Our Commitment to Quality

At Examen, quality is at the heart of everything we do. Our robust quality framework ensures every test and service meets the highest international standards, giving confidence to our partner clinics and to you as a patient.

ISO 15189

UKAS Accredited Laboratory

ISO 13485

BSI Certified Quality Management

UK Registered

MHRA Medical Devices Registration

View Accreditations

Verify Certification

ISO Certification & Accreditation

We hold two distinct certifications that work together to guarantee the quality of our entire testing service — from the design and manufacture of our tests through to the delivery of results in our accredited laboratory.

UKAS MEDICAL 25925

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED MD 723205

ISO 15189

Accredited for laboratory service delivery — verifying the technical competence, integrity, and impartiality of our medical laboratory. Laboratory no: 25925.

ISO 13485

Certified for test design and safety — covering quality management systems for in vitro diagnostic (IVD) medical devices, including our Exact® and Extend® tests.

UK Medical Devices

Registered with the MHRA under UK Medical Devices Regulations. Certificate number 25925, confirming compliance with UK regulatory requirements for medical devices.

ISO 15189 — Accredited Laboratory Service

ISO 15189 is an internationally recognised standard that verifies the technical competence, integrity, and impartiality of medical laboratories. This accreditation applies specifically to the delivery of our medical laboratory services, including the testing process itself. Our laboratory holds accreditation number **25925**, independently verified by UKAS.

Expert Team

The technical competence and integrity of our laboratory team who handle your sample is fully assured under this accreditation. Every member of staff operates within a rigorously controlled quality environment.

Accurate Results

Stringent quality control measures and external comparisons are used to continuously verify the accuracy and reliability of all produced test results, giving you and your clinician complete confidence in every report.

Independently verified by UKAS · Laboratory no: 25925

ISO 13485 — Certified for Test Design & Safety

ISO 13485 is an internationally recognised standard for quality management systems in the medical device industry, including in vitro diagnostic (IVD) tests. This certification applies to the design, development, and manufacture of our DNA-based assays — the Exact® and Extend® tests — and is certified by BSI under certificate number **MD 723205**.

Safe & Reliable Tests

Every test and all of its components have been designed and manufactured with rigorous risk management and quality controls embedded throughout the entire development process.

Guaranteed Best Practices

We follow best practices throughout the entirety of the test's life cycle — from initial design through to manufacture and post-market surveillance — ensuring the quality of the test itself never wavers.

BSI Certified · MD 723205 · ISO 13485 Quality Management for Medical Devices

UK Medical Devices Registration

In addition to our ISO certifications, Examen holds registration with the Medicines and Healthcare products Regulatory Agency (MHRA) under the UK Medical Devices Regulations. This registration, under certificate number **25925**, confirms that our medical devices — including our sperm DNA fragmentation tests — meet the regulatory requirements applicable in the United Kingdom. It is an important layer of assurance for UK-based clinics and patients, demonstrating that our products have been assessed against UK regulatory standards and are legally placed on the UK market, complementing our ISO 15189 laboratory accreditation and ISO 13485 quality management certification.

Regulatory Body

MHRA — Medicines and Healthcare products Regulatory Agency

Certificate Number

25925 — UK Medical Devices Registration

Scope

Covers our sperm DNA fragmentation and semen analysis tests placed on the UK market

The Exact® Test — Total SDF Damage

The Exact® test measures **Total SDF damage**, encompassing both single and double strand breaks in sperm DNA. It is intended for use with sperm concentrations **above 0.1M/ml** and provides a comprehensive picture of overall sperm DNA integrity. This test is self-certified as a general IVD in accordance with EU IVDD 98/79/EC and holds full ISO 15189 accreditation.

Parameter	Detail
Measures	Total SDF damage (single and double strand breaks)
Used For	Sperm concentrations above 0.1M/ml
CE Mark Status	Self-certified as a general IVD — EU IVDD 98/79/EC
ISO 15189 Status	Accredited — Laboratory no: 25925

The Extend® Test — Double-Strand DNA Breaks

The Extend® test specifically measures **double-strand DNA break (dsDB) damage** in sperm — a more targeted assessment that provides additional clinical insight beyond total fragmentation. Like the Exact® test, it is designed for use with sperm concentrations **above 0.1M/ml** and is self-certified as a general IVD in accordance with EU IVDD 98/79/EC. It holds full ISO 15189 accreditation under laboratory number 25925.

Parameter	Detail
Measures	Double-strand DNA breaks (dsDB) damage
Used For	Sperm concentrations above 0.1M/ml
CE Mark Status	Self-certified as a general IVD — EU IVDD 98/79/EC
ISO 15189 Status	Accredited — Laboratory no: 25925

ⓘ The Extend® test is particularly valuable in clinical scenarios where double-strand break damage is suspected as a contributing factor to male factor infertility or recurrent pregnancy loss.

Semen Analysis — Accredited Diagnostic Testing

Our ISO 15189 accredited Semen Analysis assesses sperm **concentration, motility, and morphology** — the three core parameters of male reproductive health. This test serves multiple clinical applications and is accredited under laboratory number **25925**.

Fertility Diagnosis

Assists clinicians in diagnosing male factor infertility by providing a detailed, standardised assessment of sperm quality across all key parameters.

