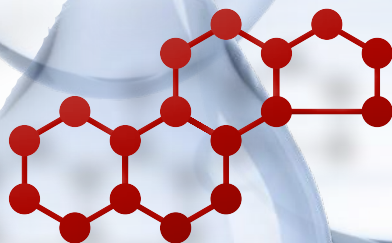


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Your partner in...
salivary
...diagnostics





Demeditec Diagnostics GmbH is a privately owned company located in northern Germany. Since the foundation in 1987 Demeditec has rapidly grown to become a successful and reliable manufacturer and supplier of in-vitro diagnostic test kits. We are, therefore, proud to present an extensive product panel of non-radioactive (ELISA, PCR) and radioactive (RIA) test systems.

Our top-selling products feature Human and Veterinary Diagnostics, Endocrinology - especially Salivary Diagnostics-, Infectious Diseases, Autoimmunity, Biogenic Amines and Tumor Markers.

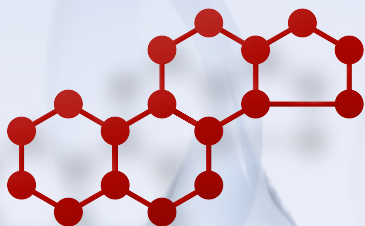
Our customers are located worldwide and include private laboratories, hospitals, universities as well as other research institutions and pharmaceutical companies.

To ensure the quality of our products, services and support, Demeditec has been certified according to EN ISO 9001 and EN ISO 13485 since 2003 and according to the GMP standard since 2011. These certifications, along with qualified and creative personnel, enable the development of innovative test kits in our R&D department.

We welcome you to be a part of our network and hope to convince you of the quality of our products and support.



Dr. Arndt Stüber
General Manager



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■ Introduction

3	Dear partner,
4	recognition of salivary diagnostics
4	has highly increased in the last few
7	years. Hence we also put our main
	focus and efforts on this field.
8	With this product brochure we'd
9	like to introduce our top-selling
	salivary assays to you!

General Information

Applications



Introduction: The exact measurement of hormone concentrations is important for the correct estimation of the hormone balance and endocrine function. This measurement traditionally is performed in blood/serum/plasma samples. Several hormones also can be analysed in saliva. This technique offers several advantages. The sampling is non-invasive and can be done anytime, anywhere. Especially in the case of steroid hormones such

as Cortisol, Testosterone, Progesterone, Estradiol and DHEA, reliable saliva testing offers significant additional advantages. The diagnostic relevance is much higher than compared to serum/plasma analytics.

The hormone activity: Steroid hormones are almost completely bound to their specific binding globulins. This bound fraction is biologically inactive and is considered to be just a kind of hormone reservoir. Only less than 5 % of the total hormones are free and represent the active fraction. This free fraction is therefore considered to be responsible for the hormone action. In serum or plasma the steroid measurement will result mainly in a number representing the concentration of the total inactive hormone. This total concentration at best gives only an approximate indication of the advantage to just measure the free fraction of the hormones. This is exactly what we can achieve by testing salivary samples.

General Information



Episodic hormone secretion: Due to the episodic secretion pattern of steroid hormones any result based on a single sample is completely arbitrary. We only can expect reproducible and reliable results in cases of multiple sampling. Therefore we always recommend taking 5 samples within at least a 2 hour period. This is valid for serum/plasma as well as for saliva. In contrast to blood, this sampling strategy easily can be done in cases of salivary testing. Please note that

there shouldn't be any food intake several hours prior to saliva sampling. Optimally saliva should be collected while morning-fasting. Intake of water will not affect test results. Other liquids are not recommended.

Sampling device: As saliva contains only tiny amounts of protein non-polar analytes such as steroids tend to absorb to various plastic surfaces. Glass would tend to be the best material for saliva

General Information

sampling and for the most part Polyethylene, although it is still in use in many laboratories worldwide, should be avoided. However there is an inexpensive polypropylene device available from Demeditec Diagnostics or other suppliers. It does not show any interference in saliva even in Progesterone testing, which is the most critical steroid.

Blood in saliva: Traces of blood might interfere with the results of saliva testing. It is therefore important that the salivary samples should not show any red colour. In cases of visible blood traces in saliva the sample should be discarded. After rinsing the device several times with tap water a new saliva sample can be taken but only after waiting for approximately 15 minutes.

