

ADVICE FOR HEALTH CARE PROVIDERS

Melaris® Test

The aim of the test is to provide an assessment of the risk to individuals for inherited susceptibility to melanoma and pancreatic cancer.

Providing a sample for testing

Patient and sample details should be included on the Test Request Form provided. Following these instructions will avoid delays in the testing process. Initiation of testing will be delayed if the sample is improperly labelled or if the test request form is incomplete.

Complete the Test Request Form (TRF)

Please ensure that the following items are recorded correctly on the Test Request Form.

- Are the ordering physician details completed, including the phone number and email address?
- Patient details: Please enter the patient's name, patient ID, date of birth and sex. If you do not have a patient ID please use the patient's initials and date of birth in the following format; XXddmmyyyy where XX represents the patient's first and last initials.
- Has the correct test been selected?
- Has the ancestry and clinical history been completed?

Patient Consent

Anonymised patient samples may be kept by the testing laboratory for use in quality assurance. In submitting this sample the clinician confirms that consent for testing and possible sample storage has been obtained from the patient.

Technical Information and Data Protection

We would like to inform our customers that samples submitted for analysis are sent to the United States for processing. This test is not required to be CE- marked under the European IVD directive 98/79/EC. (MHRA notification August 2007). The test is performed in a CAP & CLIA approved laboratory.

We request that the patient is made fully aware that any personal details they provide to the healthcare professional will be forwarded to Lab21 and Myriad; such information will not be kept longer than is necessary.

We would like to confirm that all personal data received is handled and maintained confidentially and securely.

Payment instructions

Lab21 accepts Credit Card payments and Bankers Drafts. Lab21 also provides the option for you to transfer funds directly to our bank.

If you wish to pay by credit card please fill in the details on the enclosed Payment Form (Form 122). For alternative methods of payment, please contact Lab21 Customer Services.

Sample Collection

1. Draw blood using the 10ml purple-top (EDTA) tube provided. A completed tube should contain 7ml of blood.
2. Write the patient ID number, and date of birth and initials on the bar code label found on the right hand corner of the Test Request Form: **Please note: Patient ID number must match exactly the information on the Test Request Form or the sample may be rejected.**

Sample Collection continued

3. Peel off the label and place it lengthwise **on the sample tube**.
4. Do not centrifuge, refrigerate or freeze the sample.

Packaging instructions for returning samples to Lab21 Ltd

1. Place the sample tube into the biohazard bag with the absorbent material and seal the bag as per the instructions. Place the sealed bag with the sample into the cardboard return mailer box.
2. Complete the enclosed Test Request Form and Payment Form and place into the return mailer box.
3. Seal the lid of the box with the security label provided in the kit.
4. UK customers should post back to Lab21 using the Freepost label provided on the reverse of the return mailer box. If outside the UK please contact Lab21 to advise on a suitable courier to return the sample. Alternative shipping option: If your hospital is a member of the DX network you can send samples using your hospital account to: Lab21, Dx 6055300, Cambridge 94 CB.



Please note shipping regulations within the EU require that diagnostic shipments be packaged in accordance with UN3373 / IATA Packaging Instructions 650. It is the shipper's responsibility to ensure that the package conforms to shipping guidelines. Lab21 packaging and instruction for shipping conform to this standard.

Test results

The Report is issued in 3 weeks from receipt of sample, twelve working days for Rapid Analysis. The Report will be sent to the ordering physician to be discussed with the patient.

Technical Information

The sequencing of patient DNA is carried out following polymerase chain reaction and other molecular biological techniques.

Comprehensive MELARIS®

Full DNA sequence analysis for mutations in the P16 gene.

Single site MELARIS®

DNA sequence analysis for a specified mutation in the P16 gene.

All mutations and genetic variants are named according to the convention of Beaudet and Tsui.

References

1. Beaudet AL, Tsui LC. A suggested nomenclature for designating mutations. *Hum Mut* 1993; **2**:245-248.
2. Burden AF *et al*. Genetic and environmental influences in the development of multiple primary melanoma. *Arch Dermatol*. 1999; **135**:261-265.
3. Greene MH. The genetics of hereditary melanoma and nevi. 1998 update. *Cancer*. 1999; **86**:2464-2477.
4. Hayward N. New developments in melanoma genetics. *Curr Oncol Rep*. 2000; **2**:300-306