

SALIVA TEST SPECIFICATIONS

Cortisol

Clinical Information

Under the direction of the hypothalamus and pituitary, and controlled by a negative feedback loop, the zona fasciculata of the adrenal cortex is stimulated by adrenocorticotrophic hormone to produce cortisol in response to stressors. The feedback loop is commonly referred to as the hypothalamic-pituitary-adrenal (HPA) axis. Cortisol production is normally at its highest upon waking and declines steadily during the day, reaching its lowest point at bedtime. Cortisol has a wide range of effects on mind and body and interacts with the reproductive, thyroid and immunological systems. As part of the stress response, it prepares the body for “fight or flight” and in doing so it can suppress the production of other hormones, including those involved with reproduction, and some immune functions. When cortisol levels remain high as a result of chronic exposure to stressors, this suppression of other systems is maintained for longer than normal and can result in susceptibility to infection, hypothyroidism, bone loss, infertility, and low libido. On the other hand, lower than normal cortisol levels can result from adrenal insufficiency or “burnout”, and are associated with decreasing attention span, fatigue, allergies, and blood sugar imbalances. Since both high and low cortisol levels are associated with multiple symptoms, diurnal cortisol testing can help identify the causes of complicated health issues. Saliva collection multiple times during the day is convenient for assessing diurnal variations in cortisol secretion. The ZRT reference range for cortisol levels is 3.7—9.5 ng/mL (morning); 1.2—3.0 ng/mL (noon); 0.6—1.9 ng/mL (evening); and 0.4—1.0 ng/mL (bedtime).

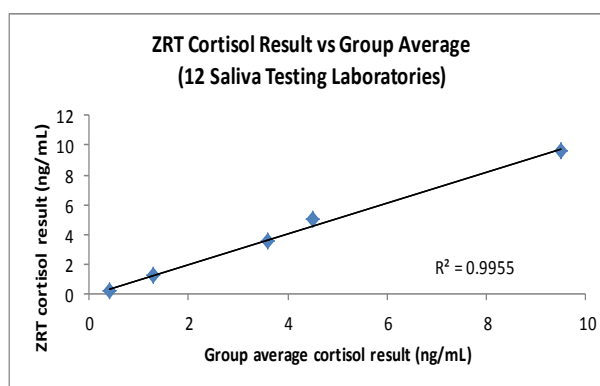
References:

Cardoso et al. Diagnostic value of salivary cortisol in Cushing's syndrome (CS). *Clin Endocrinol (Oxf)* 2009;70:516-21.
Chida Y, Steptoe A. Cortisol awakening response and psychosocial factors: a systematic review and meta-analysis. *Biol Psychol*. 2009;80:265-78.
Gozansky et al. Salivary cortisol determined by enzyme immunoassay is preferable to serum total cortisol for assessment of dynamic hypothalamic-pituitary-adrenal axis activity. *Clin Endocrinol (Oxf)* 2005;63:336-41.

Assay Method: EIA

Accuracy

ZRT has established the first salivary proficiency testing program, which includes most of the major saliva testing laboratories in the US. Twice yearly, results from carefully selected pooled samples are compared to those from 11 other laboratories that test cortisol. As shown in the graph below, ZRT results compare very favorably to the consensus of all 12 saliva testing laboratories for the cortisol assay.



Precision/Reproducibility

Inter-assay precision was determined by choosing pooled saliva samples spanning the reference range for cortisol, and analyzing them multiple times over a 30-60 day period. Results are shown below:

Mean Cortisol Concentration (ng/mL)	Coefficient of Variation (C.V. %)
1.0	8.0
4.0	7.1
12.9	7.6

Linearity

The ZRT saliva cortisol assay gives excellent linearity over the reportable range of 0.1-30 ng/mL. Samples giving results >30 ng/mL are diluted and re-assayed for accurate reporting. Values below 0.1 ng/mL are not sufficiently precise and are reported as <0.1 ng/mL.

Sensitivity

The analytical limit of detection for cortisol is 0.1 ng/mL.

Stability

Saliva samples are stable at room temperature for 30 days for cortisol determination, but customers are advised to mail samples as soon as possible after collection. Samples are rejected for analysis if they were not received within 30 days of collection and were not refrigerated or frozen.

Accreditation

ZRT Laboratory is a CLIA and New York State certified testing laboratory.