



English
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Instructions for Use: HBA-Sperm-Hyaluronan Binding Assay
www.hba-pcisi.com

Proprietary and Established Names: HBA-Sperm-Hyaluronan Binding Assay

Manufacturer: Biocat, Inc., 211 Witter Road, Horsham, PA 19044, USA

US Distributor: ORIGIC Inc., 2400 Hunters Way, Charlottesville, VA 22911, USA

EU distributor: Medical Device & Services Ltd, Spring Court, Spring, Royal, Hale, Cheshire WA14 2QD, United Kingdom, www.wmdacs.com, Fax: +44 161 903 9787

Intended Use:

The HBA-Sperm-Hyaluronan Binding Assay is indicated for use as a component of:

1. the standard analysis of semen in the diagnosis of suspected male infertility.

2. analyses for determining the proper dose of IUI of untreated oligospermia.

Summary:

In natural fertilization mature sperm bind to hyaluronic acid, the main component of the cumulus matrix, enabling them to bind to the egg (Dobruncu et al., 1993, 1991).

Mature sperm also bind to hyaluronic acid chemically attached to a support (9), such as the hyaluronan-coated slides that make up the HBA kit. Viewed in the microscope, bound sperm are differentiated from unbound sperm by their beating tails that readily make no progressive movement.

The combined data showed good specificity and positive predictive value, although sensitivity was only 40%. Therefore, at a cutoff of ~80% binding, the HBA assay detected less than half of samples with truly low morphology, but among those detected as low HBA⁺ there is a strong prediction (>80% for poor morphology).

Table 2

Significance of morphology to score to Morphology

Study Site, N Significance Specificity Positive Predictive Value P =

PA 50 43.2 76.9 84.3 0.012

PA⁺ 50 51.3 90.9 95.2 0.012

CA 52 54.2 78.6 68.4 0.015

CT 55 26.5 100 100 0.001

Combination 157 40.0 85.5 80.9 0.001

(Data site recalculated with cut-offs <5% for morphology and <80% for HBA⁺).

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