Comparison of Features of
Sedia™ BED HIV-1 Incidence EIA and *Sedia™ HIV-1 LAg-Avidity EIA*

Assay Design	***Sedia™ BED HIV-1 Incidence EIA*** Cat. No. 1000	***Sedia™ HIV-1 LAg-Avidity EIA*** Cat. No. 1002
Assay Principle	Measures proportion of HIV-1 specific antibody out of total antibody *(recent infection = low proportion; long term infection = higher proportion)*	Measures antibody avidity as an indication of antibody maturation *(recent infection = low avidity; long term infection = higher avidity)*
Assay Format	ELISA	
HIV-1 Antigen Type	"BED-peptide" containing divergent gp41 group M sequences	Multi-clade recombinant immunodominant region of gp41 group M ("rIDR-M")
Assay Plate Configuration	Two 96-well microplates; subdividable to 8-well strips or to individual wells	
Total Assay Time	~4 hours	~2 hours
User-Friendly Attributes	• Color-coded components • 30 day shelf life at RT for 1X Wash Buffer • Innovative plate design allows for testing partial strips or individual wells • Wash Buffer interchange-able with Sedia™ HIV-1 LAg-Avidity EIA	• Color-coded components • 30 day shelf life at RT for 1X Wash Buffer • Innovative plate design allows for testing partial strips or individual wells • Wash Buffer interchange-able with Sedia ™ BED HIV-1 Incidence EIA • Colored Sample Diluent for ease of use.

Performance Characteristics	***Sedia™ BED HIV-1 Incidence EIA***	***Sedia™ HIV-1 LAg-Avidity EIA***
Mean Seroconversion (Recency) Period	197 days (95% CL 173-220 days)	130 days (95% CL 118-142 days)
Specificity Across Subtype	Superior to "detuned" and other modified commercial diagnostic assays derived from only subtype B used to estimate incidence	Superior performance across all subtypes compared to BED EIA or "detuned" or avidity assays based on modified commercial assays.
False Recency Rate (FRR)	Published results vary considerably but most FRRs are 3-5%; dependent on correction factors and exclusion of confounding subjects (persons with AIDS, on ARV, or elite controllers)	FRR in populations typically ≤ 1%, significantly lower than BED; correction factors not required; less affected by confounding subjects (persons with AIDS, on ARV, or elite controllers) than other assays.
Consensus Acceptance	First commercialized by Sedia scientists in 2004. Widely used (>35 countries) and vetted over 10 years; used in U.S. National HIV Surveillance Program	First commercialized by Sedia in 2011. Quickly gaining acceptance and popularity. In use in >33 countries.

Assay Procedure	***Sedia™ BED HIV-1 Incidence EIA*** Cat. No. 1000	***Sedia™ HIV-1 LAg-Avidity EIA*** Cat. No. 1002
Sample Types	Liquid plasma or serum. Dried blood, plasma or serum spots require supplemental DBS Controls Pack, Cat. No. 1001	Liquid plasma or serum. Dried blood spot version available soon (Cat. No. 1003)
Sample Volume per Test Requirement	5 µL	
Sample Dilution	Single, simple 1:101 dilution	
Number of Wells Needed per Sample	1 for screening, 3 for confirmation if ODn ≤ 1.2 (ODn cut off = 0.8)	1 for screening, 3 for confirmation if ODn ≤ 2.0 (ODn cut off = 1.5)
Maximum Specimens Tested Per Kit (Screening Mode)	85	
Maximum Specimens Tested Per Kit (Confirmatory Mode)	28	

Quality Characteristics	***Sedia™ BED HIV-1 Incidence EIA***	***Sedia™ HIV-1 LAg-Avidity EIA***
Quality Control	Both products currently approved by the CDC. Lot release includes qualification of each lot by the U.S. CDC after Sedia's internal QC release.	
Assay Reproducibility	Excellent reproducibility; 11 consecutive lots approved by CDC	Excellent reproducibility; 9 consecutive lots approved by CDC
Shelf Life	24 months from date of manufacture	
Storage and Shipping	2 to 8°C for Refrigerator Pack, -25 to -10°C for Freezer Pack; Ships cold (not frozen) with excellent in-transit stability	

Product Applications	***Sedia™ BED HIV-1 Incidence EIA***	***Sedia™ HIV-1 LAg-Avidity EIA***
Regulatory Status	For Research Use Only; Not For Use In Diagnostic Procedures.	
Applications	• Population surveillance • Monitoring of intervention programs • Identifying optimal populations for vaccine trials and monitor effectiveness • Identifying 'hot spots' of new infections	
Descriptive Publications	Parekh BS et al. Quantitative detection of increasing HIV type 1 antibodies after seroconversion: a simple assay for detecting recent HIV infection and estimating incidence. AIDS Res Hum Retroviruses 2002,18:295-307.	Wei X et al. Development of two avidity based assays to detect recent HIV type 1 seroconversion using a multisubtype gp41 recombinant protein. AIDS Res Hum Retroviruses. 2010, 26:1-11.

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