Serum testing: Testing of steroids in serum or plasma in general is questionable. The result represents mainly the inactive hormone fraction and is arbitrary in cases of a single sample. In a relatively short time, usually less than half an hour, the concentration of the hormone in serum can easily change by the factor 2 or 3. Due to the limited specificity of current

(fully automated) routine methods serum testing is unreliable in low concentration ranges. This has been published in scientific literature. In obvious contrast to this saliva testing is the most reliable alternative in any concentration range of analytes such as Cortisol, Testosterone, Progesterone, Estradiol, Estriol, Estrone, DHEA, α -Amylase, sIgA and 8OHdG.

Summary: Saliva testing for steroid hormones is the most reliable and convenient method for measuring the hormone activity in endocrine disorders and in checking the hormonal balance. Routine test kits in ELISA technology now are available for an increasing number of steroids.

Primary advantages of salivary diagnostics:

- high diagnostic relevance (metabolic free fraction)
- painless, non-invasive sampling anytime/anywhere
- easy multiple sampling considering the episodic patterns
- stable material

Literature (selected articles)

Cortisol free in saliva:

- Nieman et al. (2008): The Diagnosis of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline; *J Clin Endocrinol Metab.*, 93(5): 1526-1540
- Vining et al. (1983): Salivary cortisol: a better measure of adrenal cortical function than serum cortisol; *Ann Clin Biochem*; 20: 329-335
- Balsalobre-Fernández et al. (2014): Relationships between Training Load, Salivary Cortisol Responses and Performance during Season Training in Middle and Long Distance Runners; *PLOS ONE*, Volume 9, Issue 8
- Steenwinkel et al (2014): The influence of foetal prednisone exposure on the cortisol levels in the offspring; *Clinical Endocrinology* 80, 804-810
- Davies et al. (2013): Physiological Stress in Koala Populations near the Arid Edge of Their Distribution; *PLOS ONE*, Volume 8, Issue 11
- Geburt et al. (2014): Validity of physiological biomarkers for maternal behavior in cows – A comparison of beef and dairy cattle; *Physiology & Behavior* 139, 361-368

Testosterone free in saliva:

- Taleb et al. (2003): Testosterone Measured by 10 Immunoassays and by Isotope-Dilution Gas Chromatography-Mass Spectrometry in Sera from 116 Men, Women, and Children; *Clinical Chemistry* 49:8, 1381-1395
- Yasuda et al. (2007): Low testosterone level of middle-aged Japanese men – the association between low testosterone levels and quality-of-life; *Journal of Men's Health and Gender*, Vol.4, No.2, pages 149-155
- Yasuda et al. (2008): Diagnostic significance of salivary testosterone measurement revisited: using liquid chromatography/mass spectrometry and enzyme-linked immunosorbent assay; *Journal of Men's Health*, Vol. 5, No.1, pp 56-63,
- Guenther et al. (2013): Photoperiodic effects on reproductive development in male cavies (*Cavia aperea*); *Physiology & Behavior* 123, 142-147
- Andersson et al. (2017): Comparisons between commercial salivary testosterone enzyme-linked immunosorbent assay kits; *Scandinavian Journal of Clinical and Laboratory Investigation*, 2017, Vol. 77, No. 8, 582-586

Progesterone free in saliva:

- Priya et al. (2013): Salivary progesterone as a biochemical marker to predict early preterm birth in asymptomatic high-risk women; *BJOG: An International Journal of Obstetrics and Gynaecology* 120(8):1003-11
- Wegerer et al. (2014): Low levels of estradiol are associated with elevated conditioned responding during fear extinction and with intrusive memories in daily life; *Neurobiology of Learning and Memory* 116, 145-154

Estriol free in saliva:

- Kos-Kudla et al. (1999): Comparative studies of serum and salivary estriol concentrations in the third trimester of normal pregnancy; *Med Sci Monit*, 5(2): 285-288
- Lechner et al. (1987): The Relation between Saliva Estriol Levels in Pregnancy and Infant Birth Weight; *Arch Gynecol Obstet* 241: 9-12
- Evans et al. (1984): Salivary Concentrations during Normal Pregnancies, and a Comparison with Plasma Estriol; *Clinical Chemistry*, Vol. 30, No.1

DHEA free in saliva:

