DRG:HYBRiD•XL®
Testpanel

25-OH Vitamin D
Renin
Aldosterone
17-OH Progesterone
Estradiol
Testosterone
Progesterone
Cortisol
Free Testosterone
CRP

DRG

DRG

Production Facility
Produktionsstätte, Marburg

DRG:HYBRID•XL®

Testpanel

Fully automated Continuous Access Analyzer for Immunoassays and Clinical Chemistry

Vollautomatischer Continuous Access Analyzer für Immunoassays und klinisch-chemischen Parametern

Innovation

The **DRG:HYBRID•XL®** Analyzer is an innovative and unique bench-top instrument that allows the simultaneous measurement of up to 20 samples, with up to 40 different assays.

Ready-to use reagents are provided in single use reagent cartridges, which are stable for 12 month from production date. After loading of samples in the sample arc and reagent cartridges in the rotor segments, typical assay times range from 10-90 minutes.

Samples, reagent cartridges and lot-specific master standard curve are easily identified by barcodes. The barcoded master curve can be adjusted by 2-point recalibration.

The integrated touchscreen monitor and the intuitive software guarantee easy system operation.

Testpanel

Immunoassays	Cat.No.	No. of Tests
25-OH Vitamin D	HYE-5334	40
Renin (active)	HYE-5373	40
Aldosterone	HYE-5338	40
17-OH Progesterone	HYE-5333	40
Testosterone	HYE-5376	40
Estradiol	HYE-5349	40
Progesterone	HYE-5368	40
Free Testosterone	HYE-5378	40
DHEA	HYE-5346	40 (coming soon)
DHEA-S	HYE-5347	40 (coming soon)
Cortisol	HYE-5343	40
TSH	HYE-5385	40 (coming soon)
T3	HYE-n.a.	40 (coming soon)
T4	HYE-n.a.	40 (coming soon)

Clinical Chemistry	Cat.No.	No. of Tests
CRP	HYC-5319	80
Homocysteine	HYC-5327	80 (coming soon)
Cystatin C	HYC-5320	80 (coming soon)
HbA1c	HYC-5325	80 (coming soon)

Combination

The unique concept of the **DRG:HYBRID•XL** allows each user to combine individual diagnostic panels from immunoassays and clinical chemistry, e.g. a cardiac panel, a diabetes panel, or a metabolic syndrome panel.

DRG:HYBRID•XL can determine immunoassays quantitatively, as well as qualitatively (cut-off).
The analyzer is validated for detection of antigens and antibodies in serum, plasma or saliva.

17-OH Progesterone

The steroid 17-Hydroxyprogesterone (17·-OHP) is produced in the adrenal cortex and in smaller quantities in the Corpus Luteum in women and in testes in men. During the menstrual cycle, the 17-OHP concentration increases in non-pregnant women -together with progesterone - from follicular to luteal phase.
During pregnancy, 17-OHP is produced in large amounts by the fetus and the adrenal gland. More than 95% of the 17-OHP in serum is biologically inactive, because it is bound to the carrier proteins albumin, Corticosteroid Binding Globulin (CBG) and Sex Hormone-Binding Globulin (SHBG).

Clinical Applications

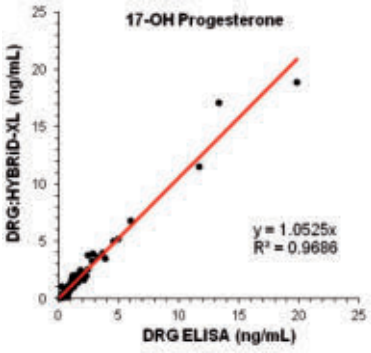
- Congenital Adrenal Hyperplasia (CAH) caused by 21-hydroxylase or 11-Beta-hydroxylase deficiency (17-OHP is increased)
- evaluation of acne vulgaris in men and women
- some subtile forms of infertility

Assay Characteristics

- Sample: 25µL serum or plasma (60 µL dead volume)
- Assay principle: Competitive ELISA
- Dynamic range: 0.11-20 ng/mL
- Total assay time: 90 min
- Intra assay/device precision: 3.77 %
- Inter assay/device precision: 10.3 %
- Inter lot precision: 6.62 %
- Sensitivity: 0.11 ng/mL
- Recovery range: 94.9-106.7 %
- Linearity range: 97:6-108.6 %

