Point-of-Care, In-Home SARS-CoV-2 IgG Antibody Testing to Assess Seroprevalence in At-Risk Health Care Workers

Eric G. Meissner[1], Christine Litwin[2], Tricia Crocker[3], Elizabeth Mack[4], Lauren Card[5]

[1]Division of Infectious Diseases, [2]Department of Pathology and Laboratory Medicine, [3]Department of Pharmacy, [4]Department of Pediatrics, [5]South Carolina Clinical & Translational Research Institute, Medical University of South Carolina, Charleston, SC. Contact: meissner@musc.edu

BACKGROUND/METHODS

- Health care workers are at significant risk for infection with the novel coronavirus SARS-CoV-2.
- We utilized a point-of-care, lateral flow SARS-CoV-2 IgG immunoassay (RayBiotech) to assess seroprevalence in a cohort of at-risk health care workers (n=339) and normal-risk controls (n=100) employed at an academic medical center.
- To minimize exposure risk during the study, consents were performed electronically, tests were mailed and then self-administered at home using finger stick blood, and subjects uploaded a picture of the test result while answering an electronic questionnaire.
- We validated the assay using de-identified serum samples from patients with PCR-proven SARS-CoV-2 infection.

RESULTS

- 439 subjects were enrolled between 4/14-5/6/20 via contactless REDCap e-consent.
- Subjects completed testing every 30 days for up to 5 rounds.
- Subjects were 68% female, 93% white, and most were physicians (38%) and nurses (27%). At baseline, 34% had cared for SARS-CoV-2 patients and 57%/23% were worried about exposure at work or in the community, respectively.
- 11% of initial tests were inconclusive and re-testing lowered this overall rate to 3%.
- Laboratory validation in those with PCR-proven infection >13 days prior showed 23/30 were IgG positive (76% sensitivity).
- Laboratory validation in those with a negative prior PCR test showed 1/26 were seropositive (95% specificity).
- 5 subjects reported PCR-proven infection prior to study start and 15 reported PCR-proven infection during the study (18/20 were in the high-risk cohort).
- 95% of subjects reported the kit was either very easy or somewhat easy to use.
- Temporal infection prevalence (Figure 1) and serologic patterns of those who reported infection (Table 1-2) or those who were seropositive without infection (Table 3) are shown.

This work was supported by the MUSC College of Medicine COVID Research Fund

Figure 1: **Self-reported cases in the study cohort primarily occurred during the community SARS-CoV-2 surge in Charleston**

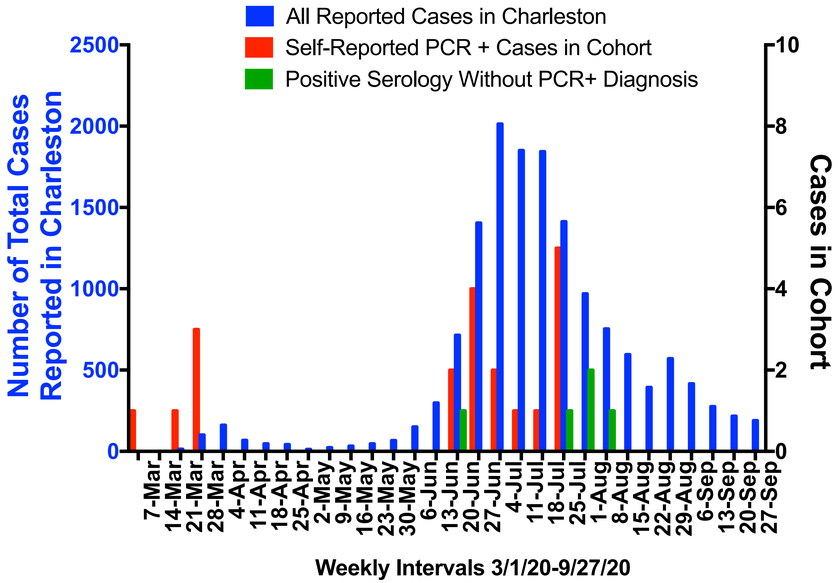

Figure 1: Epidemiology of SARS-CoV-2 in Charleston community and serologic cohort. In blue are the total number of South Carolina Department of Health confirmed cases in Charleston County per week. In red are the number of self-reported, PCR confirmed SARS-CoV-2 infection in the study cohort per week. In green are the number of positive serologic tests occurring during the study in subjects not reporting a PCR-proven SARS-CoV-2 infection.

Table 1: **Positive serology in PCR+ diagnosed subjects**

Round 1	Round 2	Round 3	Round 4	Round 5
			9	
30				
27	54	84	117	149
			18	42
		11	41	87
			27	
			26	
43	77	102	130	156
		18	56	87
			8	52

Table 2: **Negative serology in PCR+ diagnosed subjects**

Round 1	Round 2	Round 3	Round 4	Round 5
		15	34	
			6	
				23
31				
			24	52
		12	43	
			35	
47				
		3	34	58
			26	

Tables 1 and 2: Shown are the serologic results for the 20 subjects in the cohort who self-reported a PCR confirmed SARS-CoV-2 infection either before (n=5) or during the study (n=15). Each row represents data for an individual study subject. "Round" refers to the monthly round of testing. Yellow = a negative serologic test **prior to** a future SARS-CoV-2 confirmed diagnosis. Red = a positive serologic test **after** confirmed infection with days post PCR-confirmed infection the serologic test was performed indicated. Green = a negative serologic test **after** confirmed infection with days post infection indicated. White = testing was not performed or was inconclusive. Table 1 shows n=10 subjects who had a positive serologic test at at least 1 time point. Table 2 shows n=10 subjects who never had a positive serologic test.

Table 3: **Positive serology in subjects with no history of PCR-diagnosed infection**

Round 1	Round 2	Round 3	Round 4	Round 5	Symptoms in 2 months prior to + result
					Fever, chills, headache, nausea round 4
					No symptoms
					Fatigue, runny nose, loss of smell round 4
					No symptoms
					No symptoms

Table 3: Serologic testing results for n=5 subjects in the study who had a positive serologic test during the study but who never reported a positive SARS-CoV-2 diagnosis. Yellow = a negative serologic test. Blue = a positive serologic test. White = inconclusive test or test not done. Figure 1 shows the timing of positive serologic tests. The final column shows symptoms reported by subjects.

CONCLUSIONS

1. We successfully conducted a study utilizing longitudinal at-home, self-administered serologic testing that was entirely contact-free.
2. Sensitivity of the test was lower than expected: Only half of subjects who reported a PCR+ diagnosis had serologic evidence of immunity using this lateral flow IgG assay (Table 1-2), indicating inadequate sensitivity of this serologic test, in isolation, to accurately measure seroprevalence.
3. Specificity of the test was higher than expected: Only 5 subjects without PCR confirmed SARS-CoV-2 infection had a positive serologic test (Table 3). These primarily occurred during the interval in which disease prevalence was surging in our area and some subjects had suggestive symptoms, indicating these may have been true positive results.
4. Appreciating these limitations, we did not identify serologic evidence of wide-spread occupational SARS-CoV-2 infection as part of this study, which was a significant concern at the onset of the study.
5. This work informs approaches to conducting self-serologic testing when and if an appropriate sensitive and specific point-of-care test becomes FDA-approved.