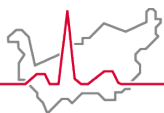




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Validation of the Cobas/Ssdw system for trisomy 21 screening in the first trimester of pregnancy: Comparison with the Kryptor/ FastScreen combination

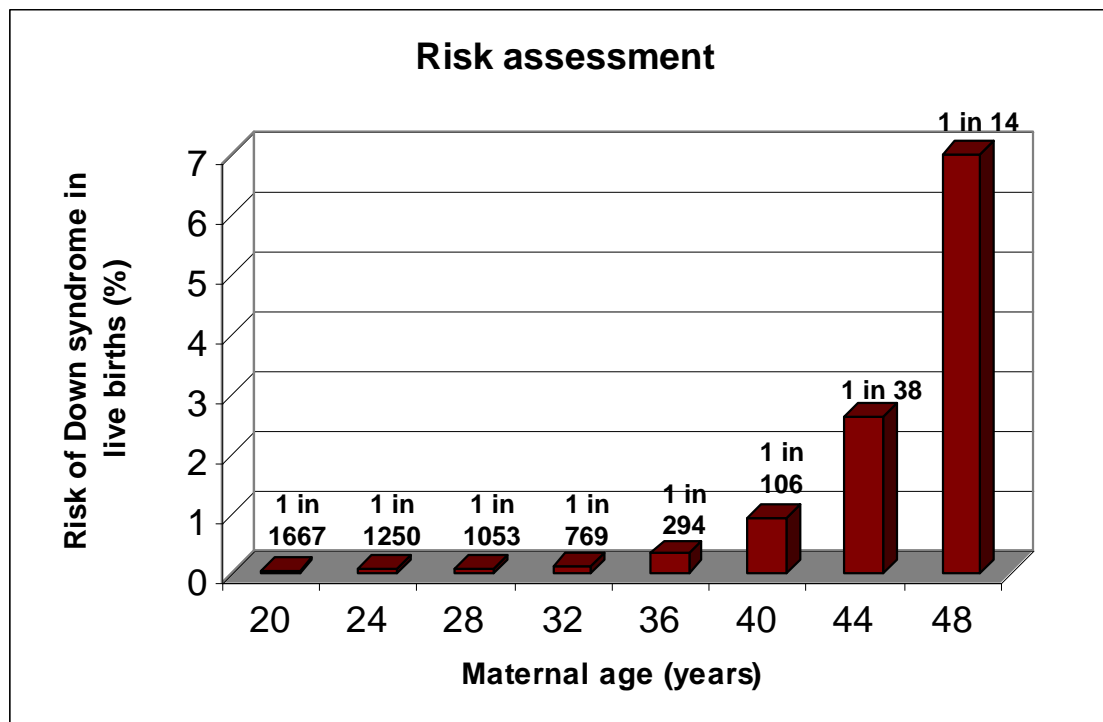
MF Rossier, N Beloeil, J Hediger-Bonfantini, S Dahoun,
R Stricker, E Dayer, O Irion, DF Hochstrasser, and I Kern



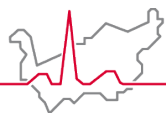
Introduction

Prenatal Screening

Increasing Down syndrome risk with increasing maternal age



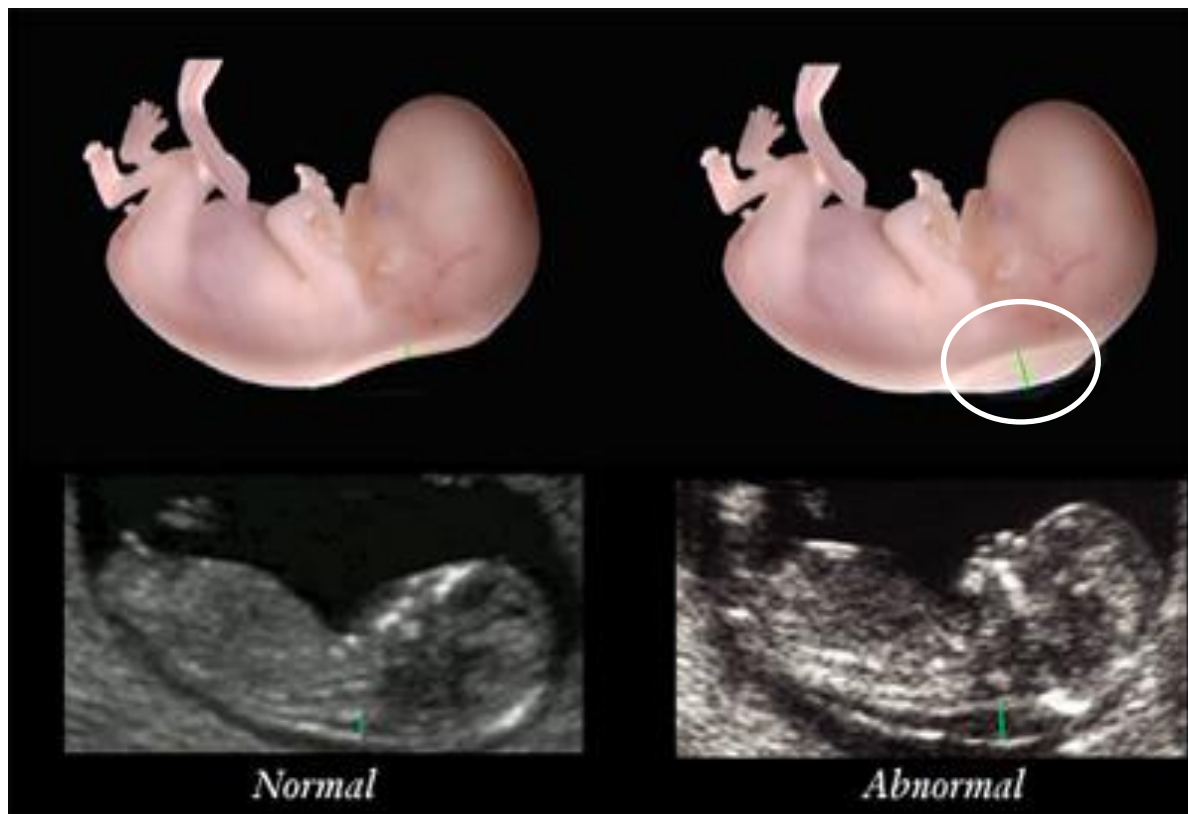
Source: Merck Manual of Medical Information

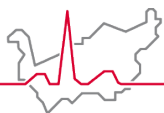


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Introduction

Nuchal Translucency (*NT*)



