stewart, Huilin Jin, Fiona E. A. McGuigan, Omar M. E. Albagha, Natalia Garcia-Giralt, Amelia Bassiti, Daniel Grinberg, Susana Balcells, David M. Reid, and Stuart H. Ralston. 'Haplotypes defined by promoter and intron 1 polymorphisms of the COL1A1 gene regulate bone mineral density in women'. *J Clin Endocrinol Metab*. 2006;91(9):3575–83.

Osteoporosis

Osteoporosis kit (Ref 70-01)

Kit use

- Fast and qualitative detection of polymorphisms of the vitamin D receptor gene (*VDR*) and the gene encoding the basic bone matrix protein (*COL1A1*), both associated with osteoporosis.

Assay principle

Simultaneous detection of polymorphisms in the *VDR* and *COL1A1* genes by means of multiplex PCR with subsequent restriction and polyacrylamide or agarose gel electrophoresis.

Polymorphisms detected

- *COL1A1* -1997G>T (rs1107946) and +1245G>T (rs1800012)
- *VDR* -3731A>G (rs11568820) and +61968T>C (rs731236)

Sensitivity to anticoagulants

Oral anticoagulants are high-performance drugs prescribed for venous thrombosis, pulmonary embolism, in relation to ciliary arrhythmia, and following heart valve transplants, myocardial infarctions and embolic complications. Detection of individual sensitivities to commonly prescribed anticoagulants – warfarin, acenocoumarol and phenprocoumon – at initial prescription of these drugs is important as correct dosage can vary seven-fold according to genotype.[1] The therapeutic range is narrow and a small excess of the drug can cause adverse reactions, with bleeding complications being the principal danger.

The main biotransformation enzyme of oral anticoagulants is an isozyme of cytochrome P4502C9 (CYP2C9). *CYP2C9* gene activity has a wide range within a population and includes extensive metabolizers, intermediate metabolizers and poor metabolizers. Three alleles of this gene differing in activity level are found in the European population:

- Wild type allele of *CYP2C9*1* characterised by normal catalytic reactivity of the enzyme.
- Allele *CYP2C9*2* with polymorphism +430C>T (10% of European population) characterized by low catalytic reactivity.
- Allele *CYP2C9*3* with polymorphism +1075A>C (6% of European population) characterized by very low catalytic reactivity.

Alleles *CYP2C9*2* and *CYP2C9*3* lead to poor metabolism which is associated with:

- Higher concentrations of anticoagulants in the blood.
- Lesser degradation of these drugs.
- Increased risk of hypocoagulation and haemorrhages.
- Lower therapeutic drug dosage.[2]

CYP2C9 also takes part in biotransformation of some loop diuretics and blocking agents of angiotonin II receptors. Therefore patients with mutations in alleles of the *CYP2C9* gene can have adverse reactions following certain drug treatments.

Another gene whose polymorphism influences sensitivity to oral anticoagulants is *VKORC1*, encoding the subunit of vitamin K epoxide reductase complex, the target of oral anticoagulants. The promoter region of this gene contains a polymorphism, -1639G>A, which influences the level of expression. The A allele lowers the level of protein expression, which means that patients with genotype -1639AA should receive a lower dose of warfarin, while patients with genotype -1639GG require a higher dose.[3] Frequency of *VKORC1* -1639GA genotype in European populations reaches 40–50%; *VKORC1* -1639AA genotype, 10–15%.

1. Stehle S, Kirchheiner J, Lazar A, Fuhr U. 'Pharmacogenetics of oral anticoagulants: a basis for dose individualization'. *Clin Pharmacokinet*, 2008, 47(9), 565–94.
2. Lindh JD, Holm L, Andersson ML, Rane A. 'Influence of CYP2C9 genotype on warfarin dose requirements – a systematic review and meta-analysis'. *Eur J Clin Pharmacol*, 2009, 65(4), 365–75.
3. Glurich I, Burmester JK, Caldwell MD. 'Understanding the pharmacogenetic approach to warfarin dosing'. *Heart Fail Rev*, 2008.

Sensitivity to anticoagulants

CYP2C9 (Ref 82-01)

Kit use

- Determination of individual susceptibility to indirect anticoagulants (warfarin) – in conjunction with the VKORC1 kit.
- For genetic diagnostics of response to loop diuretics and blocking agents of angiotonin II receptors.

Assay principle

Detection of polymorphisms in the *CYP2C9* gene by means of real-time PCR.

Polymorphisms detected

- *CYP2C9* +430C>T (rs1799853)
- *CYP2C9* +1075A>C (rs1057910)

Kit contents

- Buffers for restriction enzymes
- PCR mixes for analysis of polymorphisms *CYP2C9* +430C>T and +1075A>C
- DNA-polymerase

VKORC1 (Ref 82-02)

Kit use

- Determination of individual susceptibility to indirect anticoagulants (warfarin) – in conjunction with the CYP2C9 kit.

