Advancing Women's Health Through Novel ABEI Based assays

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Conflict of interests statement

Thanks to SNIBE for supporting the participation to this educational activity

Brussels, Belgium

Cliniques Universitaires Saint-Luc

Huni

Emerging technologies require laboratory medicine specialists and IVD teams who are well-prepared and in top form ☺

Women live longer — but not necessarily healthier lives

10

additional healthy days per woman, every year

£36B

potential annual UK economic gain by 2040

1 in 8

women affected by PCOS / PMOS

The invisible cost is diagnostic delay

Symptoms are fragmented.

Care is fragmented.

Data are fragmented.

A connected laboratory pathway can turn fragments into a phenotype.

PCOS is bigger than the ovary

POLYENDOCRINE

METABOLIC

OVARIAN SYNDROME

The proposed PMOS name makes the systemic biology visible.

Polyendocrine metabolic ovarian syndrome, the new name for polycystic ovary syndrome: a multistep global consensus process

Helena J Teede, Mahnaz Bahri Khomami, Rachel Morman*, Joop S E Laven, Anju E Joham, Michael F Costello, Madhuri Patil, D Aled Rees, Lorna Berry, Melanie G Cree, Han Zhao, Robert J Norman*, Anuja Dokras*, Terhi Piltonen*, on behalf of the Global Name Change Consortium†*

One syndrome. A lifetime of consequences.

Reproductive	ovulatory dysfunction • subfertility
Metabolic	insulin resistance • type 2 diabetes
Cardiovascular	risk factors across the life course
Psychological	anxiety • depression • stigma

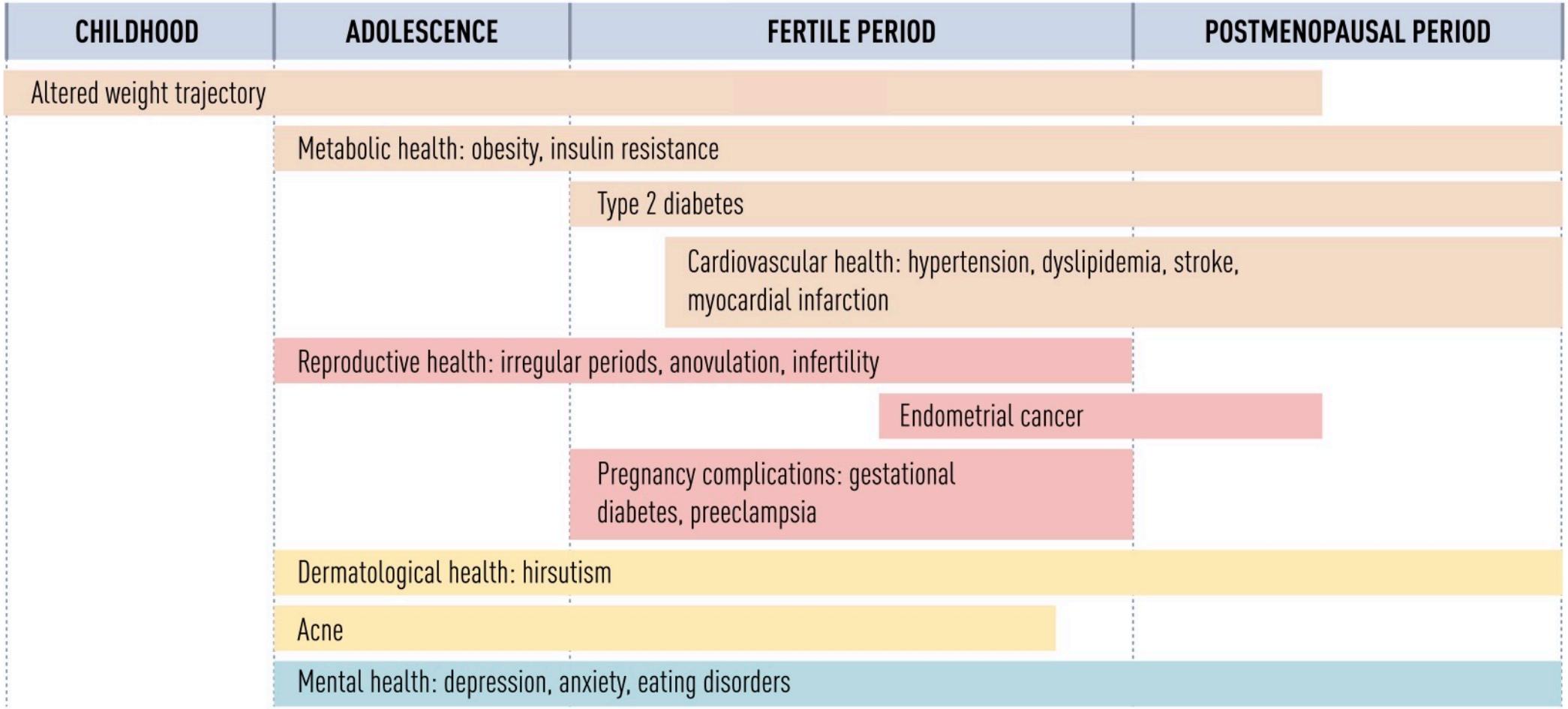
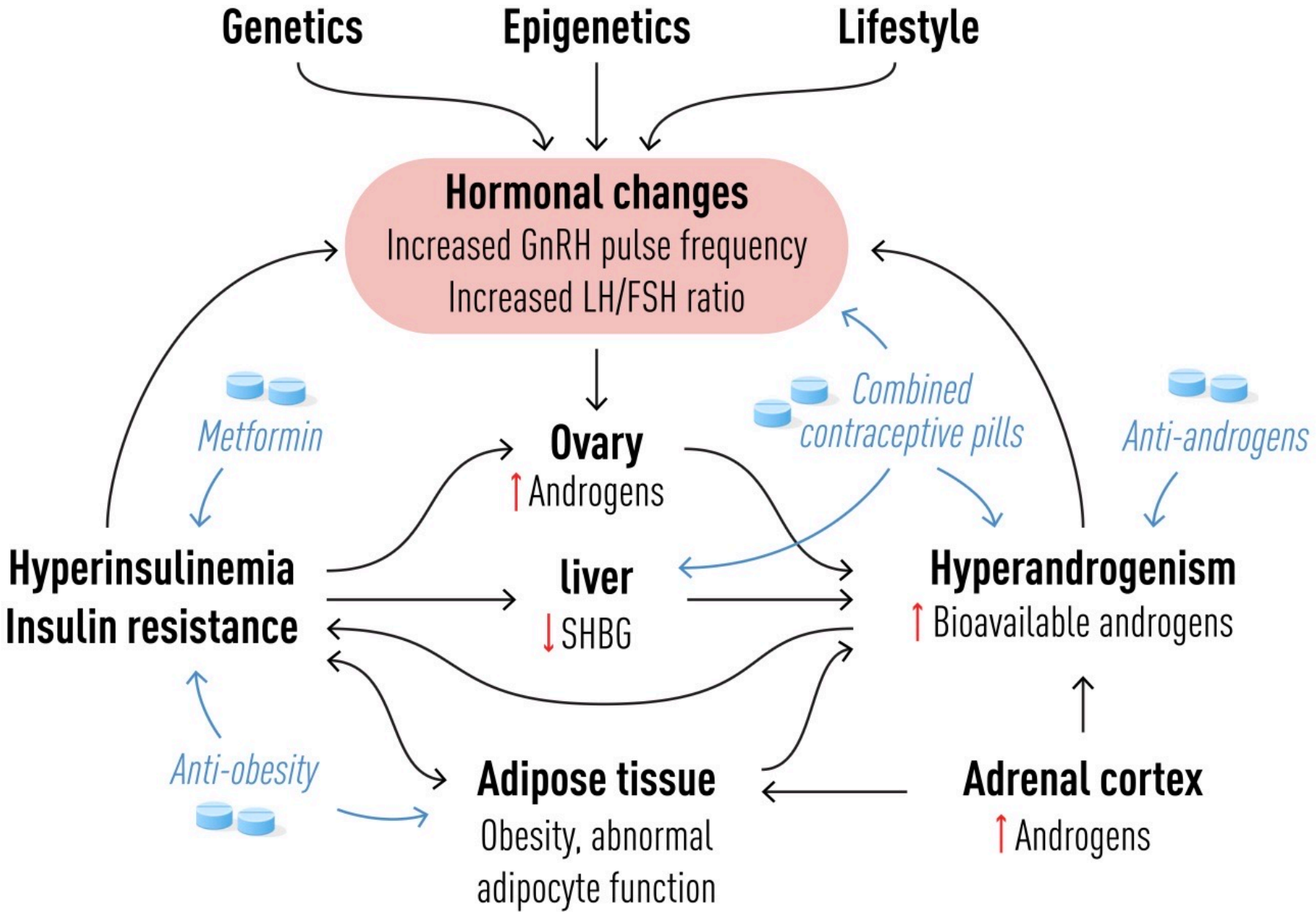


