

B2B Clinical Objections

Examen Lab Limited

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All claims substantiated by peer-reviewed literature. SpermComet® is a registered trademark of Examen Lab Limited. Regulatory status varies by jurisdiction.



OBJECTION 1

The Pricing Barrier

"4,500 AED is far too expensive for a single diagnostic add-on. Our patients are already financially stretched by the base cost of an IVF/ICSI cycle."

0.51

Live Birth OR

Published association
when IOD $\geq 6\%$ (RBMO)*

AUC 0...

Diagnostic
Accuracy

SpermComet® published
validation*

Reframe the Cost

The diagnostic fee is a clinical filter — not an add-on cost.

The Real Risk

A failed IVF/ICSI cycle carries substantial financial, physical, and emotional burden. Informed diagnostics support more targeted treatment planning.

Evidence-Based

Data sourced from Reproductive BioMedicine Online (RBMO). Diagnostic selection guided by validated clinical evidence may contribute to improved patient outcomes.

* Peer-reviewed published data (RBMO). Clinical outcomes vary. Results not guaranteed. References available from Examen Lab Limited.



OBJECTION 2

Belfast Logistics & Cold-Chain Transit

"Shipping frozen biological samples internationally to Belfast is an operational nightmare — transit delays, customs risks, and costs our clinic cannot absorb."

Logistics pathways vary by country. Clinicians should confirm import/export requirements with Examen prior to dispatch.

Local Hand-Off

Accredited domestic partners. No international logistics burden on your team.

Dry Shipper Deployed

Up to 100 cryovials. Optimal temperature maintained up to three weeks, subject to operational conditions.

ISO 15189 Reporting

Digital diagnostic reports delivered to your secure clinic portal within agreed turnaround times.





OBJECTION 3

Methodology vs. Other Approaches

"Why switch to SpermComet®? We already run SCSA, TUNEL, or Halosperm locally at a fraction of the cost."

SpermComet®

Direct Measurement

Physical quantification of broken DNA strands at the single-cell level.

Double-Strand Specific

Quantifies double-strand breaks (dsDNA) specifically — not a composite fragmentation index.

Minimal Sample Volume

Requires only a very small semen volume — suitable for oligozoospermic patients and low-count samples where other methods may be impractical.

Single-Cell Resolution

Analyses each sperm cell individually — not a population average — enabling detection of heterogeneity within the sample.

Published AUC: 0.930*

High clinical predictability validated in peer-reviewed literature.

Other Methodologies (e.g. SCSA, TUNEL, Halosperm)

Indirect Measurement

Chemical susceptibility or fluorescent dye-based detection of chromatin vulnerability.

Total Index Only

Typically measures total DNA fragmentation index; strand-specific differentiation may be limited.

Higher Volume Requirement

Methods such as SCSA typically require larger semen volumes and higher sperm concentrations, which may limit applicability in some patient populations.

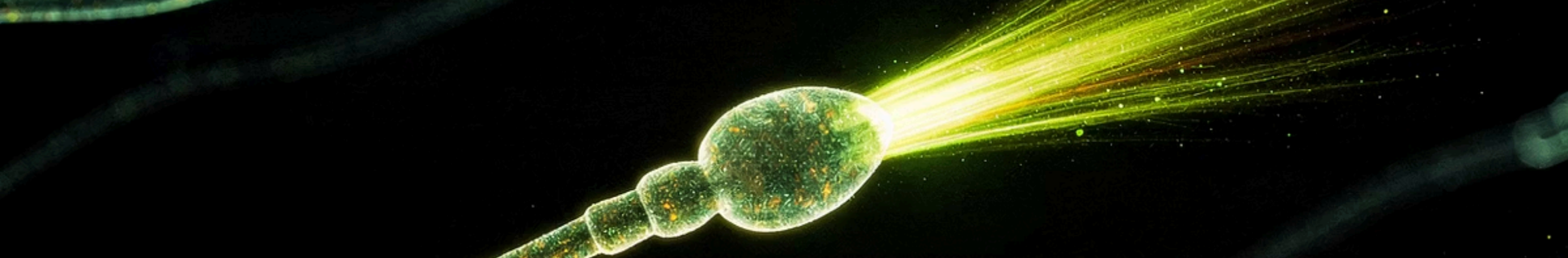
Population-Level Readout

Results reflect a population average across the sample — individual cell-level variation may not be captured.

