

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K032874

B. Analyte:

HBA Sperm-Hyaluronan Binding Assay

C. Type of Test:

Qualitative assay for the maturity of sperm in a fresh semen sample.

D. Applicant:

Biocoat, Inc.

E. Proprietary and Established Names:

HBA Sperm-Hyaluronan Binding Assay

F. Regulatory Information:

1. Regulation section:

N/A

2. Classification:

Class II

3. Product Code:

MNA

4. Panel:

OB/ GYN, 85

G. Intended Use:

1. Indication(s) for use:

1. As a component of the standard analysis of semen in the diagnosis of suspected male infertility, 2. as a component of analyses for determining the proper course of IVF treatment of infertility.

2. Special condition for use statement(s):

N/A

3. Special instrument Requirements:

N/A

H. Device Description:

The device is a disposable plastic slide with two hyaluronan-coated sperm counting chambers.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Tru-Trax Cervical Mucous Penetration Assay
2. Predicate K number(s):
K894851
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample	Fresh liquefied semen	Fresh liquefied semen
Assay temperature	Room temperature	Room temperature
Test Result	Qualitative	Qualitative
Intended User	Professional use only	Professional use only
Differences		
Item	Device	Predicate
Data	Count of bound and unbound motile sperm, viewed under a microscope at 400x.	Linear distance swum by the sperm, viewed under a microscope at 200x.
Physiological basis	Binding of sperm to immobilized hyaluronan.	Velocity of sperm in cervical mucous.
Assay time	10-20 minutes	30 minutes

J. Standard/Guidance Document Referenced (if applicable):

N/A

K. Test Principle:

The assay is based on the ability of mature, but not immature, sperm to bind hyaluronan, the main mucopolysaccharide of the *cumulus oophorus* matrix and a component of human follicular fluid.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

Inter and intra-lot precision with normal specimens was 4.5 to 5.3 % CV. Inter and intra-lot precision with abnormal specimens was 17 to 34 % CV

- b. *Linearity/assay reportable range:*
N/A
- c. *Traceability (controls, calibrators, or method):*
N/A
- d. *Detection limit:*
N/A
- e. *Analytical specificity:*
N/A
- f. *Assay cut-off:*
N/A

2. Comparison studies:

- a. *Method comparison with predicate device:*
N/A
- b. *Matrix comparison:*
N/A

3. Clinical studies:

- a. *Clinical sensitivity:*
40 %
- b. *Clinical specificity:*
86%
- c. *Other clinical supportive data (when a and b are not applicable):*
81 % Positive Predictive Value

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

<80% binding=diminished maturity and physiological function. >80% binding=normal maturity and physiological function.

M. Conclusion:

Biocoat, Inc. has demonstrated the HBA Sperm Hyaluronan Binding Assay to be substantially equivalent to the TruTrax Cervical Mucous Penetration Assay.