Fig. 1 ***PMOS as a life course disorder: expanding beyond reproductive features***. *Schematic illustration of the evolving understanding of polyendocrine metabolic syndrome (PMOS) across the life course. Although reproductive manifestations often prompt clinical presentation during adolescence and early adulthood, endocrine, metabolic, cardiovascular, psychological, and reproductive consequences may emerge at different stages of life. The figure highlights the transition from a traditional reproductive-centered view of the condition toward a life-course model emphasizing early metabolic dysfunction, cardiometabolic risk, and long-term health outcomes.*

Forslund et al.; 2026



Forslund et al.; 2026

The diagnostic logic is simple. The execution is not.

1. Ovulatory dysfunction
2. Clinical or biochemical hyperandrogenism
3. PCOM by ultrasound or AMH
4. **Diagnosis: ≥2 of 3 after exclusions**

Adults only: AMH may define PCOM — it does not diagnose PCOS alone.

2023 changed the role of AMH

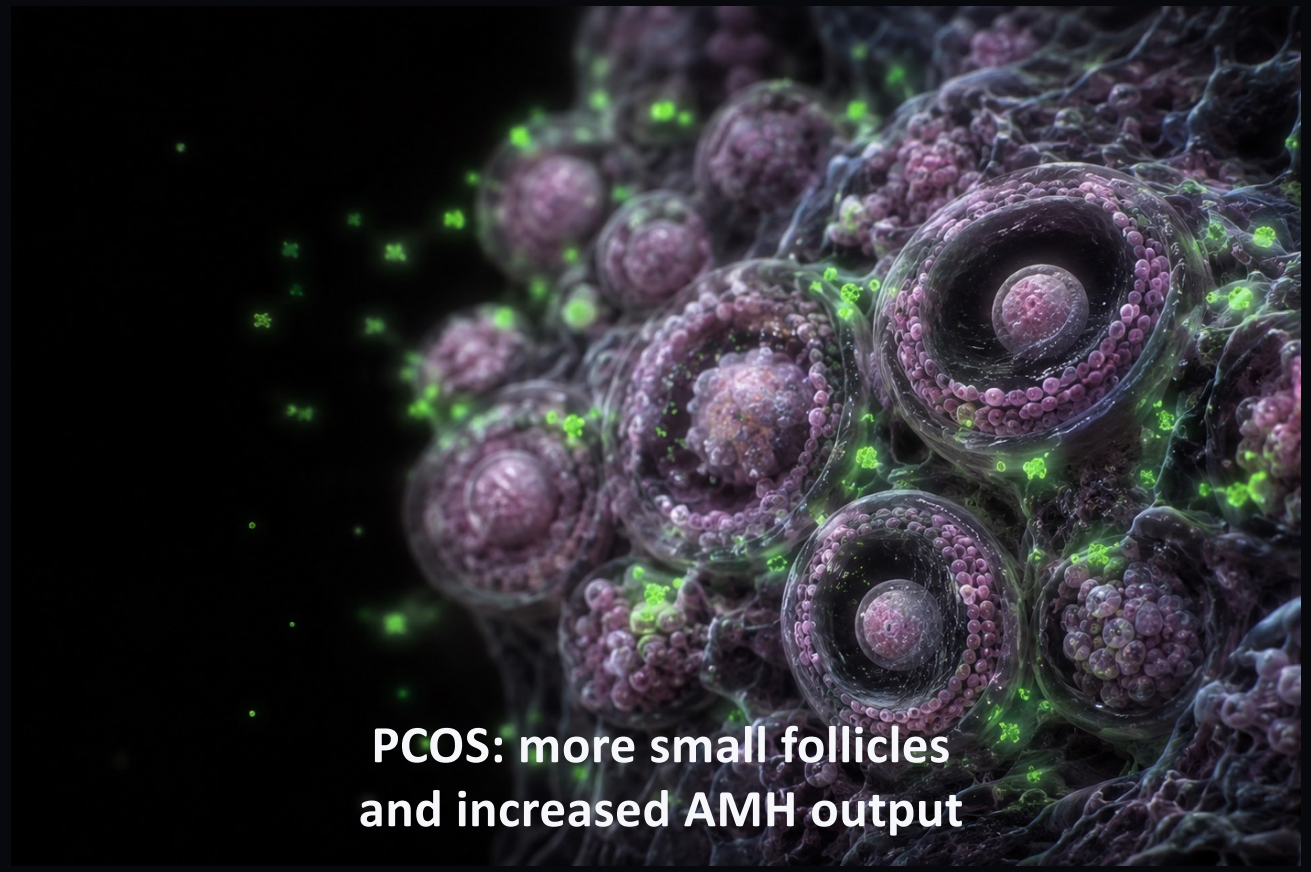
BEFORE	NOW
Ultrasound defined PCOM	Ultrasound OR serum AMH

A blood test can bring part of the pathway closer to primary care.

AMH is a biological signal from the growing follicle pool

Pre-antral + small antral follicles

major source of circulating AMH



AMH is powerful — when used with discipline

USE	as an alternative to ultrasound for PCOM in adults
DO NOT USE	as a stand-alone PCOS test
DO NOT USE	for adolescent diagnosis
AVOID DUPLICATION	do not routinely perform both AMH and ultrasound

There is no universal AMH cut-off

AGE

changes the expected concentration

ASSAY

changes the numerical result

CONTEXT

BMI, contraception, surgery and cycle matter

Population- and assay-specific thresholds are the clinical requirement.

