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LIVE BIRTH FROM IN VITRO FERTILIZATION WITHOUT INJECTIONS OR SERUM HORMONE ASSESSMENT

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PURPOSE

To determine the feasibility of our novel at-home and non-invasive In Vitro Fertilization (IVF) approach.

MATERIAL & METHODS

POPULATION AND SETTING

All patients aged 21-38 years with indication of IVF who visited New Hope Fertility Center since January 2022 were offered to participate in the study.

CLINICAL PROTOCOL

An ultra minimal ovarian stimulation was performed by orally administering 25-100 mg of clomiphene citrate (CC) daily from cycle day (CD-) 3, with occasional addition of 5 mg letrozole. On CD-10, follicle development was monitored by transvaginal ultrasound. Levels of luteinizing hormone (LH) and progesterone (PG) were determined in urine using Oova, a commercially available at-home ovulation testing system (*Oova kit shown in Figure 1*). For research purposes only, serum hormone levels were collected in parallel for future review, however this data was kept from the clinical team treating patients in this study.

Monitoring continued every 24-48h if needed. When the dominant follicle reached 18 mm in diameter, ovulation induction was initiated by leuprolide acetate via nasal spray, followed by oocyte retrieval 34-38 hours later and IVF (*Protocol shown in Figure 2*).

Up to two fresh day-2 or day-3 (D-2/3) embryos were transferred to the participants. Two mg of estradiol orally and 400 mg of micronized progesterone vaginally were administered daily for luteal phase support.

