PRODUCT SPECIFICATIONS

B·R·A·H·M·S PAPP-A KRYPTOR

Gold standard in combined first trimester screening

Thermo Scientific™ B·R·A·H·M·S™ PAPP-A
KRYPTOR™ is an automated immunofluorescent
assay for the quantitative determination of
pregnancy associated plasma protein-A (PAPP-A)
in human serum.

- CE mark for trisomy and pre-eclampsia first trimester screening
- Outstanding precision: UK NEQAS data 2003-2016 prove mean CV of 3.1%
- 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

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



Sample volume	50 μL
Sample type	Serum
Incubation time	19 min
Direct measurement	0.0046 IU/L
Measuring range with automatic dilution	0.00490 IU/L
Detection limit	0.004 IU/L
Kit stability on board	29 days
Calibrator	1 point
Calibration stability	15 days





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Excellent Precision

Reproducibility		
Sample	Mean [IU/L]	Within-assay CV %
1	0.070	2.5%
2	0.346	1.0%
3	2.563	1.7%
4	23.781	1.3%

Sample	Mean [IU/L]	Between-assay CV %
1	0.069	3.4%
2	0.463	3.1%
3	3.377	3.9%
4	45.299	3.9%

Normal Values During Pregnancy

Gestational age (completed weeks)	n	5 th percentile [IU/L]	Median [IU/L]	95 th percentile [IU/L]
8	6884	0.11	0.33	0.93
9	16 179	0.22	0.64	1.76
10	14 215	0.41	1.17	3.20
11	33 512	0.79	2.18	5.62
12	98011	1.14	3.17	7.72
13	52 163	1.65	4.57	11.08
14	2 114	2.31	6.34	15.56

Normal values

A study of 100 presumably healthy man and non pregnant women showed that 95% of the samples were found below 0.014 IU/L. The median value was 0.01 IU/L.

Calibration

The PAPP-A results are given in IU/L (WHO IRP 78/610 is no longer available).

Thermo Scientific Products

Article number	Description
866.075	B·R·A·H·M·S PAPP-A KRYPTOR Kit, reagents for 75 determinations
86691	B·R·A·H·M·S PAPP-A KRYPTOR CAL Calibrator kit
88192	B·R·A·H·M·S GM KRYPTOR QC Control kit prenatal screening, 3 levels

B·R·A·H·M	I⋅S PAPP-A KRYPTOR is available on
\checkmark	B·R·A·H·M·S KRYPTOR
\checkmark	B·R·A·H·M·S KRYPTOR compact
\checkmark	B·R·A·H·M·S KRYPTOR compact PLUS
$\overline{\checkmark}$	B·R·A·H·M·S KRYPTOR GOLD

B·R·A·H·M·S PAPP-A KRYPTOR is **CE marked**.

Clinical Diagnostics

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