

B·R·A·H·M·S Free β hCG KRYPTOR

Gold standard in combined first trimester screening

Thermo Scientific™ B·R·A·H·M·S™ Free β hCG KRYPTOR™ is an automated immunofluorescent assay for the quantitative determination of free β subunit of human chorionic gonadotropin hormone (free β hCG) in serum.

- Outstanding precision: UK NEQAS data 2003-2016 prove mean CV of 3.0%
- Rapid assay time: 19 min
- In routine use by FMF since 1999

Clinical Interest

- First trimester screening for fetal aneuploidies in conjunction with additional clinical evaluation to assess the risk of fetal trisomy 21, 18 and 13
- Second trimester screening for fetal aneuploidies in conjunction with additional clinical evaluation to assess the risk of fetal trisomy 21 and 18



Ease of Handling

| | |
|---|-------------------|
| Sample volume | 26 μ L |
| Sample type | Serum |
| Incubation time | 19 min |
| Direct measurement | 0.16...150 IU/L |
| Measuring range with automatic dilution | 0.16...50000 IU/L |
| Detection limit | 0.16 IU/L |
| Kit stability on board | 29 days |
| Calibrator | 1 point |
| Calibration stability | 15 days |

Excellent Precision

| Reproducibility | | |
|-----------------|-------------|-------------------|
| Sample | Mean [IU/L] | Within-assay CV % |
| 1 | 4.2 | 3.4% |
| 2 | 36.0 | 1.4% |
| 3 | 1 000.0 | 1.9% |

| Sample | Mean [IU/L] | Between-assay CV % |
|--------|-------------|--------------------|
| 1 | 5.8 | 5.9% |
| 2 | 36.0 | 4.9% |
| 3 | 119.0 | 7.3% |

Normal values

A study of 62 non pregnant women showed a 5th percentile and a 95th percentile of 0.0 IU/L and 0.08 IU/L respectively (median of 0.0 IU/L).

Calibration

The Free β hCG results are given in IU/L.
The assay is calibrated against the 1st IRP WHO 75/551.

Thermo Scientific 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 |
| 88192 | B·R·A·H·M·S GM KRYPTOR QC Control kit prenatal screening, 3 levels |

Normal Values During Pregnancy

| First trimester | | | | |
|-----------------------------------|--------|-----------------------------------|---------------|------------------------------------|
| Gestational age (completed weeks) | n | 5 th percentile [IU/L] | Median [IU/L] | 95 th percentile [IU/L] |
| 11 | >5 000 | 16.68 | 44.83 | 120.47 |
| 12 | >5 000 | 14.63 | 39.33 | 105.69 |
| 13 | >5 000 | 11.28 | 30.32 | 81.49 |
| 14 | >5 000 | 8.29 | 22.29 | 59.89 |

| Second 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 | 1 906 | 5.6 | 15.0 | 46.4 |
| 16 | 1 088 | 4.2 | 12.2 | 34.5 |
| 17 | 507 | 3.4 | 9.1 | 25.6 |
| 18 | 246 | 2.9 | 8.4 | 27.0 |

| B·R·A·H·M·S Free β hCG is available on | |
|--|---|
| <input checked="" type="checkbox"/> | B·R·A·H·M·S KRYPTOR |
| <input checked="" type="checkbox"/> | B·R·A·H·M·S KRYPTOR compact |
| <input checked="" type="checkbox"/> | B·R·A·H·M·S KRYPTOR compact PLUS |
| <input checked="" type="checkbox"/> | B·R·A·H·M·S KRYPTOR GOLD |

B·R·A·H·M·S Free β hCG KRYPTOR is **CE marked**.

Clinical Diagnostics

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