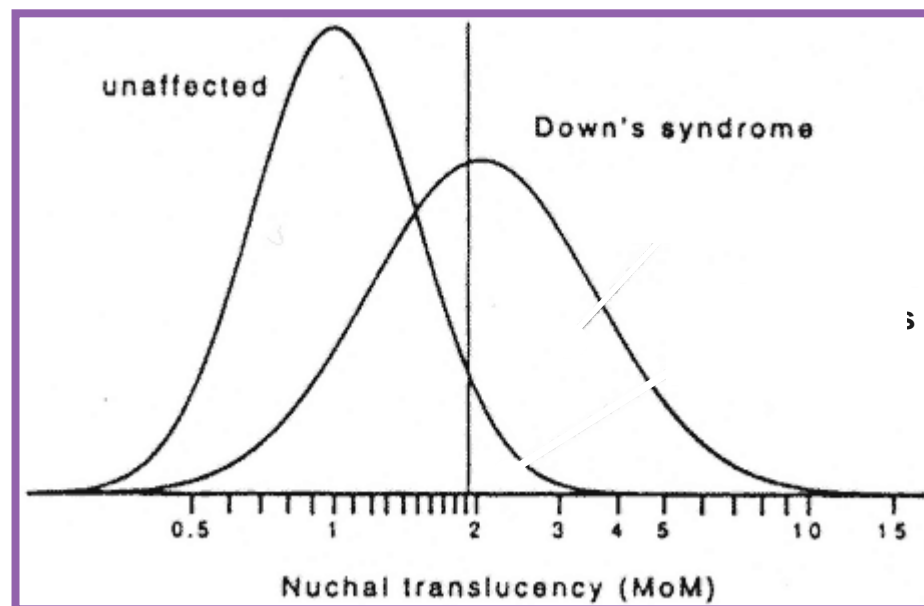


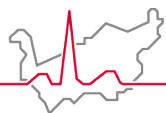
Introduction

Nuchal Translucency (NT) is increased in case of Down Syndrome, congenital heart defects, other syndromes and conditions.

**Sens = 77 % at Spec = 95 %
(NT + maternal age, medians according to gestational age and embryo size)**

Snijders et al., Lancet 1998;351:343.





Introduction

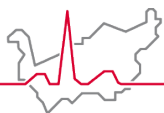
Risk Assessment

Comparison of detection rates of different screening methods

Comparison of the detection rates (DR), for a **false positive rate (FPR) of 5%** of different screening methods for trisomy 21 in prenatal screening.
Source: FMF, London 2004

Method of screening	DR (%)
Maternal age (MA)	30
MA and maternal serum biochemistry at 15–18 weeks	50–70
MA and fetal nuchal translucency (NT) at 11–13 ⁺⁶ wks	70–80
MA and fetal NT and maternal serum free β -hCG and PAPP-A at 11–13 ⁺⁶ wks	85–90
MA and fetal NT and fetal nasal bone (NB) at 11–13 ⁺⁶ wks	90
MA and fetal NT and NB and maternal serum free β -hCG and PAPP-A at 11–13 ⁺⁶ wks	95
<i>hCG human chorionic gonadotropin, PAPP-A: pregnancy-associated plasma protein A</i>	





Instruments for free β -hCG and PAPP-A determination



Kryptor (Brahms/Thermo)

(reference method)

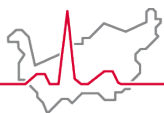


Cobas 6000 <e601> (Roche)

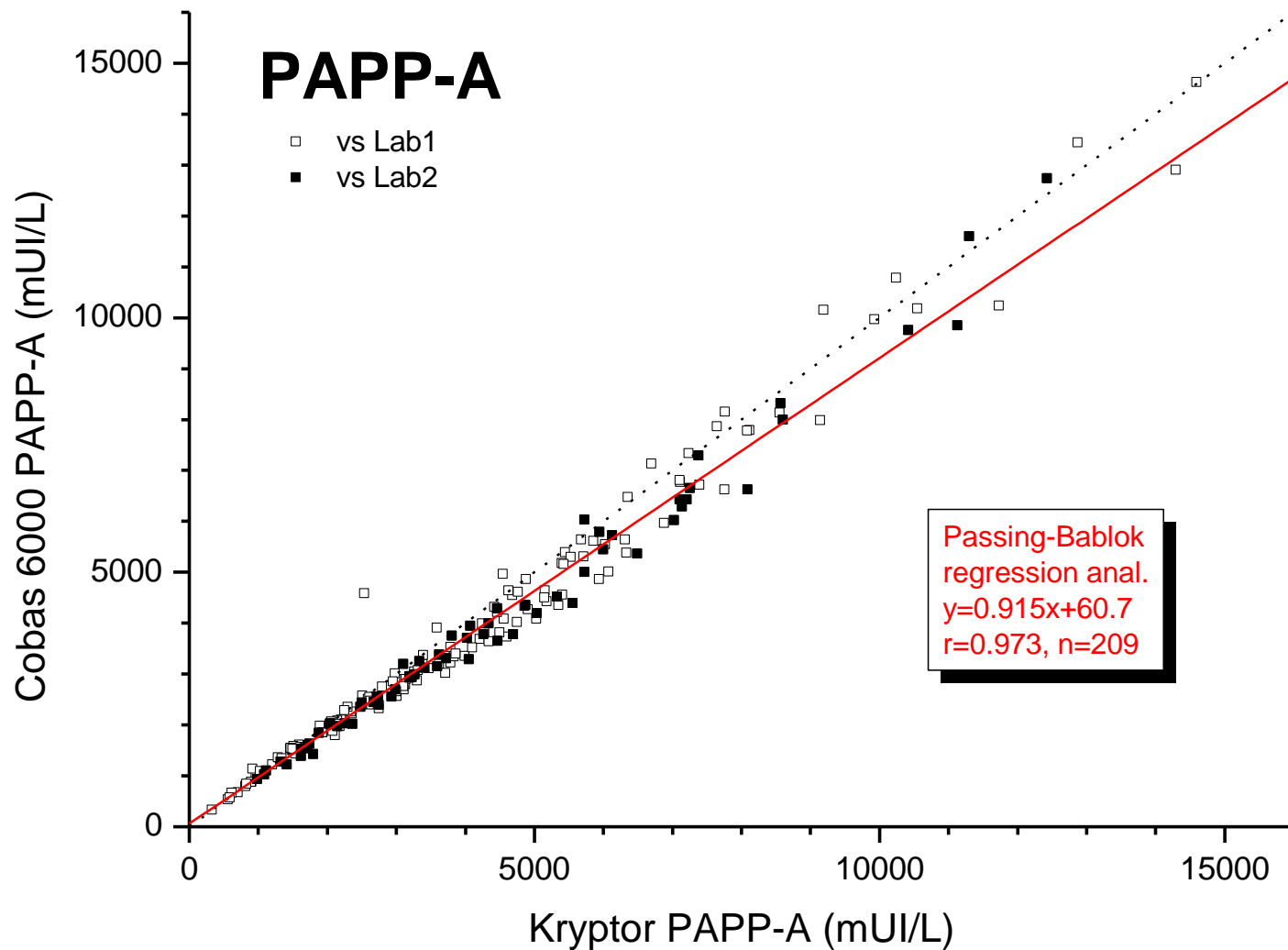
(FMF certified since 2010)