17-OH Progesterone Cat. No. HYE-5333

Method comparison



Progesterone

Progesterone is a female steroid hormone which is particularly important in preparing the endometrium for the implantation of the blastocyte and in maintaining pregnancy. In non-pregnant women, progesterone is mainly secreted by the Corpus Luteum, whereas in pregnancy the placenta becomes the major source. Minor sources are the adrenal cortex for both sexes and the testes for males. Blood progesterone concentrations are low during the follicular phase of the menstrual cycle (comparable to male levels) and increase in the luteal phase. Progesterone levels are relatively low in children and postmenopausal women. Progesterone circulates in blood mainly bound to Corticosteroid Binding Globulin (CBG), Sex Hormone-Binding Globulin (SHBG) and Albumin. Only 2-10% of the total concentration circulates as free hormone.

Assay Characteristics

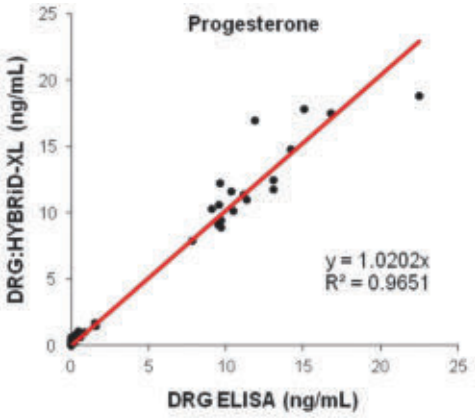
- Sample: 25µL serum or plasma (60 µL dead volume)
- Assay principle: Competitive ELISA
- Dynamic range: 0.071-40 ng/mL
- Total assay time: 60 min
- Intra assay/device precision: 3.77 %
- Inter assay/device precision: 13.64 %
- Inter lot precision: 8.48 %
- Sensitivity: 0.071 ng/mL
- Recovery range: 89.0-108.1 %
- Linearity range: 100.6-117.5 %

Progesterone Cat. No. HYE-5368

Clinical Applications

- Monitoring of activity of ovarian follicle and Corpus Luteum in non-pregnant women
- Confirmation of ovulation in non-pregnant women

Method comparison



Estradiol

Estradiol (E2) is the most potent natural Estrogen, produced mainly by the Graffian follicle of the female ovary and the placenta, and in smaller amounts by the adrenals and the male testes. Estradiol is secreted into the blood stream where 98% circulates as inactive form bound to sex hormone-binding globulin (SHBG) and to a lesser extent to albumin. In non-pregnant women with normal menstrual cycles, estradiol secretion is highest immediately prior to ovulation and reaches a plateau in the luteal phase. During pregnancy, maternal serum Estradiol levels increase considerably and high levels are sustained throughout pregnancy.

Assay Characteristics

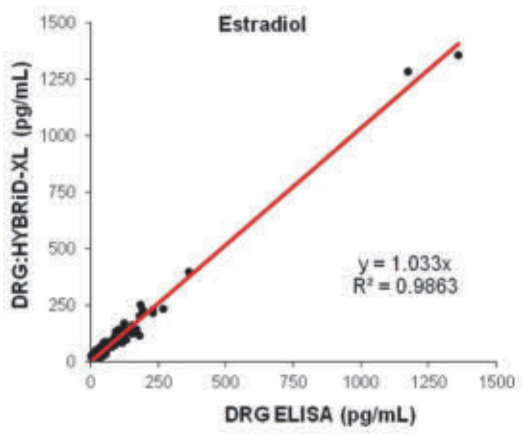
- Sample: 25µL serum or plasma (60 µL dead volume)
- Assay principle: Competitive ELISA
- Dynamic range: 18.2 pg/mL - 2000 pg/mL
- Total assay time: 90 min
- Intra assay/device precision: 4.05 %
- Inter assay/device precision: 13.4 %
- Inter lot precision: 5.0 %
- Sensitivity: 18.2 ng/mL
- Recovery range: 94.0-102.3 %
- Linearity range: 93.0-105.7 %

Estradiol Cat. No. HYE-5349

Clinical Applications

- Evaluation of menstrual dysfunctions such as precocious or delayed puberty in girls, primary and secondary amenorrhea, and menopause.
- Estradiol levels have been reported to be increased in patients with feminising syndromes, gynaecomastia and testicular tumors.
- Monitoring of human chorionic gonadotropin (hCG) administration and oocyte collection during ovarian hyperstimulation for in vitro fertilisation (IVF).

