

thermo scientific



Precision is the essence

Prenatal screening on B·R·A·H·M·S KRYPTOR analyzers

ThermoFisher
SCIENTIFIC

Proven reliability

Comprehensive solution for prenatal screening laboratories

Assessing the health of an unborn baby and a becoming mother is a sensitive matter that demands precise tests and accurate risk calculation.

Thermo Scientific™ B·R·A·H·M·S™ prenatal screening solutions provide the most accurate results for reliable calculation of individual risks during pregnancy.

>20
years

With over 20 years of market presence and expertise in prenatal screening concepts Thermo Fisher Scientific is a preferred partner of hundreds of screening laboratories worldwide.

>170
studies

More than 170 studies were performed on B·R·A·H·M·S KRYPTOR™ analyzers since the last 20 years to establish and improve prenatal screening.

8
biomarkers

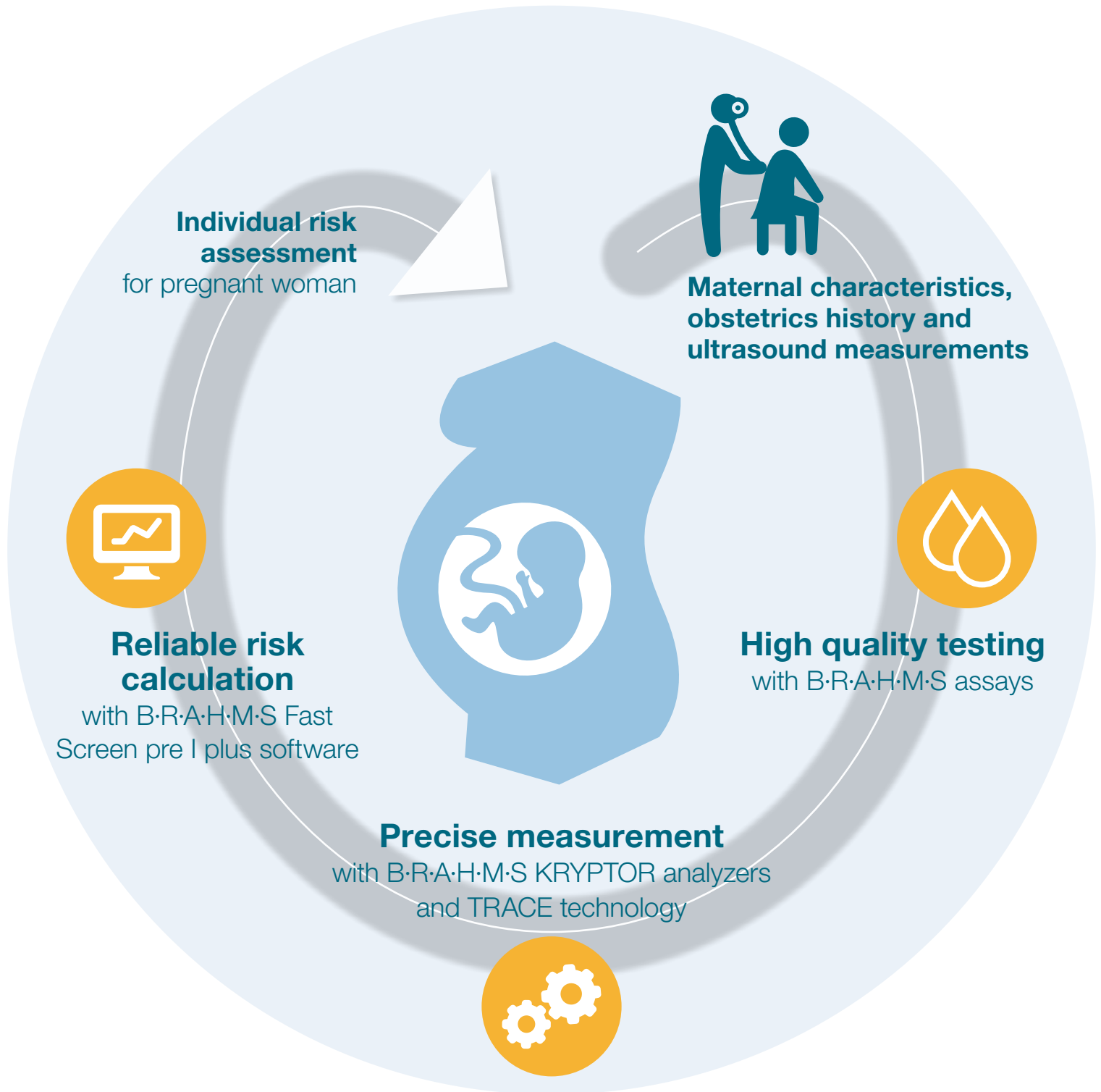
A complete portfolio of non-invasive biomarkers for prenatal testing provides highly accurate results for the risk calculation for common trisomies and preeclampsia.



