

Sperm DNA Testing for Selected Male Fertility and Wellness Pathways

How Sperm DNA Testing May Support Selected Male Fertility and Wellness Pathways

Some men with semen parameters within reference ranges may still have elevated sperm DNA fragmentation in selected study populations.

This information is intended for healthcare professional education and clinic pathway discussion only.

Partner With Examen



A Potential Gap in Male Fertility and Wellness Assessment

The male wellness and longevity sector is growing globally — yet sperm DNA fragmentation is not always assessed in male wellness pathways.

⚠️ Sperm DNA fragmentation is an area that may be under-assessed in some male wellness pathways: the paternal genome.

The global male wellness and longevity sector is booming. Clinics across major healthcare hubs worldwide are optimising hormones, maximising mitochondrial efficiency, measuring telomeres, and offering a range of wellness and metabolic assessments. They treat the modern executive as a finely tuned biological machine, tracking every metric from high-sensitivity C-reactive protein (hs-CRP) to VO_2 max.

Many premium clinics still rely on the standard semen analysis remains an important first-line assessment, but it does not directly assess sperm DNA fragmentation. Sperm DNA fragmentation testing may provide additional information beyond standard semen parameters in selected clinical contexts.

Evolving Approaches in Male Fertility Assessment

Different approaches assess different aspects of sperm health.

STANDARD

Standard Semen Analysis

Macroscopic / Mechanical

- Volumetric fluid count
- Basic swim motility metrics
- Exterior structural shape
- Does not directly assess sperm DNA integrity

ADDITIONAL ASSESSMENT

Sperm DNA Fragmentation Assessment

Molecular / Structural

- Single-strand lesion mapping
- Double-strand breakage (dsSDF)
- Incidence of Damage (IOD)
- A sperm DNA integrity marker that may be relevant in selected reproductive health assessments

Where sperm DNA fragmentation is not assessed, some patients may be without additional information that may be relevant to fertility counselling and reproductive outcomes that may warrant further clinician-led investigation.



Sperm DNA Integrity as a Reproductive Health Marker

Mature sperm have limited DNA repair capacity, making sperm DNA integrity a potentially relevant marker in selected reproductive health assessments.



Oxidative Stress

One factor associated with sperm DNA fragmentation in some studies.