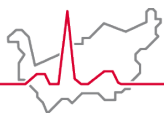
Softwares for risk assessment

Program	Furnisher	Ref Instrument	Statistics	Calculated risk	Certification required	Recommendation
→ *FastScreen (2009 - V.1.1.3.2)	Brahms	Kryptor	DoE	At sampling	FMF (D)	Recommended in Switzerland
Prisca (2004 – V.4.0.20.4)	Siemens	Kryptor or Immulite	MoM	At term or at sampling	no	Alternative to FastScreen
Astraia (2009)	Astraia		MoM	At term	FMF (UK)	Recommended in Switzerland
→ *Ssdw Lab (2007 – V.5)	Roche	Cobas	MoM	At sampling or at term	no	In process

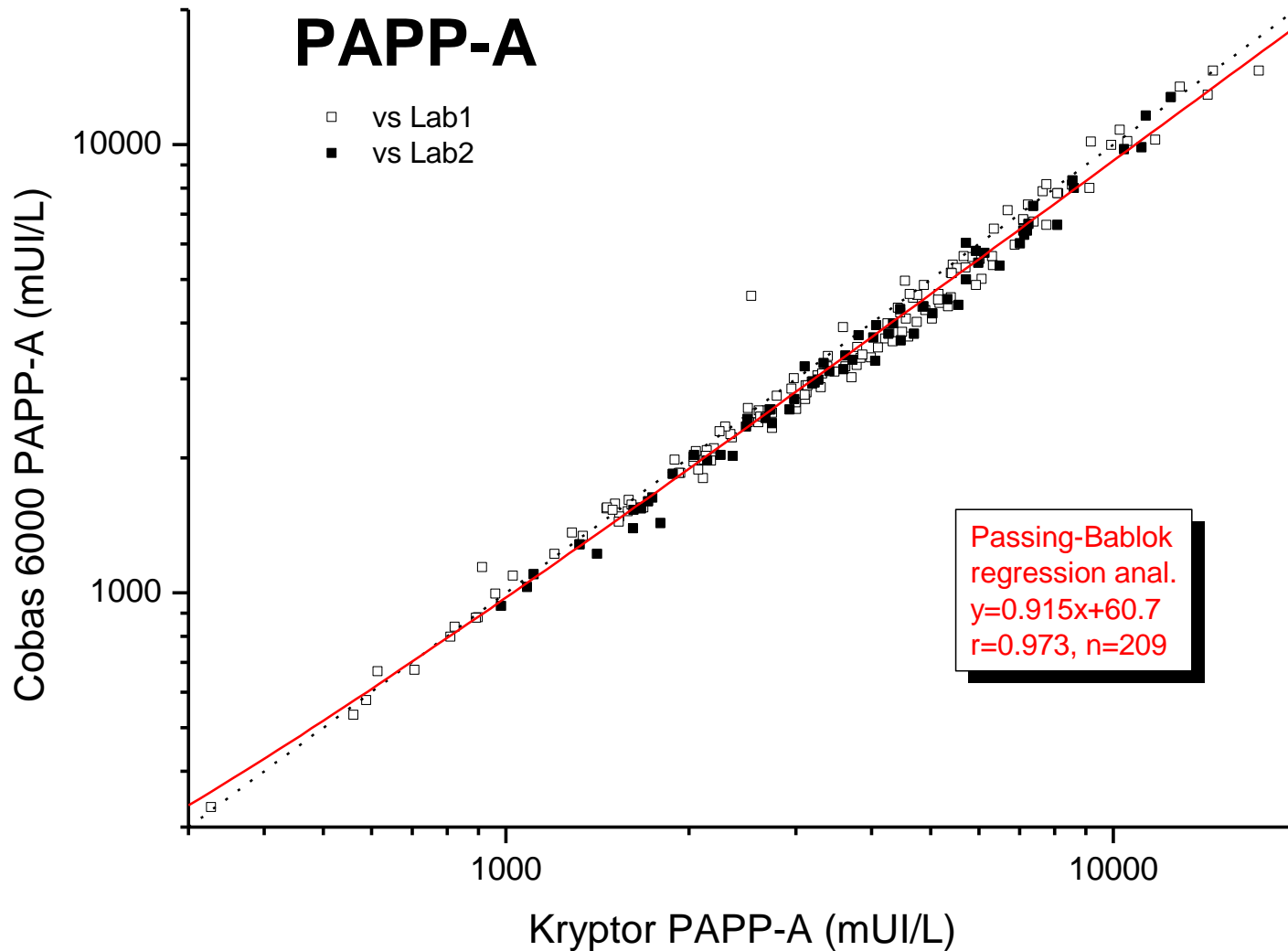


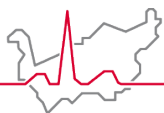