Thermo Scientific B·R·A·H·M·S analyzers and assays are certified by FMF.

Fetal Medicine Foundation approval requires commitment to the highest quality standards and ongoing quality assurance.¹





B·R·A·H·M·S prenatal screening laboratory solutions:
precise, fast, reliable, and safe

Exceptional precision

B·R·A·H·M·S KRYPTOR prenatal screening assays meet highest laboratory standards

B·R·A·H·M·S KRYPTOR is the most precise analyzer with the lowest coefficient of variation (about 3%) for PAPP-A and Free β hCG, which results in the most accurate calculation of the individual risk.²

Due to excellent precision prenatal screening on B·R·A·H·M·S KRYPTOR analyzers is considered to be the Gold Standard in 1st trimester screening.

Trisomy 21, 18, and 13 screening

PAPP-A, Free β hCG, PIGF

Outstanding precision and lot to lot stability of combined 1st trimester test markers, confirmed by UK NEQAS data 2003-2019 and internal QC over 20 years.²

Week of gestation

7+0

8+0

9+0

10+0

11+0

12+0

13+0

13+6

14+0

15+0



Preeclampsia screening

PAPP-A, PIGF

Lowest cross reactivity of B·R·A·H·M·S KRYPTOR PIGF assay for a reliable preeclampsia first trimester screening³



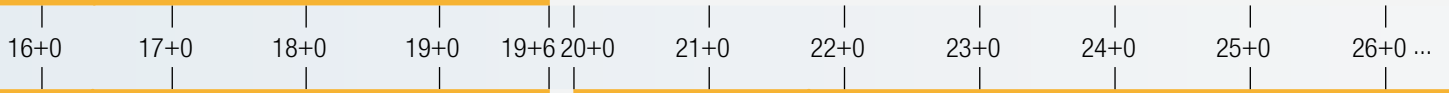
Watch an animation about
preeclampsia biomarkers
prenatal.world-of-biomarkers.com



Trisomy 21 screening

AFP, hCG+ β /Free β hCG, uE3, Inhibin A

Best option for a robust 2nd trimester screening for trisomy 21, including B·R·A·H·M·S Inhibin A KRYPTOR assay with the shortest incubation time on the market



Neural tube defect (NTD) assessment

AFP

Fast and precise AFP determination for a routine Neural Tube Defect screening in 2nd trimester

Preeclampsia diagnosis

sFit-1, PIGF

Improved preeclampsia diagnosis and prognosis of adverse outcome in symptomatic women presenting after week 20

Get everything from one source:
Thermo Scientific is the only provider with a complete prenatal screening assay portfolio.

Extraordinary performance

B·R·A·H·M·S KRYPTOR analyzers for optimal laboratory routine

The Thermo Scientific B·R·A·H·M·S KRYPTOR automated random access immunoanalyzers are user-friendly bench-top instruments that can easily be integrated into any laboratory.

