

Y. PTITSYNA<sup>1</sup>, O. UDALOVA<sup>2</sup>, A. BURRKOV<sup>1</sup>, A. OBRIADINA<sup>1</sup>

<sup>1</sup>*RPC Diagnostic Systems, Nizhniy Novgorod, Russia*

<sup>2</sup>*Regional Clinical Diagnostic Centre, Nizhniy Novgorod, Russia*

## **DETERMINATION OF MEDIAN LEVELS OF THE FREE BETA SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN IN WOMEN FROM RUSSIAN FEDERATION USING A TWO-SITE MONOCLONAL ELISA**

**Background.** The level of free  $\beta$  subunit of the human chorionic gonadotropin (free  $\beta$  -HCG) is an important serum marker for biochemical screening in the first trimester of pregnancy.

**Methods.** Serum concentration of free  $\beta$  -HCG was measured using a two-site monoclonal ELISA (DS-EIA-GONADOTROPIN-free  $\beta$  -HCG).

**Results.** We evaluated serum samples from pregnant white woman from Central Russia and Volgo-Viatsky Region, Russian Federation, mean age 27 years, range from 16 to 40 years. The study population consisted of 3345 singleton, nondiabetic pregnancies at 8-13 weeks of gestation resulting in the delivery of phenotypically normal neonates and 16 pregnancies with trisomy 21. Median values and 95 % confidence intervals were calculated for 8-13 gestational weeks. 8 weeks of gestation: median 46.5 ng/mL (12.1 to 169 ng/mL), 9 weeks of gestation: median 44.7 ng/mL (12.7 to 134.3 ng/mL), 10 weeks of gestation: median 43.8 ng/mL (6.2 to 135.8 ng/mL), 11 weeks of gestation: median 38.9 ng/mL (10.6 to 133.0 ng/mL), 12 weeks of gestation: median 35.9 ng/mL (8.2 to 135.6 ng/mL), 13 weeks of gestation: median 17.3 ng/mL (4.75 to 115.6 ng/mL). MoM values were calculated by dividing an individual's marker level by the median level. In cases of Down syndrome (trisomy 21) the median MoM values of free  $\beta$  -HCG were significantly higher than in control groups: 11 weeks of gestation - 2.4 MoM, 12 weeks of gestation - 1.8 MoM, 13 weeks of gestation - 7.8 MoM. In control groups Median Mom consisted  $1.0 \pm 0,004$ . The study population was divided according to maternal weight. Medians for groups with different weight (45, 60, 75, 90 kg) were calculated for every week of gestation. 8 weeks of gestation (54.1, 46.5, 44.3, 32.8 ng/mL), 9 weeks of gestation (56.8, 52.5, 46.1, 30 ng/mL), 10 weeks of gestation (55.0, 43.9, 39.4, 37.3 ng/mL), 11 weeks of gestation (48.4, 38.9, 34.5, 32.8 ng/mL), 12 weeks of gestation (42.5, 35.9, 34.8, 27.4 ng/mL), 13 weeks of gestation (22.0, 18.2, 14.3, 5.5 ng/mL).

**Conclusions.** We defined normal limits of maternal serum free  $\beta$  -HCG in Central Russia population with "DS-EIA-GONADOTROPIN-free  $\beta$  -HCG". It is necessary for estimation of the risk of abnormal pregnancy. A significant relationship between free  $\beta$  -HCG values and maternal weight was obtained.

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