SpermComet® Technology: A Deep Dive

Proprietary single-cell gel electrophoresis for sperm DNA damage assessment and classification for clinician-led interpretation — built on 25+ years of peer-reviewed science.

Technology Identity

SpermComet® is a validated laboratory service, within its stated scope, built on established comet assay methodology adapted for reproductive diagnostics. It is designed to provide high-resolution assessment of sperm DNA integrity for clinical laboratories and reproductive medicine specialists.

Base Methodology

Single-cell gel electrophoresis (comet assay) for single-cell DNA strand integrity.

Application Domain

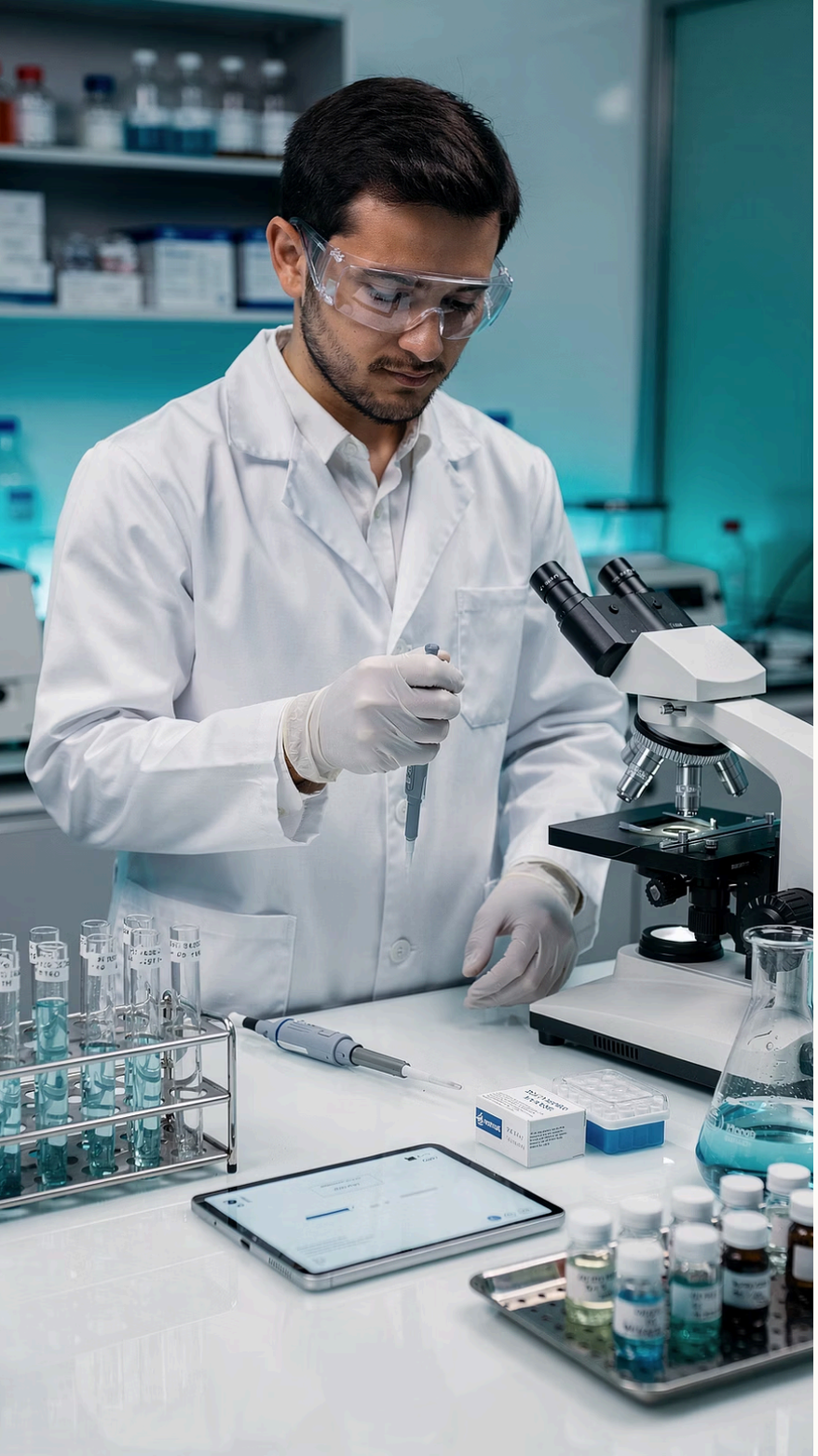
Sperm DNA damage detection and classification across three reported DNA damage categories for clinician interpretation.