MAGLUMI AMH showed strong preliminary analytical performance

<3%

within-run and between-run CVs

n=88

patient samples in method comparison

0.6

ng/mL mean bias vs ultrasensitive ELISA

Fully automated ABEI chemiluminescence • 0.1 ng/mL stated detection limit

Measurement of anti-Mullerian hormone: preliminary evaluation of an ABEI-based fully automated immunoassay

Damien Gruson [1,2], Akdim Siham[1], Catherine Fillée[1]

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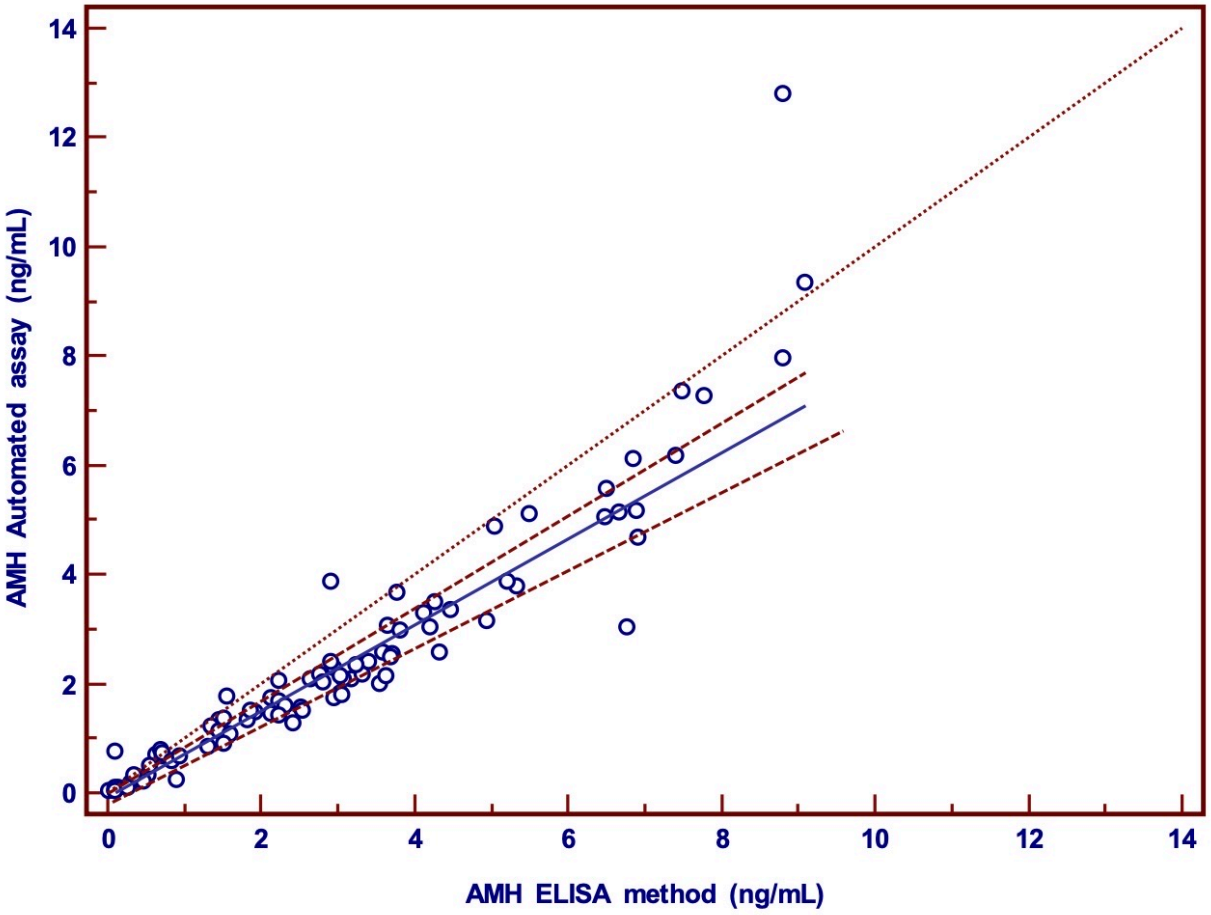
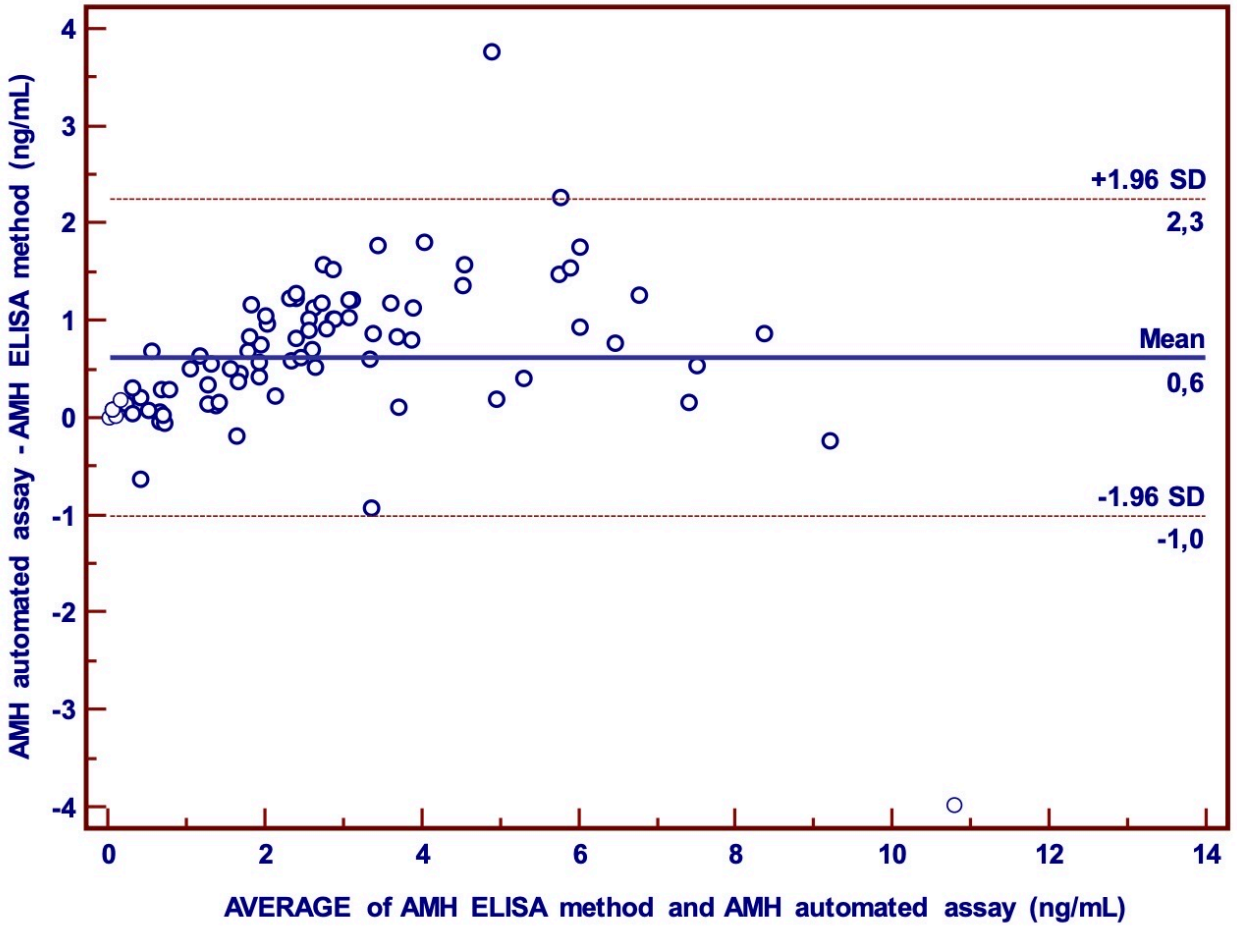
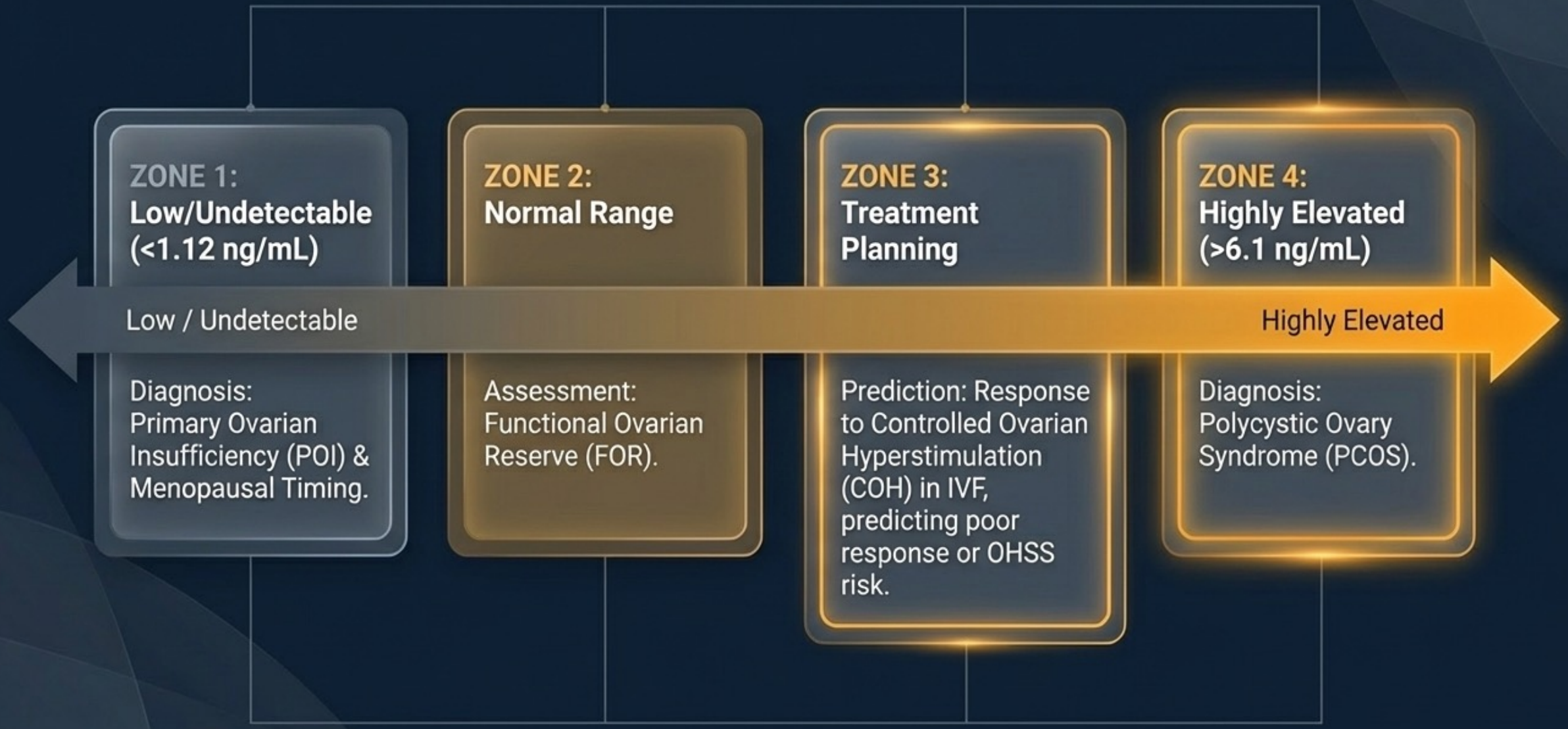
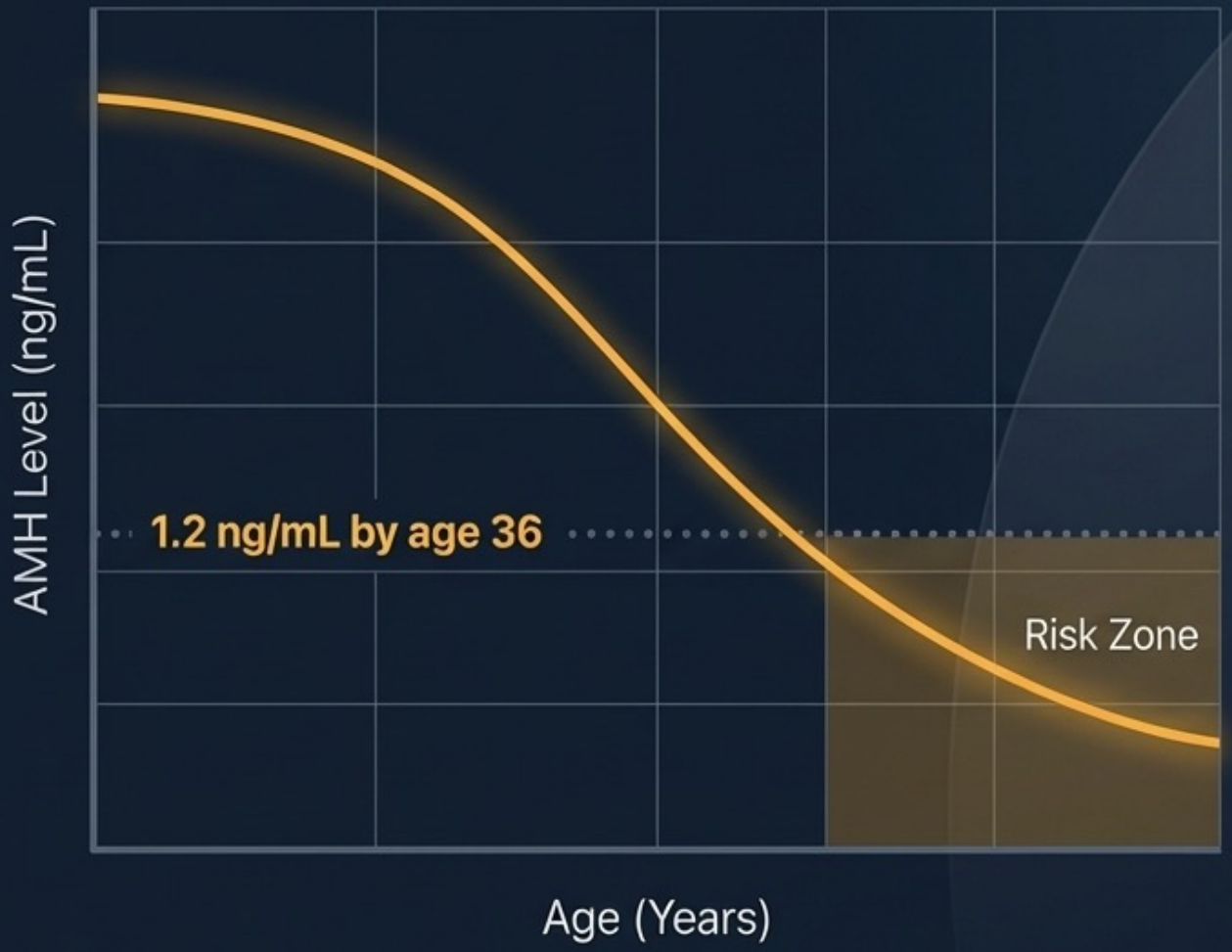