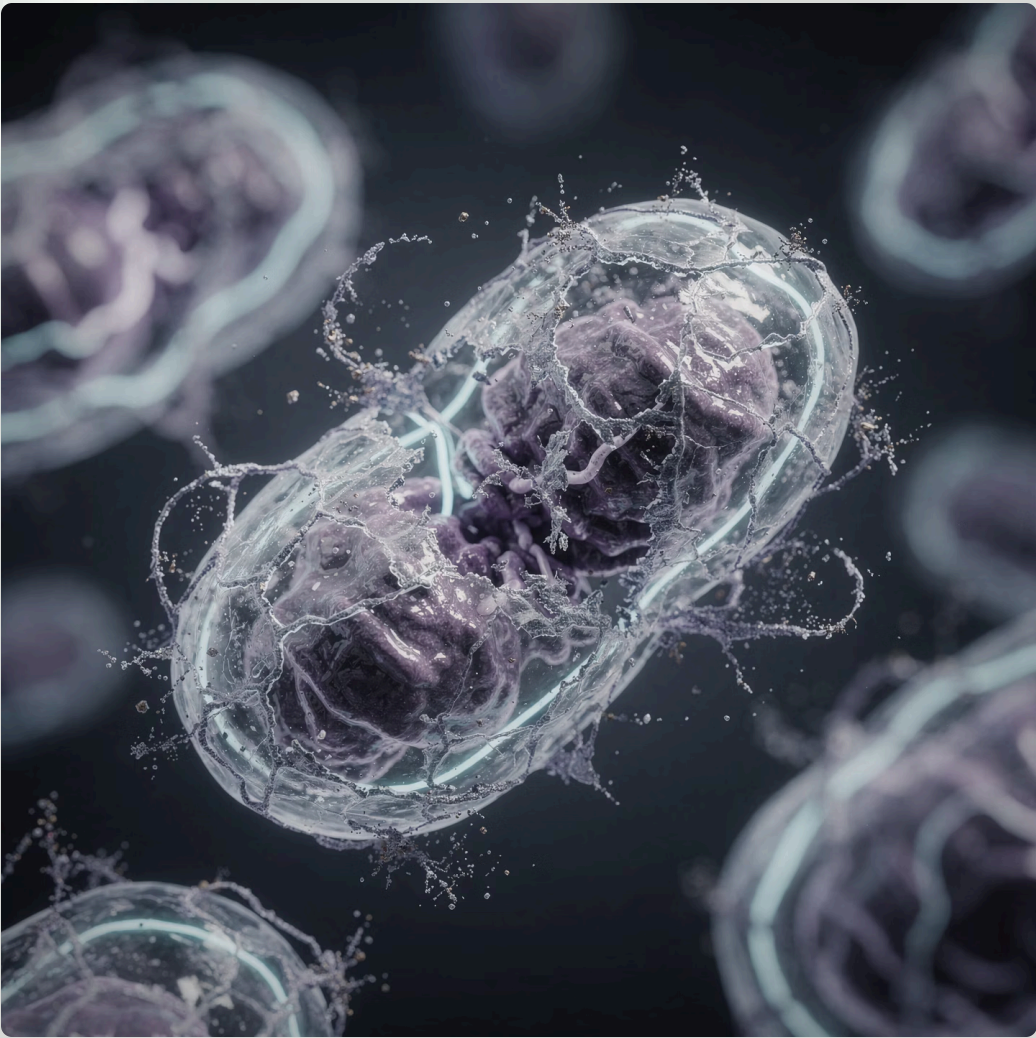
Environmental Toxins

May be associated with sperm DNA damage in some research contexts.



Subclinical Inflammation

A factor that may not be fully captured by routine assessments in all cases.



Metabolic Dysfunction

May be associated with altered reproductive health markers in some studies.

 SpermComet® testing may support selected male fertility and wellness pathways when integrated into appropriate clinical protocols, subject to local clinical governance.



Potential Integration Areas for Male Wellness Clinics

SpermComet® may be integrated into selected clinic protocols, subject to local workflow and clinical governance.



Hormone-Related Male Fertility Assessment

Exogenous Testosterone Replacement Therapy (TRT) is commonly used in selected clinically indicated male hormone management pathways, and its suppressive effect on spermatogenesis is well documented. When clinicians co-administer hCG, hMG, or SERMs to preserve testicular function, sperm DNA fragmentation assessment may provide additional information on sperm DNA integrity where fertility preservation is clinically relevant.



Sperm DNA Fragmentation and Oxidative Stress

Sperm DNA Fragmentation (SDF) — specifically double-stranded DNA breaks (dsSDF) — may be associated with oxidative stress and other factors affecting sperm DNA integrity. Where a clinic initiates antioxidant or metabolic interventions, SpermComet® may provide a repeatable measure that may support monitoring of sperm DNA fragmentation over time, where clinically appropriate.



Sperm DNA Integrity as an Additional Reproductive Health Marker

A patient may present with optimised blood panel results yet have elevated sperm DNA fragmentation associated with a varicocele, environmental exposures, or metabolic factors. Sperm DNA integrity assessment may add information to selected reproductive health assessments, and results should always be interpreted by a qualified clinician alongside other relevant investigations.

Research-Supported Sperm DNA Testing

25 years of peer-reviewed academic research. ISO 13485 | ISO 15189 | UKAS medical laboratory accreditation. A validated sperm DNA testing approach.



ISO 13485



ISO 15189



UKAS Medical Laboratory — No. 25925

Accreditation details should be verified against the current UKAS schedule. Logos used only within permitted scope.

Developed over **25 years of academic research**, Examen's proprietary SpermComet® technology is a validated sperm DNA integrity testing approach supported by published research. Operating within ISO 13485 and ISO 15189 certified frameworks, it directly assesses individual sperm cells, avoiding other testing methods that may use different analytical approaches.