Academic Pedigree

25+ years of peer-reviewed research supporting the clinical framework.

IP Protection

Patent applications filed across multiple jurisdictions — patent status should be verified and described accurately before publication



How the SpermComet® Assay Works

The SpermComet® assay is a five-stage clinical process that processes a semen sample into a structured report detailing DNA fragmentation at single-cell resolution. Each stage is standardised with standardised procedures designed to support reproducibility and clinical interpretation.

1

Sample Preparation

Isolate and embed sperm cells

2

DNA Unwinding

Alkaline treatment and electrophoresis

3

Fluorescence Visualisation

Stain and image individual comets

4

Comet Classification

Expert scoring of damage patterns

5

Report & Interpretation

Generate clinical report for clinician interpretation

Step 1: Sample Preparation

SpermComet® accepts both fresh and cryopreserved human semen samples, supporting use across IVF centres, andrology units, and remote collection sites. Rigorous preparation at intake supports analytical validity and supports interpretation of DNA fragmentation findings.

01

Input Accepted

Fresh or cryopreserved human semen samples.

02

Quality Assessment

Volume, motility, and concentration measured at intake.

03

Cell Isolation

Sperm cells washed free of debris and leucocytes.

04

Slide Loading

Cells loaded at defined density onto agarose-coated slides.

Step 2: DNA Unwinding & Electrophoresis

Following slide loading, cells are lysed within an agarose gel matrix and subjected to alkaline unwinding, exposing the DNA for analysis. An electric field then allows differential migration of DNA fragments for analysis, with the extent of migration reflecting the degree of strand breakage.

Intact DNA Behaviour

Remains tightly supercoiled near the nucleus, with minimal migration under the electric field. Produces a compact head with negligible tail extension.

Damaged DNA Behaviour

Strand breaks relieve supercoiling constraints, allowing DNA to unwind and migrate toward the positive electrode. Tail length and intensity may reflect the degree of DNA migration associated with strand breakage

Step 3: Visualisation & Fluorescence Imaging

Stained with SYBR Gold fluorescent dye, slides are imaged at high magnification under fluorescence microscopy. Strict quality controls are used so that only cells meeting defined criteria proceed to classification.

400x

Minimum Magnification

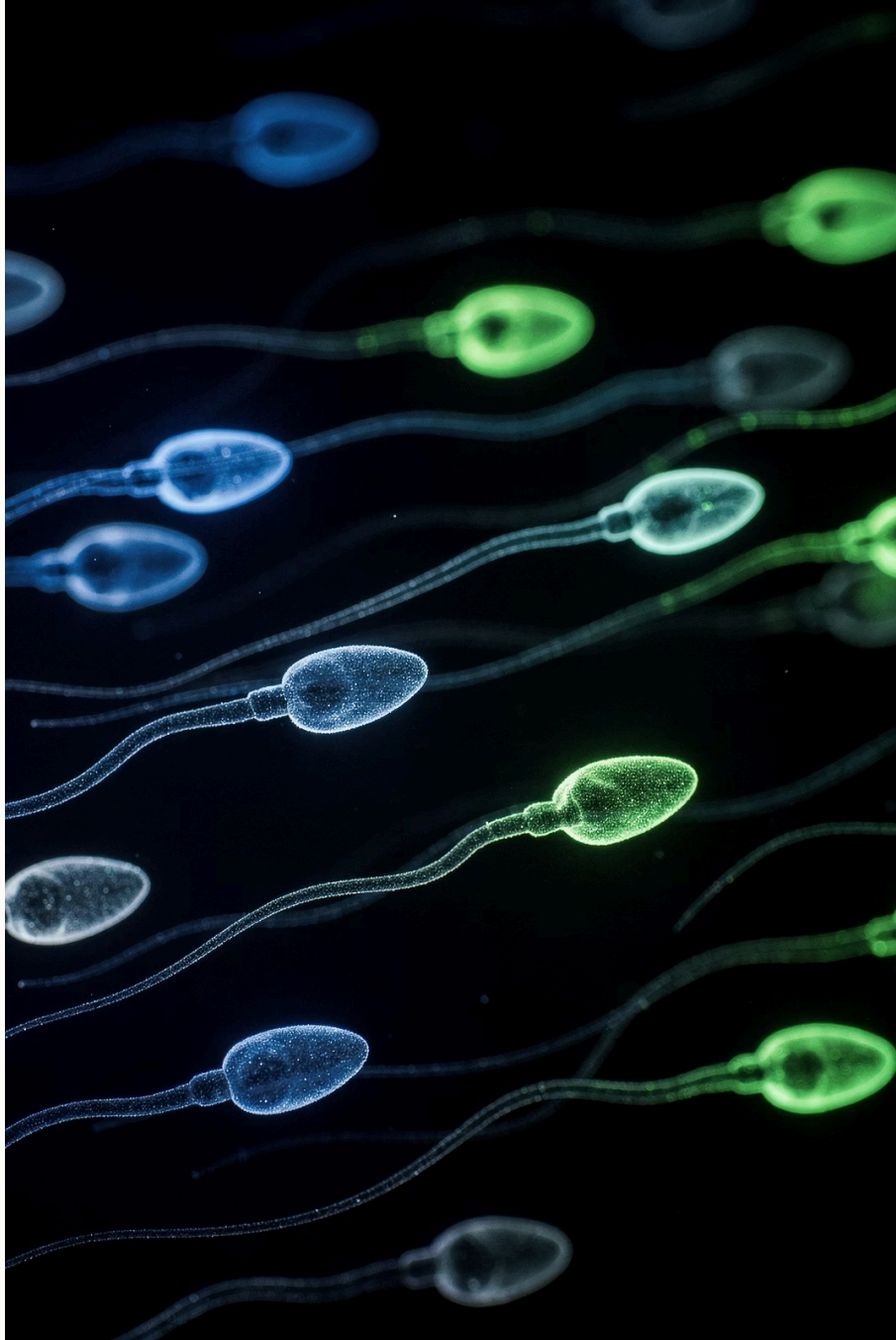
Each cell imaged at 400x to 1000x for precise comet morphology capture.

