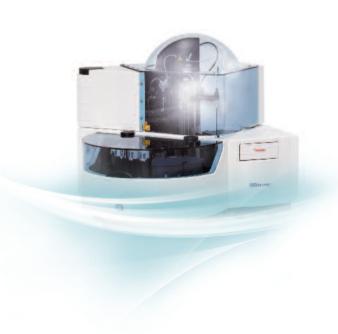
Thermo Scientific B·R·A·H·M·S Free βhCG KRYPTOR

The gold standard in combined 1st trimester screening

Automated immunofluorescent assay for the determination of free β subunit of human chorionic gonadotropin hormone (free β hCG) in human serum

- Excellent precision:
 CV less than 4% between day
- Low detection limit: 0.16 IU/L
- · Rapid assay time: 19 min
- Kinetic reading leading to automatic rediluting of high samples within 4 min
- In routine use by FMF since 1999







Clinical Interest

Prenatal Screening for chromosomal abnormalities in the 1^{st} trimester of pregnancy including maternal age, PAPP-A and Free β hCG associated with the ultrasound measurement of nuchal translucency

Prenatal Screening for chromosomal abnormalities in the **2**nd **trimester** of pregnancy including maternal age, Free BhCG and AFP

Oncology: Diagnosis and follow-up of trophoblastic tumors of ovarian, placental or testicular origin

Ease of Handling

| Sample volume | 26 μL |
|---|--------------------|
| Sample type | Serum |
| Incubation time | 19 min |
| Direct measurement | 0.16150 IU/L |
| Measuring range with automatic dilution | 0.1650 000 IU/L |
| Detection limit | 0.16 IU/L |
| Kit stability on board | 4 weeks |
| Calibrator | 1 point |
| Calibration stability | 15 days |
| Detection limit Kit stability on board Calibrator | 4 weeks 1 point |



Excellent Precision

| Reproducibility* | | | | |
|--------------------|-------|---|--|--|
| Sample Mean [IU/L] | | Between-assay/one instrument (n=~500 over 1 year for each sample) CV% | | |
| 1 | 8.05 | 3.69 | | |
| 2 | 20.88 | 2.72 | | |
| 3 | 86.40 | 2.90 | | |

3.94

2.78

3.03

| 2.72 | 12 |
|--|----|
| 2.90 | 13 |
| | 14 |
| Between-assay/between instrument (n=~1000 over | Re |
| 1 year for each sample) CV% | Ge |

Normal values

Sample

1

2

3

<0.16 IU/L (males and non pregnant females)

Mean

[IU/L]

8.12

21.22

86.11

Calibration

The Free ßhCG results are given in IU/L (WHO IRP1st IRP WHO 75/551).

Reference Values Pregnancy (1st Trimester)

| Gestational age (completed weeks) | n | 5 th percentile [IU/L] | Median [IU/L] | 95 th percentile [IU/L] |
|---|-------|---|------------------|--|
| 11 | >5000 | 16.68 | 44.83 | 120.47 |
| 12 | >5000 | 14.63 | 39.33 | 105.69 |
| 13 | >5000 | 11.28 | 30.32 | 81.49 |
| 14 | >5000 | 8.29 | 22.29 | 59.89 |

eference Values Pregnancy (2nd Trimester)

| Gestational age (completed weeks) | n | 5 th percentile [IU/L] | Median [IU/L] | 95 th percentile [IU/L] |
|---|------|---|------------------|--|
| 14 | 528 | 7.4 | 19.7 | 59.4 |
| 15 | 1906 | 5.6 | 15.0 | 46.4 |
| 16 | 1088 | 4.2 | 12.2 | 34.5 |
| 17 | 507 | 3.4 | 9.1 | 25.6 |
| 18 | 246 | 2.9 | 8.4 | 27.0 |

Products

| Article number | Description |
|----------------|--|
| 809.075 | B-R-A-H-M-S Free βhCG KRYPTOR Kit, reagents for 75 determinations |
| 80991 | B-R-A-H-M-S Free βhCG KRYPTOR CAL Calibrator kit, 6 vials |
| 88192 | B-R-A-H-M-S GM KRYPTOR QC Control kit prenatal screening, 3 levels (2 vials per level) |

| L | 3·R·A·H·M·S Free βhCG KRYPTOR available on |
|----------|--|
| √ | B-R-A-H-M-S KRYPTOR |
| / | B-R-A-H-M-S KRYPTOR compact |
| / | B-R-A-H-M-S KRYPTOR compact PLUS |

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^{*} Source: Spencer K. Risk, a QC parameter. DSNEWS 2003,10(1):30-31