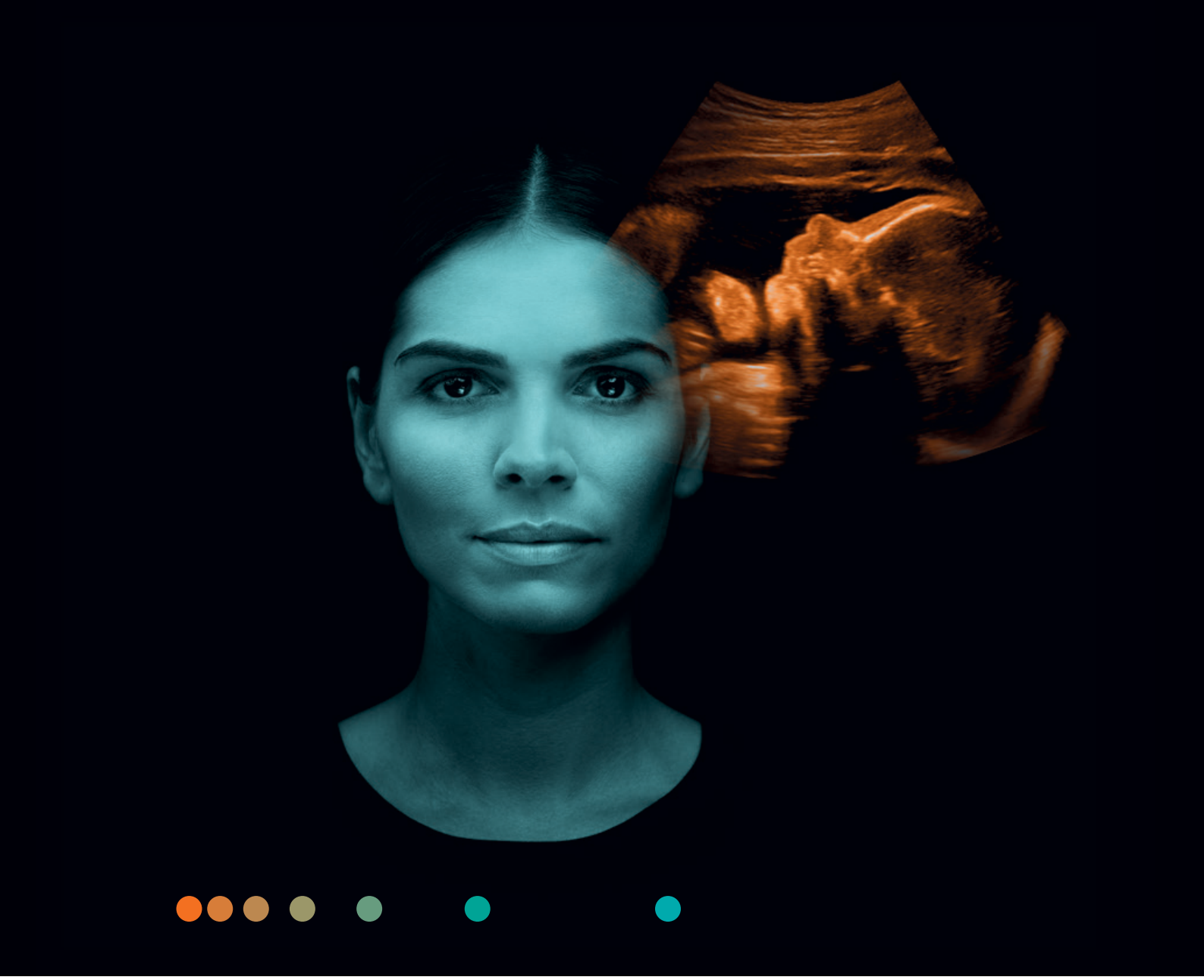

PRISCA 5 Prenatal Risk Assessment Software Version 5.3

Provide an informed prenatal risk assessment without invasive procedures

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SIEMENS Healthineers

Choose PRISCA 5 Software First

Provide a comprehensive, reliable prenatal risk assessment for trisomy 13, trisomy 18, trisomy 21, and neural tube defects. While not confirmatory for these abnormalities, PRISCA 5 software provides additional support for a woman's decision whether or not to undergo an invasive procedure such as amniocentesis, which carries a 1-in-200 risk for fetal loss.[1]

PRISCA 5 is a validated and CE certified product which works with Siemens Healthineers' assays* approved by the Fetal Medicine Foundation (FMF). With detection rates up to 93%, and a false-positive rate of 5%,[2] choose a PRISCA 5 prenatal assessment first.

Combine all the information needed for the most confident risk assessment

PRISCA 5

All data is processed through PRISCA 5 algorithms and risk calculations.

