Neuberg DIAGNOSTICS | CENTER FOR GENOMIC MEDICINE

TEST REQUISITION FORM

OpERA OPTIMAL TIME FOR ENDOMETRIAL RECEPTIVITY by NCGM

ENDOMETRIAL RECEPTIVITY ANALYSIS

PATIENT DETAILS

(In BLOCK letters)

Full Name

Patient ID

DOB D D / M M / Y Y Y Y

Age Y Y / M M

Height cm

Weight kg

Blood Type

Ethnicity

E-mail ID

Contact No.

REFERRING CLINICIAN

(In BLOCK letters)

Clinician Name

Hospital

Address

E-mail ID*

Contact No.

E-mail ID of Contact Person*

Contact No.

*Note - Report will be sent to both Emails. If any changes, please inform.

TEST INFORMATION

Details of cycle type: ☐HRT ☐Natural cycle ☐hCG

HRT Cycle: Progesterone + _____days after first progesterone intake, eg. P+5 (See Figure)

Progesterone level before start of progesterone: _____ng/ml on _____(DD/MM/YYYY)

First Progesterone Intake

Date: D D / M M / Y Y Y Y

Time:_____ AM / PM

Pre-progesterone Endometrial Thickness (mm):_____

Protocol for progesterone supplementation:_____

_____

_____

Natural / Modified Natural Cycle: LH + _____ days after LH surge, eg. LH+7

LH surge date: D D / M M / Y Y Y Y

LH surge Time:_____AM / PM

Ultrasound + _____ days after follicle rupture, eg. Ultrasound+6

Neuberg Centre for Genomic Medicine (NCGM)

"KEDAR" Opposite Krupa Petrol Pump, Near Parimal Garden, Ahmedabad - 380006 I Phone: +91-79-40408181 / 61618181 / 61618111

Email: gc.ncgm@supratechlabs.com | CIN : U85195GJ2013PTC077365,2013-14, | Web: www.supratechlabs.com

Neuberg DIAGNOSTICS | CENTER FOR GENOMIC MEDICINE

TEST REQUISITION FORM

BIOPSY INFORMATION[a,b]

Date of Biopsy (D D / M M / Y Y Y Y) ☐☐/☐☐/☐☐☐☐ Time of Biopsy_____AM / PM

Biopsy Method Used : ☐ Pipelle ☐ Curette
☐ Other _____

Biopsy : ☐ First biopsy ☐ Second biopsy ☐ Third or more

Indication of Test : ☐ Implantation failure: Number of failed attempts: ____ ☐ Recurrent Miscarriage
☐ Endometriosis ☐ Chronic Endometritis
☐ Other_____

OTHER PATIENT INFORMATION[b]

Antibiotics taken in the last three months: ☐Yes ☐No

If Yes, Active ingredient:_____Dosage:_____

Duration of treatment :_____ Dates on which it was administered: (D D / M M / Y Y Y Y) ☐☐/☐☐/☐☐☐☐

Allergies to any antibiotic: ☐Yes ☐No

If Yes,
☐ Beta-lactams ☐ Macrolides ☐Tetracyclines
☐ Lincosamides ☐ Nitroimidazoles ☐Trimethoprim/Sulfonamides
☐ Others

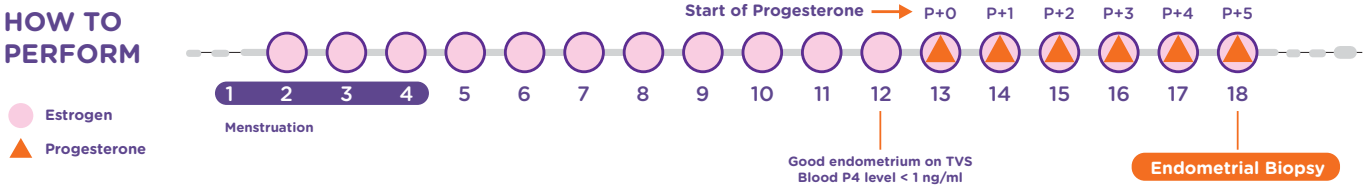
a- for endometrial receptivity analysis
b- for endometrial microbiome analysis

Neuberg Centre for Genomic Medicine (NCGM)
"KEDAR" Opposite Krupa Petrol Pump, Near Parimal Garden, Ahmedabad - 380006 I Phone: +91-79-40408181 / 61618181 / 61618111
Email: gc.ncgm@supratechlabs.com | CIN : U85195GJ2013PTC077365,2013-14, | Web: www.supratechlabs.com

Neuberg DIAGNOSTICS | CENTER FOR GENOMIC MEDICINE

METHODOLOGY

HOW TO PERFORM



Introduction

OpERA is a test to determine the receptivity of the endometrium. This may increase the chance of pregnancy by predicting the ideal time for the transfer of a blastocyst embryo in the window of implantation of the endometrium. A biopsy of endometrial tissue is taken 5 days after administration of progesterone or 7 days after LH surge and this is analyzed further using gene expression profiling of the endometrial biopsy via RNA sequencing using Next Generation Sequencing (NGS).After processing the endometrial biopsy through all quality control metrics, the bioinformatics predictor classifies an endometrial sample as “receptive” or “non-receptive.” The “non-receptive” ERA is further classified as pre-receptive or post-receptive giving an exact status of the endometrium at the time of biopsy.

