



HIV/AIDS REFERENCE & QUALITY ASSURANCE LABORATORY (HRL)
UGANDA VIRUS RESEARCH INSTITUTE
P.O. BOX 49, ENTEBBE (UGANDA)

Tel: (256) 41 - 321742

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Our Ref:.....

Your Ref:.....

Date: September 11, 2003

Mr. Apollo Muhairwe
Executive Secretary
National Drug Authority
29 Lumumba Road
Kampala
Email; nda@nda.or.ug
Fax: 041 255758
Tel:041-347391/ 2

Subject: Importation of Calypte Urine HIV Enzyme Immunoassay

Calypte Corporation is presenting for Uganda a new assay for the detection of HIV-1 antibodies in urine. Data available shows that this product has had a successful field evaluation here.

The purpose of this letter is to recommend and request for your approval of the Calypte Urine HIV-1 ELA for use in Uganda.

Yours sincerely

Dr. Benon Biryahwaho
Head, Laboratory for HIV Reference & Quality Assurance

Cc:
Mr. Stephen Hofmann <shofmann@strtrade.com>

DRUG



NATIONAL AUTHORITY

P.O. BOX 23096 KAMPALA
 Secretariat Office, Plot 46 - 48 Lumumba Avenue
 Tel: 255665/347391/2 Fax. 255758
 E-mail: ndang@nda.or.ug.
 Web site: www.nda.or.ug

Your Ref:.....

Date: 23rd Sept. 2003

Our Ref: 908/SR/NDA/09/03

Stephen Hofmann
 Senior Advisor
CALYPTE, Biomedical Corporation
 Washington DC
 1265 Harbor Bay Parkway
 Alameda, CA 94502
 (202) 216-9307 or (202) 412-2689 (Cell)

IMPORTATION OF URINE-BASED MICROWELL ELISA HIV/AIDS TEST KITS

We have received your letter dated 9th September 2003 concerning the above captioned subject and noted the contents therein.

National Drug Authority has no objection to the importation of the said kits for the Rakai Institute; however, clearance of all HIV/AIDS test kits is done by the "Uganda Virus Research Institute", Entebbe.

You will then follow the procedures for importation of pharmaceuticals (*copy attached*) in the country after clearing with the Virus Institute and also provide NDA with all the data about the product before approval is given.

Please do not hesitate to contact us for any clarification.



14 Apollo Muhairwe
EXECUTIVE SECRETARY/REGISTRAR

Copy to: Ag. Chief Inspector of Drugs
 " Dr. Benon Biryahwawo
 Director, Vidas National Research Institute

Tel: (256) 41 -321742
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HIV/AIDS REFERENCE & QUALITY
ASSURANCE LABORATORY (HRL)
UGANDA VIRUS RESEARCH INSTITUTE
P.O. BOX 49, ENTEBBE (UGANDA)

Our Ref:.....

Your Ref:.....

Date: 6th October 2003.

To: The Executive Secretary/ Registrar, ndaug@nda.or.ug
National Drug Authority,
Lumumba Avenue,
P.O. Box 23096,
Kampala.

Re: CalypteTM Urine Test.

Further to our letter on this subject dated 3rd October.

This is to clarify that Calypte HIV-1 urine test (Calypte Biomedical Corporation, CA, USA) was found to have sensitivity a score of 95.8% using stored samples and was 100% sensitive if tested with fresh urine specimens specificity score correspondingly was 97.7%. There were indications that people preferred to donate urine samples than blood for HIV testing.

I wish therefore to recommend the Calypte urine test and request that you will provide the necessary clearance.

Yours sincerely,

A handwritten signature in black ink, appearing to read "B. Biryahwaho".

Dr. Benon Biryahwaho,
Coordinator,
National Laboratory for Reference & Quality Assurance (HRL),

Cc: Mr. Stephen Hofmann shofmann@strtrade.com