eurofins | Clinical Genetics

Laboratory Guide

www.eurofins.co.uk/clinical-genetics

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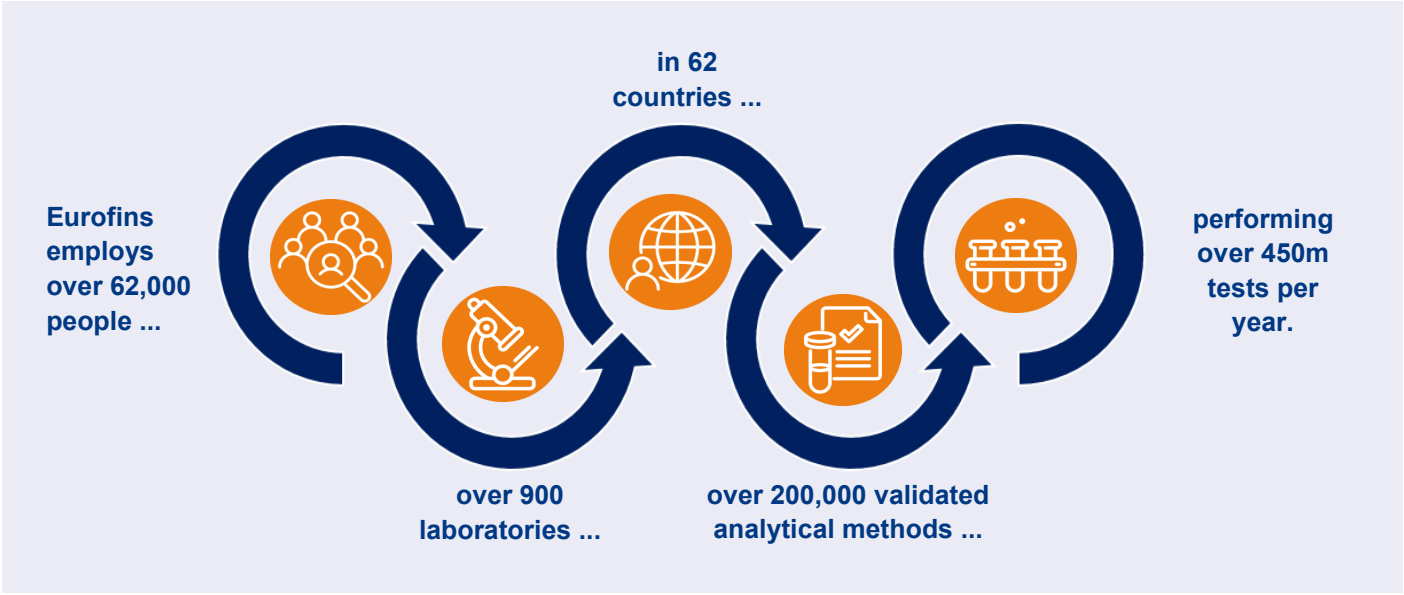
Testing for Life

Founded in October 1987, Eurofins Group's mission is to contribute to a safer and healthier world by providing our customers with innovative and high-quality laboratory, research and advisory services whilst creating opportunities for employees and generating sustainable shareholder value.



Clinical Genetics

Eurofins Clinical Genetics UK is a UKAS Accredited Medical Laboratory No. 27424, accredited to BS EN ISO 15189:2022 laboratory offering clinically led genetic tests to the NHS and private clinics across the UK.

In addition to our state of the art purpose built laboratory in Guildford, as part of Eurofins Group we work closely with numerous Eurofins laboratories across Europe.

Our laboratory guide provides an overview of key requirements to assist customers in the collection and preparation of samples to be sent to the laboratory, as well as additional information about our UKAS accreditation and tests offered.

Scope of Laboratory

Eurofins Clinical Genetics UK Ltd is a medical testing laboratory offering a broad repertoire of genetic tests. Eurofins Clinical Genetics provides a clinically led diagnostic and screening investigations with interpretive clinical comments where appropriate. The disciplines within Clinical Genetics include Non-Invasive Prenatal Testing (NIPT), Reproductive Health, Paternity, Oncology and Wellness.

Eurofins Clinical Genetics
90 Priestley Road
Surrey Research Park
Guildford
Surrey GU2 7AU

Laboratory Opening Hours:

- Monday to Friday: 9am to 5pm
- Saturday: 9am to 5pm
  (sample delivery only)
- Closed Sundays and UK Public Holidays

Contact Customer Support
Monday to Friday: 9am to 5pm
Tel: **07501 805142**
Email:
GeneticEnquiriesUK@ctuk.eurofins.com

Please contact Customer Support for Eurofins Clinical Genetics' business terms and conditions.