Assay principle

Detection of polymorphism in the *VKORC1* gene by means of real-time PCR.

Polymorphism detected

- *VKORC1* -1639G>A (rs9923231)

Kit contents

- Buffers for restriction enzymes
- PCR mix for analysis of polymorphism *VKORC1* -1639G>A
- DNA-polymerase

Sensitivity to anticoagulants

Pharmaco-ACG kit (Ref 72-01)

Assay principle

Simultaneous detection of polymorphisms in the *CYP2C9* and *VKORC1* genes by means of multiplex PCR with subsequent restriction and polyacrylamide or agarose gel electrophoresis.

Polymorphisms detected

- *CYP2C9* +416C>T (rs1799853)
- *CYP2C9* +1061A>C (rs1057910)
- *VKORC1* -1639G>A (rs9923231)

Multiple drug sensitivity

CYP2C19, an isozyme of cytochrome P450, plays an important role in the metabolism of a wide spectrum of drugs, including:

- clopidogrel
- proton pump inhibitors
- antidepressants: amitriptyline, clomipramine, imipramine, citalopram, moclobemide
- anticonvulsant & antiepileptic agents: diazepam, primidone, phenytoin, barbiphen, nordazepam
- antimalarial agent: proguanil
- tamoxifen, warfarin, gliclazide, propranolol, cyclophosphamide, nelfinavir, progesterone, teniposide, tetrahydrocannabinol, karisoprodol, voriconazole.

CYP2C19 gene is polymorphous, with common variants encoding enzymes with enhanced, reduced and even absent function. Allele *CYP2C19*1* corresponds with wild type, characterised by regular catalytic reactivity of the enzyme. The main polymorphism responsible for the enzyme function loss in European populations is 681G>A, also known as *CYP2C19*2*. The frequency of this polymorphism reaches 14%. Allelic variant *CYP2C19*17* (-806□>T), which determines the enhanced metathesis of enzymatic substrate is also quite common (up to 20%).

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CYP2C19 (Ref 83-01)

Kit use

- Determination of the individual susceptibility to the drugs listed above.
- Genetic diagnostics of the effectiveness of drug metabolism.

Assay principle

Detection of polymorphisms in the *CYP2C19* gene by means of real-time PCR.

Polymorphisms detected

- *CYP2C19* 681G>A (rs4244285)
- *CYP2C19* -806C>T (rs12248560)

Kit contents

- Buffers for restriction enzymes
- PCR mixes for analysis of polymorphisms *CYP2C19* 681G>A and -806C>T
- DNA-polymerase

Anxiety disorders

Anxiety disorders, including depression, generalized anxiety disorders, neuroticism and social phobia, are serious medical disorders with high mortality rates. Anxiety disorders are complex diseases with several factors contributing to them, such as genetic (ranging in weighting between 30 and 45%), environmental and gene–environment covariance. Moreover, anxiety and stress response modulate vulnerabilities to a variety of psychiatric disorders.

The neurobiology of anxiety disorders involves the action of multiple genes, one of the most important being *SLC6A4* which plays a key role in regulating neurotransmissions within the brain pathways underlying mood and behaviour. The *SLC6A4* gene transcribes a transmembrane protein controlling the re-uptake of serotonin after it is released into a synaptic cleft. Mutations in this gene can cause disturbances in the brain pathways.[1] Additionally, variations in the *SLC6A4* gene predict responses to serotoninergic antidepressants: patients with the mutant gene may have a delayed therapeutic response and a greater load of adverse effects.[2, 3, 4]

The results of analysis can be very useful in determining individual susceptibility to serotoninergic antidepressants, allowing detection of high risk groups and selection of the most effective treatment.

1. Luddington N, Mandadapu A, Husk M. 'Clinical implications of genetic variation in the serotonin transporter promoter region: a review'. *Prim Care Companion J Clin Psychiatry* (2009), 11 (3): 39–102.
2. Keers R, Uher R, Huezo-Diaz P. 'Interaction between serotonin transporter gene variants and life events predicts response to antidepressants in the GENDEP project'. *The Pharmacogenomics Journal* (2010), 1–8.
3. Reimherr F, Amsterdam J, Dunner D. 'Genetic polymorphisms in the treatment of depression: Speculations from an augmentation study using atomoxetine'. *Psychiatry Research* 175 (2010), 67–73.
4. Sanjuan J, Martin-Santos R, Garcia-Esteve L. 'Mood changes after delivery: role of the serotonin transporter gene'. *The British Journal of Psychiatry* (2008), 193, 383–388.

Pharmaco-SLC6A4 kit (Ref 72-02)

Kit use

- Detection of mutations in the *SLC6A4* gene that are associated with the genesis of anxiety disorders.

