



Specimen Requirements

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Specimen and Test Order Requirements

Specimen Type: Formalin-Fixed and Paraffin Embedded (FFPE) primary cutaneous melanoma biopsy tissue containing neoplastic cells (skin biopsy required), either as:

- Freshly cut curls in microcentrifuge tube provided **OR**,
- Mounted on glass slides (charged, unstained, unbaked) and placed in slide box provided **OR**,
- FFPE Block.

Specimen Volume: 5 x 10 μ m FFPE.

Labeling Instructions: Label each specimen with **at least two** patient identifiers (i.e., Patient name, DOB, medical record number, etc.).

Treating Health Care Provider's Authorization Section: The provider must be an MD, PA, NP, or DO and must sign and date to provide authorization to perform the test.

Storage Requirement: Ambient temperature (15°- 25°C or 59°- 77°F).

Special Instructions: Do not freeze or refrigerate.

Patient Inclusion Criteria

Patient Diagnosis: Newly diagnosed invasive malignant cutaneous melanoma of the skin (AJCC 8th Edition guidelines). pT1a (Breslow thickness <0.8 mm) AND one or more of the following:

- Mitotic rate $\geq 2/\text{mm}^2$
- Patient age at time of primary melanoma biopsy <40 years old
- Presence of lymphovascular invasion

pT1b-pT3 (Breslow thickness ≥ 0.8 mm to 4.0 mm or <0.8 mm with ulceration).

Patient Exclusion Criteria

Clinical evidence of nodal involvement or distant metastases (cN0M0).

Sentinel lymph node surgery was performed prior to specimen submission.

Specimen Rejection Criteria

Unacceptable specimen:

- Wide local excision material
- Any specimen that is not primary cutaneous melanoma tissue (e.g., lymph node biopsy)

Shipping Instructions

Place the **completed** Test Requisition Form and specimen(s) into the Merlin Specimen Transport Kit or other appropriate shipping container.

If using the Merlin Specimen Transport Kit:

- Place the kit(s) into the FedEx Clinical Pack and attach the pre-printed shipping label provided.
- If sending multiple kit(s) on the same day, please send them in the same clinical pack as room allows.
- Contact FedEx for same day pickup.

Note: Do not ship on dry ice. If needed, a cold pack may be used if packed inside of the transport kit during extreme heat conditions.

For questions on how to complete the Test Requisition Form or the shipping process, please contact Customer Service at **(858) 886-7907 option 1** or by email at customerserviceUSA@skylinedx.com