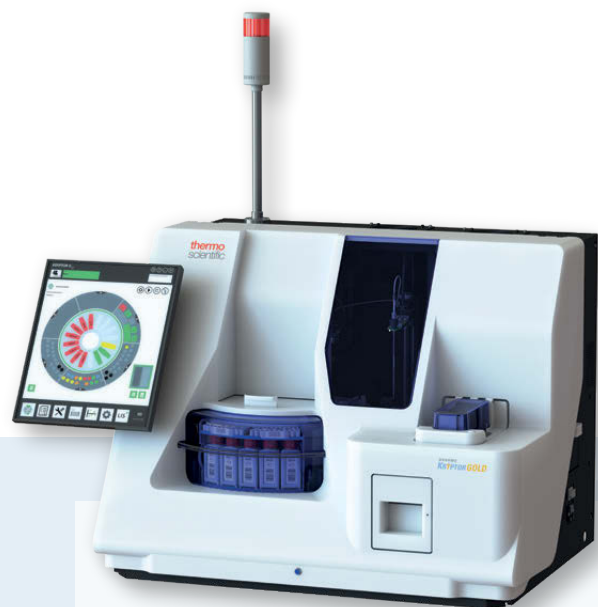
- Easy and straightforward laboratory routine with less operator intervention
- Intelligent dilution and separate calibration significantly reduce the need of sample re-run
- Cost reduction due to efficient sample processing



**B·R·A·H·M·S KRYPTOR
compact PLUS**

8 assays
on board

Up to **100 tests**
without intervention



**B·R·A·H·M·S KRYPTOR
GOLD**

16 assays
on board

Up to **600 tests**
without intervention



be OSCAR ready

With B·R·A·H·M·S KRYPTOR analyzers combined 1st trimester test results are available in 30 minutes

Save laboratory time with B·R·A·H·M·S KRYPTOR analyzers



Prepare the instrument

- Daily maintenance: 5 min
- Daily QC: 20 min
- Separate calibration: every 1st or 2nd week



Run the samples

- Flexibility: Random access and STAT sample capacity
- Fast time to result
- Up to 600 tests without intervention*
- Intelligent dilution: Full automated re-run of out of range samples within 5 min



Get your results

- Send data to LIS or risk calculation software
- Stay confident in your results due to highest analytical precision and minimized interference

Choose your B·R·A·H·M·S KRYPTOR analyzer based on your laboratory needs

Estimated number of pregnancy samples within 8h workday (+10 dilutions) by considering different parameter combinations

Prenatal screening panel	B·R·A·H·M·S KRYPTOR compact PLUS	B·R·A·H·M·S KRYPTOR GOLD
Combined 1 st trimester screening PAPP-A and free β hCG	125	250
Combined extended 1 st trimester screening PAPP-A, free β hCG, PIGF plus	90	170
Triple test 2 nd trimester screening AFP, free β hCG, uE3	90	160
Quad test 2 nd trimester screening AFP, free β hCG, uE3, Inhibin A	NA	115

