

The Diagnostic Hierarchy

Examen Labs — Male Fertility Diagnostics

Not all sperm DNA tests are equal. Each level measures something different, reveals different blind spots, and tells a different story — which is why SpermComet® delivers more actionable insight than any other test available today.

AUC 0.93 Accuracy

25+ Years Research

12,000+ Patients Supported

[Explore the Hierarchy](#)

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Why SpermComet® Sits Above the Rest

Male fertility diagnostics are not a single, uniform category. There is a clear and clinically significant hierarchy of tests — each measuring something different and each offering a different level of insight. Understanding where each test sits in that hierarchy is essential for clinicians seeking to provide the most accurate diagnosis and the most effective treatment pathway for their patients.

At the base sits Standard Semen Analysis, the most widely used first-line screen. Above it, SCSA and TUNEL tests provide a population-level view of DNA damage. At the apex, SpermComet® by Examen delivers individual sperm-level analysis — the gold standard in male fertility diagnostics, backed by over 25 years of peer-reviewed research.

1

Tier 1 — Standard Semen Analysis

Count, motility, morphology. No DNA damage detection.

2

Tier 2 — SCSA / TUNEL

Population-level DNA damage. No individual cell data.

3

Tier 3 — SpermComet® (Gold Standard)

Individual sperm analysis. Single & double strand breaks. AUC 0.93.





TIER 1

Standard Semen Analysis — The First Line Screen

Standard Semen Analysis is the most commonly requested male fertility test. It measures sperm count, motility, and morphology — the three classical parameters that have defined male fertility assessment for decades. It is a valuable and necessary starting point, but it is only a starting point.

Sperm Count

Sperm Motility

Sperm Morphology

⚠️ **7 in 10 men with normal semen analysis results may still have high levels of sperm DNA damage**

Standard Semen Analysis is best used as a first-line screen only. It should not be treated as a comprehensive assessment of male fertility, and a normal result should never be taken as confirmation that sperm DNA integrity is unaffected.

⚠️ **What it misses:** The molecular causes of male infertility — including sperm DNA damage that standard parameters cannot detect.

SCSA / TUNEL Tests — Population Averages, Not Individual Insight

SCSA (Sperm Chromatin Structure Assay) and TUNEL tests represent a meaningful step forward from Standard Semen Analysis. They do measure sperm DNA damage — a significant advantage over Tier 1 testing. However, they measure *average* DNA damage across the whole sample, rather than analysing individual sperm cells.

This means the result is often little more than pass or fail. It cannot isolate double strand DNA breaks — a particularly important category of damage linked to recurrent miscarriage — and it is less useful for low concentration samples or surgically retrieved sperm (SSR) samples.

Key limitations of Tier 2 testing:

Population Average

Reports average DNA damage across the whole sample — not individual sperm data.

Pass / Fail Only

Limited detail beyond a binary result, reducing clinical utility for nuanced cases.

No Double Strand Detection

Cannot isolate double strand DNA breaks — a key factor in recurrent miscarriage.

Limited for SSR Samples

Less useful for low concentration or surgically retrieved sperm samples.

⚠ What it misses: Individual sperm data and double strand break detection.





TIER 3 — GOLD STANDARD

SpermComet® by Examen — Precision. Personalisation. Proof.

SpermComet® sits at the apex of the diagnostic hierarchy for a reason. It is the only test that analyses individual sperm cells — not a population average — providing a level of granularity and clinical insight that no other sperm DNA test can match. With an AUC of 0.93 predictive accuracy, it is the most clinically validated tool available for assessing sperm DNA integrity.

Single Cell Analysis

Analyses individual sperm, not a population average, for true diagnostic precision.

Single & Double Strand Breaks

Detects both types of DNA damage — the only test to do so comprehensively.

AUC 0.93 Accuracy

Among the highest predictive accuracy scores of any male fertility diagnostic test.

Works from 0.1M/ml

Supports low concentration and surgically retrieved sperm samples where other tests may fail.

SpermComet® also works from as low as 0.1M/ml, making it suitable for low concentration samples and surgically retrieved sperm including SSR, TESA, and PESA — supporting more patients across a wider range of clinical scenarios than any competing test.



EXCLUSIVE FEATURE

Examen EXTEND® — Isolating Double Strand DNA Breaks

Within the SpermComet® platform, Examen EXTEND® represents a further, exclusive advancement. It is the only commercial test capable of isolating double strand DNA breaks in sperm — a category of damage that is distinct from single strand breaks and carries particular clinical significance.