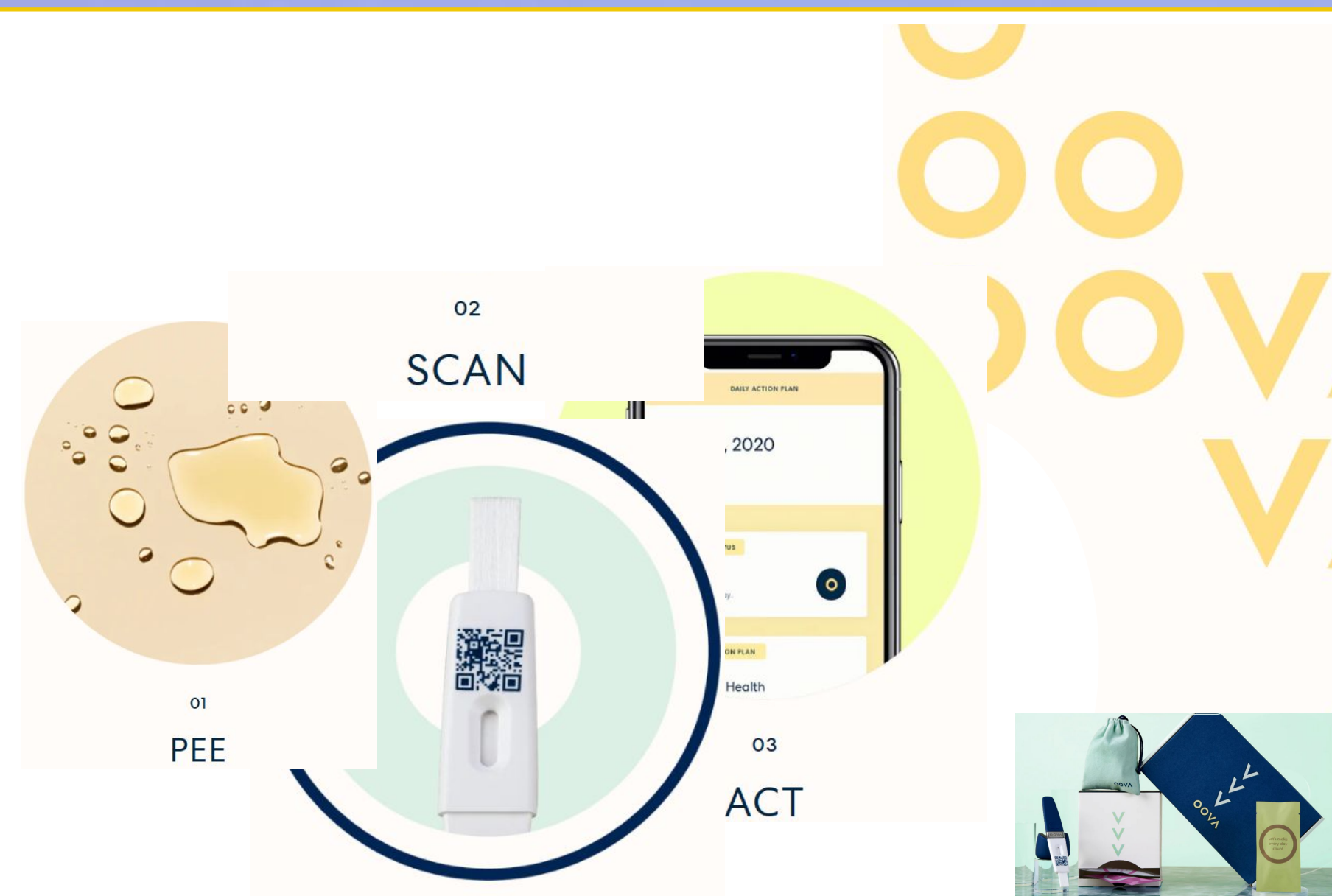


Fig.1 - Oova tests utilize advanced nanotechnology and are scanned with an artificial intelligence (AI)-powered smartphone app to measure LH and pregnanediol-3-glucuronide (PdG), a biproduct of progesterone, quantitatively with accuracy. Patient results are automatically sent to the physician in real-time.

