

A high-magnification microscopic image of cells, likely epithelial cells, showing their characteristic hexagonal shape and clear cell boundaries. The cells are arranged in a cluster, with some showing prominent nuclei. The background is a light, slightly textured blue.

INNOVATIVE **SALIVA** **DIAGNOSTICS.**



SPECIALY DEVELOPED FOR SALIVA.

Steroid hormone assessment from saliva allows the specific determination of the biologically active or “free” fraction of target hormones. Benefit from highly sensitive luminescence immunoassays and ELISAs which have been specially developed and validated for saliva.

Salivary testing

Importantly, the hormone concentrations measured in saliva, unlike in blood, represent the levels of free, biologically active hormones, which have greater clinical relevance than do measures of total hormone. The easiness and stress free collection makes it very attractive for patients and practitioners.

Mostly all Immunoassays are calibrated to LC-MS/MS and the most common parameters use interchangeable components to enable an easier automation. Meaningful reference ranges are stated in the instructions for use of the single parameters.

To buy and order immunoassays for Saliva diagnostics, please visit our web store ibl-international.com/saliva-diagnostics

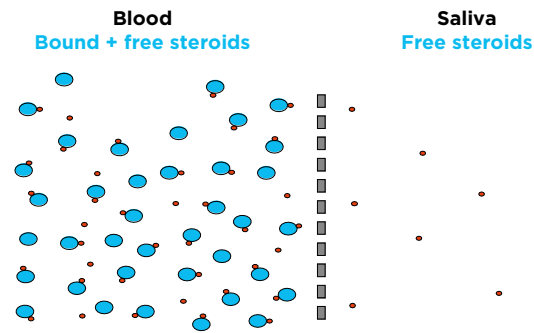


Figure 1: Diffusion of free steroid hormones from blood into saliva

Free and protein bound steroid hormones in blood (left side) and free hormones in saliva (right side). The concentration of free hormones is the same on both sides of the membrane.

Hormonal sexual disorders, androgenism, evaluation of ovarian function.

Besides assays for measuring estrogens, Tecan also offers following steroids kits:

Parameter	Catalog No.	Method	Features	CE IVDR
Progesterone Saliva	RE52281	ELISA	Wide measuring range: 13.6 - 4359 pg/mL Direct procedure without extraction	Yes
Testosterone Saliva	RE52631	ELISA	Intra-assay precision: mean CV 5.6% and a range of 2.8-12.2% Limit of Quantitation: LoQ 8.6 pg/mL with accuracy 20% Easier method than LC-MS/MS	Yes
Testosterone Saliva	30191568/ 30191569	LUM	Analytical sensitivity: 1.2 pg/mL Functional sensitivity: 3.9 pg/mL Easier method than LC-MS/MS	Yes
17β-Estradiol Saliva	30121045	ELISA	Only 50 µL sample volume needed Defined reference values for females and males Correlates to reference method LC-MS/MS	Yes
Estriol High Sensitive Saliva	30121046	ELISA	Only 100 µL sample volume needed Sensitive assay for measurement of males' and females' samples Correlates to reference method LC-MS/MS	Yes

Stress measurement

Parameter	Catalog No.	Method	Features	CE IVDR
DHEA Saliva	RE52651	ELISA	Not available on closed systems ELISA: Clearly defined reference values by gender, age and day time	Yes
Cortisol Saliva	RE52611	ELISA	Analytical specificity: LoB 0.003 µg/dL, LoQ 0.005 µg/dL Wide measuring range: 0.005-2.208 µg/dL Easier method than LC-MS/MS	Yes
Cortisol Saliva	30221150/ 30221151	LUM	Functional sensitivity: LoQ 0.12 ng/mL, total precision: CV <20% Wide measuring range: 0.12 - 32 ng/mL Easier method than LC-MS/MS	Yes
Melatonin Saliva	RE54041	ELISA	Functional sensitivity: LoQ 0.85 pg/mL Wide measuring range: 0.85-38.4 pg/mL	Yes

This need to measure biologically active hormone is somewhat aided by the fact that only free, unbound hormones leave the bloodstream via the membranes and make their way into saliva. Molecules including steroid hormones can cross the blood – saliva membrane via different mechanisms, including expression and secretion, active transport, and passive diffusion (Gröschl, 2008).

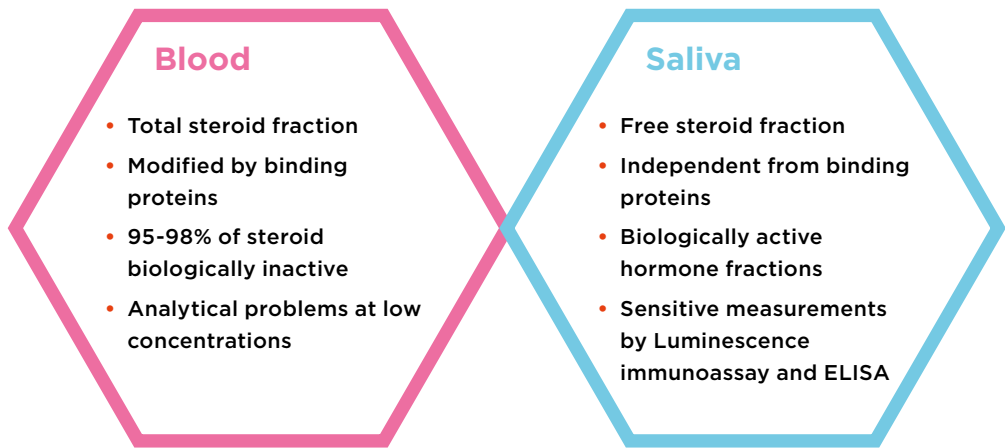


Figure 2: Steroids in blood and saliva.

Furthermore, Tecan proposes following benefits

- Collection tubes SaliCap Set (RE69981/ RE69985) available
- Expertise for saliva diagnostics, high technical support
- Free of charge EQAS for salivary steroids twice per year
- Experience in automation of Salivary assays on EVOLyzer® and ThunderBolt® ELISA systems.*

*The combined use of assays, process script and open system instrument (e.g. EVOLyzer®, ThunderBolt®) has to be validated individually on site by each laboratory. Interchangeability is only valid within same lot numbers for the single components.

Product availability and regulatory status may vary across regions outside the EU depending on local country-specific regulation. Please consult your local Tecan office for more information.

Phone: +49 (0)40-53 28 91-0
Fax: +49 (0)40-53 28 91-11
Email: IBL@Tecan.com
www.tecan.com/ibl



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