# CEPHIA

**Consortium for the Evaluation and Performance of HIV Incidence Assays**

# Assay evaluation request form

This document is used to determine whether an assay can enter the CEPHIA project Incidence Assay Performance Panel Evaluation (IAPPE). The following questions help describe what is already known about the assay proposed for evaluation and identify any areas which may hinder complete evaluation of the assay. From all assays submitted for evaluation the CEPHIA steering group will identify which assays can be assessed with the IAPPE study based on the information given on this form. Please return completed forms to MarsonK@php.ucsf.edu

1) Name of Assay
2) Proposer
3) Briefly describe the principle of the assay
4) Is this assay a proprietary assay Yes /No Answer A or B as applicable

   A) If yes:

   Name of proprietary company:

   Is assay being used for company described purpose: yes/no

   Has the assay been modified in any way and if so describe the modifications:

   Are the company aware of the changes made to the product: Yes/No

   B) If no:

   Are there any intellectual property rights attached to this product which preclude publication of results of the study:

   Is a confidentiality agreement required?:
   (it is planned that results for all assays will be compared to allow determination of the best algorithms to be applied in distinct populations. If any IPR or confidentiality agreements do not allow this, it is unlikely that an assay can proceed for evaluation)

5) What is the purpose of the assay?:
   Identifying acute infection
   Identify recent infection (within what approximate time-frame)
   Identifying long standing infections (within what approximate time frame, or as indicated by what correlates of long standing infection)

6) Is a full standard operating procedure and/or kit insert available for the assay – please supply

7) Do staff need any special training before performing the assays Yes/No

   If yes:
   Who will provide this training?
   Is there any cost for this training?

8) Is a full list of general reagents required for the assay
   Are these reagents freely available commercially yes/no
   If not who will supply them for the evaluation

9) Are any custom made reagents (e.g. peptides) required for the assay?
   If yes:
   Who supplies these reagents
   Are alternate suppliers available
   Have alternative suppliers reagents been evaluated

10) Is a complete list of equipment required for this assay available (please supply, if yes):

11) Is any proprietary equipment required for this assay
   If yes:
   What equipment is required?
   How will it be made available?

12) Is any software required to perform this assay?
   If yes:
   Is this software proprietary?
   Are there any third party Intellectual Property rights associated with this software.
   How will the software be made available for the study

13) Previous evaluations: Has the assay been evaluated previously?
   If yes:
   Please supply details of evaluation (who performed it, when, results obtained. Adverse incidents or issues raised)

14) Please supply any published data on the use of this assay
   Can a summary document be prepared to compile details of the data presented in these publications with relation to populations studied and results obtained.

15) Are there any unpublished data on the performance and development of this assay?

   If yes:
   Please describe the work undertaken. Please supply any unpublished data if possible