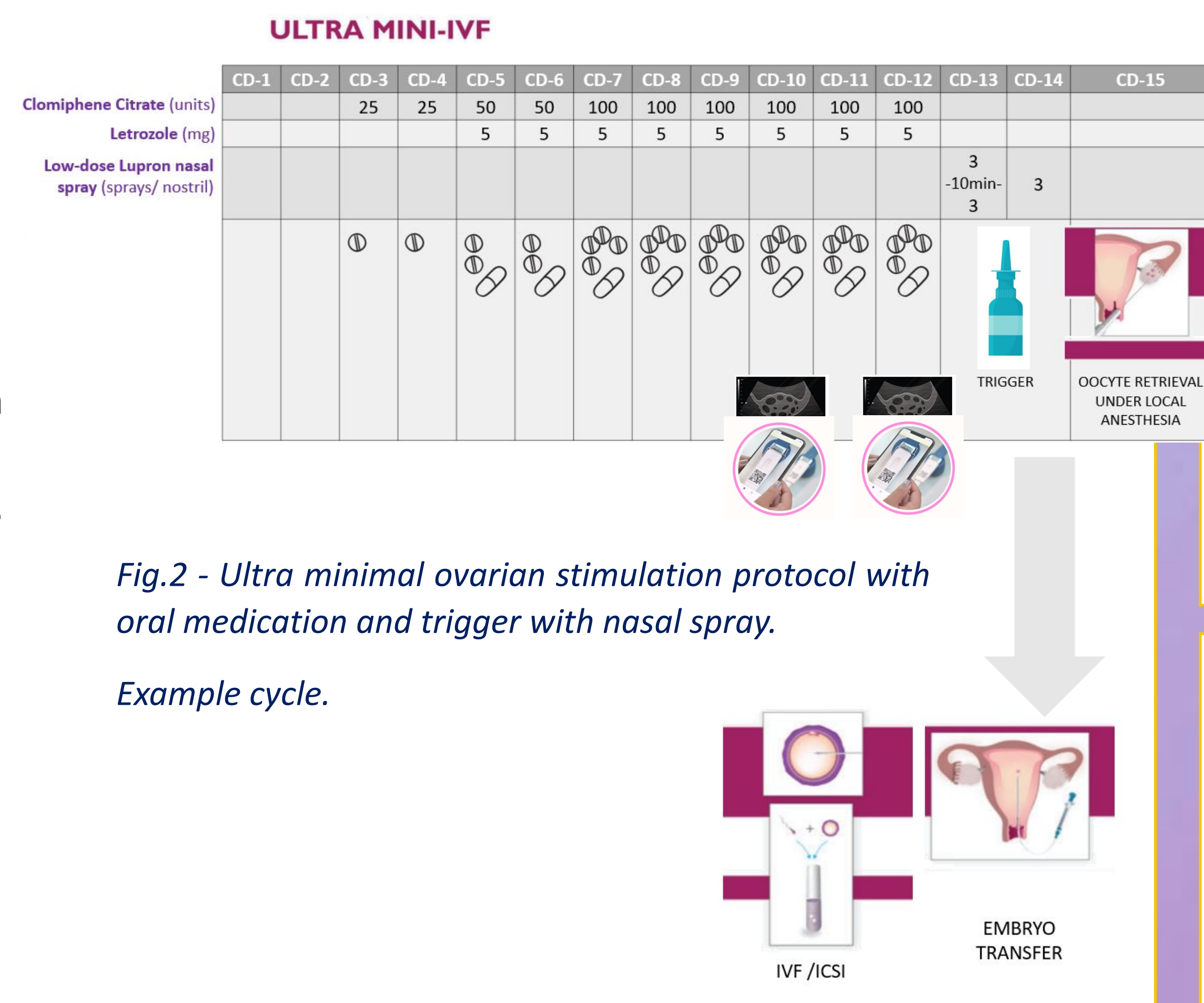


Fig.2 - Ultra minimal ovarian stimulation protocol with oral medication and trigger with nasal spray.

Example cycle.

RESULTS

Fifteen out of the eighteen patients enrolled completed the protocol. At-home hormone monitoring was successful with a great patient compliance. (*Pattern of hormone levels in urine and blood shown in Figure 3*).

After minimal stimulation, MII oocytes and D-2/3 embryos were obtained in all cases. A mean of 2.1 (range 1-6) oocytes were retrieved and 1.8 (range 1-4) embryos were generated. The fertilization rate was 91.1%.

Among the eleven patients who proceeded with fresh embryo transfers, the transfer rate was 84.6%, with seven patients having fresh single embryo transfer (SET) and four having double embryo transfer (DET). Three positive b-hcg tests were obtained, two of which resulted in early pregnancy loss. One patient delivered a healthy baby (*Outcomes summarized in Table 1*).

Age (years)	Days of stim	Oocytes retrieved	Embryos obtained	Embryo transfer (ET)	b-hcg	Outcome	Non-transferred embryos
27	8	1	1	D2 SET	-		
25	9	6	4	D2 DET	-		1 morula arrested, 1 D6 blasto cryo without PGT-A
33	13	2	2	D2 DET	+	Abortion	
36	7	1	1	D2 SET	-		
37	12	1	1	D3 SET	+	Live birth at term	
36	9	1	1	D3 SET	-		
37	18	2	1				1 2PN arrested
32	13	1	1				1 2PN arrested
37	16	2	2	D2 DET	-		
33	9	4	4				2 D5 and 2 D6 blastos PGT-A – 1 euploid cryo
32	7	2	1	D2 ET	-		
27	13	3 (1M1)	2				2 D2 embryos cryo
34	12	3	3	D2 DET	+	Chemical pregnancy	1 2PN arrested
28	9	1	1	D2 ET	-		
37	12	2	2	D2 ET	-		D6 blasto PGT-A – 0 euploid cryo