Method comparison



Testosterone

Testosterone is the most important androgen secreted into the blood. In males, Testosterone is secreted primarily by the Leydig cells of the testes and to some degree also in the adrenal cortex. In females, it is secreted mainly from the adrenal glands and the ovary. Testosterone is responsible for the development of secondary male sex characteristics and its measurements are helpful in evaluating the gonadal dysfunctions.

Clinical Applications

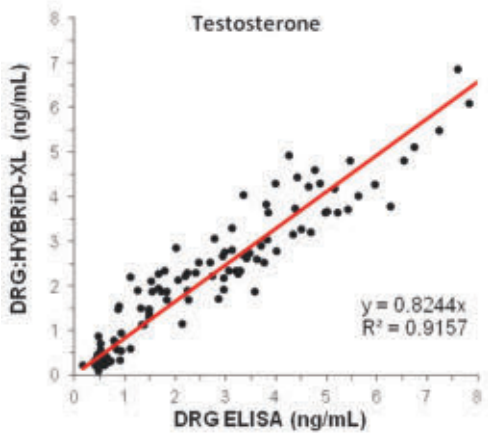
- In men, high levels of testosterone are associated to the hypothalamic pituitary unit diseases, testicular tumors, congenital adrenal hyperplasia and prostate cancer.
- In women, high levels of testosterone are generally found in hirsutism and virilization, polycystic ovaries, ovarian tumors, adrenal tumors and adrenal hyperplasia.
  Low levels of testosterone can be found in patients with the following diseases: Hypopituitarism, Klinefelter's syndrome, Testicular feminization, Orchidectomy and Cryptorchidism, enzymatic defects and some autoimmune diseases.

Assay Characteristics

- Sample: 50 µL serum or plasma (60 µL dead volume)
- Assay principle: Competitive ELISA
- Dynamic range: 0.139-16 ng/mL
- Total assay time: 90 min
- Intra assay/device precision: 4.30 %
- Inter assay/device precision: 12.28 %
- Inter lot precision: 9.06 %
- Sensitivity: 0.139 ng/mL
- Recovery range: 90.1-101.2 %
- Linearity range: 89.0-105.4 %

Testosterone Cat. No. HYE-5376

Method comparison



Free Testosterone

Testosterone is an anabolic steroid hormone from the androgen group. In serum, more than 60% of the Testosterone is bound to SHBG with high affinity, while a smaller fraction is loosely bound to albumin. Only less than 1% of circulating testosterone exists as unbound or free testosterone. Both the albumin-bound and free fractions are biologically active, while SHBG effectively inhibits testosterone action. Testosterone effects can be classified as virilizing and anabolic effects. Anabolic effects include growth of muscle mass and strength and increased bone density. Virilizing effects include maturation of the sex organs. Testosterone levels decline gradually with age in men. Measurement of the free or unbound fraction of serum testosterone has been proposed as a means of estimating the physiologically bioactive hormone.

Clinical Applications

- Free testosterone levels are elevated in women with hyperandrogenism associated with hirsutism in the presence or absence of polycystic ovarian disease.
- Free testosterone measurements may be more useful than total testosterone in situations where SHBG is increased or decreased (e.g. hypothyroidism and obesity).

Assay Characteristics

- Sample: 20 µL serum or plasma (60 µL dead volume)
- Assay principle: Competitive ELISA
- Dynamic range: 0.21-100 pg/mL
- Total assay time: 60 min
- Intra assay/device precision: n.a.
- Inter assay/device precision: n.a.
- Inter lot precision: n.a.
- Sensitivity: 0.21 pg/mL
- Recovery range: n.a.
- Linearity range: n.a.

Free Testosterone Cat. No. HYE-5378

Cortisol

Cortisol is the principal glucocorticoid produced by the zona fasciculata of the adrenal cortex. It is released in the circulation in a pulsatile and circadian pattern with highest levels in the morning that decrease throughout the day and achieve lowest concentration at night. Cortisol release is controlled by adrenocorticotropic hormone (ACTH) of the anterior pituitary and the hypothalamic corticotrophin-releasing hormone (CRH). Less than 6% of plasma cortisol circulates unbound from transcortin and albumin. Binding of free Cortisol to specific intracellular receptors effects sugar, fat and bone metabolism, renal function, and anti-inflammatory immune responses.

