



TCATF 190 04
(Relates to SOP No. TCATS CTL 003)



NOTE TO BE DISTRIBUTED
ANTI-EBV CTL PRODUCT

UNLICENSED STATUS OF PRODUCT

The anti-EBV CTL supplied is an unlicensed product. There is a legal requirement that unlicensed products are issued and used with the understanding that they do not hold a UK product licence and are supplied on a strict named patient basis.

PATIENT CONSENT AND RECORD OF USE

As the treating clinician you have the responsibility of ensuring the patient is informed that the product is not licensed in the UK and gaining their consent. As with all plasma-derived medicinal products, it is recommended that you record the product name and batch number in the patient's notes.

BAG INTEGRITY

There have been some incidents reported of bag leaks, due to faulty seals or snapped lines. If the integrity of the inner bag is compromised, please do not infuse the product. Quarantine the implicated bag and contact the CTL bank (0131 314 5545 or nss.ctlbank@nhs.scot). We will send a replacement bag where available.

CHARGES APPLIED FOR SUPPLY OF ANTI-EBV PRODUCT

SNBTS apply a charge to recover cost of this product. As the treating clinician you should ensure that payment is authorised.

RETURN OF PAPERWORK

The supply of this unlicensed product is on the understanding that the requesting clinician and/or the consultant in charge of the hospital/trust complete appropriate tests and return any forms requested by SNBTS.

- Patient consent form – TCATF 189
- Patient treatment forms should be returned (email or hardcopy) within one working day of each treatment.
- SNBTS should also be informed if the product was not used.

Return forms to

CTL bank,
SNBTS Tissues, Cells and Advanced Therapeutics
The Jack Copland Centre
52 Research Avenue North
Heriot-Watt Research Park
Edinburgh, EH14 4BE

Or scan and e-mail to nss.ctlbank@nhs.scot
(Fax number 0131 314 5799)