
Roche
From providing an essential service
to being a trusted partner in pregnancy care
Play a key role in driving the value of diagnostics. Roche's reliable pregnancy care solutions offer confidence rooted in precision, so you can aspire to excellence as a trusted partner that gives her the assurance she needs as she begins her journey to motherhood.
WHERE CARE LEADS

The Roche pregnancy care portfolio offers you screening and diagnostic solutions that empower you to excel as a trusted partner in pregnancy care.

Unleash the full value of your lab and drive healthcare transformation by playing your role in pregnancy care.

Be a trusted partner in pregnancy care.

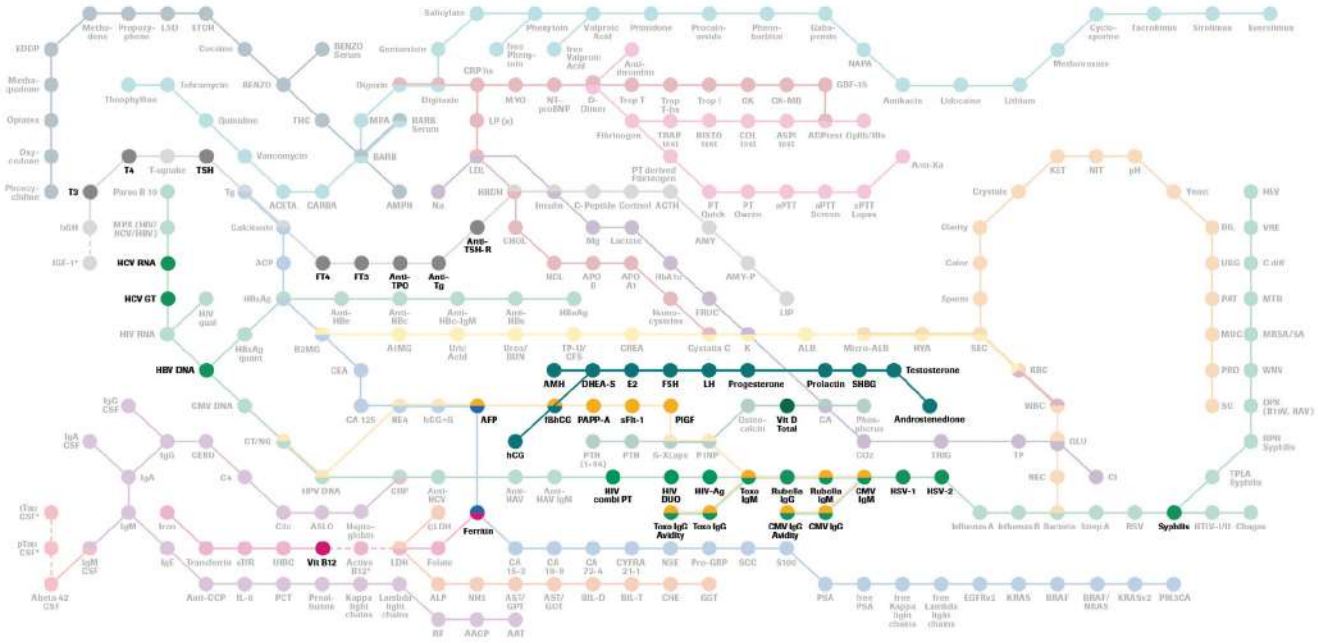
We provide high clinical value biomarkers to laboratories, so that they can provide meaningful results to clinicians and add value to decision-making in pregnancy care.

Realize the full potential of your laboratory

Doing more with less – consolidate your pregnancy care testing

A woman's journey to motherhood is paved with milestones and bridges to cross. From family planning and knowing whether she can conceive, to early pregnancy and making sure that the precious new gift growing inside is healthy. From certainty that her baby is developing as planned, to a successful delivery and effective postnatal care.
In this journey, she needs a steady hand, a trustworthy guide, and unwavering support at every step of the way. Whether you offer her comfort as the direct care giver, an impeccably reliable test result as the lab specialist, or prudent foresight as the administrator/decision maker, her journey is your own. The Roche Pregnancy Care portfolio enables you to provide her with the holistic care that she requires at every stage of her journey to motherhood.