OSCAR: One-stop Clinic for Assessment of Risk for Fetal Anomalies.⁴

* represent B·R·A·H·M·S KRYPTOR GOLD workflow

The heart of precision

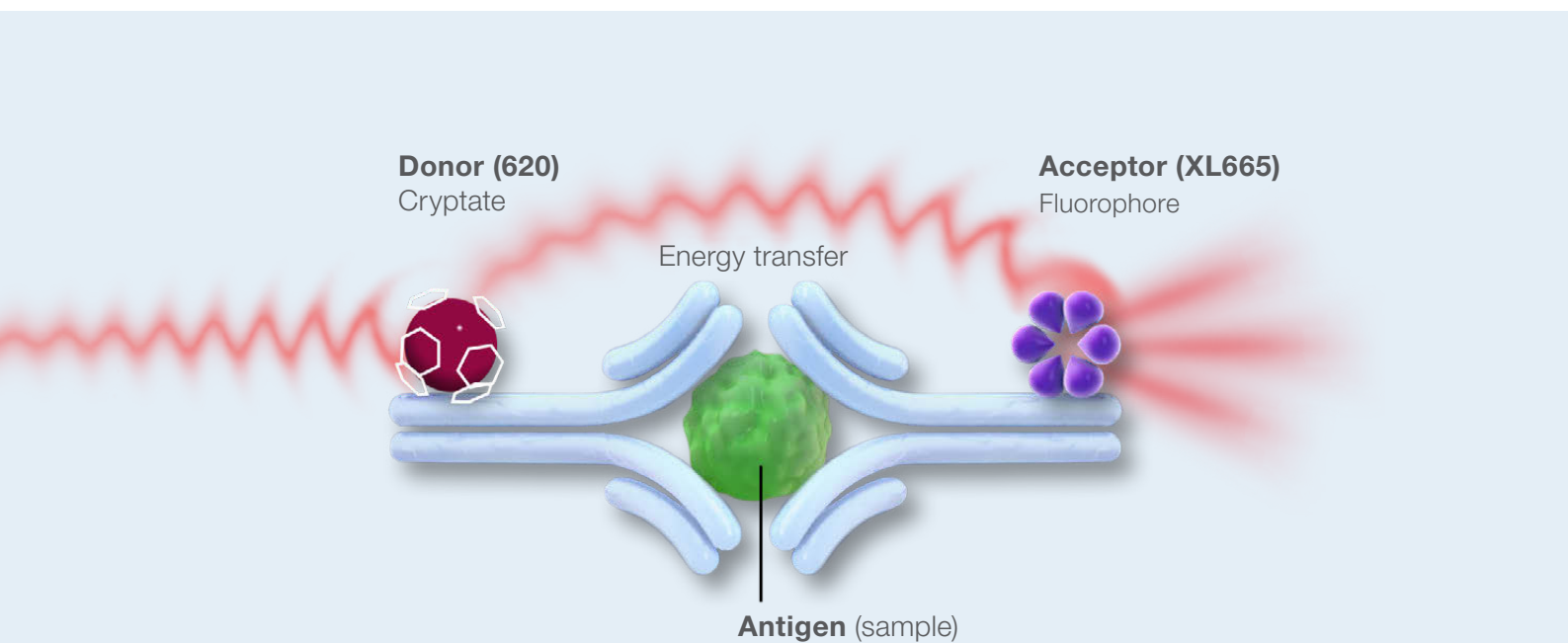
Nobel Prize[®]-winning principle behind TRACE technology guarantees highly sensitive and specific test results

Homogeneous assay design ensures excellent analytical precision and high reproducibility by eliminating the need of washing and separation steps.

TRACE™ technology provides simultaneous measurement of signals of bound and unbound antibodies, which reduces effects of possible interferences. The unspecific signals are excluded by time resolved measurement.

TRACE: Time Resolved Amplified Cryptate Emission

The unique measurement principle underlying the precision and usability of the B·R·A·H·M·S KRYPTOR analyzers



Amplified cryptate emission: Assay antibodies are labeled with cryptate, acting as a donor, and fluorophore, acting as energy acceptor. When the target antigen is present in the sample, antibodies build an immunocomplex around the target. Bringing cryptate close to fluorophore results in energy transfer and emission of the signal with the wave length much longer than the ones of unbound antibodies.



Ease of use and confidence in results



Accurate and precise



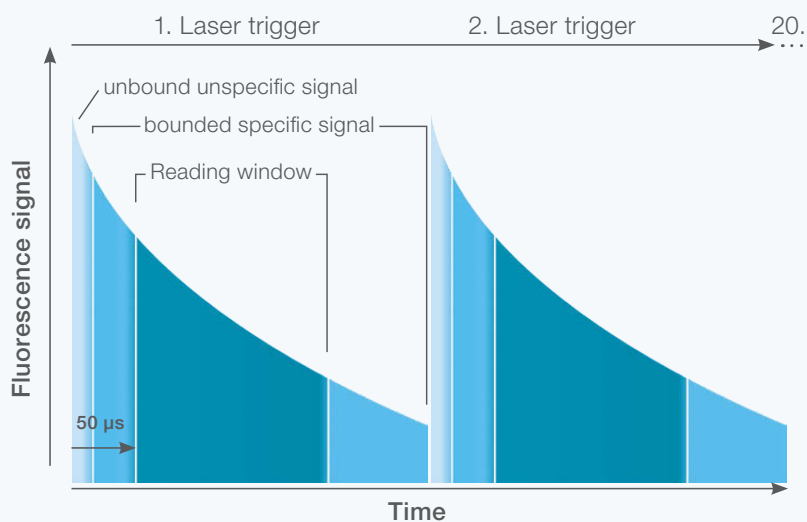
Fast time to result



Less waste and reagent consumption



Biotin independent assay design



Time resolved: Short signals of unbound fluorophores are differentiated by a 50 μs delay of reading window from the long signal of the bound immunocomplex. This long-lived signal is proportional to the concentration of the analyte of interest.

