MINISTRY OF HEALTH
STANDARDS AND REGULATION DIVISION
PHARMACEUTICAL AND REGULATORY DEPARTMENT
JAMAICA, WEST INDIES

ASSESSMENT FORM FOR HOME USE IN-VITRO DEVICES

PRODUCT PARTICULARS:

NAME OF PRODUCT:

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NAME AND ADDRESS OF MANUFACTURER:

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NAME AND ADDRESS OF APPLICANT:

_____

LIST OF REQUIREMENTS FOR ASSESSMENT PURPOSES:

1) Product information on the following:
   a) Type of procedure e.g. screening
   b) Specific disorder /Condition for which the test is intended
   c) Conditions for use
   d) Who should use the product for testing

2) A list of the reagents/physical composition of the test

3) A summary of the following:

   a) Principle of the test
   b) Interpretation of the results
   c) Limitations of the test
   d) Interfering substances/conditions which could affect the results

4) Information on specimen collection, preparation and analysis steps (On the product insert, this information should be enhanced by pictures, illustrations)

5) Lab evaluation of the analytical performance of the device e.g. analytical sensitivity etc.

6) Five (5) samples of the product in the finished form in which it is to be sold, along with the associated product insert.

   The appropriate warnings, precautions and contraindications should be included on the product label.

7) An original Certificate of Free Sale from the competent health authority in the country of manufacture.

8) Official documents such as the Certificate of Free Sale should be authenticated by the Jamaican Embassy or Jamaican Consulate in the country, and in cases where none of these is present by the British High Commission or British Embassy.

9) Implication for the impact (on the user and/or the society) at large of a false positive or false negative test result.

10) The results of a consumer field evaluation of the product performed in the country of manufacture to determine its performance when used by laypersons, unassisted, following instructions provided in the product insert.

11) All the above requirements must be submitted at the same time to the STANDARDS & REGULATION DIVISION IN THE MINISTRY OF HEALTH.

NB: A USER QUALITY CONTROL TEST SHOULD BE PROVIDED OR BUILT INTO EACH HOME USE IN-VITRO DEVICE

FOR OFFICE USE ONLY

DATE RECEIVED_____

ASSESSMENT COMMENTS ----------

DATE APPROVED/REFUSED----------

M.H.F.D May 2006