

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.

Specimen Volume: 50 µm of FFPE tissue

- Curls in tube (5 x 10 µm)
- Unstained, unbaked sections on glass slides (5 x 10 µm)
- FFPE block (≥ 50 µm)

Labeling Instructions: Label each tube or slide with **at least two** patient identifiers (i.e., Patient name, DOB, case number, etc.).

Treating 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.

Inclusion Criteria

Patients ≥18 years who have cutaneous melanoma (**T1a-T4**).

- Specimens where the primary diagnostic biopsy was performed within five (5) years of specimen submission, which may include patients where the sentinel lymph node biopsy has been performed.

Patient Exclusion Criteria

Clinical evidence of nodal involvement or distant metastases.

Specimen Rejection Criteria

Unacceptable specimens:

- Wide local excision material
- Re-excised or metastatic lesions or any specimen that is not primary cutaneous melanoma tissue in FFPE (e.g., lymph node biopsy)
- Non-melanocytic neoplasms
- Lesions subjected to prior treatment
- Specimens where a primary diagnostic biopsy was performed more than five (5) years prior to specimen submission.

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 Client Services at **858.886.7907**
or by email at **clientservices@skylinedx.com**