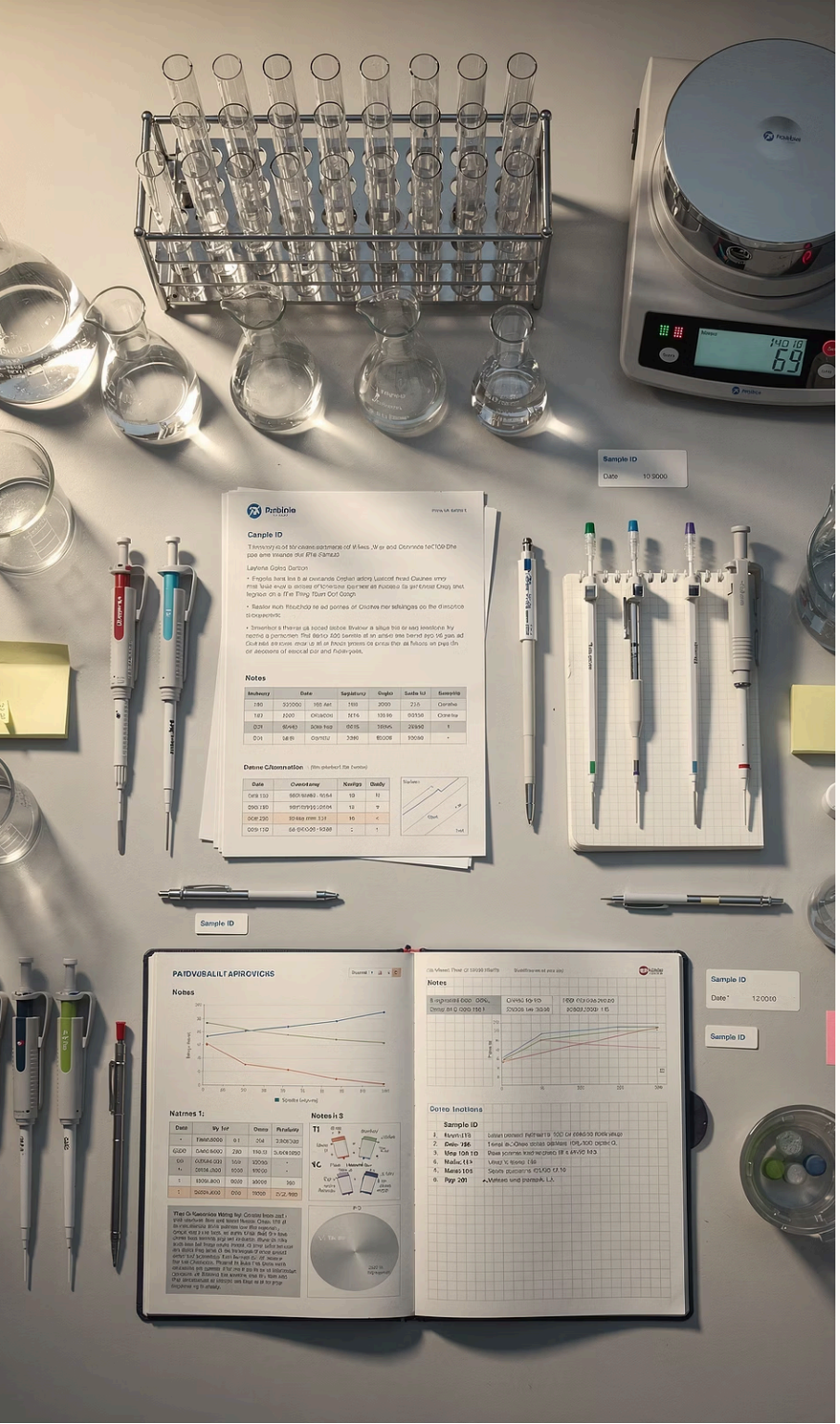
ART Procedure Guidance

Assesses male reproductive health and guides the choice of assisted reproductive technology (ART) procedure most appropriate for the patient's clinical profile.

Treatment Monitoring

Monitors a patient's response to treatments over time, enabling clinicians to evaluate the effectiveness of interventions and adjust care plans accordingly.

ISO 15189 Accredited · Laboratory no: 25925



Accreditations at a Glance

All three of our core tests hold ISO 15189 accreditation under UKAS laboratory number 25925. The table below summarises the accreditation status and key applications across our full test portfolio.

Test	Measures	CE Mark	ISO 15189
Exact®	Total SDF damage (single & double strand breaks)	Self-certified IVD — EU IVDD 98/79/EC	Accredited · Lab no: 25925
Extend®	Double-strand DNA breaks (dsDB)	Self-certified IVD — EU IVDD 98/79/EC	Accredited · Lab no: 25925
Semen Analysis	Concentration, motility & morphology	—	Accredited · Lab no: 25925

All tests require sperm concentrations above 0.1M/ml (Exact® and Extend®). Accreditation independently verified by UKAS. UK Medical Devices Registration: 25925.

Quality You Can Trust

Examen's multi-layered quality framework — spanning ISO 15189 laboratory accreditation, ISO 13485 quality management certification, and UK Medical Devices Registration (no. 25925) — represents our unwavering commitment to the highest standards in reproductive health testing.

Whether you are a clinician seeking a reliable diagnostic partner or a patient wanting confidence in your results, our accreditations provide independent, internationally recognised assurance at every stage — from test design and manufacture through to laboratory delivery and reporting.

ISO 15189

UKAS Accredited Laboratory · No. 25925

ISO 13485

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UK Medical Devices

MHRA Registered · No. 25925

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Verify Our Accredita...

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