The widest test menu on the market



Fertility

AMH · DHEA-S · hCG · E2 · FSH · LH · Progesterone · Prolactin · SHBG · Testosterone · Androstenedione

Pregnancy care

T3 · T4 · TSH · FT4 · FT3 · Anti-TPO · Anti-Tg · Anti-TSH-R

HCV RNA · HCV GT · HBV DNA · HIV combi PT · HIV DUO · HIV-Ag · Rubella IgG · HSV-1 · HSV-2 · Syphilis

AFP · ßhCG · PAPP-A · sFlt-1 · PlGF · Toxo IgM · Rubella IgM · CMV IgM · Toxo IgG Avidity · Toxo IgG · CMV IgG Avidity · CMV IgG

Vit B12 · Ferritin · Vit D Total

Unleash the value of your lab

How Elecsys® AMH provides clinical confidence

The Elecsys® AMH Plus immunoassay has been shown to provide a precise, reliable and robust measurement of AMH levels. The fully automated Elecsys® AMH Plus immunoassay, run on the cobas e and Elecsys® immunoassay analyzers, determines AMH levels in 18 minutes, making it appropriate for routine clinical use.[1,2] AMH is a reliable marker for prediction of response to controlled ovarian stimulation and can therefore add prognostic information to the counseling and planning process for infertile couples seeking treatment.[3]

Excellent features

- Wide measuring range
- Fast and reliable results
- High precision and sensitivity
- Age-specific Reference values

AMH

Fully automated immunoassay with the following intended uses:

- Assessment of ovarian reserve
- Prediction of response to COS
- Individualized dosing of follitropin delta

[1] Anti-Müllerian Hormone. Elecsys and cobas e analyzers package insert 2020. [2] Anckaert E, Öktem M, et al. (2016). Clin Biochem 49(3):260-7 [3] The Practice Committee of the American Society for Reproductive Medicine. (2011). Fertil Steril; 98:1407–1415.

Assessment of ovarian reserve

Clinical agreement with Antral-Follicle-Count (AFC)[1,2]

- Providing reassurance when concordant results confirm expected level of ovarian reserve
- High agreement with AFC (Spearman's Rank coefficient=0,68)
- Performed in a 7 sites multicenter evaluation
- Lower variability of results between sites and operators with AMH in comparison to AFC
- The data was obtained in a prospective study with n=451 women between 18-44 years old, where AMH values were correlated to the antral follicle count (AFC)of women (Roche study No. RD001542)

	Poor	Normal	High	
	AFC 0-7	AFC 8-15	AFC>15	N
AMH≤4.86 pmol/L (0.681 ng/mL)	63.2%	32.4%	4.4%	68
4.86 pmol/L (0,681 ng/mL) <AMH ≤16.2 pmol/L (2.27 ng/mL)	12.0%	56.9%	31.1%	167
AMH > 16.2 pmol/L (2.27 ng/mL)	1.4%	24.1%	74,5%	216
N	66	169	216	451

Prediction of response to COS

Prediction of response to controlled ovarian stimulation

AMH was determined in 149 women undergoing an antagonist treatment protocol while receiving a standard FSH stimulation dose of 150 IU/day'.

Prediction of hyper-response was significant with an AUC (area under the curve) of 82.1%
(Roche study No.CIM RD 001695)

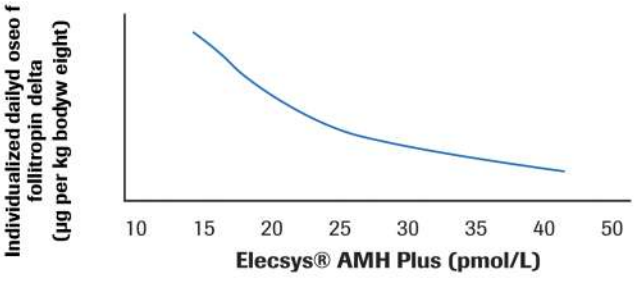
Hyper- response

AMH cutoff	15.0 pmol/L (2.10 ng/mL)	
	Estimate	**95%CI**
Sensitivity	81.3%	54.4-96.0%
Specificity	64.7%	55.9-72,8%
PPV	21.7%	12.1-34.2%
NPV	96.6%	90-5%-99.3%