LABORATORY MANAGEMENT

Clinical Advisory Services

Ordering Examinations and Interpretation of Results: a clinical service is available for ordering examinations and interpretation of examination results, please contact Customer Support with your query.

- Customer Support: GeneticEnquiriesUK@ctuk.eurofins.com / 07501 805142
- Chief Scientific Officer & Laboratory Director: Dr Roy Naja

Key Contacts & Managers

- Managing Director: Sam Vine
- Commercial Director: Hannah Blackburn
- Head of Quality and Governance: Dayan Wijesinghe

REFERRAL LABORATORIES

For over 35 years Eurofins laboratories have provided general pathology and specialised diagnostic tests. Eurofins Clinical Genetics' testing is performed at our UKAS medical testing laboratory in Guildford, and as part of Eurofins Group we offer an extensive repertoire of tests through our sister laboratories:

- Eurofins Genoma, Rome
- Eurofins Genoma, Milan

Eurofins Clinical Genetics only refer samples directly to Eurofins Group, all of which laboratories are accredited to ISO standards.

Full details of our referral laboratories are available upon request.

QUALITY ASSURANCE

CQC Registration

Eurofins Clinical Genetics is registered with the Care Quality Commission (CQC) - click here for further details.

Accreditation (UKAS ISO 15189)

Eurofins Clinical Genetics is a UKAS Accredited Medical Laboratory No. 27424, accredited to BS EN ISO 15189:2022. Click here to view our current UKAS Schedule of Accreditation. (Eurofins Biomnis Limited trades as Eurofins Clinical Genetics).

Counselling

Eurofins Clinical Genetics offers an end to end service with clinical oversight, providing both pre and post test counselling dependent on the tests requested and results. Contact the laboratory for further details.

Data Protection (GDPR)

Eurofins Clinical Genetics, as part of the Eurofins Group, take steps to ensure that personal information is collected, used and shared lawfully, in accordance with data protection and privacy laws, and that the confidentiality and integrity of personal information is upheld. The position of the Eurofins Group towards data protection and privacy is clearly described in the Eurofins Group Code of Ethics: “Eurofins is committed to treating information with respect and protecting personal data from unauthorised disclosure.”

The Eurofins Group respects the privacy of its employees, customers, and other individuals whose personal information it processes in the course of its business activities. If you have any data protection queries, please contact Eurofins Clinical Genetics’ Data Protection Officer on **DPO@ctuk.eurofins.com**. Data storage is within the UK.

Feedback, Compliments & Complaints

The satisfaction of our service is of paramount importance. All feedback on this Laboratory Guide or any other aspect of the service is welcomed, please email us on **GeneticEnquiriesUK@ctuk.eurofins.com** to suggest improvements, make a complaint or give a compliment we can share with our staff. All complaints are treated as confidential, an investigation is undertaken, with corrective and preventive actions introduced where identified.

BLOOD SAMPLE COLLECTION

Good Phlebotomy Practice: Venous Samples

- Those taking blood must have received appropriate training as defined by the National Patient Safety Agency guidelines. The identity of the person collecting the primary sample must be recorded on the form and / or sample with collection date (and time where relevant).
- Identify patient correctly before taking blood. Ask patient to state their name and date of birth and ensure that all details match the request. Ensure the patient meets any pre-examination requirements eg. fasting status, medication status and record on the form as appropriate.
- Use the correct blood tube for the test required. Mix the blood tube gently after collection to ensure activation of any additive. Do not shake.
- The sequence of venous blood tube collection should be:

Urgent test requests must be notified via email or phone:
GeneticEnquiriesUK@ctuk.eurofins.com
07501 805142