The Power of Single-Cell Gel Electrophoresis

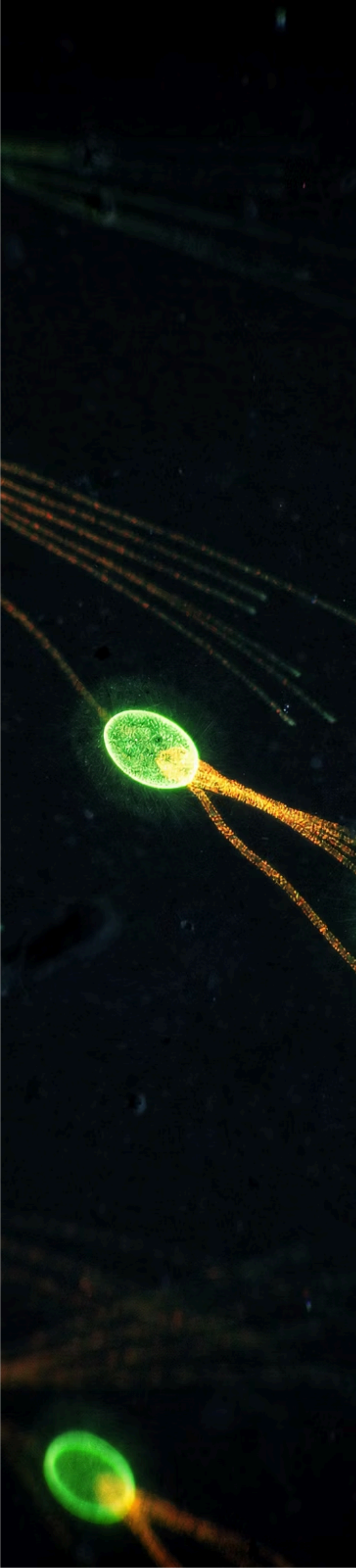
The SpermComet® technique uses an alkaline single-cell gel electrophoresis assay to physically pull damaged, fragmented DNA away from the intact sperm head. Under fluorescence microscopy, this creates a distinct "comet" shape. The length and intensity of the comet tail are used to assess the degree of DNA migration associated with strand breakage.

- **Normal Cell:** Intact nucleus — no tail visible
- **Damaged Cell:** Nucleus with elongated comet tail indicating strand breaks

The Critical 6% Diagnostic Threshold

While single-strand DNA breaks are often caused by transient oxidative stress and can sometimes be repaired by a healthy oocyte, **double-strand breaks** are far more severe and difficult to resolve.

⊗ In specific published study populations, an Incidence of Damage (IOD) of **≥ 6%** in double-stranded sperm DNA fragmentation has been associated with less favourable reproductive outcomes, even when semen parameters are within reference ranges. Thresholds should be interpreted only by qualified clinicians in context.





A scenario model can compare the cost of SDF testing with repeated ART cycles. Costs vary by clinic, country, and patient pathway.

Scenario-Based Cost Considerations

The following is a scenario model for illustrative purposes only. Actual costs, outcomes, and clinical pathways vary by clinic, country, and individual patient circumstances.

Option A: Without SDF Assessment

- Legacy semen analysis: low upfront cost
- Failed IVF/ICSI Cycle 1: a major financial loss
- Failed IVF/ICSI Cycle 2: another major financial loss

Total scenario cost: higher in this illustrative model

Option B: With SDF Assessment

- SpermComet® Screen: a fraction of the cost of a failed cycle
- Targeted Lifestyle Prep (Antioxidants / Varicocele)
- Treatment planning discussion informed by additional data

Total scenario cost: lower in this illustrative model. Scenario-dependent.

Positioning sperm DNA fragmentation assessment earlier in the male clinical evaluation may support earlier diagnostic discussion and reduce uncertainty in selected cases, supporting more informed treatment planning. All clinical decisions should be made by a qualified clinician.



Designed to support international logistics, subject to local requirements. Two available tracks.

International Sample Logistics: Two Available Pathways

Examen aims to reduce operational complexity for international sample shipping from partner clinics to its central reference facility in Belfast, through a dual-track logistics system. Availability is subject to local regulatory requirements and approved logistics pathways.



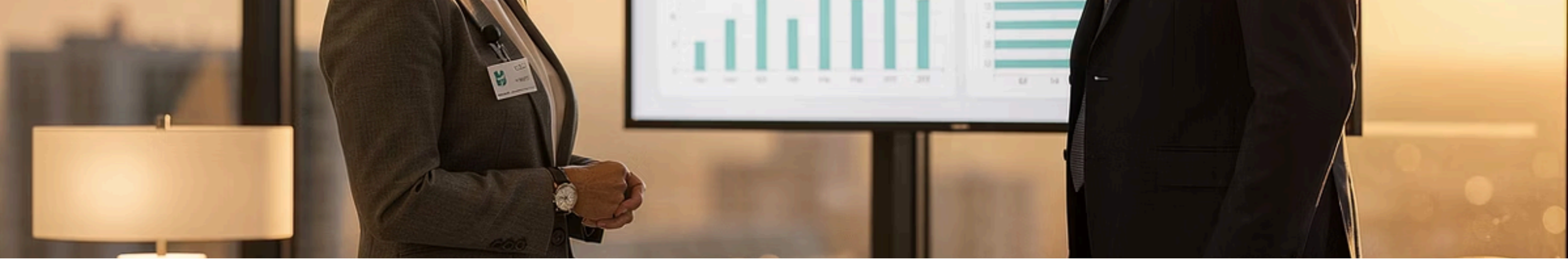
Track 1: Strategic Laboratory Hub Alliances

Examen integrates directly with established, licensed local laboratory networks that maintain established international cold-chain shipping routes, where available through approved local logistics pathways, aiming to reduce operational burden on the clinic.



