

Test Request Form (TDL)



NB: ExamenLab will not perform any test unless this Test Request Form is completed.

Please email the completed form to TRF@examenlab.com and send with the patient sample.

Results are usually sent out within 10 working days from receipt of your sample at Examen's laboratory.

Test: (Tick ONE box only)

Exact® (CMET)

Extend® (CMT3)

ExactFocus® (CMT2)

ExtendFocus® (CMT4)

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

Sample Details:

Date of Sample Collection:

DD / MM / YYYY

Abstinence (days):

Sperm Concentration (M/ml):

Type (Ejac, Prep Ejac, SSR):

Was All Sample Collected?

Yes

No

Patient/Clinic Details: (Please complete in BLOCK CAPITALS)

Patient First Name & Surname:

Patient Date of Birth:

DD / MM / YYYY

Tick here if you were referred:

Clinic Name:

Referring Clinician:

Clinic Patient ID:

Email Results to:

Patient Consent:

Below we ask that now and in the future you a) allow us to use any left-over sample not used in your test for some very specific purposes, and b) you allow us to contact you in the future about your test outcome.

Enduring consent to retain and use any remaining sample:

Once testing has been completed, I hereby give my explicit and enduring consent for any remaining sample of mine (and associated data) to be stored and retained by ExamenLab **solely for the purposes of training, performance assessment, quality assurance and future test development**. I acknowledge that the remaining sample will only be used for the purposes specified above; any personal identifiable information will be protected and will never be disclosed in relation to the use of the remaining sample; and I have the right to withdraw my consent at any time using the contact details below. By initialling the **Opt In** box below, I confirm that I have read and understood the information provided and agree to the retention and use of my remaining sample as described.

To **OPT IN** to enduring consent, please initial box:

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

Consent for future contact:

I hereby consent to ExamenLab Ltd or its representatives storing and using my contact details for the purpose of providing me with test results related to the sample provided by me on the date of this form, and to be contacted in the future to obtain information regarding outcomes related to that sample. I acknowledge that all personal data will be processed in accordance with all applicable data protection laws; and that I have the right to withdraw my consent at any time using the contact details below without affecting the lawfulness of any processing based on consent before its withdrawal.

To **OPT IN** to future contact consent, please initial box:

Patient Contact Details

Email:

Phone:

I have read and understood this form and give consent for ExamenLab to handle and process my sample and data.

Patient Signature:

Date:

DD / MM / YYYY

ExamenLab Use Only:

Storage location:

No. of Vials:

ExamenLab ID:

Operator:

Accepted:

Biohaz:

How to complete the Test Request Form (TRF):

Select the correct test and complete all sections of the TRF. For information on the available tests and bundles, see test overview below or please refer to www.examenlab.com. Forms can be completed electronically or handwritten (please use BLOCK CAPITALS) and sent to ExamenLab. Each accepted TRF by ExamenLab is considered an agreement between ExamenLab Ltd and the patient.

Patient Preparation:

Abstain from ejaculation for 2-7 days before sample collection (except where your referring clinician advises less than 2-days abstinence). Do not urinate just prior to producing your sample.

Instructions for collecting your sample:

Collect your sample via manual masturbation only without using lubricant, saliva, or condoms. Ejaculate fully into the sample pot provided and report any spillage of the sample on the TRF form. If producing your sample at home you must deliver the sample to a hub within 60 minutes of production, keeping it as close to body temperature as possible (see QF176 Kit Information Leaflet for detailed transport conditions).

Instructions for Transportation of Samples (Clinics):

Contact ExamenLab at lab@examenlab.com to arrange a dry vapor shipper to transport your samples. Samples are frozen at -190°C during transport and stored in liquid nitrogen until analysis.

Interfering Factors:

Factors affecting test performance can include: insufficient sample volume (at least 100µl needed); failure to collect the initial part of the ejaculate may result in the loss of the most sperm-rich element of it; excessive cellular debris; and failure to freeze samples within 60 minutes.

Laboratory sample acceptance/rejection criteria:

FOR EACH TEST REQUESTED we require:

1. a fully completed and signed TRF per test, and
2. 2 x 100µl vials of sample per test, and not less than 100µl for each test (NB samples for Focus variant can still be accepted if only 1 x 100µl vial of sample is available), and
3. each vial to be labelled with Patient Full Name OR Clinic Patient ID, Date of Sample Collection, and Patient Date of Birth

If a sample does not meet all criteria in 1 to 3 above it cannot be tested and will be rejected. Samples will also be rejected if they are unlabelled/incorrectly labelled, have been compromised during shipping, were improperly collected, or are from an unacceptable source/type. We will inform you or your clinic if a sample is rejected and provide the reason for this.

Clinical advice and result interpretation:

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

Self-referred patients: can access clinical advice, for an additional charge, from ExamenLab by contacting myresults@examenlab.com.

Patient consent:

By submitting a specimen and TRF for testing, you consent to ExamenLab recording clinical information data about you to provide your test results. ExamenLab may also use your anonymised information to advance future tests and medicines, potentially sharing it with both non-profit and commercial research partners. Your data will be securely stored under all applicable data protection laws including GDPR regulations, and only accessible by authorised personnel. You understand that your information will be kept confidential, used in a way that protects your identity, and that you will not benefit financially from any resulting new treatments or tests. **Medical professionals submitting a specimen confirm patient consent for this data use has been obtained.** Where we seek your consent to store and retain any remaining sample, we mean any surplus amount of your sample that is left-over after all testing has been completed. Left-over samples are retained solely for the purposes of training, performance assessment, and quality assurance, and all left-over samples are anonymised with no identifying details recorded against them.

Protection of personal information:

ExamenLab Ltd records and stores certain information about you to provide accurate diagnostic test results. Wherever possible we remove identifying details to ensure data confidentiality according to our legal duty to do so. For our full data privacy policy please visit <https://examenlab.com/privacy-policy/>

Your right to complain:

If you are unhappy with our service, please speak to an ExamenLab staff member on +44 (0)28 9023 8915 or contact us at TRF@examenlab.com. We handle complaints quickly and confidentially to both ensure your customer satisfaction and to help improve our services.

ExamenLab Details:

ExamenLab Ltd, Unit 18A Block K, Weavers Court Business Park, Belfast, BT12 5GH. Laboratory operating hours 08:00-16:00 GMT, Mon-Fri.



Overview of Sperm DNA Fragmentation (SDF) Tests

Exact (CMET): total SDF damage (single and double strand DNA breaks)

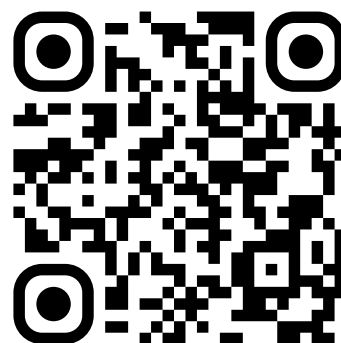
ExactFocus (CMT2): total SDF damage for severe oligozoospermia samples (<5M/ml)

Extend (CMT3): double strand DNA breaks (dsDB) damage only

ExtendFocus (CMT4): dsDB damage for severe oligozoospermia samples (<5M/ml)

Please ask your referring clinician if you are unsure which test you should select

Scan the QR code for full Terms & Conditions and full test descriptions at examenlab.com



QR241907