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SARS-CoV-2 immunity, infective and naïve incidence in fertility clinics after lockdown

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Conflict of interest R.K.; D.V.; J.C. are employed by Igenomix US, LLC and C.S. is the Head of the Scientific Advisory Board of Igenomix. R.F and D.S. are employees in the different fertility centers that participate in this study.

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Short Title: Testing for SARS-COV-2 in fertility clinics

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RESEARCH LETTER

Objective: The outbreak and second wave of the COVID-19 pandemic poses concern to the public, including couples wishing to conceive and pregnant women.¹ During the pandemic, many fertility clinics suspended treatment. When reopening was undertaken, routine triage, social distancing and masks were necessary. However, this may be insufficient, as there is a 5-day asymptomatic window until infection becomes evident and 30% of infected people are asymptomatic.² The aim of the present study was to report the incidence of immune, infected and naïve status for SARS-CoV-2 among asymptomatic clinical staff and patients in two fertility centers located in Massachusetts and Utah, states with different COVID-19 prevalence rates.

Study Design: This prospective study enrolled 339 asymptomatic individuals, from June 18 to July 30, 2020. After a routine symptom-based screening, exclusively asymptomatic individuals attending or working in the two clinics were tested by RT-PCR on nasopharyngeal swab for SARS-CoV-2 RNA detection (Thermofisher, Waltham, MA, USA), and for IgG detection on blood samples (Abbott Inc, Scarborough, ME, USA), following FDA-EUA protocols. In Clinic A (Utah Fertility Center) located in a low prevalence state (312 cases per 100,000 during the study), 154 individuals were analyzed. Whereas in clinic B (Boston IVF), (1,462 cases per 100,000 during the study), 185 individuals were tested. The study was approved by an independent review board and registered in ClinicalTrials.gov (ID NCT 04466644). All results were reported to the applicable health authority.

Results: From the 339 asymptomatic individuals, the percentage of informativity was 100% for RT-PCR and 99.4 % (337 out of 339) for the IgG test. In a total of 337 individuals with informative results for both tests, SARS-CoV-2 presence was detected in 2/337 (0.59%) and 5/337 (1.48%) were positive for IgG serology. In clinic A we found 0.65% (1/154) infected, 0.65% (1/154) immune and 98.7% (152/154) individuals still naïve for this virus, whereas in clinic B we showed similar findings, being 0.5% (1/183) infected, 2.2% immune (4/183), and 97.3% (178/183) naïve (Table 1). Individuals with a positive result for the RT-PCR analysis were quarantined in accordance with CDC guidelines.³ Remarkably, both RT-PCR positive individuals were also IgG positive, suggesting virus persistence or reinfection with a high risk of viral transmission that, if tested by serology alone, would be considered immune.

Conclusion: Asymptomatic transmission is the Achilles' heel of current strategies to control COVID-19.⁴ Our study provides an omnibus description of the scenario inside fertility centers at the time of resumption of treatment. SARS-CoV-2 presence was detected in 0.6% of the population tested, whereas 98.62% were still naïve for this virus. Taking into account the rapid spread of SARS-CoV-2, with 2-3 people infected from every index case⁵, transmission remains a risk in the studied population. Also, the impact of the pandemic is far from reaching the level required to achieve herd immunity. In addition to routine protective measures, these results draw attention for the possible implementation of testing for SARS-CoV-2 in reproductive clinics as a means of preventing reemerging outbreaks.

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TABLE**TABLE:** Incidence of immune, infected, and naïve individuals for COVID19 in Clinic A and B.

	CLINIC A	CLINIC B	P value
	Utah Fertility Center	Boston IVF Center	
IMMUNE	0.65%	2.20%	0.46
RT-PCR (-)/ IgG (+)	(1/154)	(4/183)	
INFECTED	0.65%	0.50%	1
RT-PCR (+)	(1/154)	(1/183)	
NAÏVE	98.70%	97.30%	0.46
RT-PCR (-)/IgG (-)	(152/154)	(179/183)	

Chi-square test was used to compare the study groups and p values below 0.05 should be considered statistically significant.