

**CERTIFICATION FOR USA INSTITUTIONS REGARDING RESEARCH USE OF  
THE CALYPTE ® HIV-1 BED EIA**

The undersigned hereby declares and certifies that the institution named below will use the Calypse HIV-1 BED EIA exclusively as a research tool for estimating HIV-1 incidence as an aid to population research and epidemiology studies. The Calypse HIV-1 BED EIA shall not be used to diagnose individuals for the presence of or absence of HIV-1 antibodies. The named institution furthermore hereby certifies that neither it nor its employees shall divulge the results obtained with the Calypse HIV-1 BED EIA to research subjects, patients or their physicians, and that the Calypse HIV-1 BED EIA shall not be used:

- a) on samples from citizens or residents of the USA, nor
- b) as a diagnostic or patient monitoring tool that may impact patient therapy and management

Certified by:

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**Name of Authorized Representative (print)**

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**Signature**

**Date:** \_\_\_\_\_

**Institution Name and Address:**

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**Institutional Review Board (IRB) Name or Number / Expiry Date :**

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**Return the completed form by facsimile to:**

Calypse Biomedical Corporation  
Customer Service Department    **FAX: 971-204-0284**