Receptive: This gene expression profile is attuned with a normal receptive endometrium and blastocyst(s) transfer may be performed following the same protocol utilized during this Endometrial Receptivity Analysis testing.

Pre-receptive: This gene expression profile is concordant with an endometrium at a pre-receptive stage due to the potential displacement of the window of implantation. To confirm this result, the analysis of 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 due to the potential displacement of the window of implantation. To confirm this result, the analysis of a second biopsy on the recommended day might be needed.

Insufficient RNA/Inconclusive Result: It was not possible to determine the gene expression profile of the sample because there was not enough genetic material or due to the poor quality. It is necessary to evaluate a new endometrial biopsy.

Process

For this test, an endometrial biopsy is required and the first biopsy is usually performed on the seventh day after LH surge in the natural cycle or after five days of progesterone supplementation with hormone replacement therapy (HRT) cycles. In case OpERA indicates displacement of the window of implantation, a second endometrial biopsy may be required in some cases. The endometrial biopsy is taken by the treating clinician by inserting a Pipelle Endometrial Suction Curette through the vagina into the uterus, from which a small piece of endometrial tissue is taken and collected in the provided container. The endometrial biopsy is then sent to the laboratory for analysis. Results of the biopsy are available approximately three to four weeks after it is received by the laboratory. It is necessary to send the complete test requisition form alongwith the endometrial biopsy in order to avoid delaying of the results.

Limitations

OpERA with Receptive results does not guarantee a pregnancy or successful implantation. Other underlying factors should also be taken into account which might be responsible for implantation failure.

This test only analyzes the gene expression and gives no idea about the other existing pathological conditions related to endometrium or the embryo quality.

The recommendation in the OpERA report is only applicable to the same type of cycle treatment as the one used for that particular endometrial biopsy and if the endogenous progesterone measured prior to the first progesterone intake is <1 ng/ml.

Complications

In case the biopsy procedure fails to obtain a sufficient quantity and/or quality of tissue, a 'non-informative' report is given out. In case of “NonInformative” results, a new biopsy will be required.

Non-disclosure

Your identity and your all personal information shall be kept confidential. Relevant authorities will be permitted access to this information by the law of the applicable jurisdiction. The Health Authorities shall have access to them to review medical records. As part of their occupational duties, the personnel with access to your personal details shall be subject to permanent professional secrecy.

Neuberg Centre for Genomic Medicine (NCGM)

“KEDAR” Opposite Krupa Petrol Pump, Near Parimal Garden, Ahmedabad - 380006 I Phone: +91-79-40408181 / 61618181 / 61618111
Email: gc.ncgm@supratechlabs.com | CIN : U85195GJ2013PTC077365,2013-14, | Web: www.supratechlabs.com

Neuberg DIAGNOSTICS | CENTER FOR GENOMIC MEDICINE

CONSENT / ASSENT FORM

ACKNOWLEDGEMENT

I acknowledge that

- ☐ I have read and understood this written material.
- ☐ I understand the purpose, risks and benefits of this procedure.
- ☐ I am aware that there may be other risks and complications, not discussed, that may occur. During the course of the procedure, unforeseen conditions may be revealed requiring the performance of additional procedures.
- ☐ Technical problems with the instrumentation may prevent the completion of the procedure. No guarantees or promises have been made to me concerning the results of this procedure or any treatment that may be required as a result of this procedure.

PATIENT CONSENT

This procedure has been explained to me in a language that I understand. I have been given the opportunity to consider other options and alternatives. I have been counselled about the risks, benefits and limitations of this test. I willingly request NCGM Supratech to carry out this test. I opt in to donate extra DNA material, if available, for research.
I have read and have received a copy of the consent form.

Patient Name: _____

Signature:_____ Date, Time and Place:_____

DOCTOR AUTHORIZATION

I certify that the information on this form is correct to the best of my knowledge. I have requested this test based on my professional clinical judgement. I have counseled the patient about the possible testing outcomes and have explained the limitations of this test. I agree to share any other information if requested by the providers.

Doctor Name: _____

Signature:_____ Date, Time and Place:_____

Neuberg Centre for Genomic Medicine (NCGM)
"KEDAR" Opposite Krupa Petrol Pump, Near Parimal Garden, Ahmedabad - 380006 I Phone: +91-79-40408181 / 61618181 / 61618111
Email: gc.ncgm@supratechlabs.com | CIN : U85195GJ2013PTC077365,2013-14, | Web: www.supratechlabs.com