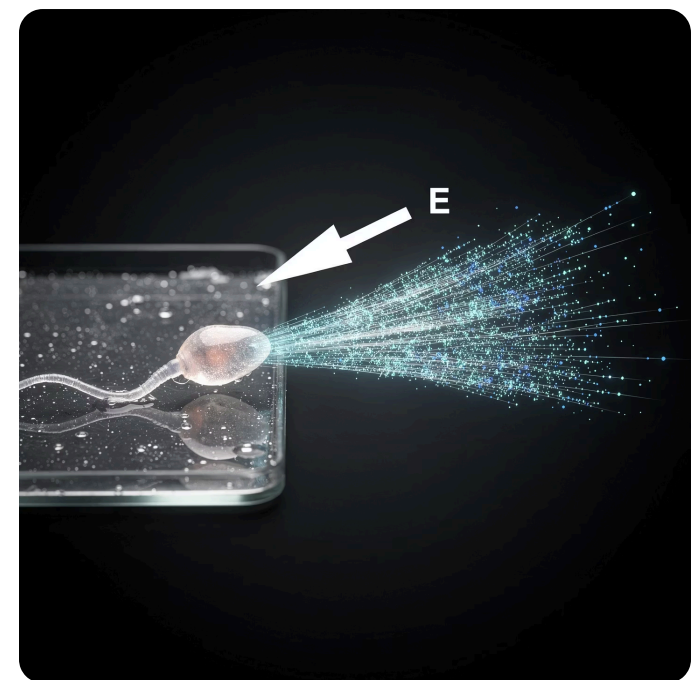
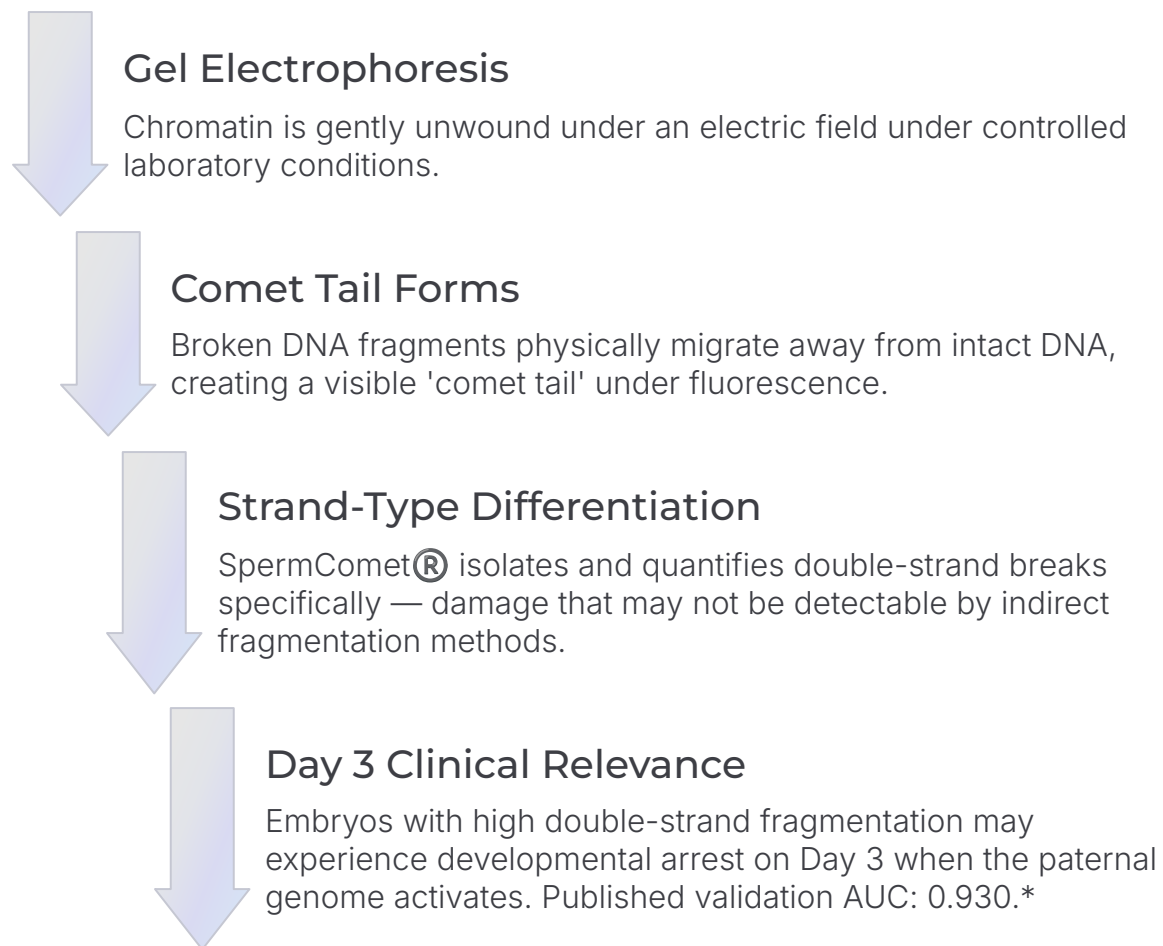
Variable Predictability*