100–500

Cells Analysed

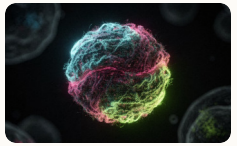
Per-sample cell count supporting statistical confidence in fragmentation indices.

Cells that are overlapping, out of focus, or at the slide periphery are excluded — only those meeting defined morphological and positional criteria proceed to classification.



Step 4: Comet Pattern Classification

Classification is performed by trained laboratory scientists using defined criteria, who manually examine every imaged cell and assign it to a damage category. This approach differs from fully automated methods.

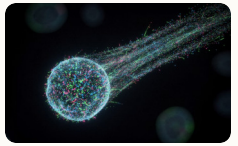


Class 0: Intact DNA

Tight nuclear sphere with minimal or absent tail extension. DNA remains fully compacted; no strand breaks detected within the assay criteria. Reported category: Intact DNA pattern.

Class 1: Single-Strand Breaks

Visible comet tail of moderate length. One strand of the DNA double helix is broken; the other remains intact. May be more amenable to oocyte-mediated repair, depending on clinical context. Reported category: Single-strand DNA break pattern.



Class 2: Double-Strand Breaks

Extensive tail with large migration distance. Pattern consistent with double-strand DNA damage by assay criteria. May be less readily repaired after fertilisation. Reported category: Double-strand DNA break pattern.

Clinical Interpretation of Damage Categories

The distinction between single-strand and double-strand DNA damage may have clinical relevance in selected fertility investigations. These findings may support clinician-led discussion of possible next steps, and should not be used in isolation to determine treatment.

Class 1 — Single-Strand Breaks

Single-strand DNA breaks (ssDB) represent damage to one strand of the double helix. Because the complementary strand remains intact, it may serve as a reference for repair processes. In some circumstances, oocyte repair mechanisms may contribute to repair of certain lesions after fertilisation, depending on multiple factors including oocyte quality.

Clinician-led considerations may include:

- Lifestyle modification: antioxidant supplementation, dietary improvement, exercise
- Medical treatment with targeted vitamins and micronutrient protocols
- Suitability for timed intercourse, IUI, IVF, or ICSI should be determined by the treating clinician using the full clinical picture

