

Salivary Cortisol (SC) assay with a direct immunometric method DKO020 CORTISOL SALIVA (Diametra, Milano)

In collaboration with Diametra and Grifols (laboratory where the assays of SC with immunoenzimatic kit on microplate ELISA Diametra have been carried out using the automatic analyzer Triturus), the salivary cortisol evaluation has been performed on a group of Healthy subject, both males and females, to verify the reference ranges indicated by the manufacturer in order to assess the reliability of this direct method to the routinely use in hypo and hyper cortisolemia diagnosis.

105 healthy subjects, 60 females and 45 males, with age ranging between 25 and 65 years have been studied; from these patients, received by the **Laboratory of Clinical Pathology of Pordenone Hospital**, three saliva samples have been collected at time 8,00, 16,00 and 23,00 using the Salivette system (Sarstedt).

The obtained results are summarized in table 1

Sample	Males Median (ng/mL)	Males Range (ng/mL)	Males CV (%)	Females Median (ng/mL)	Females (ng/mL)	Females CV (%)	M-F (ng/mL)	CV (%)
08.00	3.96	1.82-9.26	47,4	4.44	2,73-8.28	33.2	2.17-8.83	39.4
16.00	1.64	0.62-2.88	35,5	1.86	1.07-3,33	30.9	0.80-3.20	33.2
23.00	0.77	0.30-1.99	33.2	0.79	0.42-2.70	60.3	0.31-2.50	60.6
AM	3.96	1.82-9.26	47.4	4.44	2.73-8.28	33.2	2,17-8.83	39.4
PM	1.16	0.31-2.84	55.2	1.40	0.46-2.96	51.4	0.33-2.93	53,3

From the above reported data it is possible to drawn:

1. The median value progressive decrease in the three time slots, both in females and males, similarly to what happens in serum for the total cortisol.
2. The resulting decrease in the reference range values in both males and females

3. The absence of statistical meaning in the difference between the two medians related to the sex and consequently the possibility to adopt a unique reference range that, due to the round up, can be defined as follows:

hour 08.00: 2.15-8.85 ng/mL

hour 16.00: 0.80-3.20 ng/mL

hour 23.00: 0.30-2.50 ng/mL

4. The reduced individual analytical variability (CV%) included between 30,9% and 60,6 %.
5. The confirmation of the reference ranges proposed by the manufacturer; be noted the need to better define the reference range related to the time 23,00, because the salivary cortisol night level represents one of the fundamental tool for the Cushing Syndrome diagnosis.

Finally, the Diametra test can be used in routine laboratory for the initial diagnosis of hypercortisolism, instead of Urinary Free Cortisol.