CORRESPONDENCE

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Response: Seroprevalence of SARS-CoV-2 antibodies among first-trimester pregnant women during the second wave of the pandemic in India

We read with interest the Letter to the Editor from Sookaromdee & Wiwanitkit regarding our recent publication on seroprevalence of SARS-CoV-2 antibodies among first-trimester pregnant women during the second wave of the pandemic in India.[1]

The comment regarding false positive antibody tests is valid. However, antibody testing using the new generation kits is highly specific, excepting reported cross-reactions with other coronaviruses. The virologic surveys in India during the study period do not show a prevalence of non-COVID-19 strains in India during this time (unpublished data). The reference quoted in the Letter to the Editor for false positives in dengue discusses a lateral flow technique. We, on the other hand, performed antibody testing using the Vidas platform, which gives a quantitative reading. It detects the presence of antibodies using the S1/receptor-binding domain (RBD) of the SARS-CoV-2 S protein, with high sensitivity (PPA*) and specificity (NPA**).

Tables 1 and 2 show the US FDA findings for sensitivity and specificity for the Biomeriux Vidas IgG and IgM platforms.[2]

In a study conducted to evaluate Vidas-based antibody testing for COVID-19,[3] (CE-marked, authorized, automated, qualitative assays for the detection of SARS-CoV-2-specific IgM and IgG), both assays showed high within-run and within-laboratory precision (coefficients of variation < 11.0%) and very low cross-reactivity toward sera of patients with a past common coronavirus or respiratory virus infection. Clinical specificity determined on up to 989 pre-pandemic healthy donors was ≥99% with a narrow 95% confidence interval for both IgM and IgG assays. Clinical sensitivity was determined on up to 232 samples from 130 reverse transcriptase PCR (RT-PCR)-confirmed SARS-CoV-2 patients. The positive percent agreement (PPA) with SARS-CoV-2 PCR reached 100% at ≥16 days (Vidas SARS-CoV-2 IgM) and ≥32 days (Vidas SARS-CoV-2 IgG) of symptom onset. Although anti-SARS-CoV antibodies were reported to bind cross-reactively to the S, S1, RBD, and N proteins of SARS-CoV-2, this cross-reaction is of less significance because there has been no SARS case report since 2004, and the number of infections with SARS-CoV was limited to 8096 worldwide according to WHO.[4]

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TABLE 1 US FDA findings for sensitivity and specificity for the Biomeriux Vidas SARS-CoV-2 IgG platform

Antibody	Performance measure	Estimate of performance	95% confidence interval
IgG	Sensitivity (PPA)	100% (29/29)	(88.3%; 100%)
IgG	Specificity (NPA)	99.9% (988/989)	(99.4%; 100%)

TABLE 2 US FDA findings for sensitivity and specificity for the Biomeriux Vidas SARS-CoV-2 IgM platform

Antibody	Performance measure	Estimate of performance	95% confidence interval
IgM	Sensitivity (PPA)	100% (23/23)	(85.7%; 100%)
IgM	Specificity (NPA)	99.4% (306/308)	(97.7%; 99.8%)

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