Instrument comparisons





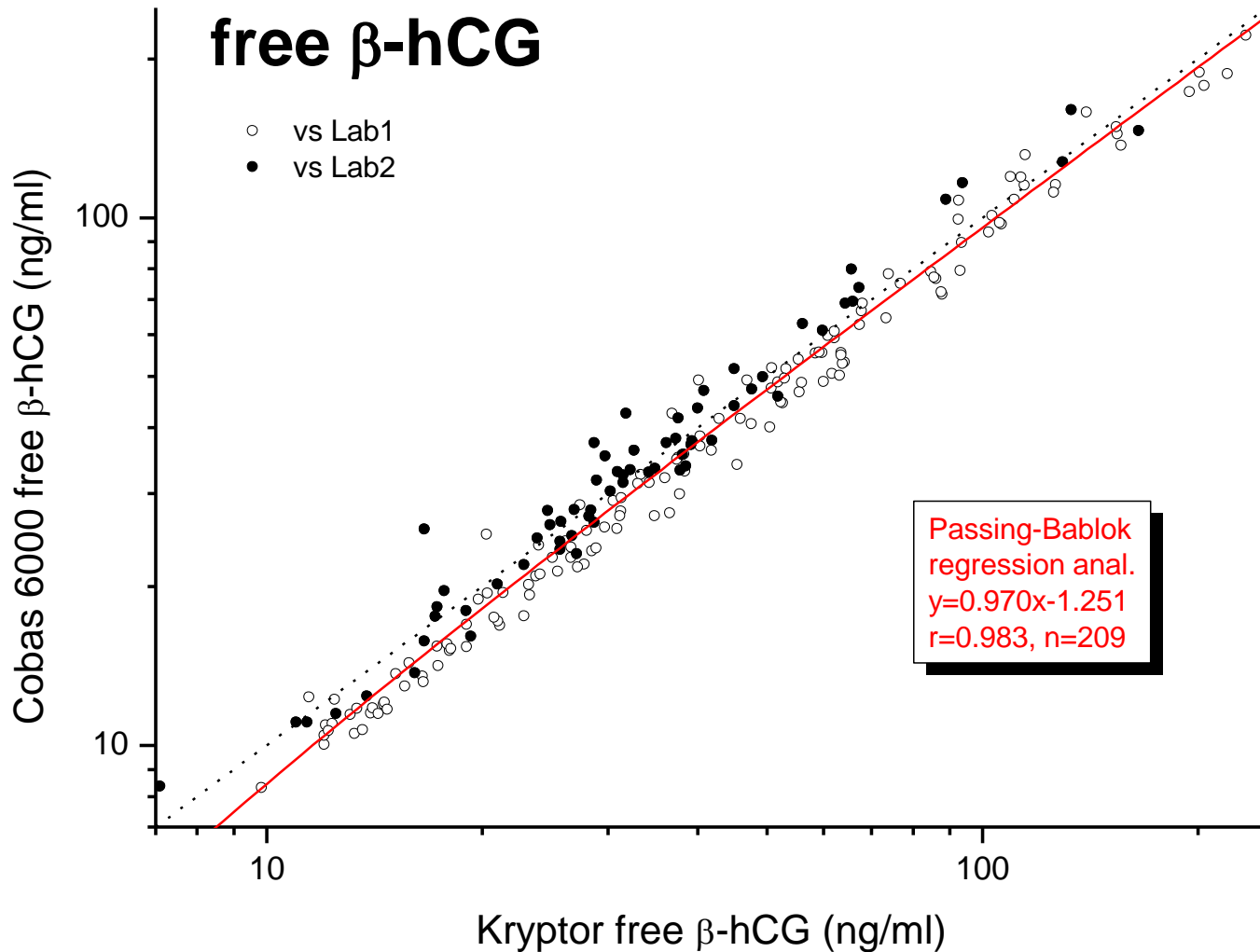
Instrument comparisons

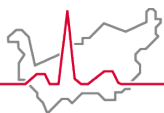




Instrument comparisons

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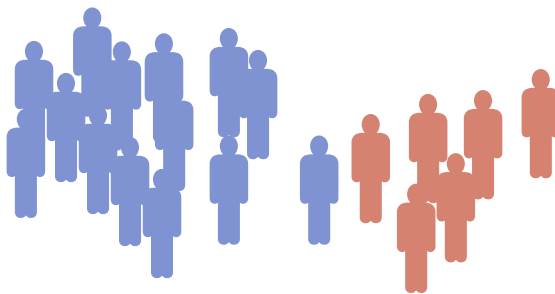
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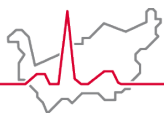
Performance evaluation

Cohort: 143 pregnancies including

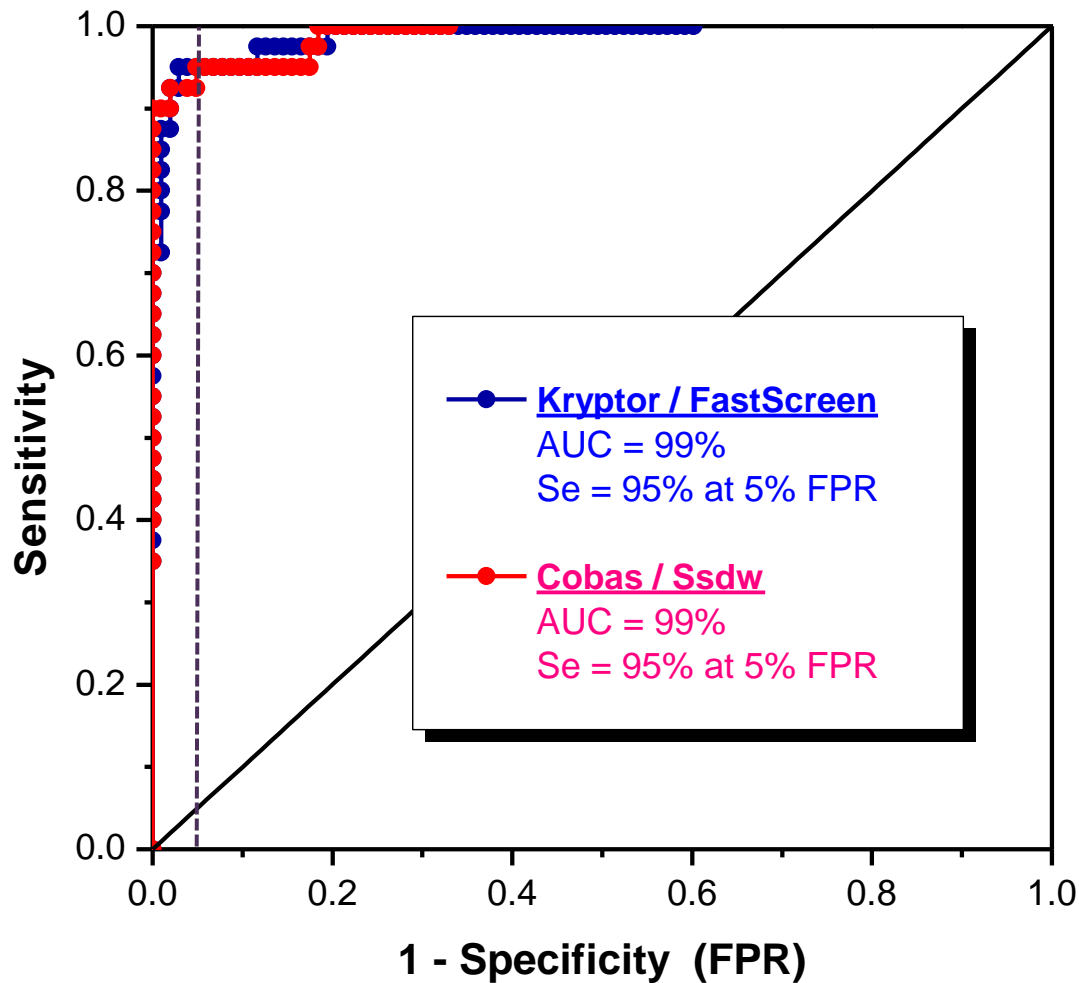
- 40 cases of trisomy 21, plus
- 103 consecutive controls

Analysis: ROC curve characteristics
Sensitivity and specificity
Illegitimate combinations
Influence of nuchal translucency