Track 2: On-Site Cryogenic Dry Shippers

For high-volume clinics, Examen deploys a specialised liquid-nitrogen dry shipper valued at **£600 GBP**. Holds up to **100 patient vials** at stable ultra-low cryogenic temperatures. Clinics collect locally, store securely, and ship in batches — which may reduce per-vial costs at sufficient volume.



Clinic Integration and Service Planning

SpermComet® testing may support further clinician-led assessment where appropriate.

Revenue Streams Diagnostics, further assessment, and repeat monitoring where clinically appropriate	ROI Scenario-based ROI modelling available on request	Zero Capex No equipment investment required — Examen handles all lab infrastructure
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Institutional Pricing

Commercial terms may be discussed with partner clinics. Institutional pricing arrangements can be explored individually.



Supporting Further Clinical Assessment

Elevated sperm DNA fragmentation results may prompt further clinician-led review, which may include consideration of varicocele assessment, lifestyle factors, antioxidant approaches, or other management options, depending on clinical findings and individual patient circumstances.



Clinic Differentiation

Offering sperm DNA fragmentation testing may support clinic differentiation in advanced male fertility assessment pathways, for clinics where this aligns with their clinical governance and patient population.

Early adopters may explore differentiated male fertility pathways. Considerations for clinic integration.

Considerations for Clinic Integration

The Financial Case



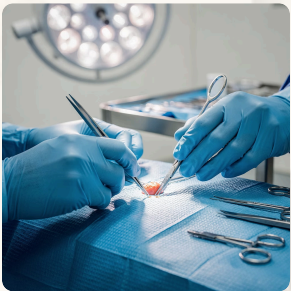
Additional Diagnostic Service Line

SpermComet® testing may represent an additional diagnostic service line. Pricing may vary by market and clinic model. No capital expenditure is required.



Supporting Clinical Documentation

Offering sperm DNA fragmentation testing may support clinical documentation and governance in male fertility assessment pathways.



Supporting Further Clinical Review

Elevated results may warrant clinician-led review. Further assessment options such as varicocele evaluation, lifestyle factors, or other management approaches may be considered depending on clinical findings.



Repeat Monitoring

Patients on hormone management, antioxidant protocols, or fertility pathways may benefit from repeat sperm DNA fragmentation assessment over time, where clinically appropriate.

The Strategic Case



Differentiate in a Crowded Market

In a sector with many diagnostic options, SpermComet® is a research-supported diagnostic option that may support clinic differentiation in advanced male fertility assessment.



Align With Growing Interest in Male Reproductive Health

The longevity and wellness sector is projected to grow, although estimates vary. Sperm DNA fragmentation testing may contribute to evolving clinical pathways in male reproductive health.



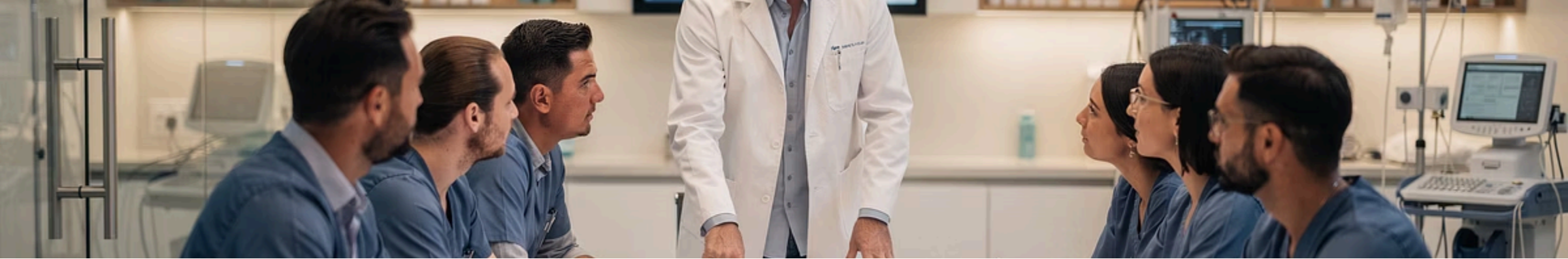
Attract & Retain Patients Seeking Advanced Assessment

Patients seeking advanced male fertility assessment may be attracted to clinics offering sperm DNA fragmentation testing as part of a comprehensive reproductive health pathway.