- Sripada et al. (2013): DHEA Enhances Emotion Regulation Neurocircuits and Modulates Memory for Emotional Stimuli; *Neuropsychopharmacology* 38, 1798-1807
- Ahn et al. (2007): Salivary Cortisol and DHEA Levels in the Korean Population: Age-Related Differences, Diurnal Rhythm, and Correlations with Serum Levels; *Yonsei Medical J* 48, 379-388

Cortisol free in saliva ELISA

Cat.-No.: DES6611

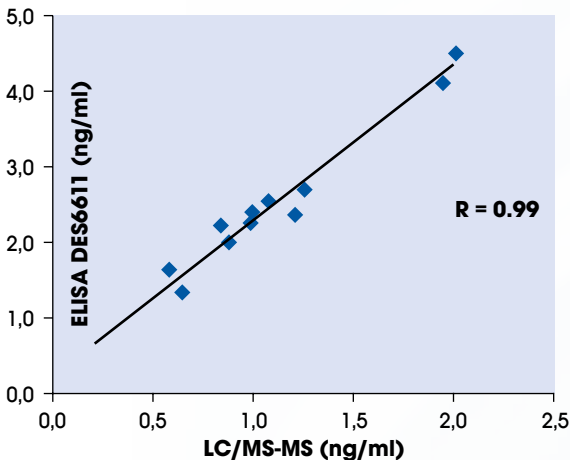
The DEMEDITEC Cortisol free in saliva ELISA is an immunoassay for the measurement of free Cortisol in saliva.

Technology	: ELISA
Kit size	: 96 wells
Sample material	: saliva
Sample preparation	: freeze, thaw, centrifuge
Sample volume	: 50 µl
Standard range	: 0.1 - 30 ng/ml
Incubation	: 1 h (RT), 30 min (RT/dark)
Measuring system	: TMB 450 nm
Sensitivity	: 0.024 ng/ml
Internal Controls	: 2



Applications:

- Adrenal function (e.g. Hyper- and Hypocortisolism / Cushing's Syndrome)
- Stress Monitoring
- Sport Medicine
- Sleep Disorders
- Veterinary Diagnostics
- Occupational Medicine
- Pediatrics
- Psychology



A correlation was performed with 13 saliva samples comparing the Demeditec Cortisol free in saliva ELISA (DES6611) to LC/MS-MS.

Testosterone free in saliva ELISA

Cat.-No.: DES6622

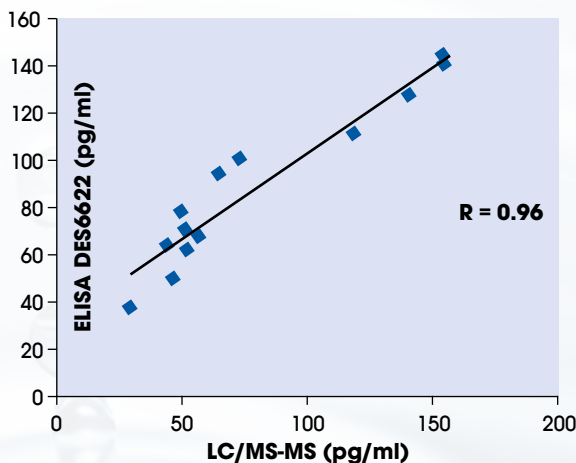
The DEMEDITEC Testosterone free in saliva ELISA is an immunoassay for the measurement of free Testosterone in saliva.

Technology	: ELISA
Kit size	: 96 wells
Sample material	: saliva
Sample preparation	: freeze, thaw, centrifuge
Sample volume	: 100 µl
Standard range	: 10 – 1,000 pg/ml
Incubation	: 1 h (RT/shaker), 30 min (RT/dark)
Measuring system	: TMB 450 nm
Sensitivity	: 2.2 pg/ml
Internal Controls	: 2



Applications:

- Endocrine disorders
(e.g. hypogonadism, hirsutism)
- Infertility
- Sport Medicine
- Psychology
- Veterinary Diagnostics
- Research



A correlation was performed with 13 saliva samples comparing the Demeditec Testosterone free in saliva ELISA (DES6622) to LC/MS-MS.