Powerful and robust

B·R·A·H·M·S Fast Screen pre I plus clinical prenatal screening software

B·R·A·H·M·S Fast Screen pre I plus algorithms allow reliable risk calculation for

- **1st trimester trisomy 21, 18, and 13** with biomarkers PAPP-A, Free β hCG, PIGF, nuchal translucency (NT) and additional ultrasound markers
- **1st trimester preeclampsia screening** with biomarkers PAPP-A, PIGF, Mean Arterial Pressure (MAP), and Uterine Artery Pulsatility Index (UAPI)
- **2nd trimester trisomy 21 and 18** with biomarkers AFP and hCG+ β /Free β hCG (double test)
- **2nd trimester neural tube defect (NTD) assesment** with biomarker AFP

Meeting the lab's need with state-of-the-art features



High quality 1st trimester trisomy and preeclampsia algorithms

Based on FMF data



Maximum data security and traceability

Software audit option for external quality control, internal audits and several user access levels



Easy and efficient data management tools

Including statistics, flexible reports, outcome management, and various data export options



High connectivity

Connection to B·R·A·H·M·S KRYPTOR analyzer and Laboratory Information System (LIS)

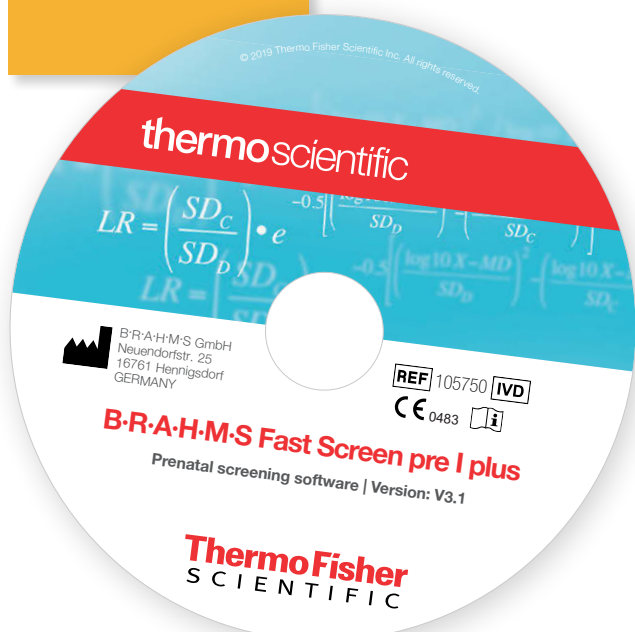


7 languages

(English, German, French, Spanish, Italian, Turkish, and Russian)

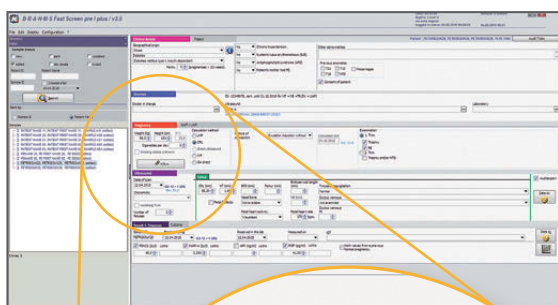
CE IVD certified clinical software

60 days trial version available



Visit the B·R·A·H·M·S Fast Screen pre I plus demonstration
fastscreen.world-of-biomarkers.com

B·R·A·H·M·S KRYPTOR medians are included in the FMF software (Astraa, ViewPoint and FMF online calculator)



Pregnancy MAP / UAPI

Weight (kg) 59,0 Height (cm) 151,0 BMI 25,9
 Cigarettes per day 1
 Smoking status unknown

