

Test Request Form (TDL)

Please note: Examen cannot perform any testing unless this Test Request Form is fully completed.

Please email the completed form to TRF@examenlab.com OR include a hard copy inside the shipper with the patient sample. Results are typically issued within **10 working days** of Examen receiving both the sample and a completed TRF.

Test: (Tick ONE box only)

- Exact® (CMET)
 Extend® (CMT3)
 Extensiv (CMT5)

(Please see Test Overview at the foot of page 2)

Sample Details:

Sample Collection Date (DD-MMM-YYYY):	<input type="text"/>
Abstinence (Days, Hours):	<input type="text"/>
Sperm Concentration (M/ml):	<input type="text"/>
Type (Ejac, Prep Ejac, SSR):	<input type="text"/>
Was All Sample Collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the Sample Biohazardous?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes", Provide Details (E.g. HIV, HepB, etc):	<input type="text"/>

Patient/Clinic Details: Please use BLOCK CAPITALS

Patient First Name & Surname:	<input type="text"/>	Patient Date of Birth (DD-MMM-YYYY):	<input type="text"/>	Tick here if you were referred:	<input type="checkbox"/>
Clinic Name:	<input type="text"/>	Referring Clinician:	<input type="text"/>		
Clinic Patient ID:	<input type="text"/>	Email Results to:	<input type="text"/>		

I have read and understood this form and give consent for Examen to handle and process my sample and data to produce my test result.

Patient Signature:	<input type="text"/>	Date (DD-MMM-YYYY):	<input type="text"/>
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Additional Patient Consents Below, we ask for your permission to: a) allow us to use any leftover sample from your test for specific purposes, and b) allow us to contact you in the future to ask about outcomes related to your test.

Optional consent - R&D and collaboration

After my test has been completed, I agree that any leftover sample (and related test information) may be stored and used by Examen to support the research and development of new or improved tests. This may include sharing leftover samples and/or related information with trusted research or academic partners for research purposes, only where appropriate approvals are in place and the sample and associated data is anonymised to protect my identity. I understand that:

- This is **optional** and my decision will **not affect my care or test**.
- My personal identity will **not be shared** with partners where the sample/data is anonymised.
- I will not benefit financially from any newly developed tests.
- I can **withdraw this consent at any time** by contacting Examen (however, it may not be possible to withdraw once my sample/data has been anonymised and used).

I consent to the use of my leftover sample for R&D and collaboration as described above.

Initials: Date (DD-MMM-YYYY):

Optional consent - Future Contact

I consent to Examen (or its authorised representatives) storing and using my contact details to contact me in the future to request follow-up information relating to my test, for the purpose of ongoing clinical performance evaluation and regulatory compliance (including under the In Vitro Diagnostic Regulation (IVDR)). This follow-up may include questions about relevant health and outcome information (e.g. any further investigations, treatment, or other outcomes following my test). I understand that:

- This consent is **optional** and does **not affect my test or results**.
- My personal data will be processed in accordance with applicable data protection laws.
- I can **withdraw my consent at any time** using the contact details below.

I consent to being contacted for follow-up outcomes

Initials: Date (DD-MMM-YYYY):

Preferred Contact Method:

- Email
 Phone

To withdraw your consent at any time, please contact TRF@examenlab.com or phone +44 (0)28 9023 8915.

Examen Use Only:

Storage location:	<input type="text"/>	No. of Vials:	<input type="text"/>	Examen ID:	<input type="text"/>	Operator:	<input type="text"/>	Accepted:	<input type="checkbox"/>
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How to complete the Test Request Form (TRF):

Please select the appropriate test and complete all sections of the TRF. For details on available tests and bundles, see the test overview below, access additional information via the QR code supplied or visit examenlab.com. The form may be completed electronically or handwritten (please use **BLOCK CAPITALS**) and returned to Examen. Each TRF accepted by Examen is treated as an agreement between Examen and the patient.

Patient Preparation:

Abstain from ejaculation for at least 48 hours and no more than 7 days (unless your referring clinician advises a shorter period). Do not urinate immediately before producing your sample.

Instructions for collecting your sample:

Collect your sample by manual masturbation only, without using lubricant, saliva, or condoms. Ejaculate fully into the sample pot provided and record any spillage on the TRF. Your clinic must ensure your sample is cryogenically frozen within 60 minutes of production, in line with the Examen Sample Handling Protocol (QF164).

