

CLINICAL STUDY TO VALIDATE PERFORMANCE OF OPAL

Description:

This clinical study evaluates OPAL, a device specifically designed to assess the quality of human oocytes and how they impact the fertilization rate, blastocyst formation rate, implantation rate, clinical pregnancy rate and live birth rate.

Inti Labs has partnered with Lee Women's Hospital to conduct this study.

Study Objectives:

1. **Enhancing Fertilization Rates:** We are investigating whether higher-graded eggs evaluated by OPAL correlate with improved fertilization rates.
2. **Embryo Grading and Quality:** By analyzing embryo development, we are investigating whether higher-grade eggs evaluated by OPAL lead to higher-quality embryos. This part of the study will also compare OPAL's grading against Gardner's grading system and time-lapse AI scores.
3. **Euploidy and Implantation Potential:** We are examining whether higher-graded eggs evaluated by OPAL result in more euploid embryos, which play a crucial role in successful implantation.

Methodology:

- **Patient Recruitment:** We recruit patients and select mature oocytes (MII) for evaluation.
- **OPAL Grading:** Selected MII oocytes undergo precise grading using OPAL device.
- **Evaluation:** We assess fertilization rates, Day 3 embryo development, and Day 5 blastocyst formation.

- Correlations: We correlate OPAL's grading with various parameters, including implantation rates and clinical pregnancy outcomes.

Clinical Impact:

Our study contributes to evidence-based fertility treatments, empowering clinicians and patients with data-driven decisions. By leveraging OPAL's advanced technology, we aim to enhance ART success rates and improve patient outcomes.