Individualized dosing of follitropin delta

Use of AMH for the Individual daily dose determination of follitropin delta of Ferring

- Follitropin delta is a human recombinant follicle stimulating hormone (rFSH) produced in a human cell line (PER. C6) by recombinant DNA technology
- The AMH concentration (in pmol/L) determined by the Elecsys AMH Plus assay, in combination with body weight was validated for the individual daily dose delermination of follitropin delta In controlled ovarian stimulation for the development of multiple follicles in women undergoing an assisted reproductive technology program
- The AMH-based individualized dosing regimen of follitropin delta was validated in the prospective phase 3 clinical study ESTHER-1, a randomized controlled, assessor-blind trial comparing the efficacy and safety of follitropin delta with follitropin alfa[3]



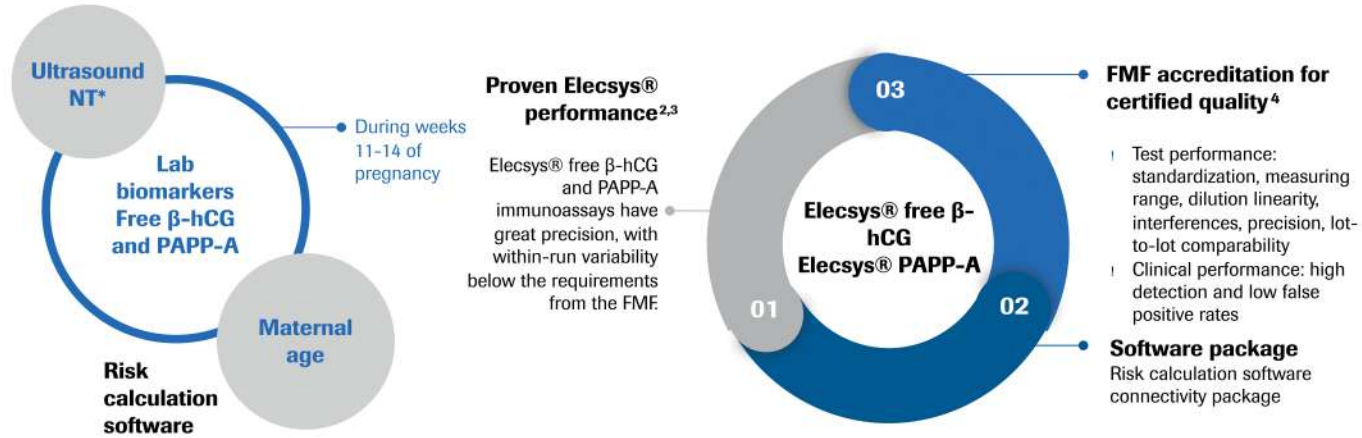
[1] Anti-Müllerian Hormone. Elecsys and cobas e analyzers package insert [2] Anderson, R.A., Anckaert, E., Bosch, E. et al. (2015). Fertil Steril 103(4), 1074-1080.e4. [3] Andersen, A.N., Nelson, S.M. et a¹ (2017). Fertil Steril 107(2), 387-396.

In which classic cases could FTS be added?

- In contingent screening models 1:1.000
- Pregnant with triplets (or more)
- If NIPT quality metrics provide no result
- Price sensitive markets

When traditional prenatal screening provides confidence in clinical decision-making[1]

First trimester combined screening



Detection rate is 85-95% at 95% specificity

1.) Nicolaides, K. H. (2011). Screening for fetal aneuploidies at 11 to 13 weeks. Prenat. Diagn. 31, 7-15.
2.) Elecsys® Free β-hCG. Method sheet
3.) Elecsys® PAPP-A. Method sheet
4.) Fetal Medicine Foundation, accreditation certificate for Elecsys assays, 2017

Unleash the value of your lab

Elecsys® sFlt-1 and PlGF provide confidence in clinical decision-making

Angiogenic factors (sFlt-1 and PlGF) are proven to play an important role in the pathogenesis of preeclampsia and their concentrations in maternal serum are altered even before the onset of the disease, making them a tool for prediction and aid in diagnosis of preeclampsia.[1-3]