THE CLINICAL SPECTRUM



NAVIGATING THE EXTREMES: POI & MENOPAUSE



PRIMARY OVARIAN INSUFFICIENCY (POI)

AMH cutoff of <8 pmol/L (1.12 ng/mL) yields 85% sensitivity and 100% specificity for diagnosing POI in women with secondary oligomenorrhea.

MENOPAUSAL PREDICTION

Undetectable AMH in women aged 45–49 predicts a 60% probability of menopause within 5 years. However, serial tracking over time is vastly superior to single age-specific snapshots for accurate prediction.

Based on a 5,230-woman community cohort.

Key Challenges in Anti-Müllerian Hormone (AMH) Testing and Interpretation

Analytical variability

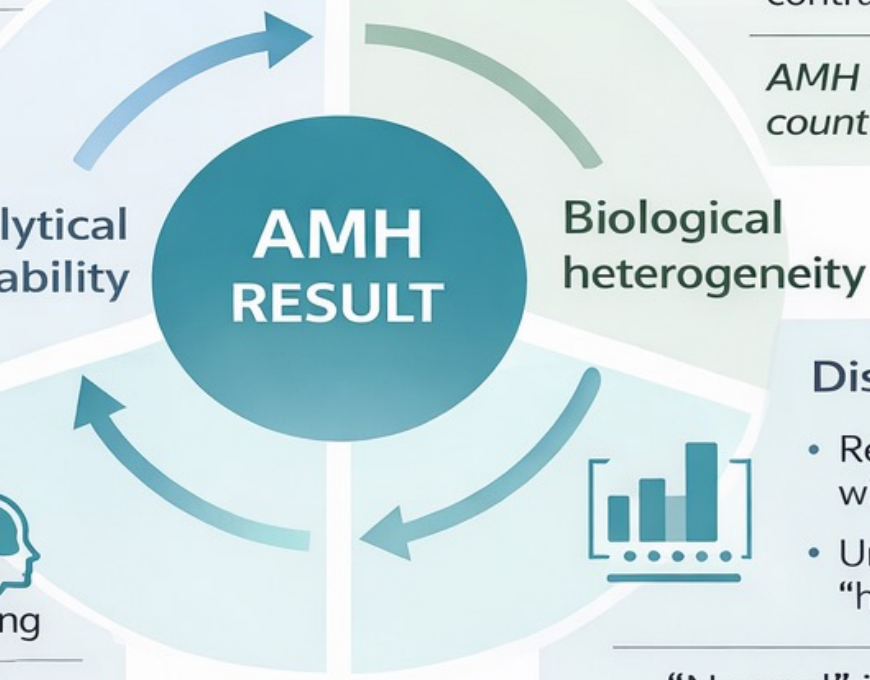
- Significant inter-assay bias (30–50%)
- Platform-specific calibration differences
- Limited assay harmonization

Same sample ≠ same *AMH result*

Biological heterogeneity

- Strong age dependency
- Major influence of PCOS (2–4× higher)
- Effects of BMI, smoking, oral contraception

AMH reflects follicle activity, not egg count



Clinical & psychosocial misinterpretation

- AMH misused as fertility predictor
- False reassurance vs unnecessary alarm
- Psychological distress, altered life planning

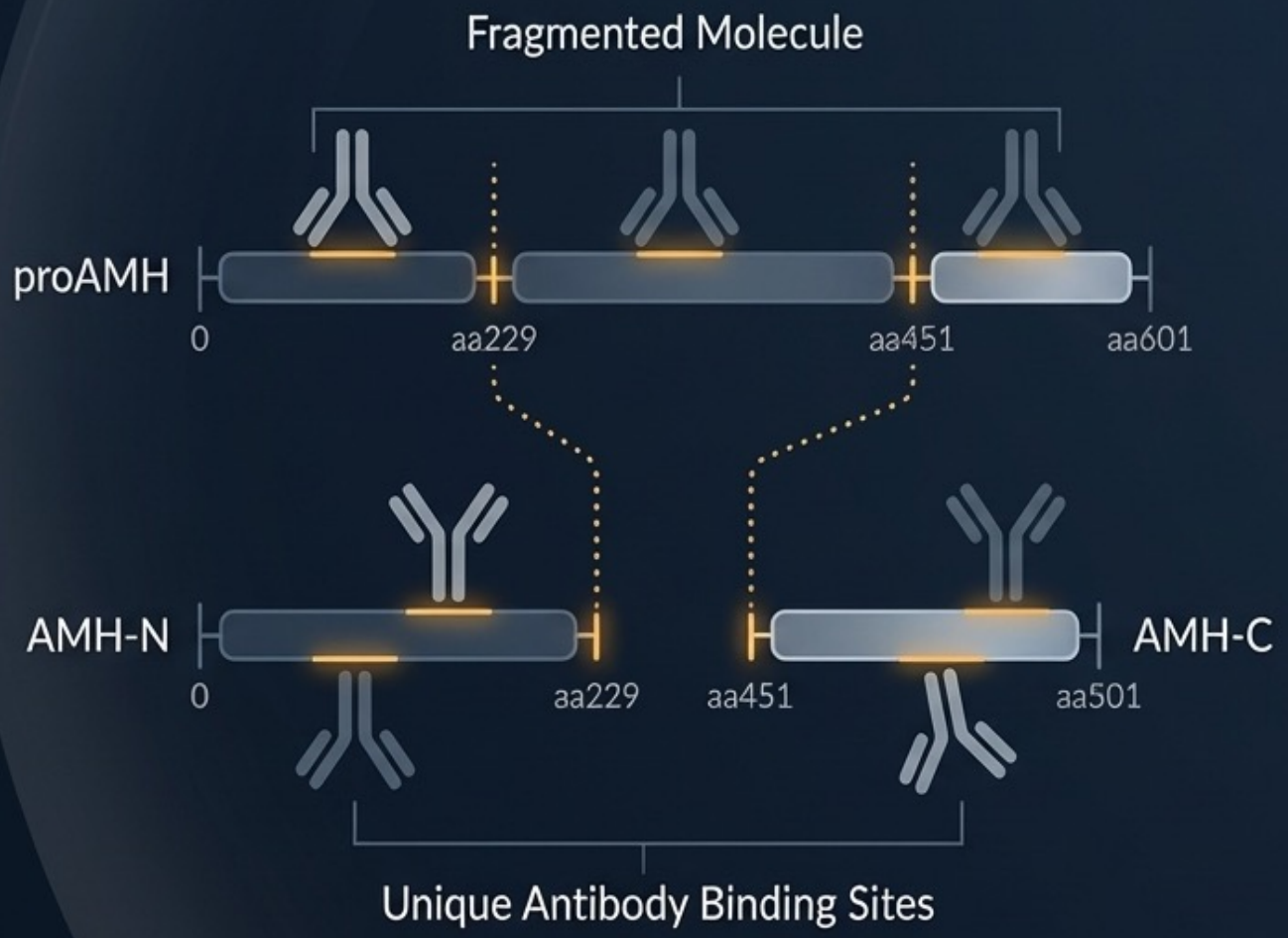
A lab value can become a life verdict

Distorted reference ranges

- Reference populations enriched with infertility & PCOS
- Undiagnosed PCOS contaninates “healthy” cohorts

“Normal” is often **not normal**

THE DIAGNOSTIC DILEMMA: STANDARDIZATION CRISIS



THE CORE PROBLEM

There is currently no universally accepted international reference standard for AMH.

