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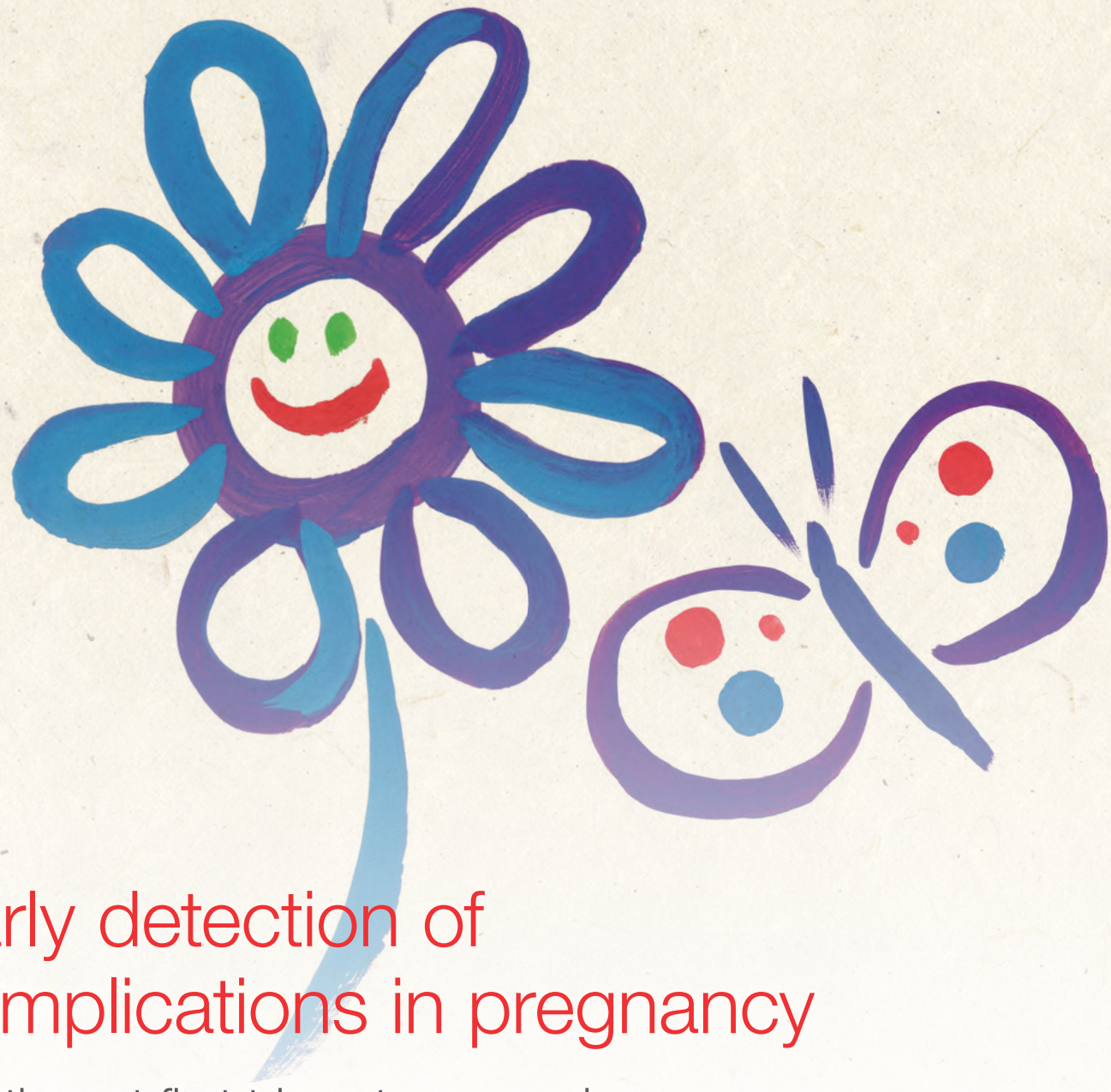