Assay Characteristics

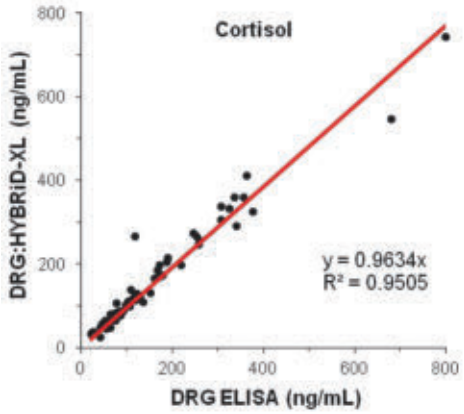
- Sample: 20µL serum or plasma (60 µL dead volume)
- Assay principle: Competitive ELISA
- Dynamic range: 1.88-800 ng/mL
- Total assay time: 60 min
- Intra assay/device precision: 2.84 %
- Inter assay/device precision: 10.9 %
- Inter lot precision: 5.70 %
- Sensitivity: 1.88 ng/mL
- Recovery range: 90.8-101.5 %
- Linearity range: 97.3-106.2 %

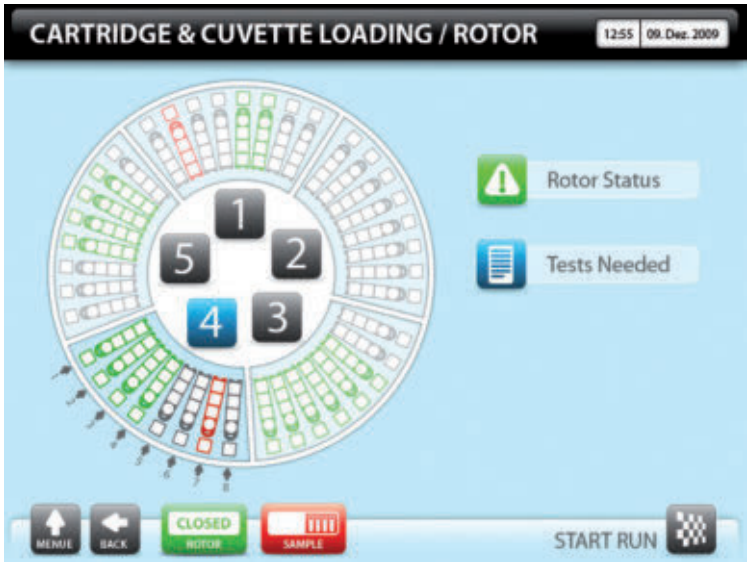
Cortisol Cat. No. HYE-5343

Clinical Applications

- Diagnosing conditions related to functions of the adrenal cortex, including Cushing's syndrome (hypercortisolism), Addison's disease (hypocortisolism) or secondary adrenal insufficiency (hypocortisolism) and adrenal tumors.
- Abnormal cortisol levels may also be linked to stress, prostate cancer, depression and schizophrenia.

Method comparison





Renin (active)

The enzyme Renin is a member of Renin-Angiotensin-Aldosterone System (RAAS) that controls blood pressure, renal blood flux, glomerular filtration, and sodium/potassium homeostasis. Renin is produced constitutively as inactive precursor prorenin in the juxtaglomerular cells of the kidney. Active renin can be released as response to low intra-renal blood pressure, reduced sodium reabsorption, hypokalemia or activity of the sympathetic nervous system. Renin mediates cleavage of angiotensinogen into Angiotensin I, which ultimately is processed by Angiotensin Converting Enzyme (ACE) to the octapeptide Angiotensin II. Direct physiological effects of Angiotensin II include vasoconstriction, increase of tubular reabsorption of sodium and chloride, water retention, and release of aldosterone, antidiuretic hormone (ADH, Vasopressin), and adrenocorticotropic hormone (ACTH, Corticotropin). Release of these hormones further supports sodium retention and secretion of potassium/H^+ in the kidney. Plasma renin is a good index for the activity of the RAAS.