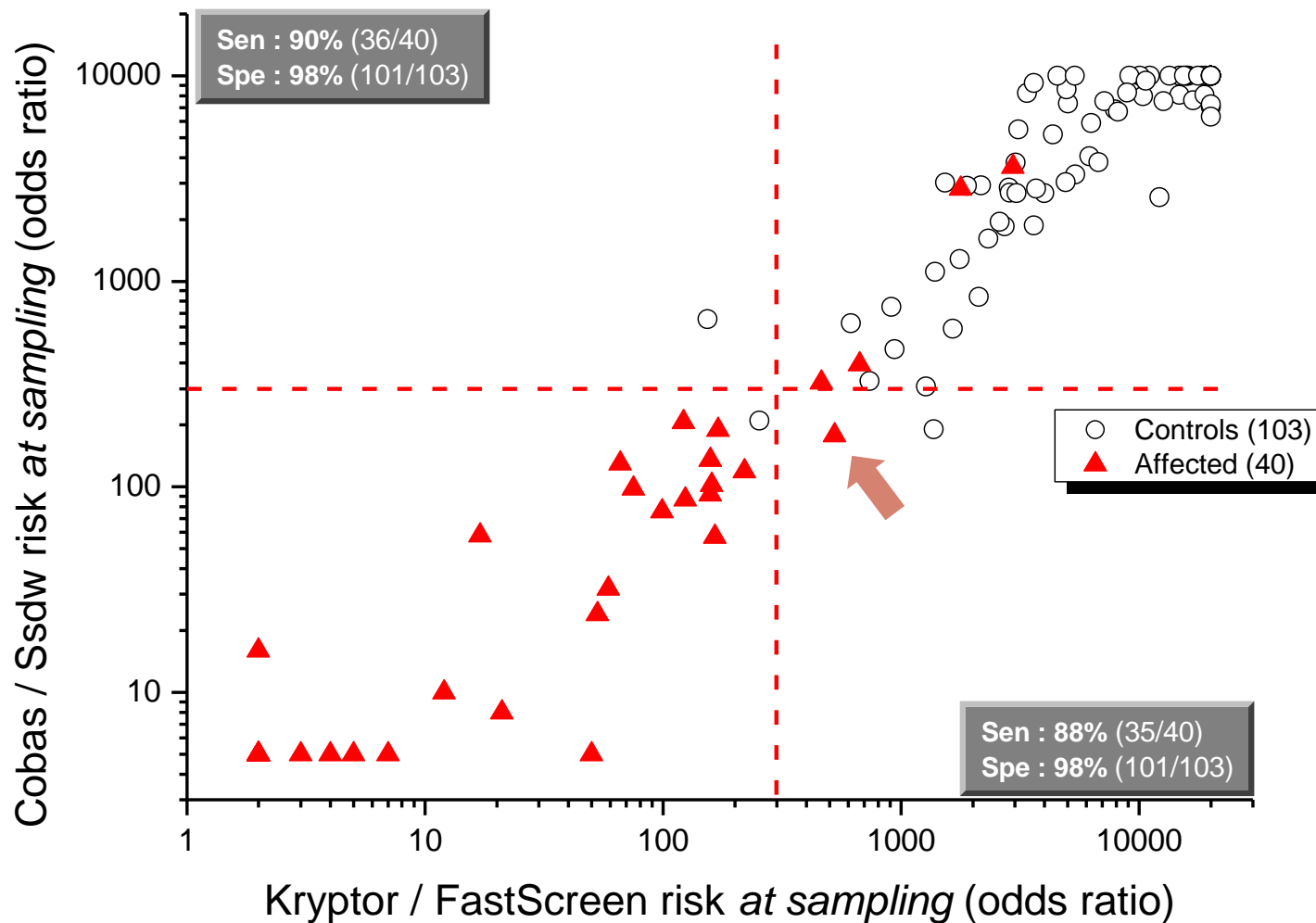
ROC curve analysis

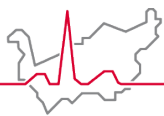


Analysis on

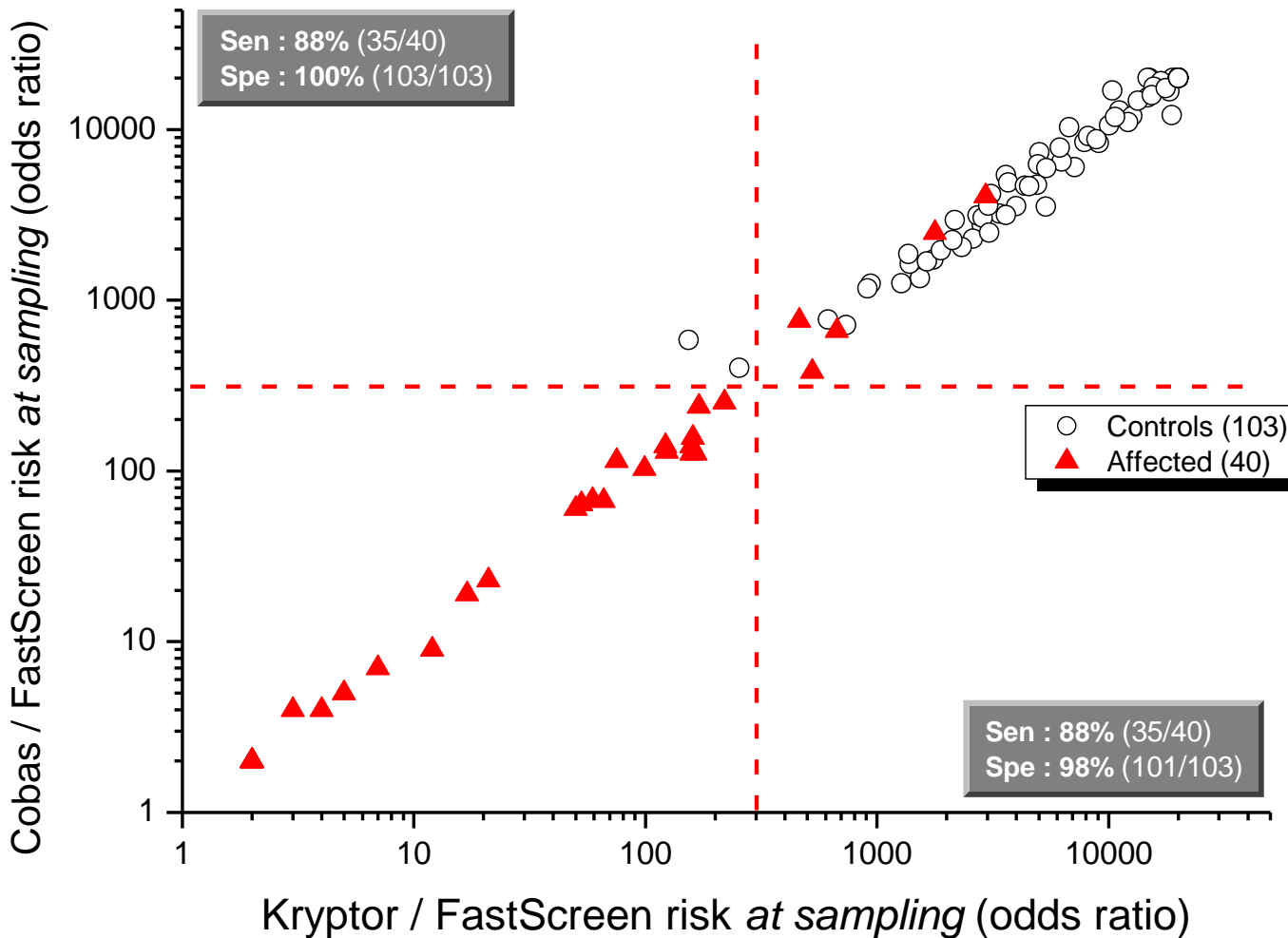
- 40 T21 cases
- 103 controls

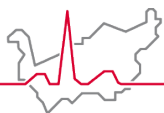
Comparison Kryptor/FastScreen and Cobas/Ssdw



