OPEN HEARING

STATEMENTS FROM EPITOPE

STATEMENTS FROM AABB
Indeterminate Non-viral Band Blots for HIV-1

FDA Blood Products Advisory Committee Meeting

March 16, 2000

Epitope, Inc.
Beaverton, Oregon 97008
Nonviral Bands on Epitope's Western Blots

- Epitope manufactures two Western Blot assays for different body fluids
  - Serum/plasma
  - OraSure oral fluid

- Epitope's Western blot assays are distributed by Organon Teknika Corporation

- HIV Western blot assays prepared from viral lysates contain cellular antigens (e.g., HLA, actin)

- Nonviral bands on Epitope's Western blots usually appear in two locations
  - p70
  - p45

- Epitope Western blot assays can show two additional "pseudo-bands"
  - Gel edge mark near green reference line
  - Gel edge mark near bottom of strip

- Epitope Western blot nonviral bands do not react with anti-gag, anti-pol, or anti-env monoclonal antibodies
Epitope Western Blot

HIV-1 Positive

Green reference line

gp160

gp120

p66

p55

p51

gp41

p31

p24

p18

Nonviral band

Indeterminate

HIV-1 Negative

Gel mark

p70

p45

Gel mark

FDA BPAC meeting March 16, 2000
Western blot nonviral bands
Epitope, Inc. Beaverton, OR
Epitope Western Blot Nonviral Bands

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Nonviral band indeterminate Western Blots
Epitope, Inc., Beaverton, Oregon

NVB p70 & p45.doc
Epitope Western Blot Tested with Monoclonal Antibodies

\[ \alpha_{-gag} \quad \alpha_{-env} \quad \alpha_{-RT} \quad \text{Mab pool} \]

Strip #1 – High Positive Control
Strip #2 – Low Positive Control
Strip #3 – Negative Control
Strip #4 – Anti-HIV Mab

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Indeterminate Western Blot References