Assay principle

Simultaneous detection of polymorphisms in the *SLC6A4* gene by means of multiplex PCR with subsequent restriction and polyacrylamide or agarose gel electrophoresis.

Polymorphisms detected

- *SLC6A4* L>S (44 bp ins/del) (rs4795541)
- *SLC6A4* +168 A>G (rs25531)

Cystic fibrosis

Cystic fibrosis (CF or mucoviscidosis) is a common recessive genetic disease with approximately 4% of the Caucasian population in Europe carrying one or more cystic fibrosis alleles. The disease develops when both genes are defective and the median age of survival is around 30 years.

The leading cause of morbidity and mortality is a progressive decline in pulmonary function resulting from airway damage caused by thickened secretions complicated by chronic microbial infection. In addition, about 85% of CF patients develop insufficiency of the exocrine pancreas that necessitates lifelong administration of dietary enzyme supplements.

Diagnosis of the disease frequently takes place when symptoms are already obvious, rather than in very early stages, thereby delaying disease management and allowing disease progression to do considerable harm. Over 10% of the population is only diagnosed in adulthood, at which point damage is irreversible.

Cystic fibrosis is routinely diagnosed by newborn screening for immuno-reactive trypsinogen (IRT), complemented by sweat testing. The newborn screen initially measures for raised blood concentration of IRT. Because of false-positive and negative tests from carriers and individuals with mild mutations in the CFTR gene, CF screening in newborns can be controversial. Diseases like AIDS, suprarenal capsule dysfunction, atopic dermatitis, Down's syndrome, adrenogenital syndrome and coeliac disease can also lead to a false-positive sweat test result.

In order to get more reliable CF diagnosis genetic testing is ultimately required. CF can result from more than a thousand different mutations, and it is not yet possible to test for each one.

However, a high risk CF group is characterized by a presence of about 20 (depending on the population) most frequent common mutations with a strong CF phenotype. Best practice guidelines for molecular genetic diagnosis of cystic fibrosis and CFTR-related disorders (updated European recommendations) have been developed and published in 2009.[1] The suggested panel of CF-causing mutations for population or prenatal screening of Caucasians consists of 17 mutations, each of which is found with a frequency of more than 0.1%.

1 Dequeker E, Stuhrmann M, Morris MA, Casals T, Castellani C, Claustres M, Cuppens H, des Georges M, Ferec C, Macek M, Pignatti PF, Scheffer H, Schwartz M, Witt M, Schwarz M, Girodon E. 'Best practice guidelines for molecular genetic diagnosis of cystic fibrosis and CFTR-related disorders – updated European recommendations'. *Eur J Hum Genet*. 2009 Jan:17(1):51–65.

Cystic fibrosis

Microarray-on-a-chip test for cystic fibrosis (Ref 90-01)

Astra Biotech GmbH has developed a new platform for the rapid simultaneous detection of 25 of the most common CF-causing mutations in pan-European populations. In addition to the mutations for this disease most commonly found in Western European populations, the mutation panel is extended by nine mutations most frequently found in Eastern European ethnic groups.

Applications

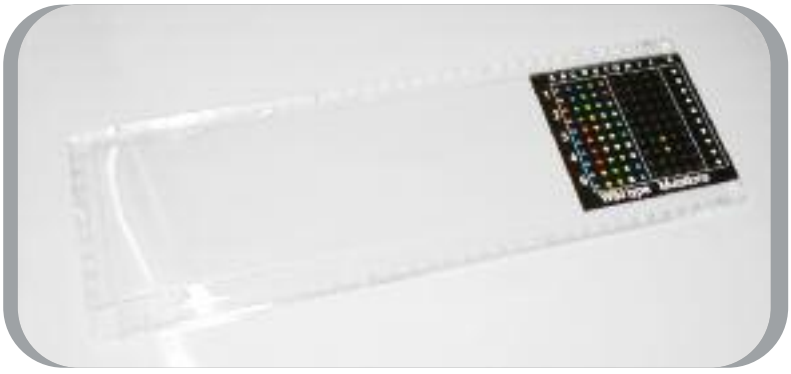
- CF newborn screening
- CF prenatal diagnostics
- Diagnostics of people with CF-associated family history
- Family planning
- Diagnostics of male infertility

Technical steps

- PCR probe labelling
- Hybridization
- Microarray scanner detection
- Software data analysis

Mutations detected

- Dele 2, 3
- G85E
- 621+1G>T
- R334W
- R347P
- R347H
- 1078delT
- I507del
- F508del
- R1162X
- S1196X
- 3732delA
- 3821delT
- 3849+10kbC>T
- W1282X
- N1303K
- 1677delTA
- G542X
- G551D
- R553X
- 1717-1G>A
- 2143delT
- 2184insA
- 2183AA>G
- 2789+5G>A



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