ERA (ENDOMETRIAL RECEPTIVITY ANALYSIS) DIAGNOSIS REPORT

Patient information		Sample information		Clinic information	
MRN:		**Date received:**		**Clinic:**	
Sample type:	Endometrial biopsy	**Report Date:**			
Name:		**First intake of P4:**		**Doctor:**	
DOB:		**Date of biopsy:**		**No. biopsy:**	1
		Cycle type:	HRT (110 hours)		

RESULT:

PRE-RECEPTIVE

Recommendation: Blastocyst/s transfer 1 day later than the time at which this endometrial biopsy was performed (134 ± 3 hours with progesterone administration)*

INTERPRETATION OF YOUR RESULT:

An 89% of women with similar endometrial profiles reached receptivity with 1 more day of progesterone administration (confidence interval of 95% [86%-91%]), so in these cases new endometrial biopsy is not needed. Therefore, blastocyst/s transfer is recommended at 134 ± 3 hours with progesterone administration.

For a day-3 embryo(s), the transfer should be performed two days earlier than indicated in recommendation for blastocyst transfer above.

*** This recommendation is only applicable to the same type of cycle treatment as the one used for this endometrial biopsy and if the endogenous progesterone measured prior to the first progesterone intake is <1ng/ml.**

Signature

Sample name, PhD

Biologist

Signature

Sample name, PhD

Laboratory Manager

Interpretation of ERA Analysis Results:

Receptive:

This gene expression profile is compatible with a normal receptive endometrium. In case of an early or late receptive profile, it means that the endometrium is at the beginning or at the end (respectively) of the receptive stage. This would imply to add or rest 12 hours of treatment for the blastocyst transfer regarding the moment in which the biopsy was performed.

Pre-receptive:

This gene expression profile is concordant with an endometrium at a pre-receptive stage. It may be due to the displacement of the window of implantation, and to confirm a second biopsy on the recommended day could be required.

Post-receptive:

This gene expression profile is concordant with an endometrium at a post-receptive stage. It may be due to the displacement of the window of implantation, and to confirm a second biopsy on the indicated day should be analyzed.

Proliferative:

This gene expression profile is concordant with an endometrium at a proliferative stage. It is recommended to contact the ERA laboratory to discuss the type of cycle in which the biopsy was taken.

Non-informative:

The profile analyzed does not match the control gene expression profiles present in the ERA predictor. It is recommended to contact the ERA laboratory to discuss the protocol and repeat the biopsy.

Insufficient RNA:

It was not possible to determine the gene expression profile of the sample because there was not enough biopsy material. This occurs in approximately 2.5% of samples received. It is recommended to do a second biopsy.

Invalid RNA:

It was not possible to determine the gene expression profile of the sample due to the poor quality of genetic material obtained. This occurs in approximately 3% of samples received. It is recommended to do a second biopsy following the sample stabilization instructions.

METHOD:

The ERA test was developed and patented by Igenomix (PCT/ES2009/000386).

The ERA test simultaneously analyzes the expression of 236 genes selected for their endometrial receptivity profile. Analysis of the expression of these genes utilizes Next Generation Sequencing in conjunction with a bioinformatics tool (computational predictor) that gives an endometrial receptivity diagnosis with a specific diagnostic probability.

After receiving the endometrial biopsy and extracting the genetic material (RNA), sample minimum quality requirements are evaluated before use of the ERA diagnosis tool.

LIMITATIONS:

The aim of this test is to provide physicians with an objective molecular diagnosis of the patient's endometrial reproductive health. Depending on the result of this analysis, the physician may use it to guide personalized embryo transfer.

Following ERA report recommendations does not guarantee implantation. Failed implantation may be caused by other factors such as poor embryo quality, genetic abnormalities, or previous pathologies.

INFORMATION

Development of this tool was published by Díaz-Gimeno et al., 2011 (Fertil Steril. 2011 Jan;95(1):50-60, 60.e1-15. doi: 10.1016/j.fertnstert.2010.04.063). Accuracy and reproducibility of the ERA test was proven in Díaz-Gimeno et al.,2013 (Fertil Steril. 2013 Feb;99(2):508-17. doi: 10.1016/j.fertnstert.2012.09.046). Clinical applicability in patients with repeated implantation failures was demonstrated in Ruiz-Alonso et al., 2013 (Fertil Steril. 2013 Sep;100(3):818-24. doi: 10.1016/j.fertnstert.2013.05.004) and Ruiz-Alonso et al., 2014 (Hum Reprod. 2014 Jun;29(6):1244-7. doi: 10.1093/humrep/deu070).

A prospective, randomized study on the effectiveness of the ERA test in patients who have not received previous assisted reproduction treatments is presently underway (ClinicalTrials.gov Identifier:NCT01954758). Interim results from this study were presented at the American Society of Reproductive Medicine (ASRM) 2016 Scientific Congress (Fertil Steril. 2016 Sep;106(3):e46-e47). This abstract was awarded Prize Paper by the Society of Reproduction, Endocrinology and Infertility (SREI).

Igenomix Spain has submitted ERA documentation to CLIA and is currently under review for a CLIA license.