Sensitivity and predictive value vary by methodology and clinical context.

* Comparative data from peer-reviewed literature. For educational purposes only. Does not constitute a guarantee of clinical superiority. References available from Examen Lab Limited.



The Science Behind SpermComet®



* AUC of 0.930 from peer-reviewed validation studies. Individual clinical outcomes may vary. For qualified healthcare professionals only.

OBJECTION 4

The Commercial Profitability Equation

"Introducing an expensive external service could disrupt our internal profit margins from in-house andrology panels."



Zero CapEx

No hardware, kits, or specialist staff required. Examen operates under ISO 13485 quality management and ISO 15189 accreditation standards.



Auxiliary Revenue

Clinics may apply a structured markup to the applicable service fee. Commercial terms agreed directly with Examen. Indicative only — not a financial guarantee.



Expanded Clinical Offering

SpermComet® data may support earlier clinical consideration of microfluidic sorting or testicular sperm extraction where clinically indicated.

Commercial terms are indicative and subject to individual clinic agreement. Not a binding commercial offer.



Further Clinic Objections: Quick Responses

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"We already do DNA fragmentation testing."

SpermComet® differentiates between specific damage types via direct single-cell quantification — published data indicates this may provide additional clinical information for tailored ICSI/IVF decisions.

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"How much does it cost?"

Pricing scales with monthly sample volumes — zero upfront capital expenditure. Contact Examen to discuss a structure for your location or network.

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"Is this approved in the UAE / India?"

SpermComet® is an LDT performed at Examen's ISO 15189-accredited Belfast facility under UK/EU regulatory frameworks. Sample prep kits are subject to local IVD regulations. Examen provides full regulatory documentation support upon request.

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Regulatory status varies by jurisdiction. This material does not constitute regulatory advice. Clinicians should seek independent regulatory guidance applicable to their country of practice.

Technical Logistics & Partner Integration



Kit Stability

60-second preparation protocol stabilises the sample immediately. Specialist couriers manage temperature-regulated cold-chain transport. Customs coordinated by Examen with the receiving clinic.



Onboarding & Training

Dedicated training session for embryology staff, plus validation support materials and diagnostic interpretation guides from Examen upon integration.



Clinic Portal Reporting

Digital diagnostic reports delivered to your secure clinic portal, reducing manual data entry and result follow-up.

Onboarding timelines and turnaround times are indicative and subject to individual clinic agreement with Examen Lab Limited.

The Retention Argument

Live Birth OR

IOD $\geq 6\%$ associated with significantly reduced live birth odds (RBMO, published data)*

AUC Score

SpermComet® published validation — fertility discrimination accuracy*



* OR from RBMO publication. AUC from SpermComet® validation studies. Individual outcomes vary. Not a guarantee of clinical outcome.

Precision Supports Retention

Precise diagnostics support informed patient expectations and enable clinicians to pivot to appropriate interventions — microfluidics, Testi-ICSI, or antioxidant protocols — where underlying causative factors are identified.

Outcomes Data Matters

Repeated unexplained failures can erode patient confidence and affect clinical outcomes data. Targeted diagnostics support more informed treatment decisions.



The Examen Partnership Proposition

A validated diagnostic framework addressing clinical, operational, and commercial needs.



Diagnostic Precision

Direct single-cell quantification of double-strand DNA breaks.
Published validation AUC: 0.930.*



Structured Logistics

Two cold-chain pathways designed to minimise administrative and logistics complexity for your team.



Zero CapEx Growth

Potential auxiliary revenue, full onboarding, and ISO-accredited reporting — no capital investment required.



Examen Lab Limited — supporting clinicians with validated diagnostic tools and the infrastructure to advance evidence-based fertility medicine.

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