Elecsys® sFlt-1 and PlGF immunoassays for preeclampsia are the first available and approved automated diagnostic tests for fast and easy assessment in a clinical context.[4-5]

The measurement of the Elecsys® sFlt-1/PlGF ratio is a reliable tool that enables clinicians to identify and closely monitor the patients that are at high risk of developing preeclampsia, while discharging the patients that are not likely to develop the disease. Early and precise diagnosis of preeclampsia can lead to effective clinical management with very high confidence, and better pregnancy care and reassurance for both mother and child.[3-7]

The additional value of a preeclampsia first trimester risk assessment combined with the value of the sFlt-1/PlGF ratio provides a comprehensive solution for preeclampsia testing during pregnancy.

First-trimester screening

Maternal factors and history alone for the detection of PE have not been found to have a high detection rate

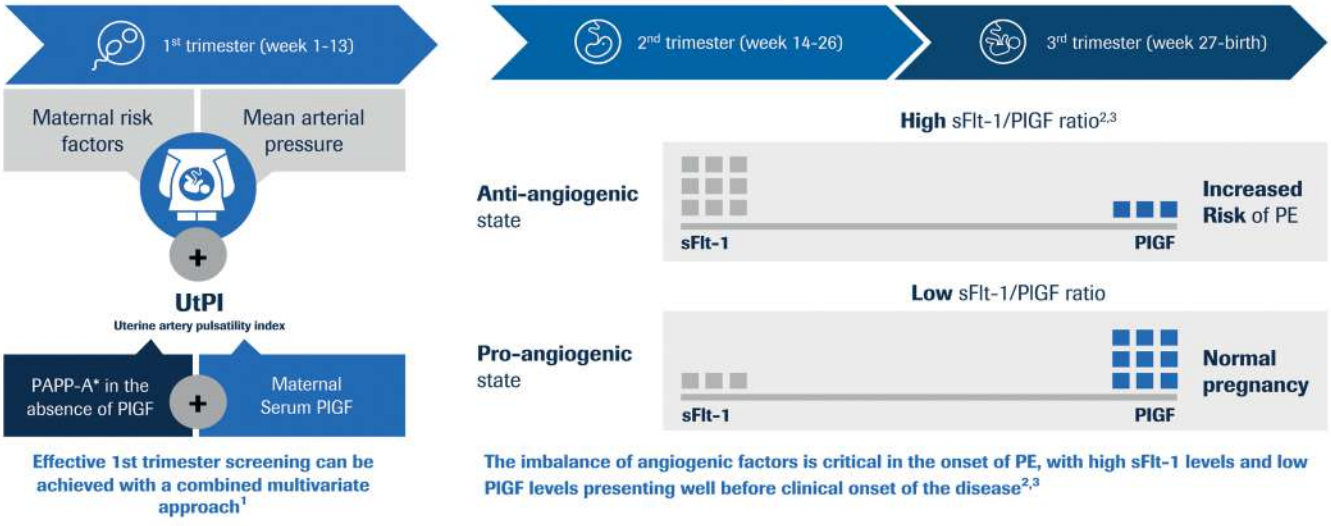
Accurate identification of high-risk patients in the first trimester can result in use of prophylactic aspirin, which can lead to reduced incidence of PE [9].

Second and third-trimester prediction and diagnosis

Currently, approximately 80% of pregnant women with **suspected PE**, never developed it[8]

Need for improved accuracy and sensitivity for PE prediction and diagnosis in the second and third trimesters to reduce over-treatment and unnecessary hospitalization [10].