MOLECULAR COMPLEXITY

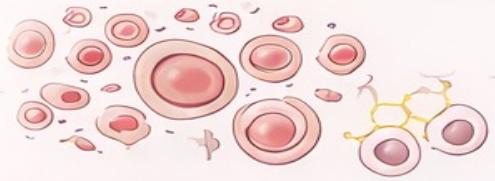
AMH circulates as various isoforms. Enzymatic processing and cleavage occur both within the follicle and in peripheral circulation.

ASSAY DISCREPANCY

Different assays (Gen II, Elecsys, picoAMH) utilize unique antibody pairs. Because they bind to different epitopes, they are biologically capturing and measuring different fragments of the hormone.

Circulating Forms of Anti-Müllérian Hormone (AMH)

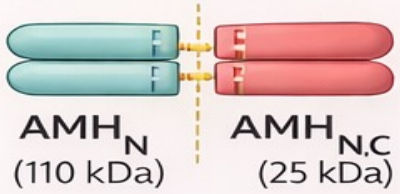
1 Synthese ovarienne



Granulosa celles

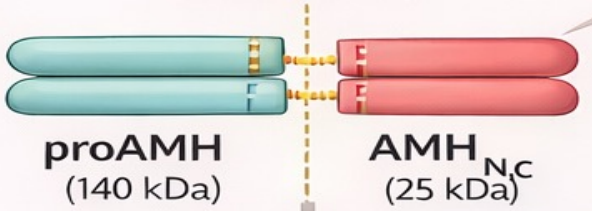
1. proAMH (140 kDa)

- Dimer precursor
- Biologically inactive form
- Synthesized by granulosa cells



2 Main circulating form

Proteolytic cleavage
(at site aa 451)



2. AMH$_{N,C}$ Complex

- AMH$_N$ (110 kDa): N-terminal proregion
- AMH$_C$ (25 kDa): mature C-terminal domain
- Non-covalent association

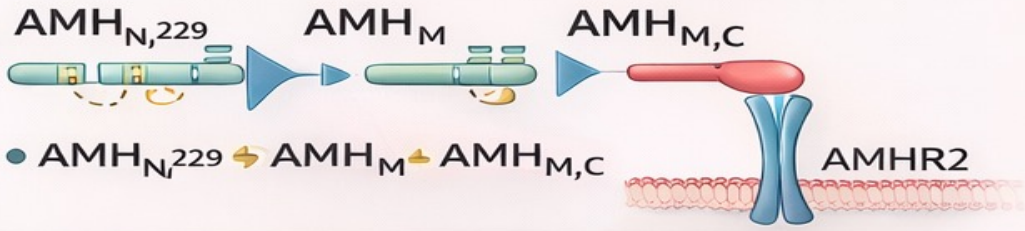
→ ▶ Main form primarily measured by immunoassays

3 Biologically active form

AMH$_C$ free

- Active at the **AMHR2** receptor
- Barely or not detectable in the bloodstream
- Likely generated locally at the tissue level

4 Alternative isoforms (cleavage at site aa229)



Analytical key message

Current assays measure a "total AMH" dominated by the cleaved AMH$_{N,C}$ form, without fine differentiation of isoforms. Antibody differences account for some of the inter-method variability.

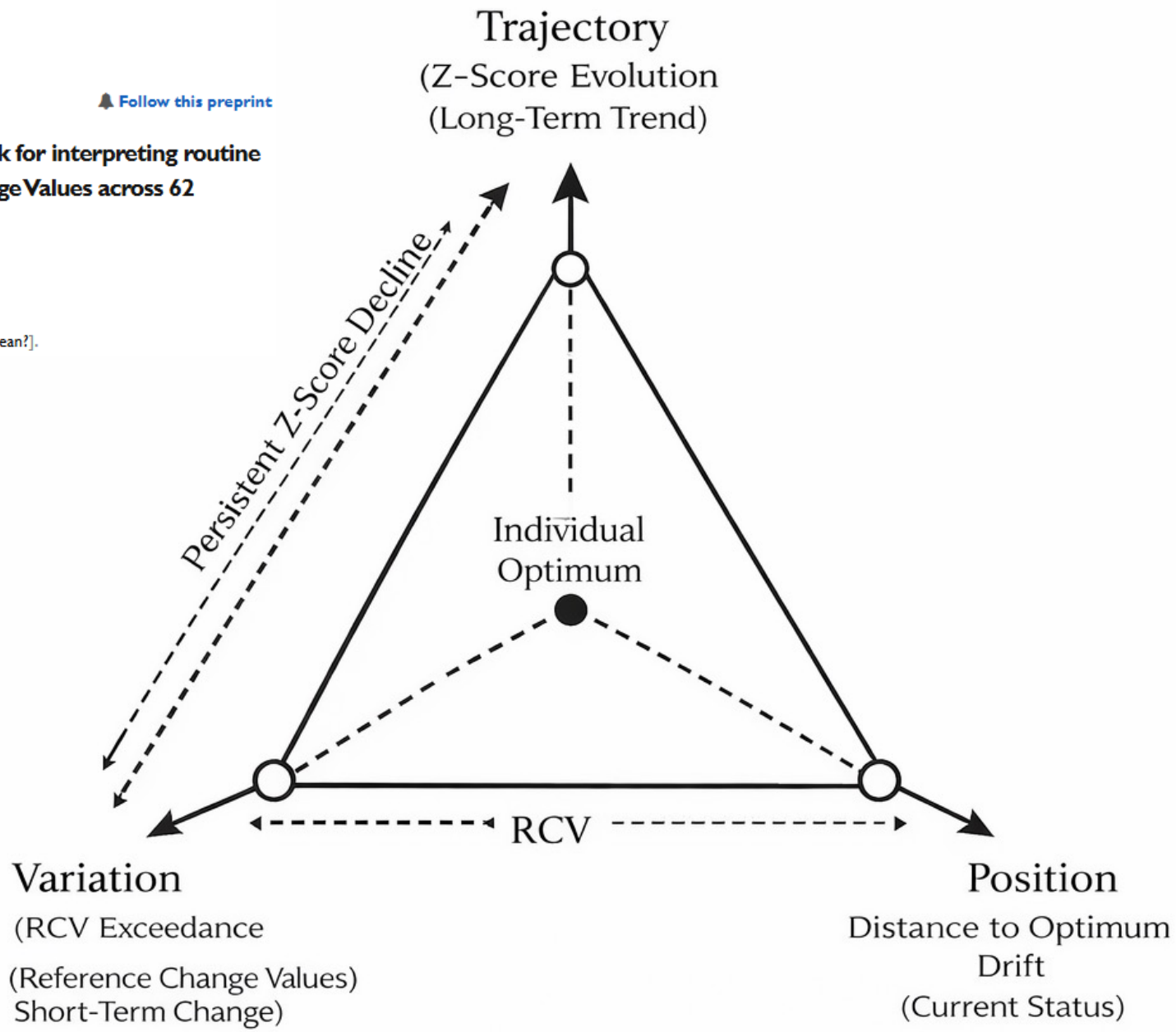
Circulating AMH ≠ Biologically active AMH → reflection of functional follicular pool, not a classical hormonal signal

I believe in Chocolate ☺

Distance-to-optimum biological drift as a new framework for interpreting routine laboratory results: a benchmark against Reference Change Values across 62 routine biomarkers

Clément Bézier, Jakez Rolland, Ronan Boutin, Damien Gruson

doi: https://doi.org/10.64898/2026.07.06.736744



Automation makes AMH easier to operationalize

1. Random-access workflow
2. Stable ABEI chemistry
3. Fast analytical reaction
4. Integrated women’s-health menu

The strategic value is not one test. It is a connected endocrine workflow.

