

# Cutter

BERKELEY & EMERYVILLE, CA USA

REPLY TO TELEX:  
335-380 CUTTERFIN EMVL  
470-132 CUTTERIL EMVL

## TELEX/FACSIMILE MESSAGE

MILES

REPLY TO FAX TERMINAL:  
GROUP II & III (415) 420-4008  
GROUP II & III (415) 420-4009

DATE February 20, 1986  
TO/NAME Marie Tatt  
LOCATION Miles U.K.  
FAX NUMBER \_\_\_\_\_  
TELEX NUMBER \_\_\_\_\_  
FROM/NAME Karen Fernandez  
LOCATION Cutter Emeryville  
DEPARTMENT TO CHARGE 10-66606

FOR ASSISTANCE CALL (415) 420-4007

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ACKNOWLEDGE RECEIPT \_\_\_\_\_

DELIVER IMMEDIATELY \_\_\_\_\_

REPLY REQUESTED \_\_\_\_\_

CONTROL DESK NO. \_\_\_\_\_

CONFIRMATION NO. \_\_\_\_\_

KF-6.43 CC: B. Dyos  
R. Rousell

TEXT: ~~KOATE-HT~~ YOUR TELEX OF 19 FEBRUARY.

Marketing advised me that the labeling on HTLV-III antibody screening is included on U.S. material only. The date of 1st November 1985 applies only to U.S. material.

I have received confirmation today from Gary Mull that the first lot of Koate-HT for the U.K. prepared from 100% screened plasma is lot 5P114 manufactured in December and shipped Jan/Feb.

We are not planning on applying screening statement "stickers" to product other than U.S. material. However, we will be revising all Koate-HT final product labeling this year and we will be in contact with you on this as soon as we have enough information to proceed. This revision is necessary due to specific wording required by the FDA on hepatitis and HTLV-III antibody screening.

The specific timetable for labeling revisions has not yet been established as we are waiting on additional input from within Cutter and from the FDA.

Re: KOATE-HS, YOUR TELEX OF 20 FEBRUARY. STUDIES IN HAEMOPHILIC DOGS.

This needs to be discussed with Willi Ewald before proceeding. He will be back in the office tomorrow. Either R. Rousell or I will get back to you.

GRO-C

KF/jwk

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