The role of Elecsys® PlGF



Effective 1st trimester screening can be achieved with a combined multivariate approach[1]

The imbalance of angiogenic factors is critical in the onset of PE, with high sFlt-1 levels and low PlGF levels presenting well before clinical onset of the disease[2,3]

[1] Verlohren, S., et al. (2012). Am J Obstet Gynecol 206(1), e1-8 [2] Verlohren, S., et al. (2010). Am J Obstet Gynecol 202(161), e1-11 [3] Verlohren, S., et al. (2014). Hypertension 63(2), 346-352 [4] Hund, M., et al. (2014). BMC Pregnancy and Childbirth 14, 324 [5] Zeisler, H., et al. (2016). N Engl J Med 374(1), 13-22 [6] Hund, M., et al. (2015). Hypertens Pregnancy 34(1), 102-115 [7] Klein, E., et al. (2014). PLoS ONE 11(5), e0156013
[8]-Park HJ., et al (2015). Int J Mol Sci. 2015;16(8):17952–17974. [9]-U.S. Preventive Services Task Force: Screening for Preeclampsia: Recommendation Statement (2018). Am Fam Physician. 2018 Jan 15;97(2):online. Available at: https://www.aafp.org/afp/2018/0115/od1.html [10]-Hund M, et al. (2014). BMC Pregnancy Childbirth. 2014;14:324.
[11]-Poon LC,. Hypertension 2009; 53:812–818. [12]-Levine, R.J., et al. (2004). N Engl J Med 350, 672-683; [13]-Villa, P.M., et al. (2013). BMC Pregnancy and Childbirth

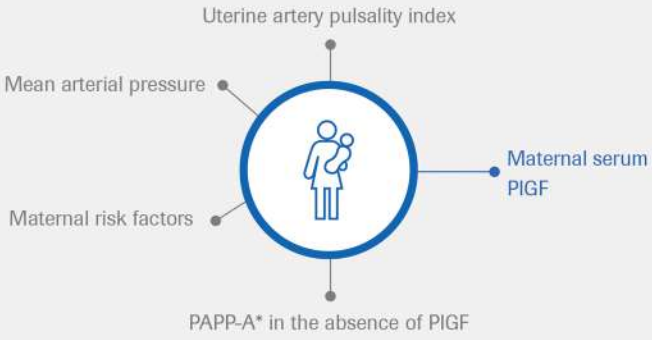
Intended use

Evaluate the risk of early-onset PE in the first trimester (PIGF in combination with other parameters)[1].

Medical need

Aids in identification of high-risk individuals, initiation of prophylactic measures[2] and closer monitoring of these individuals.

FMF multivariate algorithm for first-trimester screening[3]

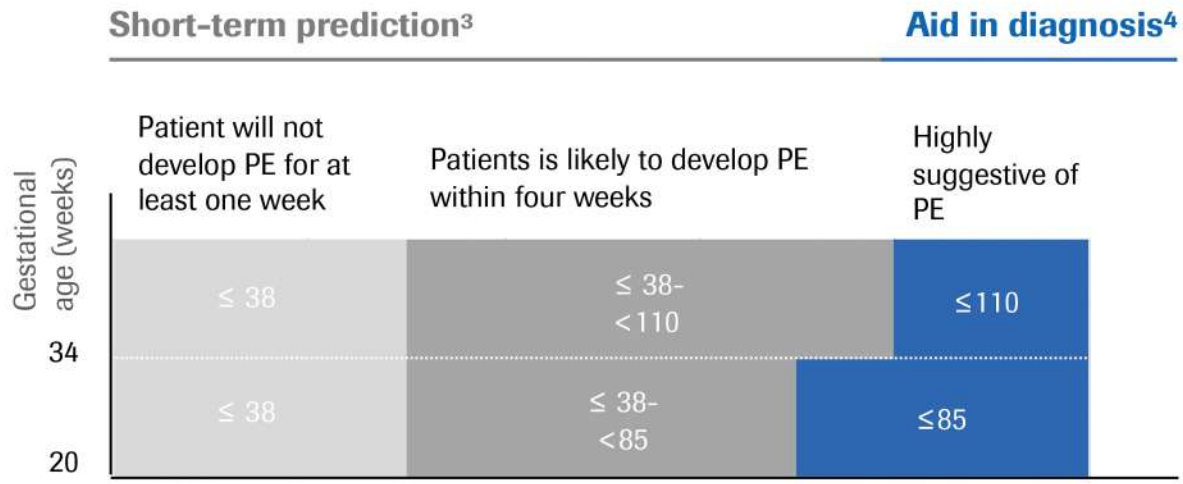


The FMF combined algorithm can predict 90% of cases for early-onset, 75% of preterm and 41% of term PE[4].

