

# MELARIS<sup>®</sup> - A genetic test for hereditary melanoma

## SERVICE SPECIFICATION SHEET

If you have any queries regarding the test specifications outlined below please contact Lab21 Customer Service to discuss prior to sending samples for analysis.

**Intended Use:** To provide a service to test samples from individuals for inherited susceptibility to melanoma and pancreatic cancer.

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

Comprehensive MELARIS<sup>®</sup>

Full DNA sequence analysis for mutations in the P16 gene.

Single site MELARIS<sup>®</sup>

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. (Beaudet AL, Tsui LC. A suggested nomenclature for designating mutations. *Hum Mut* 1993; **2**:245-248).

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.

**Testing Time:** Turnaround: report issued in 3 weeks from receipt of sample. Twelve working days for Rapid analysis.

**Specimen Requirements:** Lab21 will provide suitable testing kits and packaging which should be returned for analysis to Lab21 Ltd.

**Specimen Handling:** See 'Advice for Healthcare Providers – Myriad Genetic Tests'.

**Reporting of Results:** Test results will be sent to the ordering physician to be discussed with the patient.

- References:**
1. Burden AF *et al.* Genetic and environmental influences in the development of multiple primary melanoma. *Arch Dermatol.* 1999; **135**:261-265.
  2. Greene MH. The genetics of hereditary melanoma and nevi. 1998 update. *Cancer.* 1999; **86**:2464-2477.
  3. Hayward N. New developments in melanoma genetics. *Curr Oncol Rep.* 2000; **2**: 300-306