Merlin

CE IVD UK CA

Technical Sheet Merlin™

The Merlin Assay is an in vitro diagnostic test (CE-IVD) intended to qualitatively predict if a primary cutaneous melanoma patient (newly diagnosed) can forgo the sentinel lymph node biopsy surgery due to their low risk of having nodal metastasis. This assessment is achieved through the integration of data obtained from real-time singleplex qPCR using RNA derived from the primary tissue biopsy, and clinicopathologic information using an automated algorithm.

Target genes & corresponding primers

The primer panel consists of a total of 10 primer pairs.

Name	Sequence
ACTB FW	CCTGGCACCCAGCACA
ACTB RV	AGGAGCAATGATCTTGATCTTCA
RPLP0 FW	CCAACTACTTCCTTAAGATCATCCA
RPLP0 RV	CCACAATGAAACATTTCGGATA
MLANA FW	AGAGAAAAACTGTGAACCTGTGG
MLANA RV	ATAAGCAGGTGGAGCATTGG
PLAT FW	CAGTGCCTGTCAAAAGTTGC
PLAT RV	CCCCGTTGAAACACCTTG
ITGB3 FW	CTTCTCCTGTGTCCGCTACAA
ITGB3 RV	CATGGCCTGAGCACATCTC
IL8 FW	CTTGGCAGCCTTCCTGATT
IL8 RV	GCAAAACTGCACCTTCACAC
GDF15 FW	AAGATTCGAACACCGACCTC
GDF15 RV	GCACTTCTGGCGTGAGTATC
LOXL4 FW	AGTGCCAAGTACGGCCAAG
LOXL4 RV	GCACATTGTCCAGCCAGAT
TGFBR1 FW	CCTGGGATTTATAGCAGCAGA
TGFBR1 RV	TGACACCAACCAGAGCTGAG
SERPINE2 FW	TGAGATACGGCGTAAATGGA
SERPINE2 RV	GATGGCCTTGTTGATCTTCTTT

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Specimen requirements

Sample Type

Merlin has been validated to be used with formalin fixed paraffin embedded primary cutaneous melanoma lesion biopsies, punched/shaved and fully excised FFPE primary lesions. Samples should be held at room temperature or cooled (4°C) conditions during storage and transport.

Patient Eligibility criteria

Merlin is validated for newly diagnosed cutaneous melanoma patients:

- with a confirmed diagnosis;
- presenting a primary lesion of a T1 through to T3 tumor;
- who have not yet undergone an SLNB surgery but is eligible for SLNB.

The criteria for tumor categorization are according to the AJCC 8th edition on melanoma staging.

Result reporting

Merlin provides one of three possible results:

Low Risk: This means that the patient may have a low probability of sentinel node metastasis and may not be considered for a sentinel lymph node biopsy (SLNB).

High Risk: This means that the patient may have a high probability of sentinel node metastasis and should be considered for a sentinel lymph node biopsy (SLNB).

Invalid test: This means that the sample did not pass one of the processing QC criteria

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Processing time

Total Time

~370 min

Hands on Time

~155 min

Waiting Time

~215 min

Performance

Limit of Detection (LOD)

Determined LOD for each of the targets of Merlin.

Target	LOD (copies/reaction)
ACTB	1.067
RPLP0	18.990
MLANA	3.360
ITGB3	0.956
PLAT	5.823
IL8	6.240
GDF15	6.430
LOXL4	11.486
TGFBR1	6.235
SERPINE2	4.125

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