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Solidifying diagnostics in SARS-CoV-2 research



To the Editor:—Large population-based studies analogous to that recently published by Hill et al¹ are essential to furthering our understanding of COVID-19 during and after pregnancy. There is often a tendency to amalgamate publications via a meta-analysis, which engenders many problems when variable data are coanalyzed.² Clinical studies, however, often rely on the presumed sanctity of available laboratory methods to establish infection in case or control groups. Given the considerable advances in and insights into the laboratory diagnosis of SARS-CoV-2 infection, it is both desirable and possible to adhere to greater stringency when defining true infections. For example, Hill et al¹ suggest that the molecular diagnostic testing for their patients had a positive predictive value of only 77%. If such a frequency was truly applicable to their patient population, 23% of patients deemed positive would have been erroneously diagnosed. Such patients with false positive diagnoses would inherently be more likely to have been asymptomatic. The authors also acknowledged that patient follow-up was often amiss. Such factors have the potential to skew the analysis considerably. Ambiguity of a similar nature is also seen when assessing for coinfections.³ Other diagnostic problems may arise with the definition of true infection. Because there are multiple viral amplification targets in a single assay for laboratory diagnosis, how would the authors confirm single target amplifications? How many assays would be deemed indeterminate? Do the authors definitively subscribe to laboratory diagnostic cutoff values suggested by the test providers? At this stage in the pandemic, accurate confirmations during laboratory diagnosis should be one of the key anchors of such studies and would add

considerably to the scientific impact of such large prospective experiences. As SARS-CoV-2 infections may become established in the populace otherwise akin to endemic respiratory coronaviruses, there is plenty of opportunity to continue with critical and relevant data acquisition and analysis.⁴ ■

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