Early detection of complications in pregnancy

Contingent first trimester screening reduces unnecessary invasive tests

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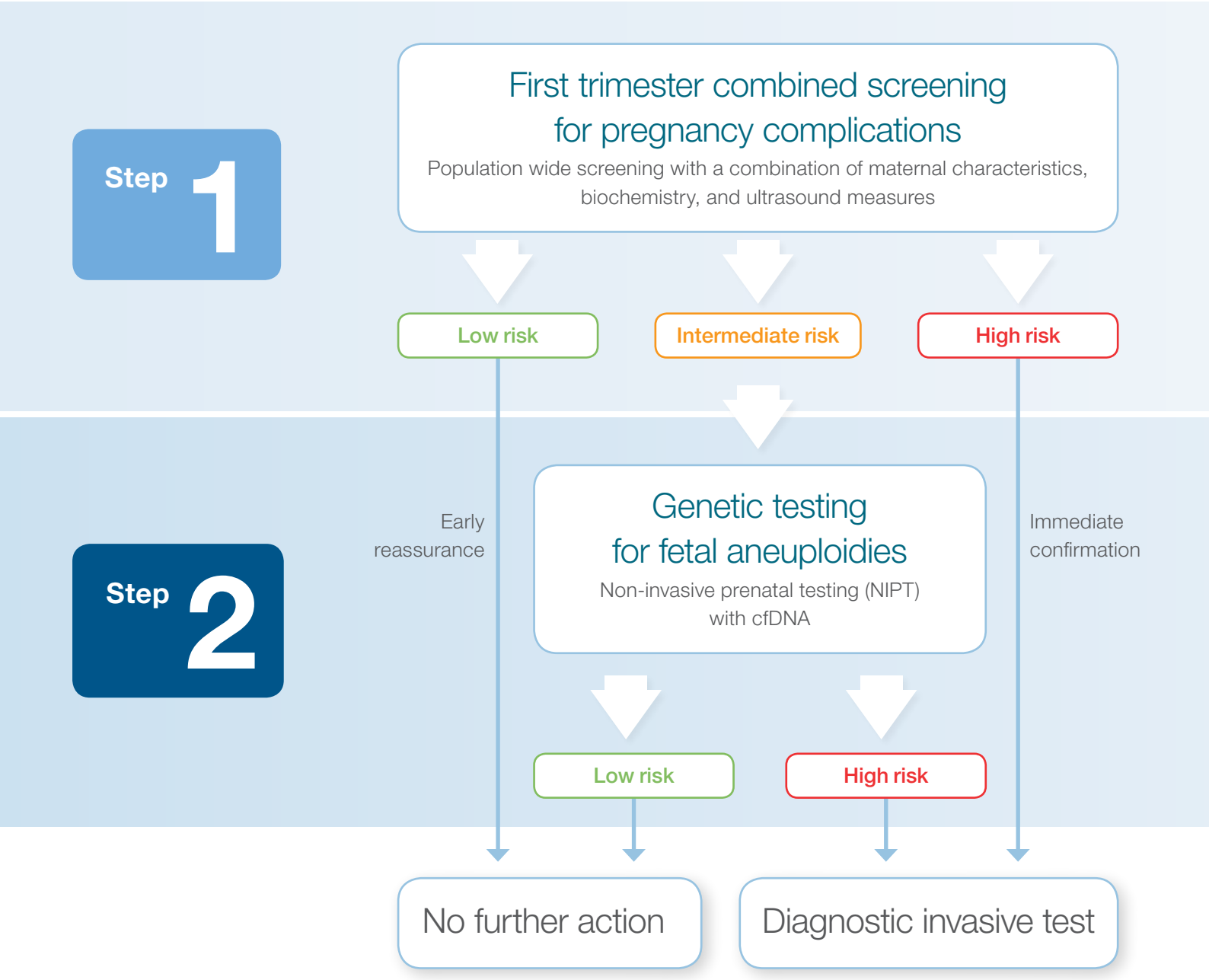
Contingent screening

