



**ANOGEN** - A Division of YES Biotech Laboratories Ltd.

2355 Derry Road East, Unit 23, Mississauga, ON L5S 1V6

March 19, 2004

To Whom It May Concern:

In accordance with the **APHIS Animal Product Manual** (08/2003-32 PPQ, VRS), as per section 3-8-22, Test Kits and Kit Components, the following statement applies to this shipment:

The product being shipped to **company** consists of a test kit and its respective components that are prepackaged, labeled accordingly, and ready for use.

The product is directed against human **Hepatitis E Virus, IgG** and was raised in mouse hosts.

The product is manufactured for **in vitro general laboratory research use only**. This product is **not** for diagnostic or therapeutic use, and therefore does not carry, nor requires a 510K form.

The product is manufactured and produced in Canada and **does not come from a facility where work with exotic viruses affecting livestock and avian species is conducted**.

The product is non-hazardous, non-infectious, does not contain any **genes, and does not express products of exotic livestock or poultry disease agents**.

Sincerely,

Anogen  
Director of Operations