Ultrasound

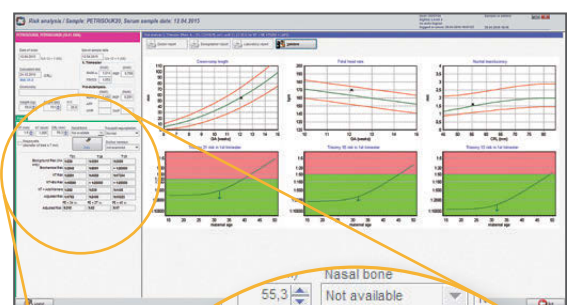
Date of scan 12.04.2015 GA 12 + 1 (85)
 Chorionicity MA: 31-2

Fetus

CRL (mm) 55,30 NT (mm) 1,60

Calculation method: LMP, direct ultrasound, IVF, GA direct

Convenient data entry:
All patient details on one screen



Nasal bone: 55,3 Not available

Background Risk (MA only)

	T21	T18	T13
Background Risk (MA only)	1:539	1:1261	1:3969
Biochemical Risk	1:3642	1:8981	< 1:20000
NT Risk	1:2891	1:4089	1:17304
NT+Bio Risk	1:19590	< 1:20000	< 1:20000
NT + Add.Markers	1:262	1:339	1:1435
Adjusted Risk	1:1763	1:2406	1:10323
PE < 34 w.		PE < 37 w.	PE < 40 w.
Adjusted Risk	1:215	1:52	1:17

Support of decisions:
Detailed presentation of risks

Based on

>220 000
pregnancies

Stable and robust medians guarantee a reliable risk calculation

The 1st trimester medians of B·R·A·H·M·S KRYPTOR biomarkers Free βhCG and PAPP-A were established on over 220 000 healthy pregnancies.⁵ These medians are included in the B·R·A·H·M·S Fast Screen pre I plus and FMF software.

B·R·A·H·M·S KRYPTOR assay portfolio



Prenatal Screening



Infectiology



Acute Care



Oncology



Endocrinology

Thermo Scientific B·R·A·H·M·S Biomarkers Prenatal Screening Portfolio on B·R·A·H·M·S KRYPTOR Analyzers



Biomarkers

B·R·A·H·M·S AFP KRYPTOR	Art. no.: 816.075
B·R·A·H·M·S Free β hCG KRYPTOR	Art. no.: 809.075
B·R·A·H·M·S hCG+ β KRYPTOR	Art. no.: 841.050
B·R·A·H·M·S Inhibin A KRYPTOR*	Art. no.: 850.075
B·R·A·H·M·S PAPP-A KRYPTOR	Art. no.: 866.075
B·R·A·H·M·S PIGF plus KRYPTOR**	Art. no.: 859.075
B·R·A·H·M·S sFlt-1 KRYPTOR**	Art. no.: 845.075
B·R·A·H·M·S uE3 KRYPTOR***	Art. no.: 803.075



Software

B·R·A·H·M·S Fast Screen pre I plus	Art. no.: 105750
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Instruments

B·R·A·H·M·S KRYPTOR GOLD	Art. no.: BMKSYS0201
B·R·A·H·M·S KRYPTOR compact PLUS	Art. no.: 106172

* Available on B·R·A·H·M·S KRYPTOR GOLD

** Available on B·R·A·H·M·S KRYPTOR compact PLUS and B·R·A·H·M·S KRYPTOR GOLD

*** Available on B·R·A·H·M·S KRYPTOR, B·R·A·H·M·S KRYPTOR compact PLUS and B·R·A·H·M·S KRYPTOR GOLD

References

1. <https://fetalmedicine.org/>
2. Monthly UK NEQAS reports, February 2003 – September 2019
3. Nucci M et al. Fetal Diagn Ther 2014; 36(2): 106-116
4. Bindra R et al. Ultrasound Obstet Gynecol 2002; 20(3): 219-225
5. Wright D et al. Ultrasound Obstet Gynecol 2010; 36: 404-411

Clinical Diagnostics

Thermo Fisher Scientific
B·R·A·H·M·S GmbH
Neuendorfstr. 25
16761 Hennigsdorf/Germany

+49 (0)3302 883 0
+49 (0)3302 883 100 fax
info.brahms@thermofisher.com
www.thermoscientific.com/brahms

Find out more at thermoscientific.com/brahms

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