Two screening steps for a most comprehensive pregnancy management

Contingent screening combines the well established routine first trimester risk assessment with cell-free DNA screening to benefit from major advantages of both screening approaches, and to further reduce unnecessary invasive tests.[1]



The contingent screening model is recommended by[1]

The Fetal Medicine Foundation

Prediction of a wide range of pregnancy complications[2]

- Early detection of major **maternal complications**
- Early detection of major **fetal complications**
- Accurate pregnancy dating

Superior screening performance for fetal trisomies

Further reduction of unnecessary invasive tests

<0.5% of pregnant women would require an invasive test when applying the contingent approach to trisomy 21 screening[1]

First trimester combined screening

for multiple pregnancy complications

The advantage of first trimester combined screening is the possibility to predict much more than only fetal aneuploidies: many major fetal and maternal complications can be detected by combining data from maternal characteristics and history with findings of biochemical and biophysical test.[2]

Maternal age and history

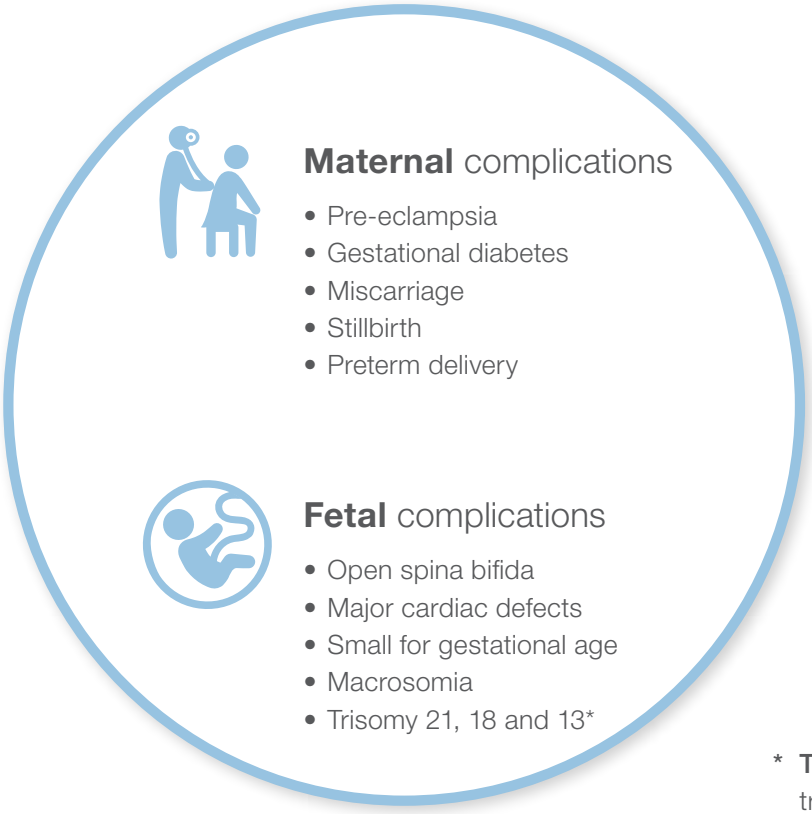
Ultrasound markers, fetal nuchal translucency thickness (NT)

Biomarkers Free βhCG, PAPP-A and PIGF in maternal blood

Use the Biomarker Gold Standard to achieve best results

For a reliable risk determination the quality and precision of the biomarkers are of utmost importance. The **coefficient of variation (CV)** is a measure for precision. The lower the CV the higher the precision of the biomarker measurement.