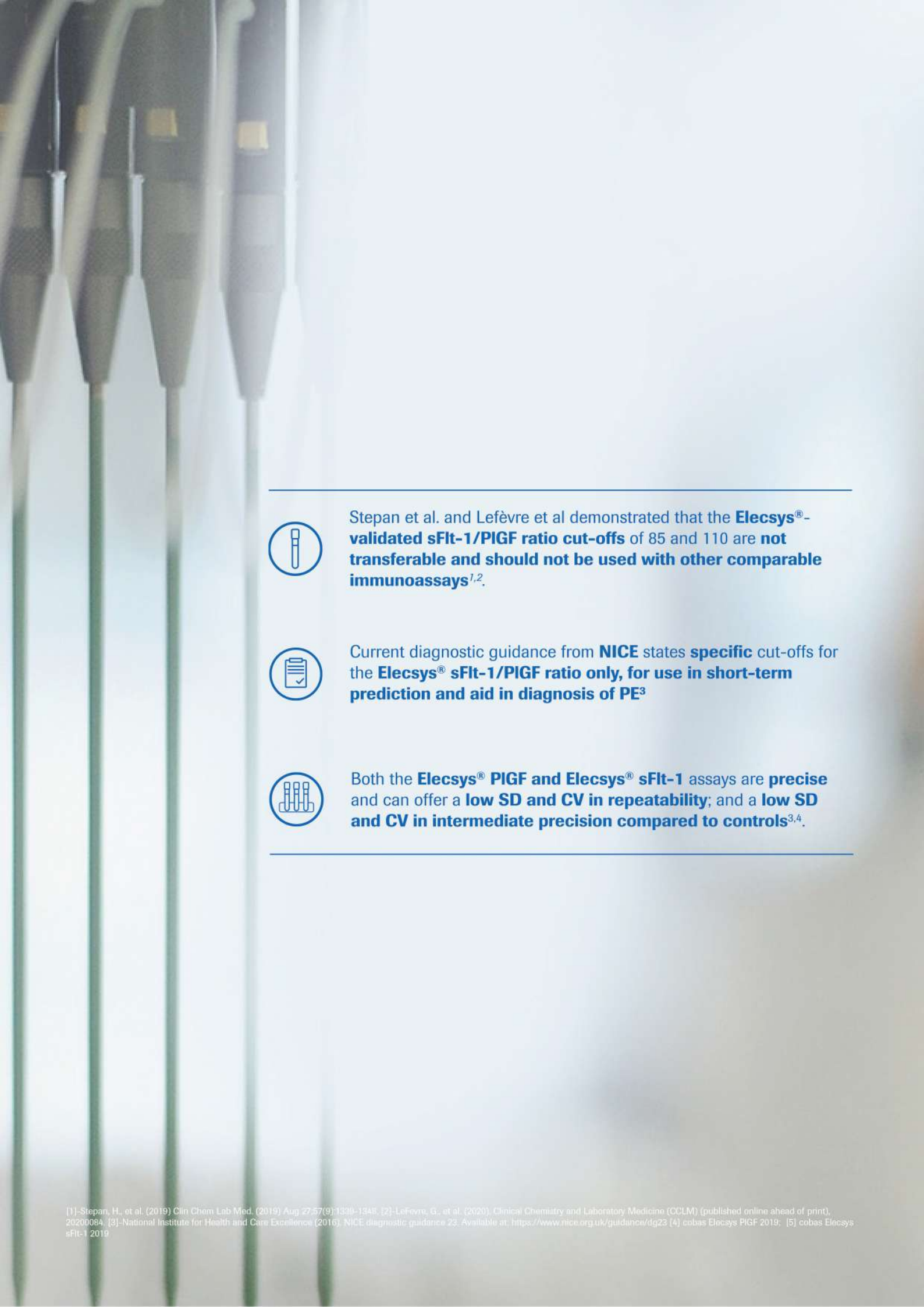
The role of Elecsys® sFIT-1/PIGF ratio

Intended uses and medical needs

Aid in diagnosis of PE[3,4]	Detect early-onset PE with a specificity of 99.5% (early gestational phase) and 95.5% (late gestational phase) at a sFlt-1/PlGF ratio cut-off of 85 and 110.
Aid in short-term prediction of PE[3,4]	Rule out PE for 1 week with an NPV of 99.3% and sensitivity of 80% at a ratio cut-off of ≤38. Rule in PE within 4 weeks with a PPV of 36.7% and specificity of 83.1% at a sFlt-1/PlGF ratio cut-off of >38.