Progesterone free in saliva ELISA

Cat.-No.: DES6633

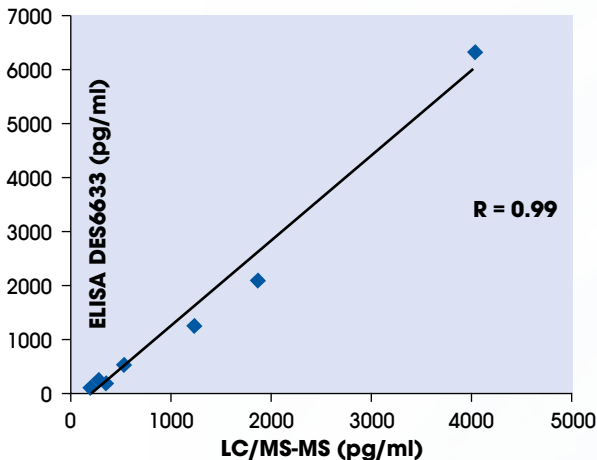
The DEMEDITEC Progesterone free in saliva ELISA is an immunoassay for the measurement of free Progesterone in saliva.

Technology	: ELISA
Kit size	: 96 wells
Sample material	: saliva
Sample preparation	: freeze, thaw, centrifuge
Sample volume	: 100 µl
Standard range	: 10 – 5,000 pg/ml
Incubation	: 1 h (RT/shaker), 30 min (RT/dark)
Measuring system	: TMB 450 nm
Sensitivity	: 5 pg/ml
Internal Controls	: 2



Applications:

- Endocrine disorders (Corpus-luteum insufficiency, menstrual disorder)
- Determination of pregnancy
- Veterinary Diagnostics



A correlation was performed with 13 saliva samples comparing the Demeditec Progesterone free in saliva ELISA (DES6633) to LC/MS-MS.

Estriol free in saliva ELISA

Cat.-No.: DES6644

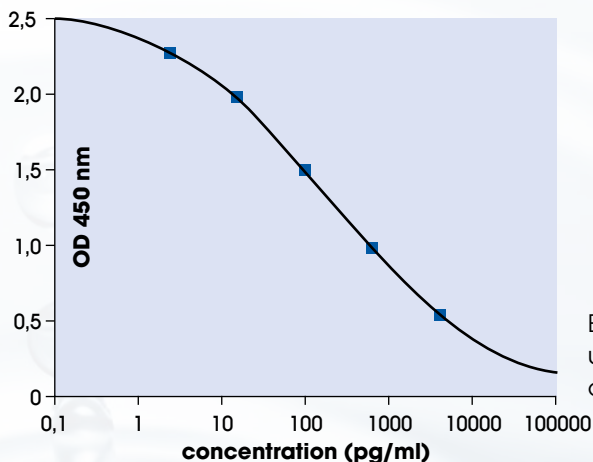
The DEMEDITEC Estriol free in saliva ELISA is an immunoassay for the measurement of free Estriol in saliva.

Technology	: ELISA
Kit size	: 96 wells
Sample material	: saliva
Sample preparation	: freeze, thaw, centrifuge
Sample volume	: 50 µl
Standard range	: 2.5 – 4,000 pg/ml
Incubation	: 1 h (RT/shaker), 30 min (RT/dark)
Measuring system	: TMB 450 nm
Sensitivity	: 1.4 pg/ml
Internal Controls	: 2



Applications:

- Monitoring of pregnancy
- Monitoring of fetal development
- Balance of hormones
- Veterinary Diagnostics



Example of typical calibrator curve using a 4 PL (4 Parameter Logistics) curve fit.

DHEA free in saliva ELISA

Cat.-No.: DES6666

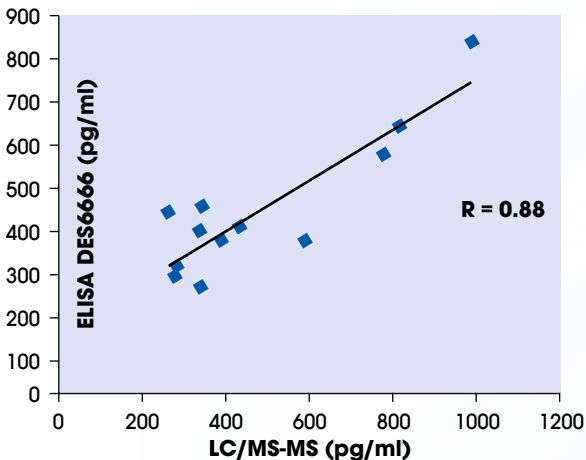
The DEMEDITEC DHEA free in saliva ELISA is an immunoassay for the measurement of free DHEA in saliva.

