TEST: DECIDUALIZATION SCORE

PRINCIPLE:
Molecular testing of endometrial biopsy samples for women with reproductive failures is important for evaluation of uterine receptivity and for a personalized therapeutic strategy [1, 2]. The test is based on molecular analysis of six factors that are associated and essential for decidualization: FOXO1, GZMB, IL15, SCNN1A, SGK1 and SLC2A1 [3-7]. The Decidualization score reflects how many of these factors are expressed at normal range in the tested sample. The Normal Decidualization score is ">4". The score "4" is Borderline Normal. The score"<4 is Low Decidualization score. This test (Decidualization Score test) helps to determine if the molecular profile in endometrium is implantationfriendly and could be used for selecting patients that require therapeutic actions to improve endometrial condition before IVF –ET procedure.

SPECIMEN REQUIREMENTS:
Endometrial biopsy sample obtained according to a standard procedure with a Pipelle catheter or similar. Natural cycle: take the biopsy 7 to 9 days after the LH surge. The day of the LH surge is considered as LH+0, and the biopsy will be taken at LH+7-9. The best way to identify the LH surge is with the urinary LH tests. Hormone Replacement Therapy cycle: upon initiation of an HRT cycle, take the biopsy after 5 full days of progesterone treatment. The day for the first intake of progesterone is considered as P+0 and the day of the biopsy is P+5. About 30-50 milligrams of tissue is required for analysis (for illustration purposes, this equates to one or two cubes of approximately 3x3 millimeters). Specimen should be collected into a tube with 3ml of RNA stabilization solution (provided by the laboratory) and shipped to the laboratory at ambient temperature.

SPECIMEN STABILITY in RNA stabilization solution: room temperature - 1 week, refrigerated - one month.

REJECTION CRITERIA: absence of sizeable endometrial tissue fragments; inadequate sample consisting only of blood and/or mucous substance. Insufficient quantity of RNA isolated to perform assay.

METHODOLOGY: Targeted RNAseq via Next-Generation Sequencing (NGS).

REFERENCES:
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3. Vasquez, Y.M., et al., FOXO1 regulates uterine epithelial integrity and progesterone receptor expression critical for embryo implantation. PLoS Genet, 2018. 14(11): p. e1007787.
4. Salker, M.S., et al., Deregulation of the serum- and glucocorticoid-inducible kinase SGK1 in the endometrium causes reproductive failure. Nat Med, 2011. 17(11): p. 1509-13.
5. Ruan, Y.C., et al., Activation of the epithelial Na+ channel triggers prostaglandin E(2) release and production required for embryo implantation. Nat Med, 2012. 18(7): p. 1112-7.
6. von Wolff, M., et al., Glucose transporter proteins (GLUT) in human endometrium: expression, regulation, and function throughout the menstrual cycle and in early pregnancy. J Clin Endocrinol Metab, 2003. 88(8): p. 3885- 92.
7. Brighton, P.J., et al., Clearance of senescent decidual cells by uterine natural killer cells in cycling human endometrium. Elife, 2017. 6.

TURNAROUND TIME: 7-10 business days