[1]-cobas Elecsys PlGF Package Insert. (2019-08, V10.0) [2]-Akolekar R., Syngelaki A., Poon L., et al. (2012) Fetal Diagn Ther 2013;33:8-15 [3]-Poon L et al. Prenatal Diagnosis 2014, 34, 618–627. Link: https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/pd.4397 [4]-Poon L., et al. (2020). Ultrasound Obstet Gynecol 2020; 55: 5–12
[3]-cobas Elecsys PlGF Package Insert. (2019-08, V10.0) [4]-cobas Elecsys sFlt-1 Package Insert. (2019-11, V9.0)
* [1]-Stepan, H., et al. (2019) Clin Chem Lab Med. (2019) Aug 27;57(9):1339-1348.
[2]-LeFevre, G., et al. (2020). Clinical Chemistry and Laboratory Medicine (CCLM) (published online ahead of print), 20200084.



Stepan et al. and Lefèvre et al demonstrated that the **Elecsys®-validated sFlt-1/PlGF ratio cut-offs** of 85 and 110 are **not transferable and should not be used with other comparable immunoassays**[1,2].

Current diagnostic guidance from **NICE** states **specific** cut-offs for the **Elecsys® sFlt-1/PlGF ratio only, for use in short-term prediction and aid in diagnosis of PE**[3]

Both the **Elecsys® PlGF and Elecsys® sFlt-1** assays are **precise** and can offer a **low SD and CV in repeatability**; and a **low SD and CV in intermediate precision compared to controls**[3,4].

[1]-Stepan, H., et al. (2019) Clin Chem Lab Med. (2019) Aug 27;57(9):1339-1348. [2]-LeFevre, G., et al. (2020). Clinical Chemistry and Laboratory Medicine (CCLM) (published online ahead of print), 20200084. [3]-National Institute for Health and Care Excellence (2016). NICE diagnostic guidance 23. Available at: https://www.nice.org.uk/guidance/dg23 [4] cobas Elecsys PlGF 2019; [5] cobas Elecsys sFlt-1 2019

Milestones and guidelines

Towards a personalized pregnancy experience

2013

- ACOG/SMFM: NIPT for high risk[5]

2014

- ISUOG: NIPT for high risk[4]

2015

- DGGG guidelines[3]
- ISPD: appropriate to offer NIPT as 1° screening test to all[2]
- Swiss approve risk-stratification NIPT testing[6]

2016

PROGNOSIS[2]
Published in the New England Journal of Medicine and validated the sFlt-1/PlGF ratio cut-off of ≤38 to rule out the onset of PE within 1 week of testing in women with suspected disease.

UK economic assessment[4]
Introduction of the sFlt-1/PlGF ratio test into clinical practice is expected to result in cost savings of £344 per patient compared with a no-test scenario.

PreOS[3]
Assessment of the impact or influence of the sFlt-1/PlGF ratio on decision-making of the physician in patients with suspected PE[4,5]

2017

ASPRE Study[5]
Among women with singleton pregnancies who were identified to be high-risk of preterm PE, the administration of 150 mg of aspirin per day from 11 – 14 weeks of gestation until 36 weeks, significantly reduced the incidence of preterm PE.

- NIPT first-line in Belgium[7]

2018

- ESC guidelines[6]
- DSOG guidelines[7]
- CGOS guidelines[8]
- EUnetHTA NIPT assessment[8]

2019

INSPIRE Study[9]
Real-world performance and clinical utility of the sFlt-1/PlGF ratio concluded that use of the sFlt-1/PlGF ratio combined with current clinical guidelines improved clinical precision without affecting admission rates.