Step 1



The usefulness of biomarkers

In addition to the risk assessment for aneuploidies, biomarkers can also be used to screen for other conditions. Measurement of serum **PIGF** and **AFP** can be performed in the same sample on the same platform and are beneficial in **screening for**

- **pre-eclampsia,**
- **fetal growth restriction and**
- **preterm birth.**[3,4,5]

* **Trisomy detection rates** in first trimester combined screening for

- Trisomy 21: 90%[6]
- Trisomy 18, 13: 95%[6]

False positive rate: 3.1%[6]

Highly precise and reliable measurements on B·R·A·H·M·S KRYPTOR

The biochemical assays **Thermo Scientific™ B·R·A·H·M·S™ Free βhCG and PAPP-A KRYPTOR™** fulfil the strict quality requirements of the Fetal Medicine Foundation (FMF) and provide continuously the highest precision and lowest biomarker CVs as proved by the UK NEQAS data since 2003.[8]

B·R·A·H·M·S Free βhCG **3.0%** mean CV

B·R·A·H·M·S PAPP-A **3.1%** mean CV

Cell-free DNA screening

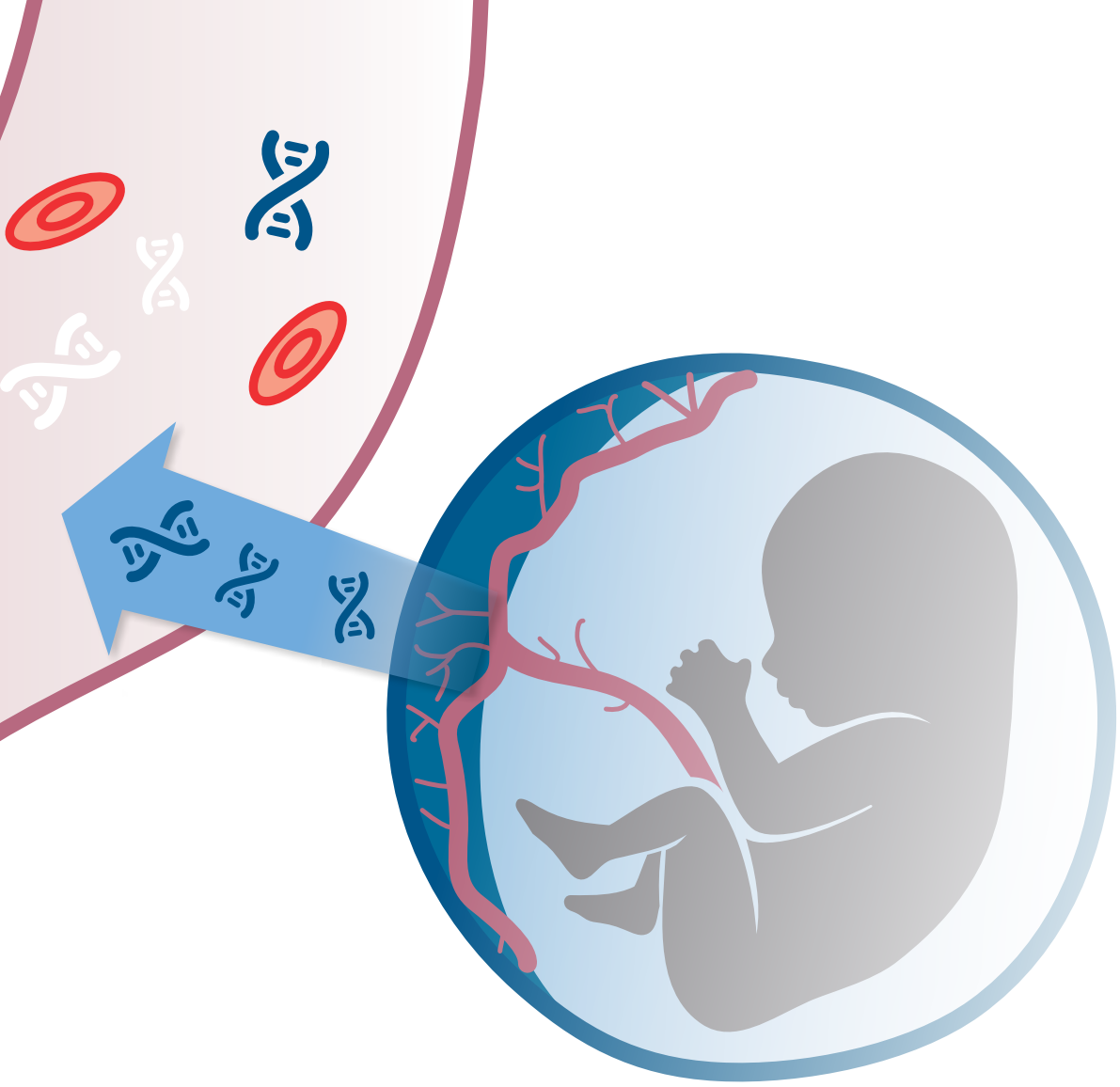
for intermediate risk pregnancies

Non-invasive prenatal testing (NIPT) or cfDNA screening is an advanced screening method for fetal trisomies. It detects fetal trisomies by analyzing placentally derived cell-free DNA fragments which are circulating in the maternal blood. Small cfDNA fragments are measured from around 10 weeks of gestation by using molecular biology techniques, such as Next Generation Sequencing (NGS). The test principle is counting the relative amount of the affected chromosomes and then calculating a likelihood ratio to predict the presence of a trisomy.

It is essential that NIPT/cfDNA corresponds to the high CE and IVD standards of the clinical tests:

- Standardized and validated workflow
- Fast turnaround time
- Low redraw rates
- Rigorous quality controls
- Measurement of fetal fraction

Step 2



cfDNA is an advanced screening for fetal aneuploidies

	Trisomy 21	Trisomy 18	Trisomy 13	
Detection rate[9] (pooled, weighted)	**99.2%**	**96.3%**	**91.0%**	