- Do not remove tops to manually fill bottles, vacuum tubes are not designed for use in this way and will leak.
- Gross errors occur when samples have been collected from an area that is receiving an intravenous infusion. Do not take samples from in-dwelling access devices unless specific training has been received.
- Needles and holders are for single use only and must be disposed of immediately into an adjacent sharps container. Needles must not be re-sheathed or removed from the holder.
- Take care to prevent needle stick injuries. If you do have a needle stick injury, contact occupational health or the local emergency department immediately.
- Under-filled / over filled coagulation (citrate) bottles will be rejected as results will be unreliable.
- Ensure that complete identification is clearly written on the bottle immediately after taking samples. Do not pre-label tubes. If labels are used on forms, ensure that they are on all layers of multi-part forms. This ensures an unequivocal link of the request to the samples.
- All blood spillages must be cleaned up immediately. Gloves must be worn, and special care taken with any broken plastic / glass. The contaminated area must be decontaminated with a locally agreed disinfectant.
- Blood cannot be accepted by the laboratory without a fully completed request form / electronic request. Black ball point pen and clear printing must be used to ensure legibility when handwriting any information. See page 9 for further information on request forms.
- Samples sent to the laboratory must arrive in a leak-proof container and comply with transport regulations, see packaging section. Blood tubes should be placed in a plastic bag and linked to the request form.
- We are unable to guarantee the processing of leaking samples. If not processed, these will be disposed of immediately and the requesting user informed.
- Samples should be delivered to the laboratory as soon as possible after collection. Some samples require special handling requirements, contact **GeneticEnquiriesUK@ctuk.eurofins.com** for details.
- It is the responsibility of the requesting user to ensure that all these requirements are met. The laboratory cannot accept the responsibility of changing any request or sample identification. Incomplete requests and incorrectly labelled samples will be brought to the attention of requesting users and discarded where appropriate.

SAMPLE REQUIREMENTS: REQUEST FORMS

Request Forms Requirements

- A Eurofins Clinical Genetics request form must accompany every sample.
- The request form ensures all the required information is provided, which enables the laboratory to provide an efficient service and reduces the risk of the sample(s) being rejected.
- In most cases, the willingness to consent to venipuncture, receipt of a sample and request form is considered inferred consent to test as requested on the request form. If accepted by the laboratory, this is considered an agreement.

Please contact Customer Support on **GeneticEnquiriesUK@ctuk.eurofins.com** to request the appropriate request form

SAMPLE REQUIREMENTS: ACCEPTANCE CRITERIA

Sample Acceptance / Rejection Criteria

Samples may be rejected if they do not meet the standard requirements for testing. Reasons for rejection are as follows but not limited to:

- Mislabelled or unlabelled samples and / or request forms.
- Haemolysed / clotted / icteric / lipidemic.
- Insufficient sample volume.
- Samples broken or leaked in transit.
- Incorrect sample type received.
- Expired consumables.

See Appendix 1 (page 15) for example capillary blood sample collection instructions (IFU) for NIPT samples.

SAMPLE REQUIREMENTS: REQUEST FORMS

Request Form Completion

- It is important that all request forms and specimen containers are labelled legibly with the MATCHING relevant patient demographic and clinical details. Accurate patient identification is obviously of vital importance.
- Care must also be taken to follow any necessary protocol where a result could otherwise be adversely affected. If any doubt exists, please contact: **GeneticEnquiriesUK@ctuk.eurofins.com.**
- Samples will NOT be accepted unless there are 3 matching points of identification on both the sample and request form. Incomplete or discrepant points of identification will be rejected and the requesting party informed. Laboratory staff are not authorised to make changes to request forms or samples.
- Please specify specimen collection date on all samples and request forms.
- Clinical information is useful for laboratory validation and clinical interpretation of results and to recommend initiation of further investigations where appropriate.
- The following legible information required on the request form includes:

  - Patient's Surname (initials are not acceptable)
  - Patient's Forename (initials are not acceptable)
  - Date of Birth
  - Gender (at birth)
  - Requesting clinician or company and location
  - Relevant clinical information and any drug therapy
  - Tests being requested
  - Date of sample collection

TURNAROUND TIMES

- Turnaround time (TAT) is calculated as the period of working days from the sample arrival at the laboratory to the reporting of results, excluding Bank Holidays.

SAMPLE REQUIREMENTS: PACKAGING & TRANSPORT

Sample Packaging Requirements UN3373

- It is important that samples and request forms are packaged securely to avoid leakages.
- Inadequate packaging may result in sample leakage which will result in loss of the sample for testing. There is also the potential exposure of couriers / transport individuals to biological material.
- All specimen transport bags have 2 pockets - the front pocket should be used for the request form, the bigger back pocket should be used for the samples. The big pocket has a sealable top, this should be checked to ensure it is fully closed. If possible place a small piece of absorbent material in with the sample. Any leakage will then be contained within this pocket.
- Placing the request form and sample in separate pockets avoids contamination of the request form should the sample leak.