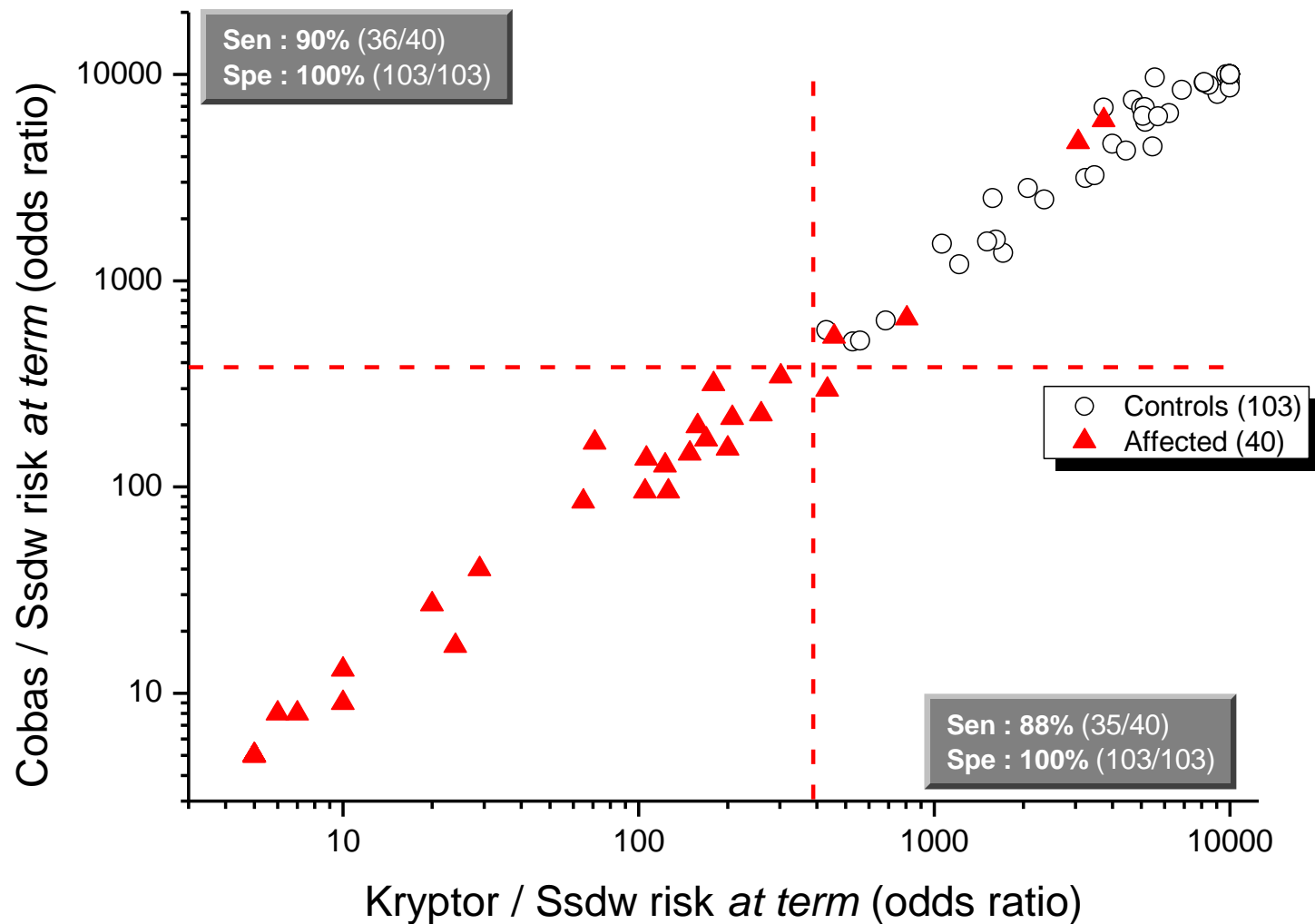


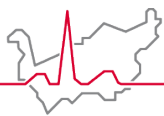
Comparison of instruments using FastScreen