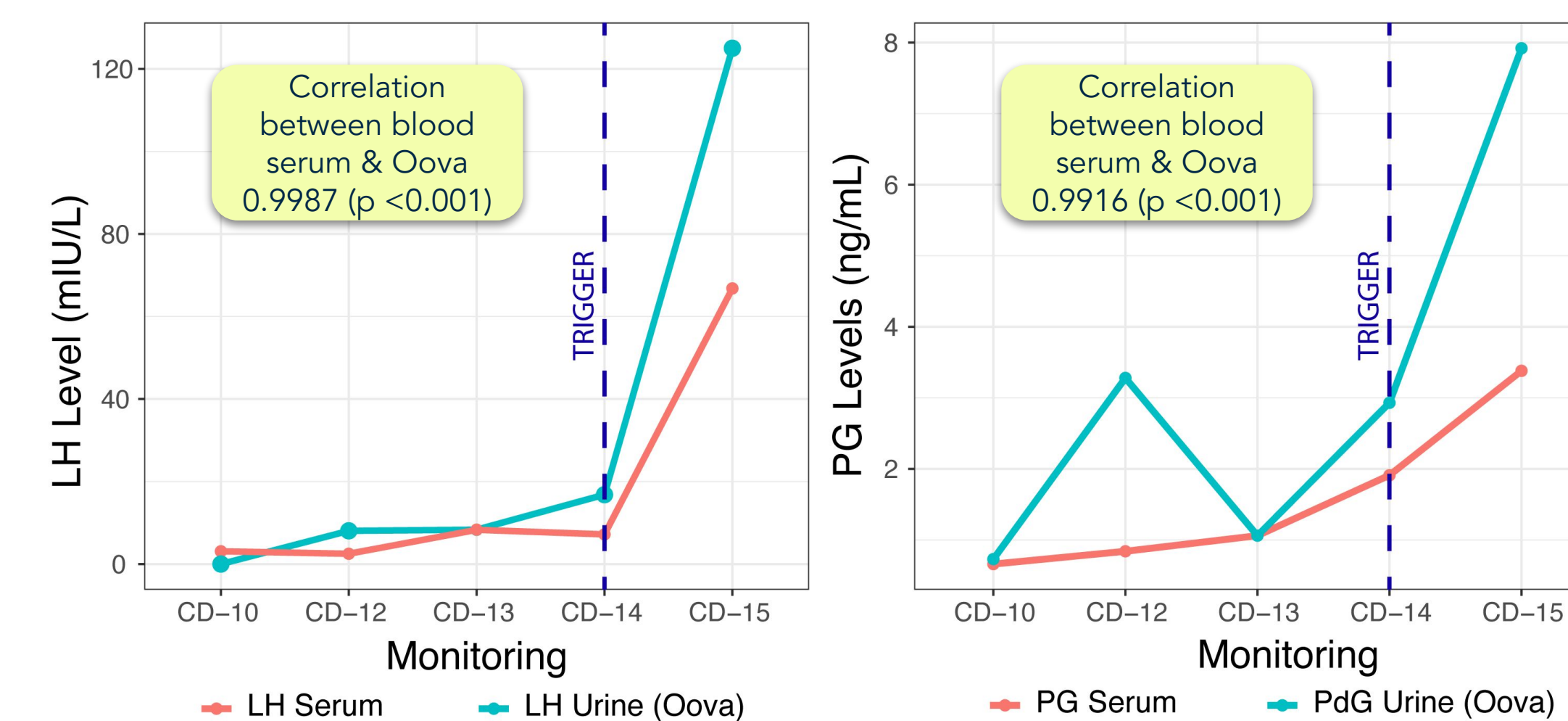


Fig.3 – Relationship of LH and PG/PdG measurements in blood and urine follow identical patterns across cycle days.

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CONCLUSION

Our study shows for the first time in the modern history of IVF that ovarian stimulation without injections or serum hormone assessment is feasible and can result in healthy live birth.

IMPACT STATEMENT

The use of ovarian stimulation with oral medications, urine hormone assessment and trigger by nasal spray offers improved accessibility to IVF over the conventional protocols that typically require daily gonadotropin injections and frequent blood draws.

This at-home IVF approach provides a viable alternative to conventional methods, which could become the patient-friendly first-line fertility treatment in the future of IVF.

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