#### PRODUCT SPECIFICATIONS

# B·R·A·H·M·S AFP KRYPTOR

# Your best option for 2<sup>nd</sup> trimester screening

Thermo Scientific™ B·R·A·H·M·S™ AFP KRYPTOR™ is an automated immunofluorescent assay for the quantitative determination of alpha-fetoprotein (AFP) in human serum, heparin plasma or amniotic fluid.

- Excellent precision
- Very short incubation time: 9 min
- Wide measuring range



- Second trimester screening for fetal aneuploidies in conjunction with additional clinical data to assess the risk of fetal trisomy 21 and trisomy 18.
- Second trimester screening for neural tube defects in maternal serum and as an aid in diagnosis of neural tube defects in amniotic fluid in conjunction with other clinical data.



### **Ease of Handling**

Sample volume	14 µL
Sample type	Serum, heparin plasma, amniotic fluid
Incubation time	9 min
Direct measurement	0.23700 ng/mL
Measuring range with automatic dilution	0.23500 000 ng/mL
Detection limit	0.23 IU/L
Kit stability on board	15 days
Calibrator	1 point
Calibration stability	15 days





# **thermo**scientific

#### **Excellent Precision**

Reproducibility		
Sample	Mean [ng/mL]	Within-assay CV %
1	7.4	2.0%
2	138.0	1.0%
3	596646.0	1.8%

Sample	Mean [ng/mL]	Between-assay CV%
1	10.3	4.5%
2	539.0	3.9%
3	743.0	3.9%

#### **Normal values**

A study of 250 healthy men and non pregnant women showed a  $5^{\,\rm th}$  and  $95^{\,\rm th}$  percentile of 0.93 ng/mL and 10.65 ng/mL, respectively (median of 3.21 ng/mL).

#### **Calibration**

The AFP results are given in ng/mL. The assay is calibrated against  $1^{st}$  IRP WHO 72/225 (1 ng B·R·A·H·M·S AFP KRYPTOR = 1 IU or 0.823 ng of the  $1^{st}$  IRP WHO 72/225).

#### **Normal Values During Pregnancy**

Serum				
Gestational age (completed weeks)	n	5 <sup>th</sup> percentile [ng/mL]	Median [ng/mL]	95 <sup>th</sup> percentile [ng/mL]
14	529	15.2	26.3	52.5
15	1908	16.2	29.4	53.4
16	1090	18.8	34.0	62.5
17	509	21.4	37.1	66.5
18	246	24.5	41.2	88.7

Amniotic fluid		
Gestational age (completed weeks)	n	Median [ng/mL]
14	382	15 580
15	512	14870
16	495	12980
17	280	10 630
18	131	8 8 3 5

### **Thermo Scientific Products**

Article number	Description
816.075	B·R·A·H·M·S AFP KRYPTOR Kit, reagents for 75 determinations
81691	B·R·A·H·M·S AFP KRYPTOR CAL Calibrator kit
81693	B·R·A·H·M·S AFP KRYPTOR Diluent Diluent AFP for amniotic fluid samples, 1 vial
88192	B·R·A·H·M·S GM KRYPTOR QC Control kit prenatal screening, 3 levels

B·R·A·H·M	S AFP 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
$\checkmark$	B·R·A·H·M·S KRYPTOR GOLD

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

**Clinical Diagnostics** 

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