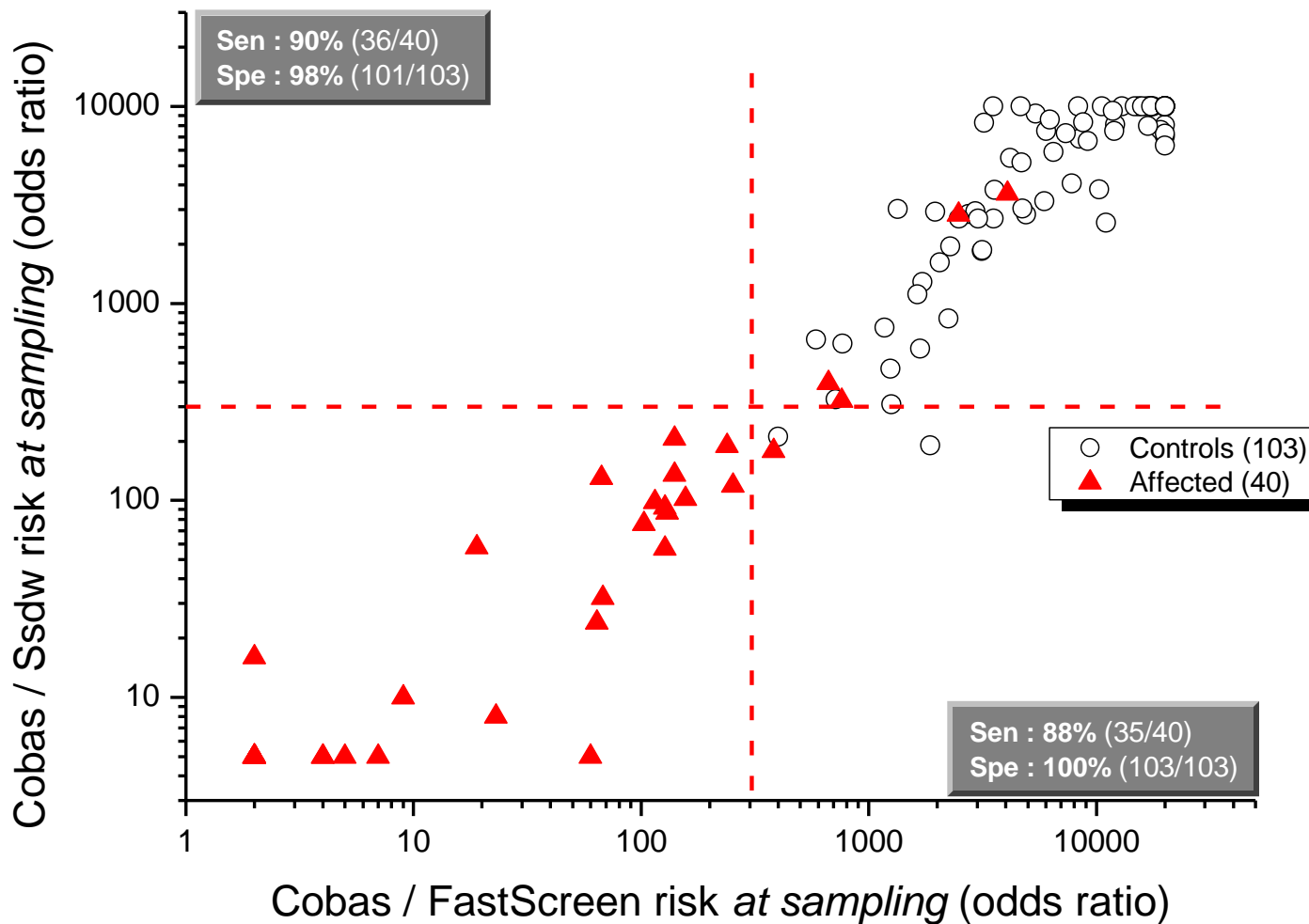
Comparison of instruments using Ssdw

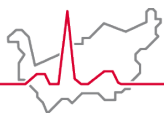




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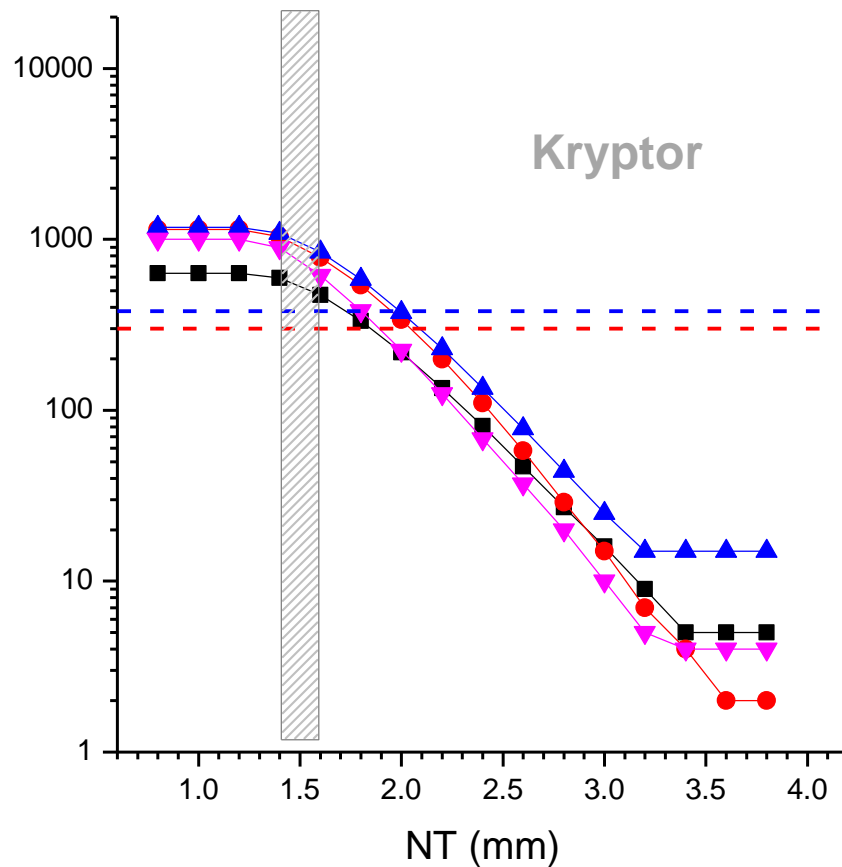
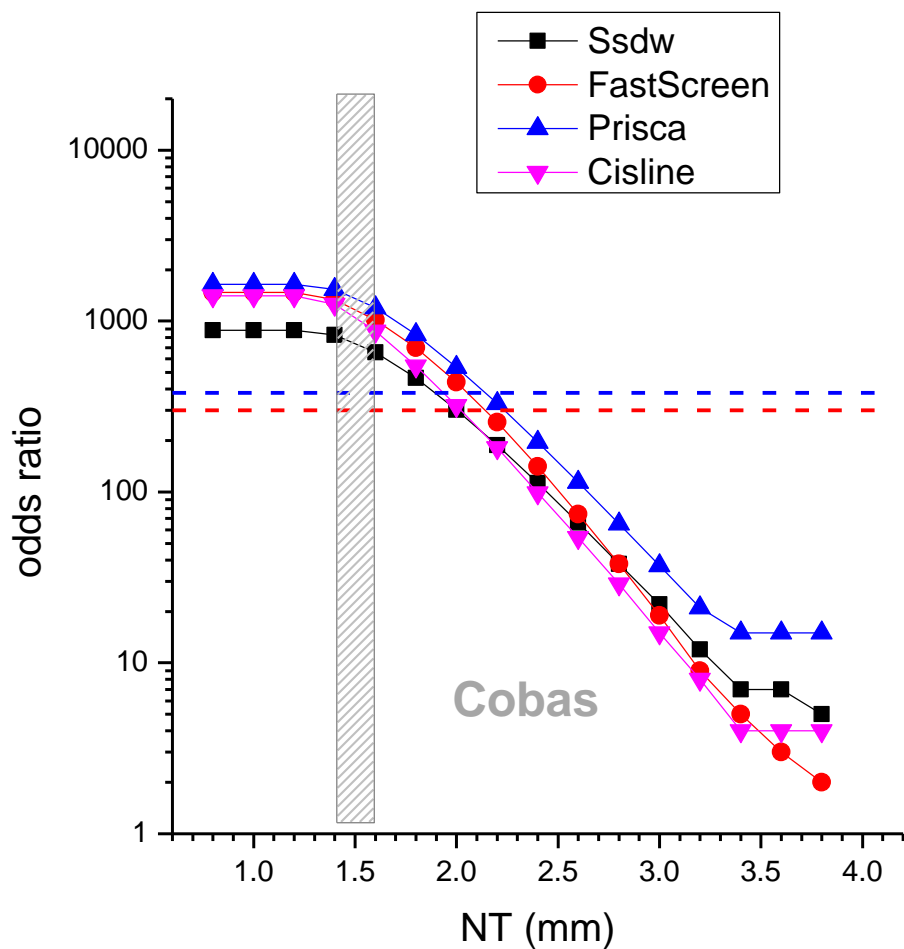
Comparison of softwares using Cobas

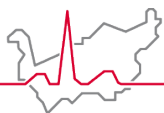




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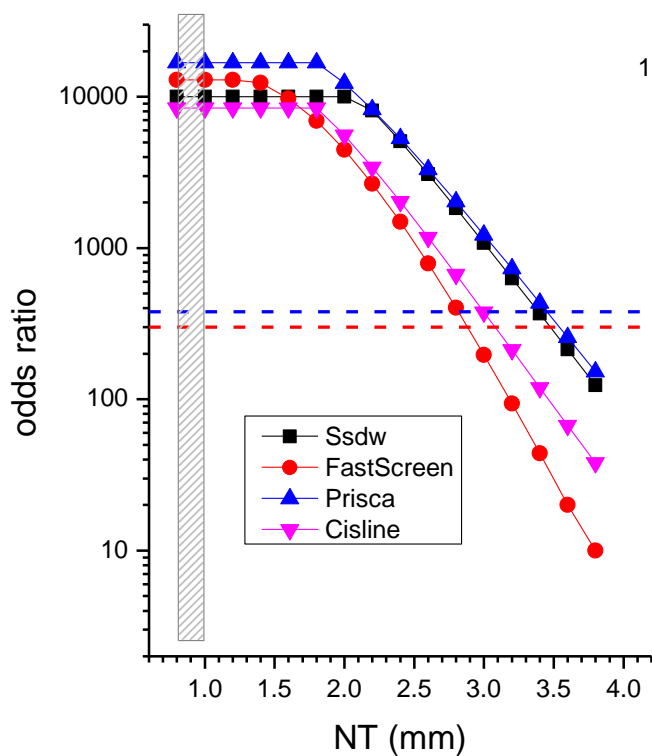
Weight of nuchal translucency in risk assessment