Technology	: ELISA
Kit size	: 96 wells
Sample material	: saliva
Sample preparation	: freeze, thaw, centrifuge
Sample volume	: 100 µl
Standard range	: 10 – 2,560 pg/ml
Incubation	: 1 h (RT/shaker), 30 min (RT/dark)
Measuring system	: TMB 450 nm
Sensitivity	: 3.7 pg/ml
Internal Controls	: 2



Applications:

- Hormone Balance
- Effect on androgen and estrogen
- Congenital adrenal hyperplasia
- Anti-Aging
- Psychology (antagonist of cortisol)
- Sport medicine
- Suspicion of adrenal tumor
- Veterinary Diagnostics



A correlation was performed with 12 saliva samples comparing the Demeditec DHEA free in saliva ELISA (DES6666) to LC/MS-MS.

Overview

Product Specification	Cortisol free in saliva ELISA DES6611	Testosterone free in saliva ELISA DES6622	Progesterone free in saliva ELISA DES6633	Estriol free in saliva ELISA DES6644
Determinations	96	96	96	96
Sample material	saliva	saliva	saliva	saliva
Sample preparation	freeze, thaw, centrifuge	freeze, thaw, centrifuge	freeze, thaw, centrifuge	freeze, thaw, centrifuge
Sample volume	50 µl	100 µl	100 µl	50 µl
Standard range	0.1 – 30 ng/ml	10 – 1,000 pg/ml	10 – 5,000 pg/ml	2.5 – 4,000 pg/ml
Incubation	1 h 30 min	1 h 30 min	1 h 30 min	1 h 30 min
Measuring system	TMB 450 nm	TMB 450 nm	TMB 450 nm	TMB 450 nm
Sensitivity	0.024 ng/ml	2.2 pg/ml	5 pg/ml	1.4 pg/ml
Control(s) included	yes	yes	yes	yes

Product Specification	DHEA free in saliva ELISA DES6666	Estradiol free in saliva ELISA DESLV4188	17-OH-Progesterone free in saliva ELISA DESLV3140	Androstendione free in saliva ELISA DESLV4780
Determinations	96	96	96	96
Sample material	saliva	saliva	saliva	saliva
Sample preparation	freeze, thaw, centrifuge	freeze, thaw, centrifuge	freeze, thaw, centrifuge	freeze, thaw, centrifuge
Sample volume	100 µl	100 µl	25 µl	50 µl
Standard range	10 – 2,560 pg/ml	1 – 100 pg/ml	10 – 1,000 pg/ml	20 – 1,000 pg/ml
Incubation	1 h 30 min	3 h	1 h 15 min	1 h 15 min
Measuring system	TMB 450 nm	TMB 450 nm	TMB 450 nm	TMB 450 nm
Sensitivity	3.7 pg/ml	0.6 pg/ml	2.5 pg/ml	5 pg/ml
Control(s) included	yes	yes	yes	yes

Product Specification	Estrone free in saliva ELISA DESLV5228	Alpha-Amylase Saliva ELISA DEEQ6231	New 8-OHdG Check ELISA DEKOG200SE	Secretory IgA ELISA DEXK276
Determinations	96	96	96	96
Sample material	saliva	saliva	saliva, urine, serum, plasma, tissue	saliva, serum, plasma, BALF, urine, nasal wash, vaginal secret, breast milk
Sample preparation	freeze, thaw, centrifuge	predilution	pretreatment	predilution
Sample volume	100 µl	20 µl	50 µl	10 µl (saliva)
Standard range	3 – 333 pg/ml	10 – 500 U/ml	0.5 – 200 ng/ml	2 – 400 µg/ml
Incubation	1 h 15 min	1 h 15 min	2 h 15 min	2 h 10 min
Measuring system	TMB 450 nm	TMB 450 nm	TMB 450 nm	TMB 450 nm
Sensitivity	0.12 pg/ml	3.6 U/ml	0.5 ng/ml	0.6 µg/ml
Control(s) included	yes	yes	no	yes



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Order Processing

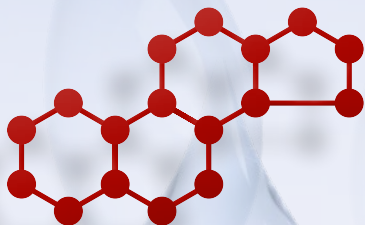
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