Assay Characteristics

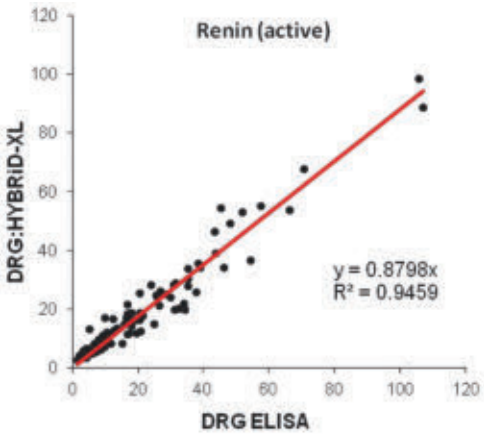
- Sample: 50µL serum or plasma (60 µL dead volume)
- Assay principle: Sandwich ELISA
- Dynamic range: 2.41 pg/mL-128 pg/mL
- Total assay time: 150 min
- Intra assay/device precision: 3.18 %
- Inter assay/device precision: 11.8 %
- Inter lot precision: 9.10 %
- Sensitivity: 2.41 pg/mL
- Recovery range: 96.0-109.1 %
- Linearity range: 103.1-112.77 %

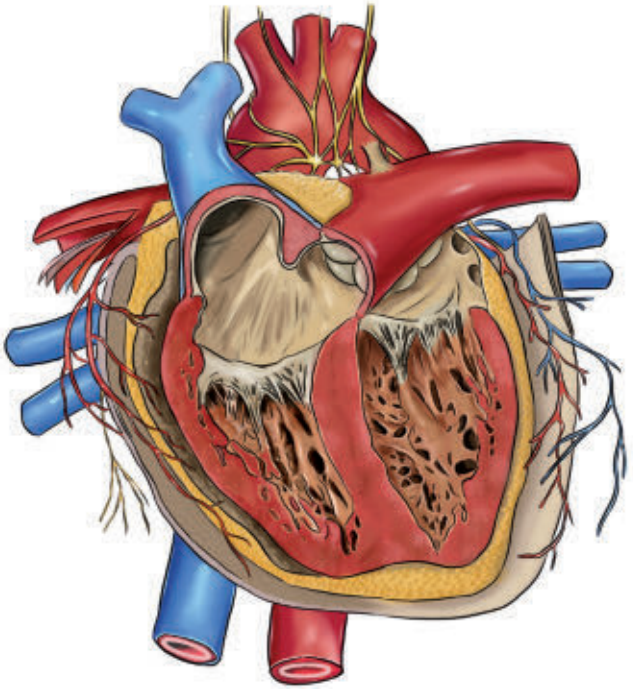
Renin (active) Cat. No. HYE-5373

Clinical Applications

- Differential diagnosis of hyperaldosteronism (primary, secondary or pseudo-hyperaldosteronism
- Diagnosis of isolated deficit in mineral corticoids
- Differential diagnosis of hypokalemia (secondary hyperaldosteronism, primary hypermineralcorticism)
- Detection of Renin producing tumors in the kidney
- Monitoring of glucocorticoid therapy
- Diagnosis of insufficient response to antihypertensive treatment

Method comparison





Aldosterone

The steroid hormone aldosterone is a potent mineralcorticoid that is produced in the adrenal cortex. The synthesis and release are controlled by the renin-angiotensin-aldosterone system (RAAS), as well as by plasma potassium concentration, the pituitary peptide ACTH, and by the blood pressure. Aldosterone increases the blood pressure by reabsorption of sodium and water from the distal tubules of the kidney into the blood, secretion of potassium into the urine, and elevation of circulating blood volume. Chronic overproduction and secretion of aldosterone leads to hypertension.

Assay Characteristics

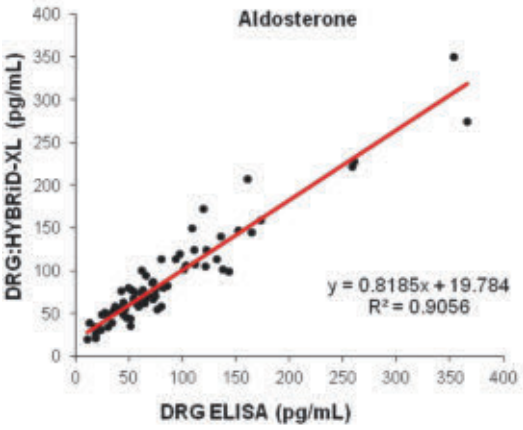
- Sample: 50µL serum or plasma (60 µL dead volume)
- Assay principle: Competitive ELISA
- Dynamic range: 8.79-1000 pg/mL
- Total assay time: 90 min
- Intra assay/device precision: 5.55 %
- Inter assay/device precision: 13.9 %
- Inter lot precision: 8.20 %
- Sensitivity: 8.79 ng/mL
- Recovery range: 93.3-106.3 %
- Linearity range: 96.1-114.4 %

Aldosterone Cat. No. HYE-5338

Clinical Applications

- Differential diagnosis of primary and secondary aldosteronism (aldosterone/renin-ratio; ARR)
- Aldosterone activity is reduced in Addison's disease and increased in Conn's syndrome.