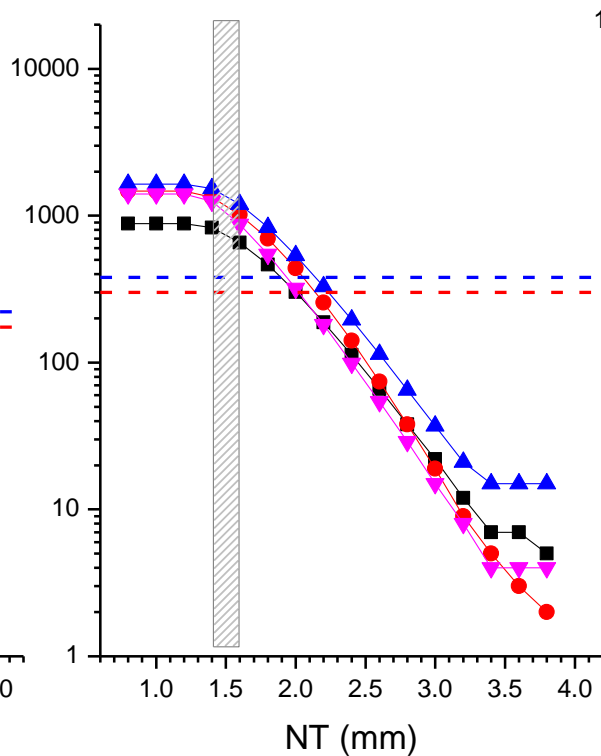


Weight of nuchal translucency in risk assessment

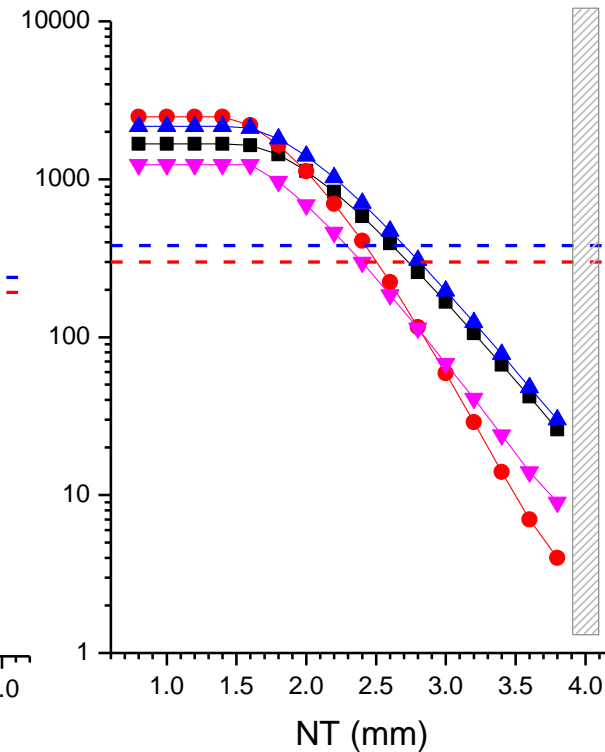
Case 1

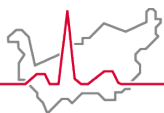


Case 2



Case 3





Conclusion

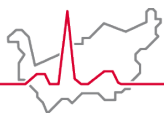
PAPP-A and free β -hCG determinations in biological samples were similar with the Kryptor and the Cobas e-601

In our cohort, both systems predicted the presence of trisomy 21 with similar sensitivity and specificity

Variability between systems was mostly due to the software, not to the analytical instrument

The weight of the nuchal translucency in the risk assessment was similar in the four tested softwares

In our limited cohort, the Cobas/Ssdw system performed as well as the Kryptor/FastScreen system and therefore could be considered as a new alternative in Switzerland for risk assessment in the first trimester of pregnancy



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Acknowledgements

Central Institute (ICHV)

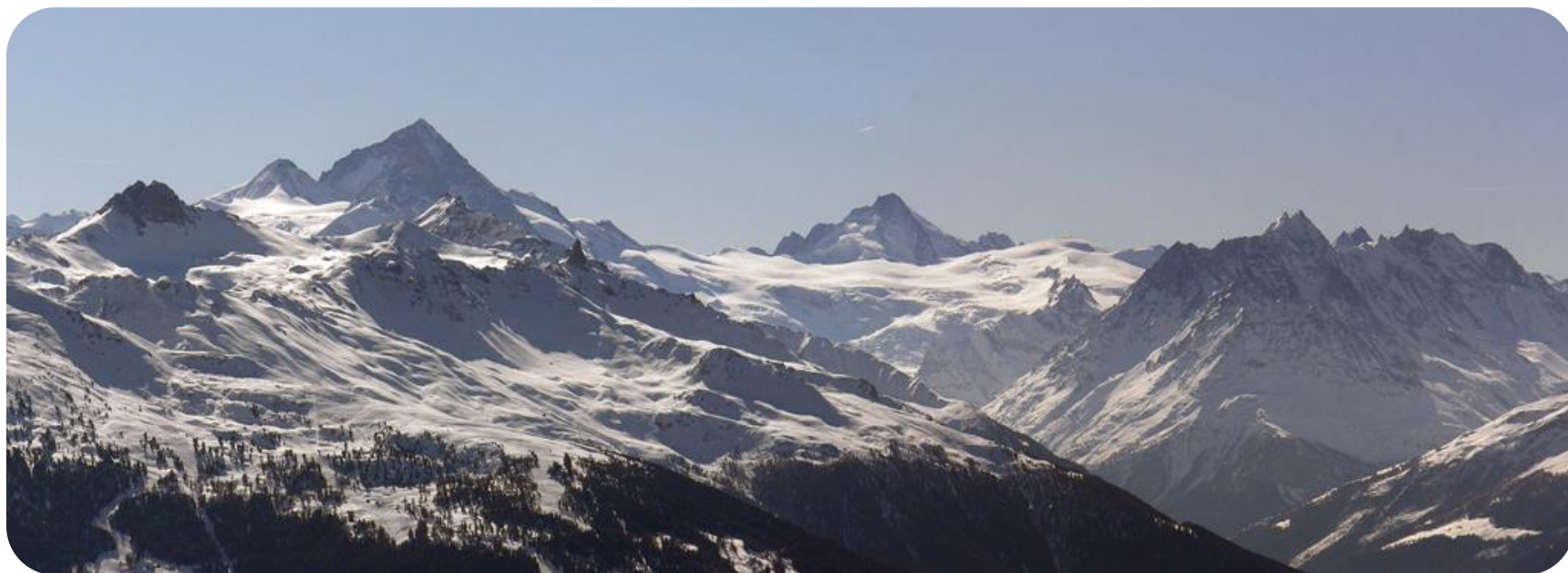
Nicole Beloeil*
Eric Dayer

Univ. Hosp. Geneva (HUG)

Jocelyne Hediger*
Sophie Dahoun
Olivier Irion
Denis Hochstrasser
Ilse Kern*

Dianalabs

Reto Stricker



Disclosure: Cobas reagents were provided by Roche