



Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Certificate No. 1965-1-2009

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor Address</u>
See Attached List (One page)	CALBIOTECH, Inc. 10461 Austin Dr. Suite G Spring Valley, CA 91978 USA

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Theresa McDonald
Chief, Regulatory Policy and Systems Branch
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 10 day of Feb month 2009 year.

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013



NAME OF PRODUCT(S)

Name of Manufacturer/Distributor Address

Brucella IgG ELISA
Chlamydia pneumonia IgA ELISA
Chlamydia pneumonia IgG ELISA
Chlamydia Trachomati-s IgA ELISA
Chlamydia Trachomatis IgG ELISA
EBV-VCA IgA ELISA
EBV-VCA IgG ELISA
Helicobacter Pylori IgG ELISA
Helicobacter Pylori IgA ELISA
Measles IgG ELISA
Mumps IgG ELISA
Mycoplasma Pneumonia IgG ELISA
Beta 2-GP I IgG ELISA
T3 Uptake ELISA
T3 ELISA
Free T3 ELISA
FSH ELISA
LH ELISA
Prolactin ELISA
Cotinine ELISA
Tricyclics ELISA
DHEA – S ELISA
Estradiol ELISA
Estron ELISA
Progesterone ELISA
Testosterone ELISA
hGH (Human Growth Hormone) ELISA
C-Peptide ELISA
Insulin ELISA
Chlamydia-Cassettes
Chagas – Cassette
H. Pylori – Cassette /Strip
Strep A –Cassette
TB – Cassette
Pregnancy Test Urine – Cassette / Strip
Pregnancy test urine /serum combo – cassette/ strip
LH cassette/strip
FSH cassette/strip
FSH CHEMILUMINESCENCE ELISA
LH CHEMILUMINESCENCE ELISA

Manufacturer
Calbiotech, Inc.
10461 Austin Dr. Suite G
Spring Valley, CA 91978
USA

“END OF PRODUCT LIST”

