

## Stop TB Partnership Global Drug Facility Info Sheet: SIILTIBCY™

The SIILTIBCY skin test (marketed in India as Cy-Tb) is a new diagnostic tool for detecting *Mycobacterium tuberculosis* (Mtb) infection, using Mtb-specific antigens (recombinant proteins of ESAT-6 and CFP-10). It offers enhanced specificity over the traditional tuberculin skin test (also known as the Mantoux test), particularly in BCG-vaccinated individuals.

Technical specifications*	rdESAT-6/rCFP-10 0.5 μg/0.5 μg. Solution for injection, vial of 1 ml. Each vial contains 10 doses/tests (0.1 ml per dose/test).
Manufacturer	Serum Institute of India Pvt. Ltd. (Pune, India)
GDF price (ex-works)	\$15.00 per vial of 10 doses/tests
GDF item code	rdESAT-6/rCFP-10-0.5/0.5-(V)-1 (SIILTIBCY)
Country eligibility	All countries are eligible
Minimum order quantity	To be ordered in multiples of 120 vials (1,200 doses/tests) due to specific shipping requirements
Shelf life	24 months
Storage requirements	2-8°C, in the original packaging, protect from light, do not freeze. After first opening, to be stored between 2-8°C and used within up to 28 days.

<sup>\*</sup> Syringes for intradermal injection must be procured separately

## Implementation considerations

Countries familiar with implementing the tuberculin skin test will find many similarities when using SIILTIBCY:

Administration: SIILTIBCY is injected intradermally in the inner forearm, requiring training of health care workers. Intradermal injection of SIILTIBCY requires use of a small volume syringe (e.g., 0.1 mL auto-disable syringe or 1 mL single-use disposable syringe) with a short-bevel, fine-gauge needle (typically 26 to 27 gauge, as per national guidelines). For countries unable to procure such syringes locally, the <a href="UNICEF Supply Catalogue">UNICEF Supply Catalogue</a> offers auto-disable syringes as well as safety boxes for disposal.

Results interpretation: Similar to the tuberculin skin test, the SIILTIBCY result should be read by a trained health care worker within 48-72 hours. The results interpretation has a single cut off, with an induration of  $\geq 5$  mm indicating Mtb infection for all populations.

Cold chain: SIILTIBCY must be refrigerated at 2-8°C and cannot be frozen. A cold chain needs to be maintained until the point of administration, and appropriate equipment (e.g. refrigerators, cold packs and coolers) must be available. Note that SIILTIBCY will be shipped in a specific box containing 120 vials (the minimum order quantity). This box allows for shipping at temperatures between 15-25°C while maintaining the vials at 2-8°C for up to 90 hours from the time the GDF/i+s freight forwarder picks them up. Consignees must therefore ensure speedy customs clearance, especially if the airport customs facility does not have a cold storage room.



For contraindications and use of SIILTIBCY in special populations including pregnant or breast-feeding women, see the Instructions for Use.

For more guidance on steps and processes for use of skin tests, see Section 3.3 of the <u>WHO</u> <u>Operational Handbook on Tuberculosis, Module 3: Diagnosis, Tests for tuberculosis infection</u>

