CERTIFICATION FOR U.S. INSTITUTIONS
REGARDING RESEARCH USE ONLY OF
SEDIA™ HIV-1 LAg-AVIDITY EIA

The Sedia™ HIV-1 LAg-Avidity EIA is labeled "For Research Use Only. Not for Use in Diagnostic Procedures" and is therefore exempt from certain requirements of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j(g)). Performance characteristics of this assay have not been established relative to diagnostic applications and such use is not permitted by law. Use of this assay is restricted to research use and is not intended for clinical investigation or clinical diagnostic use outside an investigation. Clinical diagnostic use includes any patient management based on the use of this assay.

The institution named below as certified by its legal representative hereby declares and certifies that:

- the institution will use the Sedia™ HIV-1 LAg-Avidity EIA exclusively as a research tool and will not use the product for diagnostic use or procedures, including patient management. The undersigned understands that clinical specimens may be tested provided they are either archival unlinked specimens (e.g. commercial or institutional specimen banks) or are clinical specimens that have been collected and unlinked to the patient identity prior to commencement of testing of specimens.

- neither the institution nor its employees shall divulge the results obtained with the Sedia™ HIV-1 LAg-Avidity EIA to research subjects, patients or their physicians, and that the Sedia™ HIV-1 LAg-Avidity EIA shall not be used on samples from patients as a diagnostic or patient monitoring tool that may impact patient therapy and management.

- If the institution transfers the Sedia™ HIV-1 LAg-Avidity EIA to a third party, it will do so only after exercising due diligence to ensure that the product will be used in compliance with all regulations pertaining to Research Use Only products.

Acknowledged and Certified by:

_____ _____
Signature Date

_____
Authorized Representative (print name)

Institution Name and Address:

Return the completed form to Sedia Biosciences by fax (503-459-4168) or email (customerservice@sediabio.com)