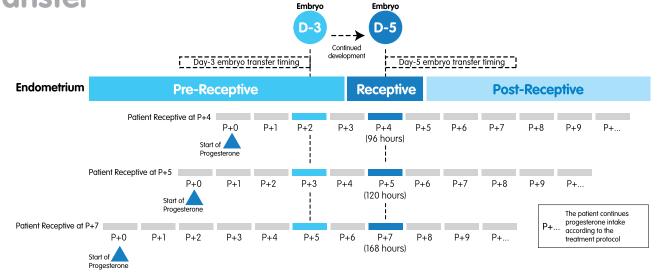




When to perform the embryo transfer

The blastocyst transfer should be performed in the same type of cycle and on the same day in which a receptive result was obtained. A receptive result indicates the ideal day on which the blastocyst transfer should be performed. A day 3 embryo should therefore be transferred 2 days earlier.

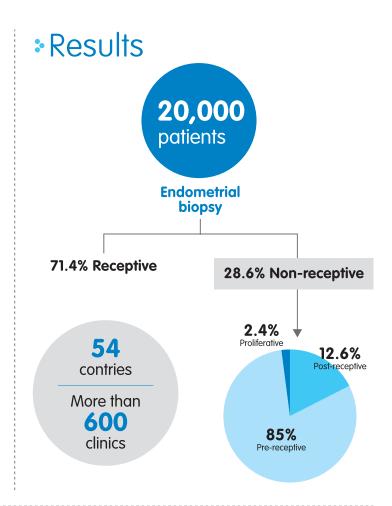


Comparison of clinical results

	CLINICAL OUTCOME		
		ET	pET
	Number of patients	17	
	Source of oocytes	Ovum donation	
	Age	40.7 ± 4.7(32-49)	
First attempt	Number of embryos transferred	1.8± 0.4	1.7± 0.5
	Implantation rate	12.9% (4/31)	34.5% (10/29)
	Pregnancy rate	23.5% (4/17)	52.9% (9/17)
	Ongoing pregnancy rate	0% (0/4)	66.7% (6/9)
	Clinical abortion	100% (4/4)	0% (0/9)
	Biochemical pregnancy	0.0% (0/4)	33.3% (3/9)

Data from a pilot study comparing Frozen Embryo Transfer (FET) to personalized Embryo Transfer (pET) in the same patient cohort. Patients underwent an FET before performing their first ERA test, on a day that was later diagnosed as non-receptive by the ERA. Patients then received a pET on their receptive day, after confirmation from a 2nd ERA biopsy.

Ruiz-Alonso et al. Human Reproduction 2014 Jun; 29(6): 1244-7



Endometrial Receptivity Analysis



PATENTED SINCE 2009

www.igenomix.com

What is the ERA test?

The Endometrial Receptivity Analysis (ERA), developed and patented by IGENOMIX (PCT/ ES2009/000386), is a test designed to evaluate the timing of endometrial receptivity.

This molecular diagnostic tool uses NGS to analyze the expression level of 236 genes related to the status of endometrial receptivity.

To do so, RNA obtained from an endometrial tissue sample is analyzed by NGS and then classified by our ERA predictor as receptive or non-receptive, depending on the expression profile of the RNA.



Who should use the ERA test and why?

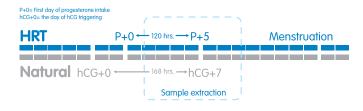
The ERA test has been proven to help patients who have experienced implantation failure while using good quality embryos.

Advantages of 4 the FRA test

The ERA test has been shown to be highly sensitive and specific in the detection of genetic expression profiles associated with receptivity. It allows the personalized window of implantation to be detected before the patient starts using assisted reproduction techniques. This is more sensitive than the classical method endometrial dating, based on histological criteria, which is highly subjective and has been proven to be unable to discriminate between fertile and infertile patients.

2 What is the purpose of the ERA test?

The ERA test is used to evaluate the stage of an endometrium to determine if a receptive or non-receptive genetic profile is present at the time of biopsy. In the case where the endometrium is non-receptive, the test enables us to find a personalized window of implantation for each patient.



5 Sample extraction and shipment

- An endometrial biopsy taken from the uterine fundus must be immediately introduced into an ERA cryotube and preserved in a refrigerator (4-8°C/39-46°F) for at least 4 hours.
- In order to ensure the highest sample quality, we recommend shipment to our laboratory take less than 120 hours at room temperature. In addition, the sample should never reach more than 35°C/95°F.

6

Methodology

MAIN STAGES OF THE ASSAY





>



RNA IS SEQUENCED TO ANALYZE THE EXPRESSION OF 236 GENES



THE DATA OBTEINED IS MEASURED AND THE SAMPLE IS CLASSIFIED BY THE COMPUTATIONAL PREDICTOR





REPORT

7. Limits of the technique. The ERA test has a specificity of 0.8857 and a sensitivity of 0.9975 for receptivity profile classification. The biopsy procedure, though simple, has a risk (less than 5%) of not obtaining a sufficient quantity and/or quality of endometrial tissue, in which case it is impossible to perform the test and a new sample extraction would be required.

IGENOMIX PUBLICATIONS:

Diaz-Gimeno P, Horcajadas JA, Martinez-Conejero JA, Esteban FJ, Alamá P, Pellicer A, Simón C. A Genomic Diagnostic Tool for Human Endometrial Receptivity based on the Transcriptomic Signature. Fertil Steril.2011 Jan; 95(1)pp: 50-60, 60.e1-15. Diaz-Gimeno P, Ruiz-Alonso M, Blesa D, Bosch N, Martinez-Conejero JA, Alamá P, Garrido N, Pellicer A, Simón C. The accuracy and reproducibility of the endometrial receptivity array is superior to histology as a diagnostic method for endometrial receptivity. Fertil Steril. 2013 Feb;99(2):508-17. Ruiz-Alonso M, Blesa D, Diaz-Gimeno P, Gómez E, Fernández-Sánchez M, Carranza F, Carrera J, Vilella F, Pellicer A, Simón C. The endometrial receptivity array for diagnosis and personalized embryo transfer as a treatment for patients with repeated implantation failure. Fertil Steril. 2013 Sep;100(3):818-24.

Ruiz-Alonso M, Galindo N, Pellicer A, Simón C. What a difference two days make personalized embryo transfer (pET) paradigm: A case report and pilot study. Hum Reprod. 2014 Apr 15.In press.