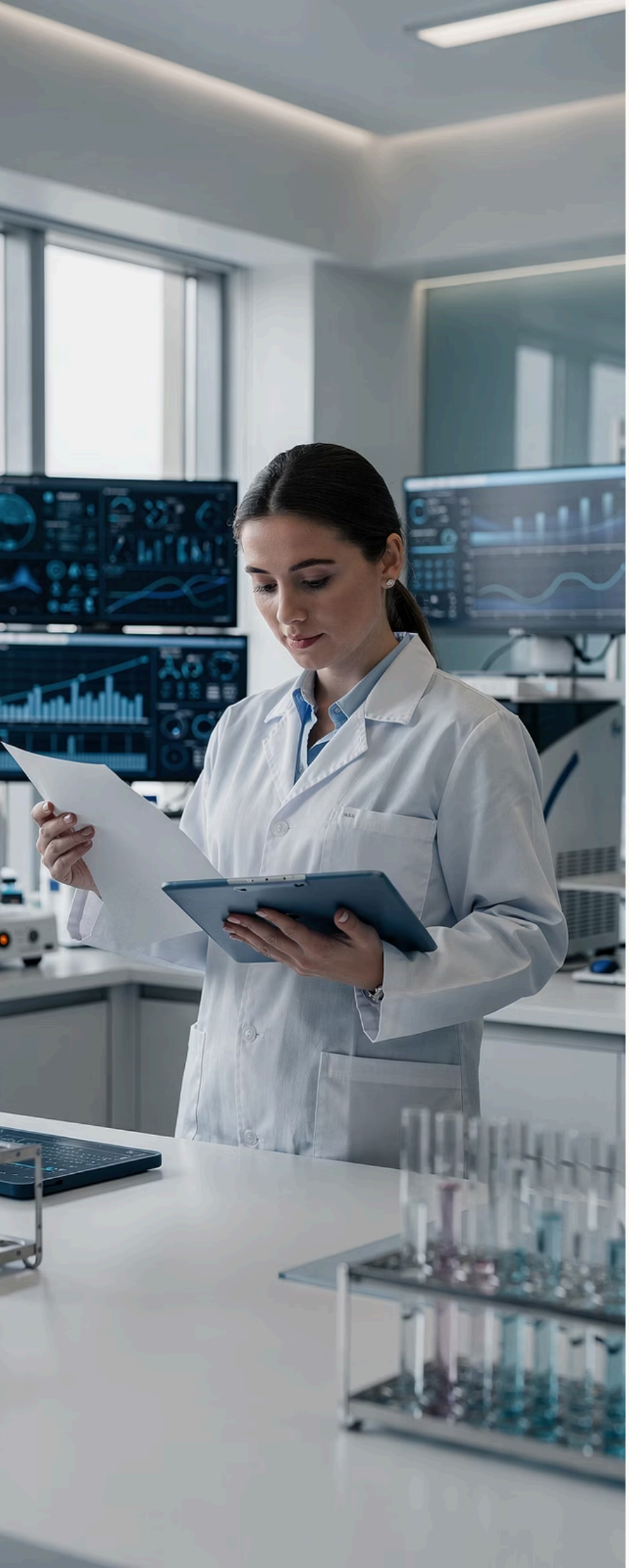
Class 2 — Double-Strand Breaks

Double-strand DNA breaks (dsDB) represent a more clinically significant pattern of DNA damage. With both strands affected, the DNA may be less amenable to accurate repair. Oocyte repair capacity may be limited, depending on multiple factors.

Reported associations in some studies may include:

- Fertilisation failure
- Embryo development arrest, depending on study context
- Implantation failure
- Pregnancy loss in some clinical contexts

Potential clinician-led considerations: Further male-factor assessment, lifestyle or medical review, ART protocol discussion, or specialist counselling may be considered where clinically appropriate.



Step 5: Report Generation & Clinical Output Metrics

The SpermComet® report translates the single-cell classification data into a structured clinical report for clinician interpretation. It disaggregates total DFI into its constituent damage types to support discussion of treatment planning in context.

Total DFI %

Percentage of all sperm cells carrying any DNA damage — the headline metric supporting clinical interpretation of sperm DNA fragmentation.

Single-Strand Breaks (ssDB) %

Proportion of cells with Class 1 damage. May contribute to clinician-led discussion of oocyte repair potential and ART options, as part of the full clinical picture.

Double-Strand Breaks (dsDB) %

Proportion of cells with Class 2 damage — a clinically relevant metric that has been associated with embryo development and pregnancy outcomes in some studies.

High DNA Stainability (HDS) %

Proportion of cells exhibiting abnormal chromatin packaging — an indicator of immature sperm or incomplete nuclear condensation separate from strand break pathology.

Intact Cells (Class 0) %

Percentage of fully undamaged sperm — may provide contextual information about overall sample quality when interpreted alongside other findings.

What the Report Delivers

The SpermComet® clinical report is produced within 10–15 business days and is structured to meet the information needs of both the referring clinician and the patient.

It combines quantitative results, representative images supporting laboratory interpretation, and expert interpretation in a single clinical document.