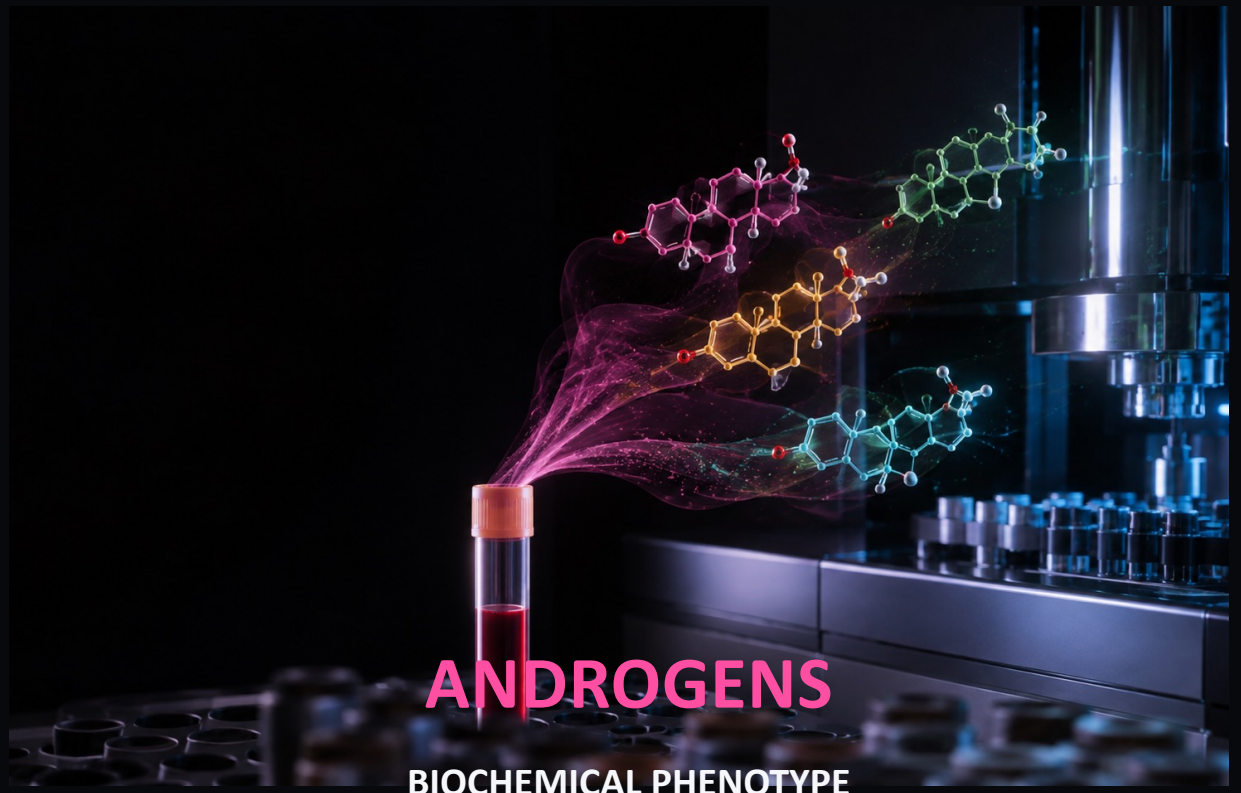

Snibe
MAGLUMI X6

AMH sees follicle excess. Androgens reveal endocrine expression.