Method comparison



25-OH Vitamin D

Vitamin D is a steroid hormone involved in the intestinal absorption of calcium and the regulation of calcium homeostasis. There are two major forms of Vitamin D, named Vitamin D3 (cholecalciferol) and Vitamin D2 (ergocalciferol). Physiological Vitamin D levels result from dietary uptake and can also be produced in the skin during sun exposure. In the liver, the Vitamin D is converted to the inactive precursor 25-hydroxyvitamin D (25-OH D), the major circulating metabolite of Vitamin D. Vitamin D and 25-OH D enter the circulation bound to Vitamin D Binding Protein (VDBP). Upon request, a small portion of 25-OH D is further hydroxylated in the kidney to form the biologically active hormone 1,25 dihydroxyvitamin D (1,25-(OH)2 D). Although 1,25-(OH)2 D portrays the biological active form of Vitamin D, it is widely accepted that the measurement of circulating 25-OH D provides better information with respect to patients Vitamin D status and allows its use in diagnosis of hypovitaminosis.

The concentration of 25-OH D decreases during winter time, with dark skin colour and with age.

Assay Chracteristics

- Sample: 25µL serum or plasma (60 µL dead volume)
- Assay principle: Competitive ELISA
- Dynamic range: 2.3-130 ng/mL
- Total assay time: 120 min
- Intra assay/device precision: 8.84 %
- Inter assay/device precision: 12.7 %
- Inter lot precision: 8.90 %
- Sensitivity: 2.3 ng/mL
- Recovery range: 93.4-101.5 %
- Linearity range: 92.2-110.5 %

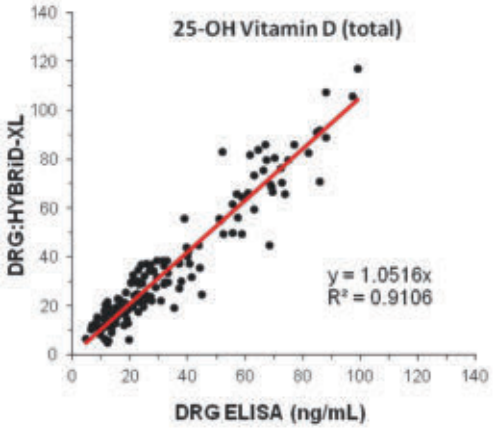
25-OH Vitamin D Cat. No. HYE-5334

Clinical Applications

Determination of 25-OH D in serum or plasma will support the diagnosis and therapy control of:

- Postmenopausal osteoporosis
- Rickets in children
- Osteomalacia, renal osteodystrophy
- Neonatal hypocalcemia
- Hyperparathyroidism

Method comparison



C-Reactive Protein (CRP)

C-Reactive Protein (CRP), the best known member of the group of acute-phase proteins, is present only at low concentration in blood of healthy individuals (< 5 mg/L), but is elevated up to 500 mg/L in an acute-phase response, caused by inflammatory processes associated with bacterial infections, post-operative conditions or tissue damage. CRP concentration increases already after 6 hours, reaching a peak after 48 hours.
CRP testing shows various advantages in comparison to the erythrocyte sedimentation rate (ESR) and the leukocyte count. In fact, CRP is more sensitive, shows earlier response and returns to reference range more rapidly after healing.