False positive rate[9] (pooled, weighted)	**0.09%**	**0.13%**	**0.13%**	**Sum: 0.35%**

Discordancy between cfDNA results and fetal karyotype (false positives and negatives) can include true fetal or placental mosaicism, presence of a maternal karyotype abnormality or maternal malignancy, insufficient counting due to low fetal fraction, or a vanishing twin.[10]

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Your ADVANTAGES of the contingent screening model

Two step policy with **combined first trimester screening** followed by **NIPT** in the intermediate risk group resulting in

- Comprehensive and cost-effective pregnancy management to predict a wide range of pregnancy complications
- High detection rates for fetal trisomies with less unnecessary invasive procedures

Your ACCESS to our interactive e-detail

Get more in-depth information on contingent screening:

www.brahms-contingent-screening.com

Thermo Scientific B·R·A·H·M·S Biomarkers Prenatal Screening Portfolio on KRYPTOR Systems	
B·R·A·H·M·S **AFP** KRYPTOR	Art. no.: 816.075
B·R·A·H·M·S **Free βhCG** 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	(under development)
B·R·A·H·M·S **PAPP-A** KRYPTOR	Art. no.: 86 6.075
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
B·R·A·H·M·S **Fast Screen pre I plus Software**	Art. no.: 105750

* Available on KRYPTOR compact PLUS
** Available on KRYPTOR and KRYPTOR compact PLUS

References

1. Nicolaides KH et al. Ultrasound Obstet Gynecol 2013; 42: 41-50
2. Nicolaides KH. Prenat Diagn 2011; 31: 7-15
3. Akolekar R et al. Fetal Diagn Ther 2013; 33: 8-15
4. Poon LC et al. Fetal Diagn Ther 2013; 33: 16-27
5. Beta J et al. Fetal Diagn Ther 2011; 30: 88-93
6. Kagan KO et al. Hum Reprod 2008; 23: 1968-1975
7. Spencer K. DSNEWS 2003; 10(1): 30-31
8. Monthly UK NEQAS reports, February 2003-March 2016
9. Gil MM et al. Ultrasound Obstet Gynecol 2015; 45: 249-266
10. Cuckle H et al. Clin Biochem 2015; 48(15): 932-41

Clinical Diagnostics

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