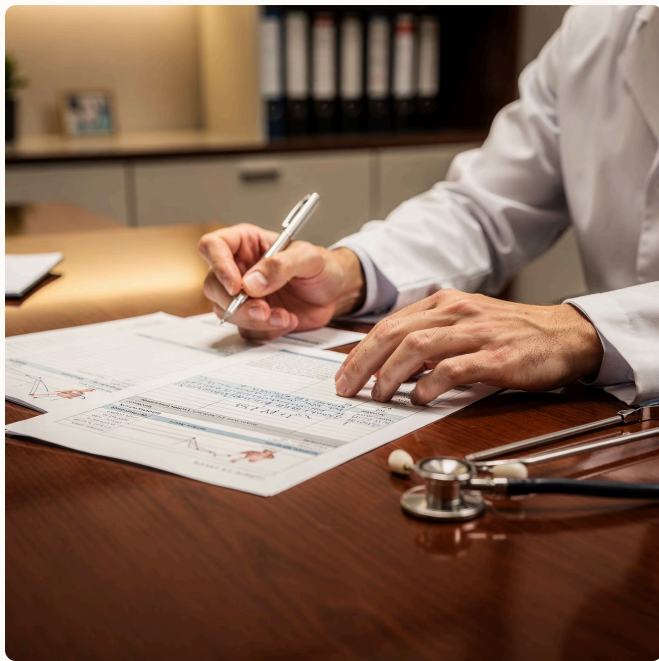
Partnership Arrangements

Examen works with a curated network of partner clinics. Commercial terms and regional partnership arrangements can be discussed individually.



B2B Onboarding Overview

From first conversation to live clinical protocol — an overview of the onboarding process.



Step 1

Retrospective Screening Review

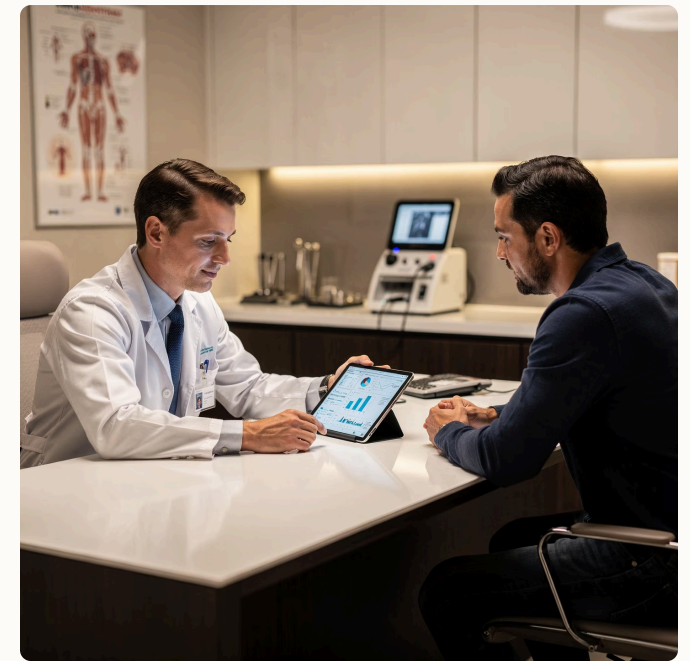
Review historical case files of patients who experienced unexplained cycle failures despite semen parameters within reference ranges. This may help review whether additional SDF assessment could have informed selected cases.



Step 2

On-Site Technical Setup

Examen delivers a specialised liquid nitrogen dry shipper from Belfast with global cold-chain logistics, and provides a 60-minute training session for your laboratory and nursing staff on sample preparation and shipping protocols.



Step 3

Clinical Protocol Launch

Integrate the SpermComet® assay into selected male fertility or preconception assessment pathways where clinically appropriate, establishing an additional sperm DNA integrity baseline for reproductive health assessment.

GET IN TOUCH

Get in Touch

Supporting advanced male fertility assessment in selected clinical pathways.

To discuss integrating sperm DNA fragmentation testing into your clinic's male fertility or preconception assessment pathways, and to explore commercial terms, contact our global development office directly.



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This information is intended for healthcare professional education and clinic pathway discussion only. SpermComet® results should be interpreted by a qualified clinician alongside semen analysis, medical history, reproductive history, partner assessment, embryo development data, and other relevant investigations. The test does not diagnose infertility or systemic disease on its own, does not measure biological age or longevity, does not prove treatment efficacy, and does not guarantee fertilisation, pregnancy, live birth, miscarriage reduction, shorter time to pregnancy, improved treatment outcomes, reduced treatment costs, reduced legal risk, or increased clinic revenue.