



Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, Maryland 20993

Certificate No. 1689-4-2010

CERTIFICATE OF EXPORTABILITY [SECTION 801(e)(1)]

The Food and Drug Administration certifies that the product(s) described below is subject to its jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act). The products described below may not be sold or offered for sale in the United States. The company has certified to the Food and Drug Administration that:

- the product(s) accords to the specifications of the foreign purchaser;
- the product(s) is not in conflict with the laws of the country to which it is intended for export;
- the shipping package for the product(s) is labeled on the outside that it is intended for export; and
- the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant to Section 801(e)(1) of the Act.

Name of Product

Name of Company, Address

FastPack® Free PSA Immunoassay
FadtPack® Free PSA Calibrators

Qualigen Inc.
2042 Corte del Nogal, Suite B
Carlsbad, CA 92011
USA

Chester T. Reynolds
Acting Director,
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 30 day of May month 2010 year.

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