Numerical results with reported reference ranges

Reported reference ranges, where applicable, are based on laboratory validation and published evidence, for clinician interpretation within reported reference categories.

Representative images of the cell population per damage class

Representative images of the cell population driving the quantitative indices — supporting clinician interpretation and patient communication.

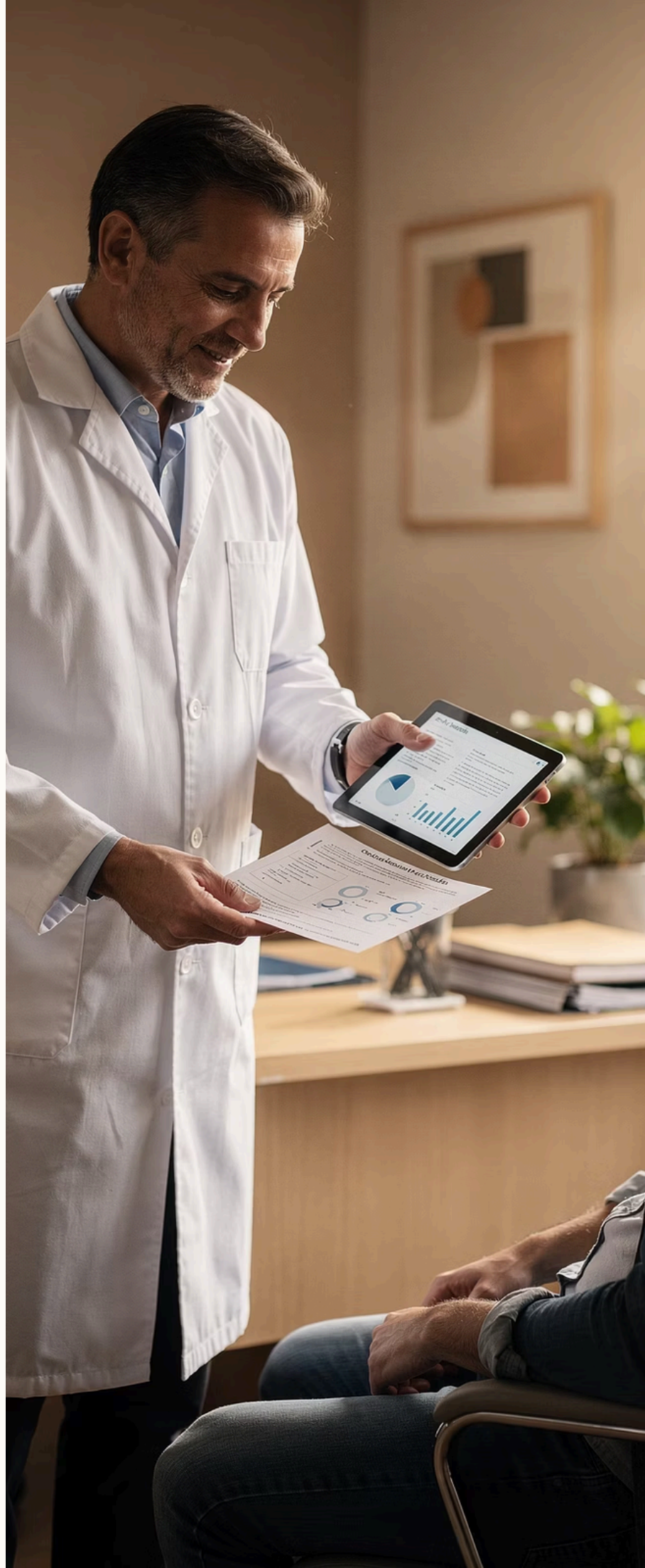
Graphical damage distribution and longitudinal comparison

Population-level heterogeneity data and comparison with prior results where available.

Clinical interpretation notes

Evidence-based clinical interpretation notes embedded within the report narrative — to support clinician-led treatment considerations where appropriate.

Turnaround Time: 10–15 business days from sample receipt. Both fresh and cryopreserved samples accepted. Contact Examen to discuss logistics for your laboratory or clinic.



This information is intended for healthcare professional education and technical understanding only. SpermComet® results should be interpreted by a qualified clinician alongside semen analysis, female-factor assessment, reproductive history, embryo development data, and other relevant investigations. The test does not diagnose infertility on its own and does not determine treatment eligibility or mandate IUI, IVF, ICSI, PICSI, PGT-A, sperm donation, or any other treatment pathway. Sperm DNA testing does not guarantee fertilisation, pregnancy, live birth, miscarriage reduction, treatment success, or improved fertility outcomes.