Transportation & Special Handling Needs UN3373

- Any sample transported by courier must adhere to the following instructions.
- Posted samples must comply with courier packing regulations.
- Place the sample and request form into the specimen transport bag as described above.
- Place the sealed sample transport bag into a UN3373 approved transport box / container.
- If using Royal Mail Track24, place the transport box / container inside the postal envelope / box with UN3373 warning label, and a Track 24 label attached.
- Track 24 samples can be posted in any Royal Mail Priority Postbox or Royal Mail Customer Service point.

RESULTS REPORTING METHODS

- Results will only be sent to the nominated clinic results report contact(s).
- Reports are sent to requesting clinics via encrypted PDF attachment to an email.

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Test Guide

TEST GUIDE

Eurofins Clinical Genetics is a UKAS Accredited Medical Laboratory No. 27424, accredited to BS EN ISO 15189:2022. Click here to view our current UKAS Schedule of Accreditation.

Turnaround time (TAT) is calculated in working days from sample receipt at the testing laboratory (excluding Bank Holidays).

Please contact Customer Support if you have any queries regarding sample requirements or additional genetic tests available:
GeneticEnquiriesUK@ctuk.eurofins.com

Test Name	TAT (working days)	Sample Requirements	In house / Referral
Prenatalsafe 3	2-5	7-10ml venous maternal blood in streck tube	In house
Prenatalsafe 5	2-5	7-10ml venous maternal blood in streck tube	In house
Prenatalsafe 5DiGeorge	5-7	7-10ml venous maternal blood in streck tube	Eurofins Genoma Italy
Prenatalsafe Plus	7-10	7-10ml venous maternal blood in streck tube	Eurofins Genoma Italy
Prenatalsafe Karyo	5-7	7-10ml venous maternal blood in streck tube	Inhouse & Eurofins Genoma Italy
Prenatalsafe Karyo Plus	7-10	7-10ml venous maternal blood in streck tube	Eurofins Genoma Italy
Prenatalsafe Complete	15	7-10ml venous maternal blood in streck tube & 1x buccal swab from the father (recommended)	Eurofins Genoma Italy
Prenatalsafe Complete Plus	15	7-10ml venous maternal blood in streck tube & 1x buccal swab from the father (recommended)	Eurofins Genoma Italy
Prenatalsafe Full Risk	15-20	2x 7-10ml venous maternal blood in streck tubes & 1x 7-10ml venous EDTA sample or buccal swab from the father	Eurofins Genoma Italy

PRENATALSAFE SAMPLE REQUIREMENTS

Keep samples at ambient temperature or refrigerated at +4°C until shipment.

TEST GUIDE

Turnaround time (TAT) is calculated in working days from sample receipt at the testing laboratory (excluding Bank Holidays).

Test Name	TAT (working days)	Sample Requirements	Inhouse / Referral
Fertility Genetics: Conventional Karyotype	15-20	7ml blood in Lithium / Sodium Heparin tube Keep sample at ambient temperature or refrigerated at +4°C until shipment. Ship within 48 hours of sample collection.	Eurofins Genoma Italy
Fertility Genetics: Cystic Fibrosis, Y-Chromosome microdeletions, Fragile-X-FRAXA, High resolution microarray	7-10	7ml blood in EDTA tube Keep sample refrigerated at +4°C until shipment. Ship within 72 hours of sample collection.	Eurofins Genoma Italy
OncoNext Risk	20	7ml blood in EDTA tube Keep sample refrigerated at +4°C until shipment. Ship within 72 hours of sample collection.	Eurofins Genoma Italy
Fertiscan	20	7ml blood in EDTA tube (recommended) or buccal swab Keep blood sample refrigerated at +4°C until shipment. Ship within 72 hours of sample collection. Buccal swabs are stable at room temperature for up to 2 weeks.	Eurofins Genoma Italy
NutriNext	20-30	7ml blood in EDTA tube (recommended) or buccal swab Keep blood sample refrigerated at +4°C until shipment. Ship within 72 hours of sample collection. Buccal swabs are stable at room temperature for up to 2 weeks.	Eurofins Genoma Italy
Genescreen (contact the laboratory to discuss options)	15-40	7ml blood in EDTA tube (recommended) or buccal swab Keep blood sample refrigerated at +4°C until shipment. Ship within 72 hours of sample collection. Buccal swabs are stable at room temperature for up to 2 weeks.	Eurofins Genoma Italy

Please contact Customer Support if you have any queries regarding sample requirements or additional genetic tests available: **GeneticEnquiriesUK@ctuk.eurofins.com**.