AMH

FOLLICULAR SIGNAL

+



Start with total and free testosterone

1 **Total testosterone**

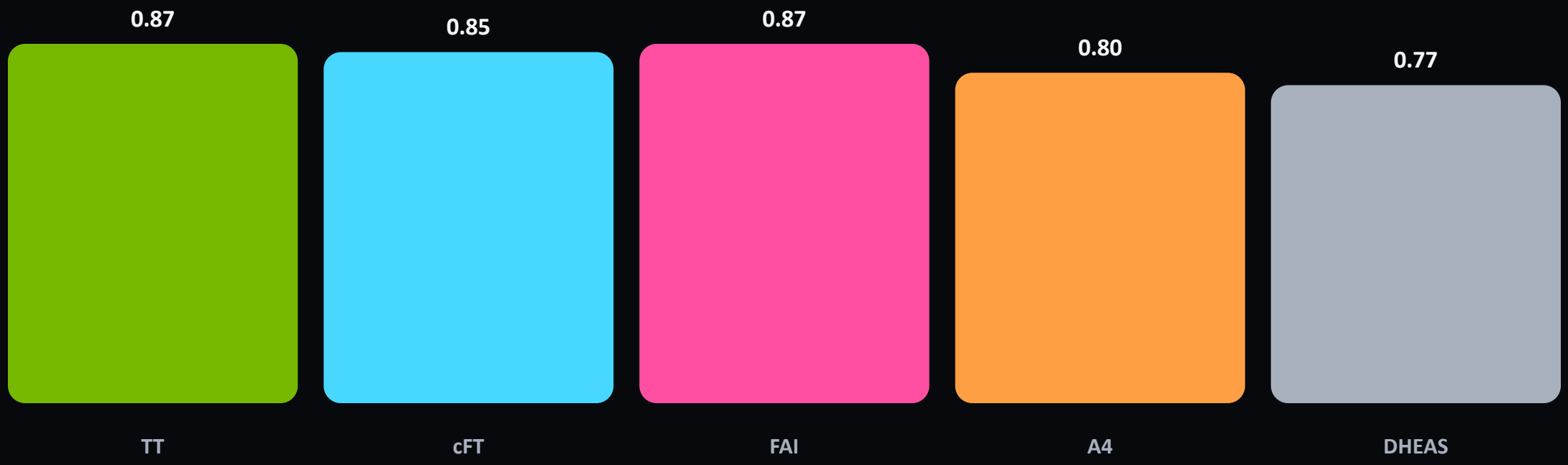
+

Calculated free testosterone
or free androgen index

2 **If not elevated**

consider androstenedione
and DHEAS

No single androgen captures every phenotype

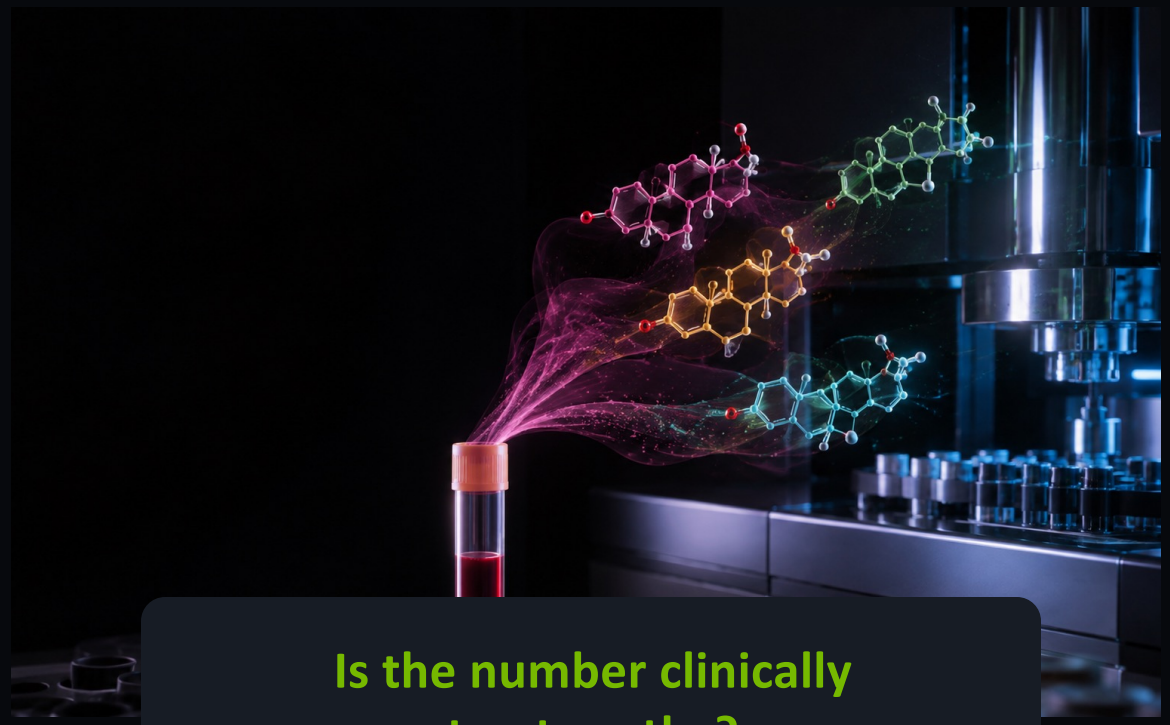


Area under the ROC curve in a 2025 diagnostic meta-analysis

Female testosterone lives in the difficult analytical range

LOW CONCENTRATIONS

make sensitivity, calibration and specificity decisive.



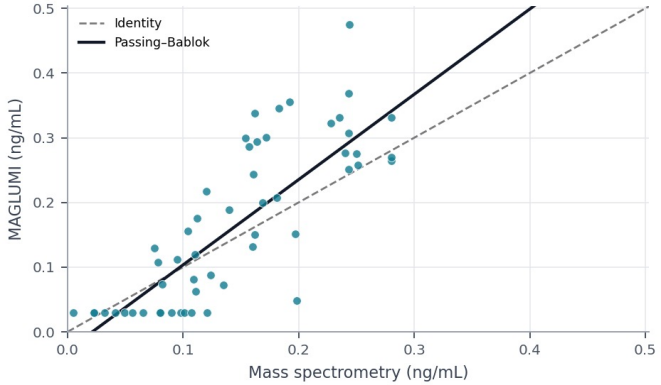
Is the number clinically trustworthy?

Method comparison differs across the testosterone range

Passing–Bablok and Bland–Altman analyses stratified by MS median (0.280 ng/mL)

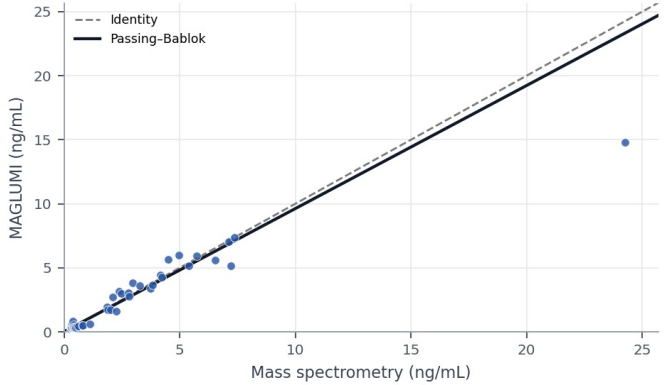
LOW RANGE | PASSING–BABLOK

y = 1.318x − 0.028 · n=54



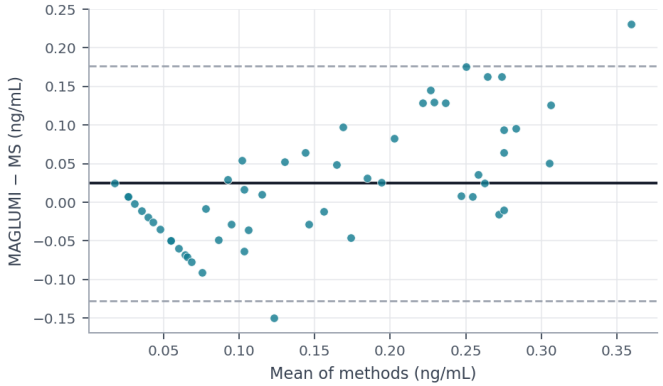
HIGH RANGE | PASSING–BABLOK

y = 0.961x + 0.013 · n=49



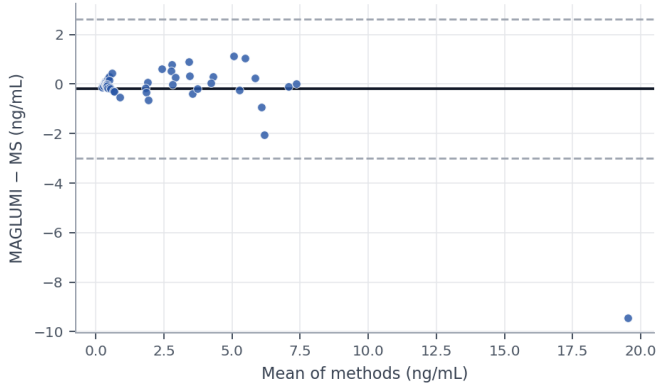
LOW RANGE | BLAND–ALTMAN

Bias 0.024 · 95% LoA -0.128 to 0.177 ng/mL



HIGH RANGE | BLAND–ALTMAN

Bias -0.185 · 95% LoA -3.000 to 2.631 ng/mL



Low range: MS ≤ 0.280 ng/mL | High range: MS > 0.280 ng/mL | Difference = MAGLUMI − MS

LC-MS/MS is the reference ambition. Access remains the implementation challenge.

REFERENCE

Validated LC-MS/MS

Accuracy at low concentrations

ROUTINE SCALE

Automated immunoassay

Access • throughput • integration

The bridge is rigorous verification.

A broader steroid menu can support a smarter reflex pathway

1 Total testosterone

2 SHBG + albumin → FAI / cFT

3 Androstenedione when indicated

4 Escalate atypical results

Standardize the sequence. Preserve clinical judgment.

Reference intervals are part of the test

POPULATION	well-characterized healthy women
METHOD	platform-specific intervals and decision points
AGE	especially for DHEAS and AMH
PREANALYTICS	COCP use, timing, clinical context
ESCALATION	rapid progression or marked elevation

One sample can trigger a more coherent diagnostic journey

1

Clinical question
+ exclusions

2

AMH if PCOM
needs definition

3

TT + SHBG
→ FAI / cFT

4

A4 / DHEAS
if indicated

5

Interpretive report
+ next action

Not more testing. Better-sequenced testing.

A credible rollout needs four proof points

01 Analytical verification

02 Clinical interpretation

03 Workflow design

04 Outcome tracking

The laboratory can close three gaps at once

ACCESS

bring PCOM assessment closer to routine care

ACCURACY

strengthen the biochemical phenotype

ACTION

translate numbers into next clinical steps

AMH + validated steroid testing + interpretive intelligence

THE FUTURE OF WOMEN'S HEALTH
WILL NOT BE CLOSED BY ONE TEST.

It will be closed
by better pathways.

AMH identifies the follicular signal.
Steroids resolve the endocrine phenotype.
The laboratory connects both to action.


Snibe
gnostic
Snibe

Find the beat.
Keep the human.

Tap along — or simply listen.

Great systems need coordination.
So do great teams.


let's
move
again

Thank you for your attention

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