Results are provided with one click through secure patient-result interface.

Patient data and risk-factor variables

Maternal age and weight, gestational age, patient demographics, and more

Ultrasound measurements, including nuchal translucency and crown-rump length

Biochemical immunoassays

- First trimester assays: PAPP-A and Free Beta HCG
- Second trimester assays: HCG, AFP, Unconjugated Estriol, Inhibin-A

Median management with shared database

PRISCA 5 software includes the option to participate in a Shared Database,† which:

- Provides interlaboratory quality-control information.
- Monitors trends and identifies outliers.
- Aids in setup and control of local medians.

Connect PRISCA 5 software to the lab's LIS using P5Link†

FREE Demo Software

A 30-day demonstration version of the PRISCA 5 software is now available. Please contact your Siemens Healthineers representative for more information.

21 Languages Available

PRISCA 5 version 5.3.1 is based on the SURUSS study[2] and allows for flexible prenatal screening workflows.‡

Possible prenatal screening workflows include:

- Single-sample first trimester testing
- Single-sample second trimester testing
- Integrated (two different samples using only the combined results of both)
- Sequential (two different samples at different gestational ages, providing risk at both first and second sample)
- Contingent (second trimester testing if first trimester testing is medium risk)
- Quadruple testing in the second trimester with inhibin A

Features

- PRISCA 5 is a validated and CE certified product which works with Siemens Healthineers' assays* approved by the Fetal Medicine Foundation (FMF)
- Supports two biomarker sample dates
- Trisomy 13/18 screening in the first trimester
- Risk calculation by PAPP-A or Free Beta HCG alone
- HCG or Free Beta HCG for second trimester risk assessment§
- Risk correction for absent nasal bone and previous trisomy 21
- Ability to use egg donor DOB in case of IVF pregnancy
- Fetus-specific risk report for dichorionic twin pregnancies
- Ability to perform linear adjustment of medians and manually enter medians
- Supports laboratory-specific nuchal translucency (NT) medians**
- Patient record validation, report preview, and custom reports**

Laboratory specifications

PRISCA 5 software integrates results from PAPP-A and Free Beta HCG assays available on Atellica® IM, ADVIA Centaur®, and IMMULITE® immunoassay systems; AFP, HCG, and Unconjugated Estriol on IMMULITE systems.

Technical specifications

Computer recommendations

RAM: 4 GB
Processor: 1.2 GHz dual core
Operating system: WINDOWS 10 (64-bit), WINDOWS 11 (64-bit)

Security specifications

- Audit trail to track activity of the last system user
- Windows authentication for customized user access
- Database backups for easy restoration
- Database encryption

**FMF approval applies for assays run on ADVIA Centaur and Atellica IM systems. The FMF is a private organization. PRISCA is CE-certified and this certification is provided by an independent notified body that confirms assays have been validated and are approved for prenatal diagnostics.*
†P5Link and Shared Database are provided by Typolog Software Ltd. & Co. KG. Contact: medical@typolog.de for more information.
‡PRISCA does not enforce any specific workflow. It enables you to follow the workflow you want to use. Performance characteristics vary depending on the workflow used for testing.
§With HCG risk assessment of Trisomy 21 and 18 is possible, whereas with Free Beta HCG only risk assessment of Trisomy 21 is possible.
***Typolog Software must be contacted for an adjustment of NT medians and custom reports.*

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. Sustainably. As a leader in medical technology, we want to advance a world in which breakthroughs in healthcare create new possibilities with a minimal impact on our planet. By consistently bringing innovations to the market, we enable healthcare professionals to innovate personalized care, achieve operational excellence, and transform the system of care.

Our portfolio, spanning in vitro and in vivo diagnostics to image-guided therapy and cancer care, is crucial for clinical decision-making and treatment pathways. With the unique combination of our strengths in patient twinning,* precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the greatest challenges in healthcare. We will continue to build on these strengths to help overcome the world's most threatening diseases, enable efficient operations, and expand access to care.

We are a team of more than 71,000 Healthineers in over 70 countries passionately pushing the boundaries of what is possible in healthcare to help improve the lives of people around the world.

**Personalization of diagnosis, therapy selection and monitoring, aftercare, and managing health.*

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

References:

1. https://www.nhs.uk/conditions/chorionic-villus-sampling-cvs/risks/
2. Wald NJ, Rodeck C, Hackshaw AK, Walters J, Chitty L, Mackinson AM; SURUSS Research Group. First and second trimester antenatal screening for Down's syndrome: the results of the Serum, Urine and Ultrasound Screening Study (SURUSS). Health Technol Assess. 2003;7(11):1-77. doi: 10.3310/hta7110. PMID: 12709291.

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