Appendices

APPENDIX 1: NIPT SAMPLE IFU

Prenatalsafe®
YOUR PATIENTS IN SAFE HANDS

Instructions for collecting, packaging and shipping of Prenatalsafe® samples

COMPONENTS & INTENDED USE

Venous Blood Collection Procedure Pack. For professional, single use only. Procedure pack for collection and transportation of venous blood specimen for laboratory analysis. Please check that the procedure pack contains all expected items. For a full list of components see Medical Devices Directive label (printed on the sleeve). Do not use the procedure pack if components are missing or damaged (e.g., tubes are broken, cloudy or contain a visible precipitate).

For advice or to report any issues, e.g. missing components, please contact geneticenquiriesuk@ctuk.eurofins.com.

PATIENT REQUEST & CONSENT FORM

Ensure that the patient is eligible for the test (at least 10 weeks gestation). Please note, sex chromosome aneuploidy cannot be reported for twin samples. For more information on eligibility, please see the corresponding patient information leaflet.

Important: Accurately fill in all mandatory fields of the patient Request & Consent Form. Ensure it is signed by the expectant mother and the Healthcare Professional who collected the consent.

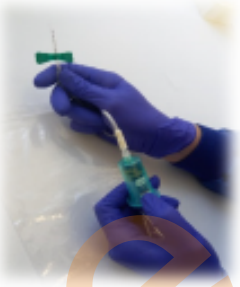
Ensure that the 'First Name', 'Surname' and 'Date of Birth' of the expectant mother are written on both the Streck tube label and the Request & Consent Form, that the Streck tube is in date, and that the information on the Streck tube matches the patient form.

Inadequately labelled samples, as well as samples without the appropriate form, may be rejected by the laboratory.

COLLECTION OF SAMPLES

Blood collection

- Carefully remove the Prenatalsafe® sleeve and open the box to retrieve the components required for blood collection.
- Write the 'Blood Draw Date' in the designated field on the patient Request & Consent Form.
- Write the patient 'First Name', 'Surname' and 'Date of Birth' on the Streck tube label.
- Apply a tourniquet about 6 cm above the selected venipuncture site (must not exceed one minute of use) and cleanse the area with the alcohol wipe.
- Remove the plastic cover from the rubber-protected needle and attach the end of the butterfly to the vacutainer by gently twisting.
- Insert the butterfly needle into the patient's vein.
- Once there is a flashback of blood, insert the Streck tube into the green attachment.
- Collect approximately 10 mL (minimum 8 mL) of peripheral blood into the Streck tube. Do not fill the Streck tube completely to avoid the stopper accidentally opening.
- Release the tourniquet prior to removing the needle. Place a cleansing wipe over the puncture site while removing the needle and then press it firmly on the puncture site before applying a plaster.
- Gently invert the Streck tube 10 times.
- Dispose of used material in accordance with local clinical waste procedures.



Samples with inadequate volume or that are sent in non-validated or expired tubes will be rejected.

PACKAGING & SHIPPING

Keep the Streck tube at room temperature or refrigerated at +4°C until shipment. Ship samples between 4°C and 30°C. Do not keep Streck tubes in the freezer. Samples must be sent to the laboratory using the transport container provided, assembled to UN 3373 standards. After blood draw, samples need to be shipped as soon as possible.

Please follow instructions below for packaging and shipping the samples:

1) Place the Streck tube (containing the blood) in the specimen holder slot.
2) Place the patient Request & Consent Form and the specimen holder in the Prenatalsafe® box.
3) Retrieve both security seals provided in the box, close the box, replace the Prenatalsafe® sleeve on the box, and apply one security seal to each of the short sides of the box.
4) Ship the samples according to one of the following methods:
   a. **DHL** - Place the Prenatalsafe® sleeved box inside the grey UN 3373 DHL bag (provided separately by the laboratory) and email the Clinical Genetics Laboratory on geneticenquiriesuk@ctuk.eurofins.com to schedule a DHL collection.
   b. **Royal Mail** – Apply the Tracked 24 label (provided separately by the laboratory) to the demarcated space on the back of the Prenatalsafe® sleeved box and drop it off at the nearest post office/post box.
   c. **Driver pickup** - Set the Prenatalsafe® sleeved box aside and email the Clinical Genetics Laboratory on geneticenquiriesuk@ctuk.eurofins.com to schedule a collection by a Eurofins' driver (UN 3373-compliant transport).

Samples must arrive at the laboratory within five days from blood draw for a validated result.

UK CA MD ②

Product Reference: PP004, PP004-02
Procedure pack produced by: REAL Digital International, 2 Queensway, Croydon, CR0 4BD

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