Assay Characteristics

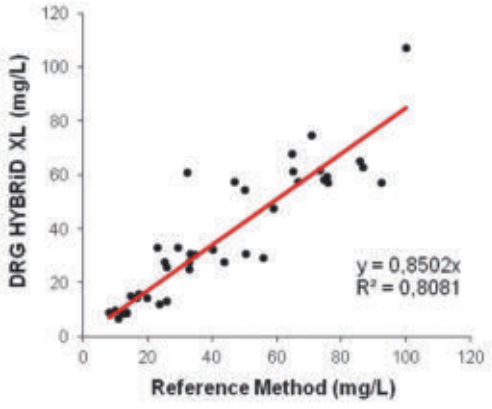
- Sample: 12µL serum or plasma (60 µL dead volume)
- Assay principle: Immunoturbidimetry
- Dynamic range: 1.0-250 mg/L
- Total assay time: 11 min
- Intra assay/device precision: 5.25 %
- Inter assay/device precision: 10.5 %
- Inter lot precision: 8.93 %
- Sensitivity: 1.0 mg/L
- Recovery range: 91.6-100.0 %
- Linearity range: 95.0-112.6 %

C-Reactive Protein (CRP) Cat. No. HYE-5319

Clinical Applications

- Detection of acute infection
- Monitoring inflammatory processes in acute rheumatic and gastrointestinal diseases

Method comparison



DRG:HYBRiD•XL®

Fully automated continuous access analyzer for Immunoassays and Clinical Chemistry

Vollautomatischer Continuous Access Analyzer für Immunoassays und Klinische Chemie

Targeted assay menu / *Projektiertes Test Menu*

Fertility /
Fertilität:
LH
FSH
Prolactin
ß-HCG
Progesterone
Estradiol
Testosterone
DHEA-S
DHEA
Free Testosterone
Androstenedione
17-OH Progesterone
Estrone
SHBG
DHT

Tumormarker /
Tumormarker:
CA 72-4
CYFRA 21-1
CA 125
CA 15-3
CA 19-9
CEA
AFP
ß-HCG
TPS
TPA
NSE
PSA
Free PSA

Thyroid Function /
Schilddrüse:
TSH
FT 3
FT 4
TPO
anti TG
TG
T 3
T 4

Prenatal Supervision /
Pränatal Diagnostik:
PAPP-A
Free ß-HCG
AFP
HCG
Free Estriol
HPL
PLGF

Diabetes /
Diabetes:
Insulin
C-Peptide
Glucose
HbA1C
IAA
ICA
anti-GAD
Microalbumin
Fructosamine
USP

Bone Metabolism /
Knochenstoffwechsel:
25-OH Vitamin D
PTH intact
Osteocalcin
Calcitonin
Phosphate
Ca++
Mg++
Alkaline Phosphatase
Iron

Anemia /
Anämie:
EPO
Hepcidin
Ferritin
Transferrin
Iron
Homocysteine

Hypertension /
Bluthochdruck:
Renin (active)
Aldosterone
Angiotensin

Cardiac Marker /
Kardiale Marker:
Troponin
Myoglobin
CK-MB
HS-CRP
Homocysteine
D-Dimer
Apo A1
Apo B
Lp(a)
HDL
LDL
Cholesterol
Triglyceride

Nephrology /
Nephrologie:
Cortisol
DHEA-S
ACTH
Hepcidin
Cystatin C
BUN/Urea
Creatinin
Calculation of Glomerular Filtration Rate

Biogenic Amines/
Neurotransmitters
Adrenalin
Dopamin
Serotonin
Normetanephrine
Metanephrine
Histamin
Melatonin

Infectious Diseases /
Infektions-Serologie:
CMV IgG/IgM
Rubella IgG/IgM
Toxo IgG/IgM
HSV 1/2 IgG/IgM
Chlamydia IgG/IgM
HCV
Fasciola IgG
Treponema Screen

TDM /
TDM:
Phenobarbital
Phenotoxin
Digitoxin
Valproic Acid
Carbamazepine
Gentamicin
Theophylline

Others /
Andere:
Uric Acid
ASAT (GOT)
ALAT (GPT)
Alpha Amylase
Gamma-GT
IgE
Lactate
Phospholipids
Sodium
Potassium
Phosphorus
Ammonium

Inflammation /
Entzündung:
CRP
alpha1 Antitrypsin
ASL-O
Ig-G
Ig-A
Ig-M
C3c
C4
RF

DRG Instruments GmbH, Germany
Frauenbergstraße 18
D-35039 Marburg
Tel. +49 (0) 64 21/17 00 0
Fax +49 (0) 64 21/170050
Internet: www.drg-diagnostics.de
E-mail: drg@drg-diagnostics.de

Local Distributor

DRG International Inc. USA
841 Mountain Avenue
Springfield, NJ 07081 USA
Phone: +1 (973) 564-7555
Fax: +1 (973) 564-7556
Internet: www.drg-international.com
E-mail: corp@drg-international.com

11/13