Instructions for Transportation of Samples (Clinics):

Contact Examen at lab@examenlab.com to arrange a dry vapor shipper to transport your samples. Samples are held at cryogenic temperatures during transport and stored in liquid nitrogen upon arrival at Examen, until analysis.

Interfering Factors:

Factors that may affect test performance or Examen's ability to run the test include: insufficient sample volume (a minimum of 100µl is required), not collecting the first part of the ejaculate (which may contain the highest concentration of sperm), excessive cellular debris, and failure to freeze the sample within 60 minutes.

Laboratory sample acceptance/rejection criteria:

For each test requested, we require:

1. A fully completed and signed TRF for that test.
2. The correct sample volume, as follows:
 - a. Exact (CMET) or Extend (CMT3): 2 x 100µl vials per test, with at least 100µl available.
 - b. Extensiv (CMT5): 4 x 100µl vials, with at least 2 x 100µl available.
3. Each vial must be labelled with the patient's full name or clinic patient ID, date of sample collection, and patient date of birth.

If a sample does not meet the requirements in points 1-3, it cannot be tested and will be rejected. Samples may also be rejected if they are not labelled or incorrectly labelled, compromised during shipping, improperly collected, or from an unacceptable source/type. If a sample is rejected, we will inform you (or your clinic, where applicable) and provide the reason.

Clinical advice and result interpretation:

Referred patients: Please seek clinical advice in the first instance from your referring clinician, who will have access to relevant clinical information for you and your partner, including medical history and any existing infertility diagnosis.

Self-referred patients: If you would like further support interpreting your results, Examen can connect you with a fertility clinician who can provide guidance (note: this is an independent service and consultation fees may apply). Please contact myresults@examenlab.com for more details.

Patient consent:

By submitting a specimen and TRF for testing, you agree that Examen may record and use the clinical information you provide in order to perform the test and issue your results.

Where a medical professional submits a specimen, they confirm that the patient's consent for this data use has been obtained. After your test is complete, any leftover sample may be used internally for quality assurance, staff training, and performance monitoring to ensure our testing remains accurate and reliable. Any such use is strictly controlled and follows appropriate governance and data protection requirements. Leftover samples used for these internal purposes are anonymised, with no identifying details recorded against them. For clarity, "remaining" or "leftover" sample means any surplus amount of your sample that remains once all requested testing has been completed. Separate optional consents are provided if you wish to:

- allow your leftover sample (and related test information) to be used for research and development (R&D) of new or improved tests and shared with approved research partners; and/or
- allow Examen to contact you in the future to request follow-up outcome information for ongoing clinical performance evaluation and regulatory compliance (including IVDR).

Protection of personal information:

Examen records and stores certain information about you in order to provide accurate diagnostic test results. Your information will be stored securely in line with applicable data protection laws (including GDPR) and will only be accessible to authorised personnel. Wherever possible, we remove identifying details to protect your confidentiality and handle your information in a way that safeguards your identity. For our full privacy policy, please visit: <https://examenlab.com/privacy-policy/>.

Your right to complain:

If you are unhappy with our service, please speak to an Examen staff member or contact us on contact@examenlab.com. We handle all complaints promptly and confidentially, both to resolve your concerns and to help improve our services.

Examen Details:

Address: Examen, Unit 10G, Weavers Business Park, Linfield Road, Belfast, BT12 5GH.

Laboratory Operating Hours: 08:00-16:00 GMT, Mon-Fri.

Contact Number: +44 (0)28 9023 8915

Overview of Sperm DNA Fragmentation (SDF) Tests Please ask your healthcare practitioner or contact Examen if you are unsure of which test to select.

Exact (CMET):	Total Sperm DNA Fragmentation damage (single- and double-strand DNA breaks). Suitable for cases that have experienced difficulty conceiving for more than 1 year. Provides a broad view of sperm DNA integrity.
Extend (CMT3):	Double-strand DNA Break (dsDB) damage only. Suitable for cases of recurrent miscarriage or advanced ART planning. Provides deeper insight into the nature and severity of DNA damage.
Extensiv (CMT5):	A comprehensive test package that includes both the Exact total SDF damage test (single- and double-strand DNA breaks) and the Extend dsDB damage test.

Scan the QR code for full T&Cs and full test descriptions

