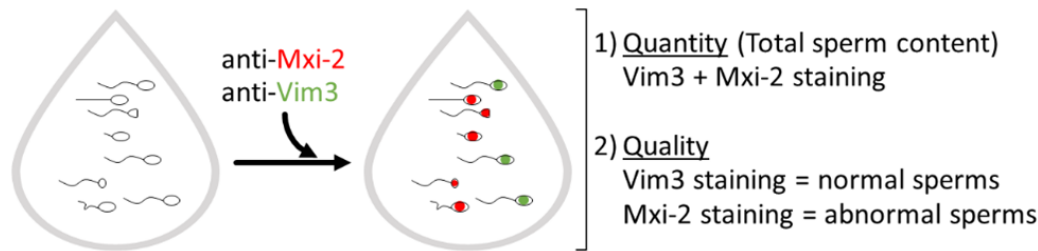


Novel Markers for Male Fertility Diagnosis

Vim3 and Mxi-2 for determining sperm quantity and quality

Invention

Novel antibody-based biomarkers allow male fertility diagnosis for determining sperm quantity and quality. The antibodies target truncated forms of the sperm proteins Vimentin 3 (Vim3) and Mxi-2, which identify the following characteristics: Vim3 is only expressed in normal sperms (e. g.



ejaculates with normozoospermia), and Mxi-2 is only expressed in abnormal sperms (e. g. ejaculates with oligo-astheno-teratozoospermia (OAT) syndrome and azoospermia). Besides a reduced number of sperm cells, deformation and immobility of sperms (abnormal sperms) cause an insufficient sperm quality, which can now be determined by using the antibodies anti-Vim3 and anti-Mxi-2. The determination of the ratio enables the differentiation of pathological subtypes. In addition, the novel antibody-based diagnosis of sperm quantity and quality offers advantages compared to the WHO-recommended standard procedure (spermogram):

- Fresh and frozen ejaculates can be used (@ RT: > 1 h or @ -20 °C: several weeks).
- Semen donation can be made at home.
- Determination of quantity and quality of the same sample.
- Consistencies in the results (reliable and objective determination).

Commercial Opportunities

	Vim3	Mxi-2
Source/Isotype	Mouse IgG	Mouse IgG
Origin	mouse, monoclonal	mouse, monoclonal
Applications	Immunofluorescence, Flow Cytometry, Western blot	Immunofluorescence, Flow Cytometry, Western blot
Reactivity	Human	Human
Sensitivity	85 %	84 %
Specificity	92 %	91 %

The antibodies can also be used for the development of diagnostic tests based on systems with automated cell analysis. Anti-Vim3 and anti-Mxi-2 antibodies are part of pending diagnostic patent applications for which a licence is offered.

Current Status

Until now, 120 patients were analyzed and categorized according to the nomenclature of the WHO. Vim3 and Mxi-2 expression were analyzed by different methods (ELISA, FACS).

Relevant Publications

- Pending patent applications: PCT/EP2018/058923 and PCT/EP2019/084015
- von Brandenstein M. et al., (2018), Beyond the 3'UTR binding: microRNA - induced protein truncation via DNA binding, *Oncotarget*, 2018; 9:32855-32867
- Funke T. et al., (2019), Vimentin 3 Allows Differentiation between Normozoospermia and Oligoastheno-teratozoospermia. *Disease Markers*, 2019 Dec 10;2019:9803498
- Huerta M. et al., (2021), EBV-induced loss of sperm quality, *Turkish Journal of Urology*, 2021

An invention of University Hospital Cologne.

Competitive Advantages

- Vim3 and Mxi-2 staining as reliable markers for determining sperm quantity and quality
- consistent results by reliable and objective determination
- results available within 30 minutes by FACS and immunofluorescence, within 3 hours by ELISA
- ejaculates usable @ RT: > 1 h or @ -20 °C: several weeks

Technology

Readiness Level

1 2 3 4 5 6 7 8 9

System prototype demonstration in operational environment

Industries

- Diagnostic Industry

Ref. No.

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