- NICE guidelines[10]

2020

- Chinese guidelines[11]
- ACOG/SMF[12]

Key medical-value milestones

Guideline milestones

[1]-[4]-Stepan H., et al. (2015). Diagnosis and Treatment of Hypertensive Pregnancy Disorders. Guideline of DGGG (S1-Level, AWMF Registry No.015/018, December 2013). Geburtshilfe Frauenheilkd. 2015;75(9):900–914. [2]-Zeisler et al. (2016). N Engl J Med 2016; 374:13-22 [3]-Klein et al. PLoS ONE 2016;11(5): e0156013 [4]-Vatish, M., et al. (2016). Ultrasound Obstet Gynecol 48, 765–771 [5]-Rolnik et al. N Engl J Med. 2017 Aug 17;377(7):613-622 [6]-Regitz-Zagrosek, V., et al. (2018). Eur Heart J 39:3165-241 [7]-DSOG (Dansk Selskab for Obstetrik og Gynækologi) Guidelines 2018. Available at: http://www.dsog.dk/obstetrik/ [8]- Vlk R., et al. (2018). Hypertension disease in pregnancy. Czech Gynecological and Obstetrical Society (CGPS). Ces. Gynek., 2018, 83, No. 2, pp. 145–154. Available at: http://www.lekaridnes.cz/wp-content/uploads/2018/06/DP_tlak.pdf [9]-Cerdeira, AS., et al. (2019). Hypertension. 2019 Oct;74(4):983-990. [10]-National Institute for Health and Care Excellence (2019) Hypertension in pregnancy diagnosis and management (NICE Guideline 113). Available at: https://www.nice.org.uk/guidance/ng133/chapter/Recommendations#management-of-pre-eclampsia https://static1.squarespace.com/static/5467abcce4b056d72594db79/t/5bac84e7652dea0a1b5fb489/1538032877105/18092 4+PE-guideline-final+sandbjerg.pdf [11]-Yang, et al. (2020). Chin J Obstet Gynecol. 2020;55(4) [12] ACOG Practice Bulletin, Number 226. Obstet Gynecol. 2020 Oct;136(4):e48–e69

Acronyms:
ESC: European Society for Cardiology. **DGGG:** German Society of Gynaecology and Obstetrics **CGPS:** Czech Gynecological and Obstetrical Society **DSOG:** Danish Society for Obstetrics and Gynecology **NICE:** National Institute for Health and Care Excellence

Be a trusted partner
in pregnancy care

Assessment of preeclampsia: a change in clinical practice at the John Radcliffe Hospital[1]

Oxford University Hospitals NHS Foundation Trust (OUH) (2018-2019)

- Turnover of £1.073 billion.
- 3,779 nurses/midwives and 1,829 doctors.
- 7,585 babies were delivered.
- The John Radcliffe Hospital is a tertiary referral center set up to serve the Thames Valley region and South Midlands.

INSPIRE trial

- Designed to assess patients with suspected symptoms and signs of PE.
- Patients had sFlt-1/PlGF ratio measurements in addition to routine blood tests. sFlt-1/PlGF ratio test requests were sent to the biochemistry lab at the John Radcliffe Hospital to be analyzed.

Laboratory perspective

"The Elecsys® sFlt-1/PlGF ratio test was easy to implement within the routine laboratory service and has demonstrated high precision, reproducibility and robustness. We can effectively provide the clinician with a result within one hour from the patient being bled, enabling timely decisions regarding treatment and disease management."[2]
– Prof. Tim James, the Trust's lead biomedical scientist

Results

	Non-reveal	Reveal
PPV	**31.3%**	**40.0%**
NPV	**97.8%**	**100%**

[1] - Cerdeira, A. S. et al. Randomized Interventional Study on Prediction of Preeclampsia/Eclampsia in Women with Suspected Preeclampsia: INSPIRE. Hypertension 74, 983–990 (2019).
[2] - Roche Diagnostics Limited. Advertorial, Elecsys® sFlt-1/PlGF ratio test: Supporting timely decisions regarding pre-eclampsia management: Health Professional Academy (2019).

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