Double strand DNA breaks are a key hidden factor in recurrent miscarriage. Unlike single strand breaks, which can sometimes be repaired by the oocyte after fertilisation, double strand breaks are far harder to resolve and are associated with poorer embryo development and higher rates of pregnancy loss. Identifying them allows clinicians to make more targeted treatment decisions and counsel patients with greater precision.

No other commercially available sperm DNA test offers this capability. EXTEND® is exclusive to Examen, making SpermComet® the only pathway to this level of diagnostic insight for patients experiencing recurrent miscarriage or unexplained implantation failure.

Single Strand Breaks

Can sometimes be repaired by the oocyte after fertilisation.

Double Strand Breaks (EXTEND®)

Far harder to resolve; linked to poorer embryo development and recurrent miscarriage. Only detectable with Examen EXTEND®.

CLINICAL IMPACT

What SpermComet® Delivers for Clinicians & Patients



Better Treatment Decisions

Individual sperm-level data enables clinicians to tailor treatment pathways with far greater confidence, moving beyond population averages to truly personalised care.

Together, these three outcomes — better treatment decisions, more precise diagnosis, and greater clinical confidence — represent the core value proposition of SpermComet® for fertility clinics across the UK and Ireland.



More Precise Diagnosis

By detecting both single and double strand DNA breaks at the individual cell level, SpermComet® uncovers the molecular causes of infertility that standard tests routinely miss.



Greater Clinical Confidence

With AUC 0.93 predictive accuracy and over 25 years of peer-reviewed research behind it, SpermComet® gives clinicians the evidence base to act decisively and communicate clearly with patients.



TIER COMPARISON

Side-by-Side: What Each Tier Measures

The following comparison illustrates the key differences between the three tiers of male fertility diagnostics — from the foundational first-line screen to the gold standard of individual sperm DNA analysis.

Feature	Tier 1: Semen Analysis	Tier 2: SCSA / TUNEL	Tier 3: SpermComet®
Measures DNA damage	<input type="checkbox"/> No	✓ Yes (average)	✓ Yes (individual)
Individual cell analysis	<input type="checkbox"/> No	<input type="checkbox"/> No	✓ Yes
Detects double strand breaks	<input type="checkbox"/> No	<input type="checkbox"/> No	✓ Yes (EXTEND®)
Works from 0.1M/ml	<input type="checkbox"/> No	<input type="checkbox"/> No	✓ Yes
Supports SSR / TESA / PESA	<input type="checkbox"/> No	Limited	✓ Yes
Predictive accuracy	Low	Moderate	AUC 0.93

TRUST & CREDENTIALS

Trusted by Leading UK & Ireland Fertility Clinics

Examen Labs operates to the highest standards of laboratory quality and clinical governance, holding dual ISO certification and underpinned by a research foundation spanning more than a quarter of a century. SpermComet® is not a new or unproven technology — it is trusted by leading fertility clinics across the UK and Ireland precisely because it delivers results that change clinical outcomes.

25+

Years Research

Peer-reviewed scientific foundation.

12K+

Patients Supported

Across UK & Ireland fertility clinics.

0.93

AUC Accuracy

Gold standard predictive performance.

ISO 13485

Medical devices quality management certification.

ISO 15189

Medical laboratory quality and competence certification.





MALE FERTILITY DIAGNOSTICS

The Gold Standard in Male Fertility Diagnostics

SpermComet® by Examen Labs represents the pinnacle of male fertility diagnostics — the only test that combines individual sperm cell analysis, detection of both single and double strand DNA breaks, and the exclusive EXTEND® capability that no other commercial test can offer. For clinicians seeking to provide the most accurate diagnosis and the most effective treatment pathway, there is no more complete tool available.

Precision. Personalisation. Proof. — The SpermComet® promise to clinicians and patients alike.

Whether your patient presents with unexplained infertility, recurrent miscarriage, failed IVF cycles, or a normal semen analysis that has not led to a successful pregnancy, SpermComet® provides the molecular-level insight needed to move forward with confidence. It works from as low as 0.1M/ml, supports surgically retrieved samples, and is backed by over 25 years of peer-reviewed research and 12,000+ patients supported across the UK and Ireland.

[Request a Test](#)

[Learn More About SpermComet®](#)