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Evaluation of independent self-collected blood specimens for COVID-19 antibody detection among the US veteran population

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ABSTRACT

Feasibility of home blood sample collection methods for the presence of SARS-CoV-2 antibodies from VA Million Veteran Program (MVP) participants was tested to determine COVID-19 infection or vaccination status. Participants (n = 312) were randomly assigned to self-collect blood specimens using the Neoteryx Mitra Clamshell (n = 136) or Tasso-SST (n = 176) and asked to rate their experience. Mitra tip blood was eluted and Tasso tubes were centrifuged. All samples were stored at -80 °C until tested with InBios SCoV-2 Detect™ IgG ELISA, BioRad Platelia SARS-CoV-2 Total Ab Assay, Abbott SARS-CoV-2 IgG and AdviseDx SARS-CoV-2 IgG II assays. Participants rated both devices equally. The Abbott assay had the highest sensitivity (87% Mitra, 98% Tasso-SST) for detecting known COVID infection and/or vaccination. The InBios assay with Tasso-SST had the best sensitivity (97%) and specificity (80%) for detecting known COVID-19 infection and/or vaccination. Veterans successfully collected their own specimens with no strong preference for either device.

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1. Introduction

Corona virus disease (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has resulted in a worldwide pandemic affecting millions of people [1]. The diagnosis of this infection is made primarily by molecular testing of respiratory samples for viral nucleic acid or antigen, or blood samples for detection of antibodies against the nucleocapsid or spike proteins of SARS-CoV-2. Over the course of the pandemic, diagnostic testing has required patients to travel to medical facilities or other testing centers to have samples taken for testing. At home, self-collection of samples may increase the number of people who can be tested to better determine infection status or inform the prevalence of COVID-19 infection or vaccine response. Recently, self-collection and testing respiratory samples for SARS-CoV-2 antigen has become available (i.e., Abbott BinaxNow self-test, Acon Flowflex).

Self-collection of finger stick blood samples has been widely adopted for glucose monitoring. Dried blood collection using dried blood spots (DBS) for detection of HIV, HCV, HBV antibodies, antigen, or nucleic acid has proven effective in the diagnosis of these infections [2]. Recently, DBS or other dried blood collection methods have been evaluated for the detection of SARS-CoV-2 or influenza antibodies [3–6] Other devices designed for the self-collection and storage of liquid blood potentially allows for different methods for SARS-CoV-2 antibody detection [7].

To examine home blood specimen collection options, The VA Million Veteran Program (MVP) performed a pilot study comparing 2 blood specimen collection devices and evaluated SARS-CoV-2 antibody assays to determine known COVID-19 infection or vaccination status. The goals of this study were to (1) to determine the feasibility of at-home blood specimen collection for scalability purposes; and (2) test the feasibility of low volume capillary blood for SARS-CoV-2 antibody detection.

2. Methods

Recruitment and enrollment for the pilot was conducted from December 2020 through March 2021. Over ten thousand MVP participants met the eligibility criteria for the pilot (currently enrolled, open to contact from MVP, not deceased, valid email address), and of this cohort 599 MVP Participants were randomly selected and emailed an invitation to participate in the pilot. Thirty percent of the eligible participants had a COVID-19 diagnosis, defined as an electronic health

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record (EHR) documented previously positive SARS-CoV-2 RT-PCR or a self-reported COVID diagnosis from the 2020-2021 MVP COVID-19 survey, prior to being invited. These participants were randomly assigned one of 2 self-collection devices selected for the pilot: Mitra® (Neoteryx, LLC, Torrance, CA) requires a finger prick to collect dried blood on a sampler tip (4 tips × 30 uL, up to 120 uL whole blood in total) and Tasso-SST (Tasso, Inc., Seattle, WA) which collects capillary liquid blood from the upper arm in a mini tube (up to 200 uL). MVP Participants were verbally consented into the pilot and within a week, were sent a collection kit, which included a feedback form to collect date/time of blood collection and feedback questions (using a Likert scale, 1 = worst and 5 = best) to rate their experience using their assigned device. Fig. 1 outlines the pilot data and workflow. The MVP Info Center conducted reminder calls to participants who did not return the kit within 2 weeks and feedback follow-up calls to participants who returned a specimen without including a completed feedback form. MVP is approved through the VA Central Institutional Review Board.

Pilot participants mailed the specimens to the Veterans Health Administration (VHA) Public Health Reference Laboratory (PHRL, Palo Alto, CA) where the specimens were accessioned, processed, and tested across 4 assays for the presence of COVID-19 antibodies (from both natural immunity from COVID-19 infection and post-vaccination). For Mitra devices, previous publications have used different buffers, volumes, and conditions to elute whole blood from Mitra tips [3,5,8]. Although phosphate buffered saline (PBS), 0.9% normal saline with 0.5% tween were the common elution mixtures, we saw variations in time duration for samples placed on a shaker. We compared elution techniques using PBS, 0.9% normal saline, and 0.5% Tween for 1 vs 24 hours of shaking at 300 rpm at room temperature and found no significant difference in COVID-19 antibody detection (data not shown). Based on this observation, we chose one of these 2 buffers and a time-conservative approach. Therefore, each Mitra tip (up to 4) of dried blood was removed by pulling the tip over the edge of each well of a 2-mL 96-well plate and eluted in 250uL (total 1 mL per participant sample) of 0.9% normal saline with 0.5% Tween for 1 hour at room temperature shaking at 300 rpm. A total of 1 mL of eluent was then transferred to a cryovial. For the Tasso-SST device, the mini tubes of liquid blood were centrifuged according to vendor instructions. Serum was removed and transferred to cryovials. All samples were stored at -80 °C until tested. The following Emergency use authorization (EUA) approved SARS-CoV-2 antibody (Ab) assays were used to test samples: SCoV-2 Detect™ IgG ELISA (InBios, Seattle, WA) Spike IgG, Platelia SARS-CoV-2 Total Ab Assay (BioRad,

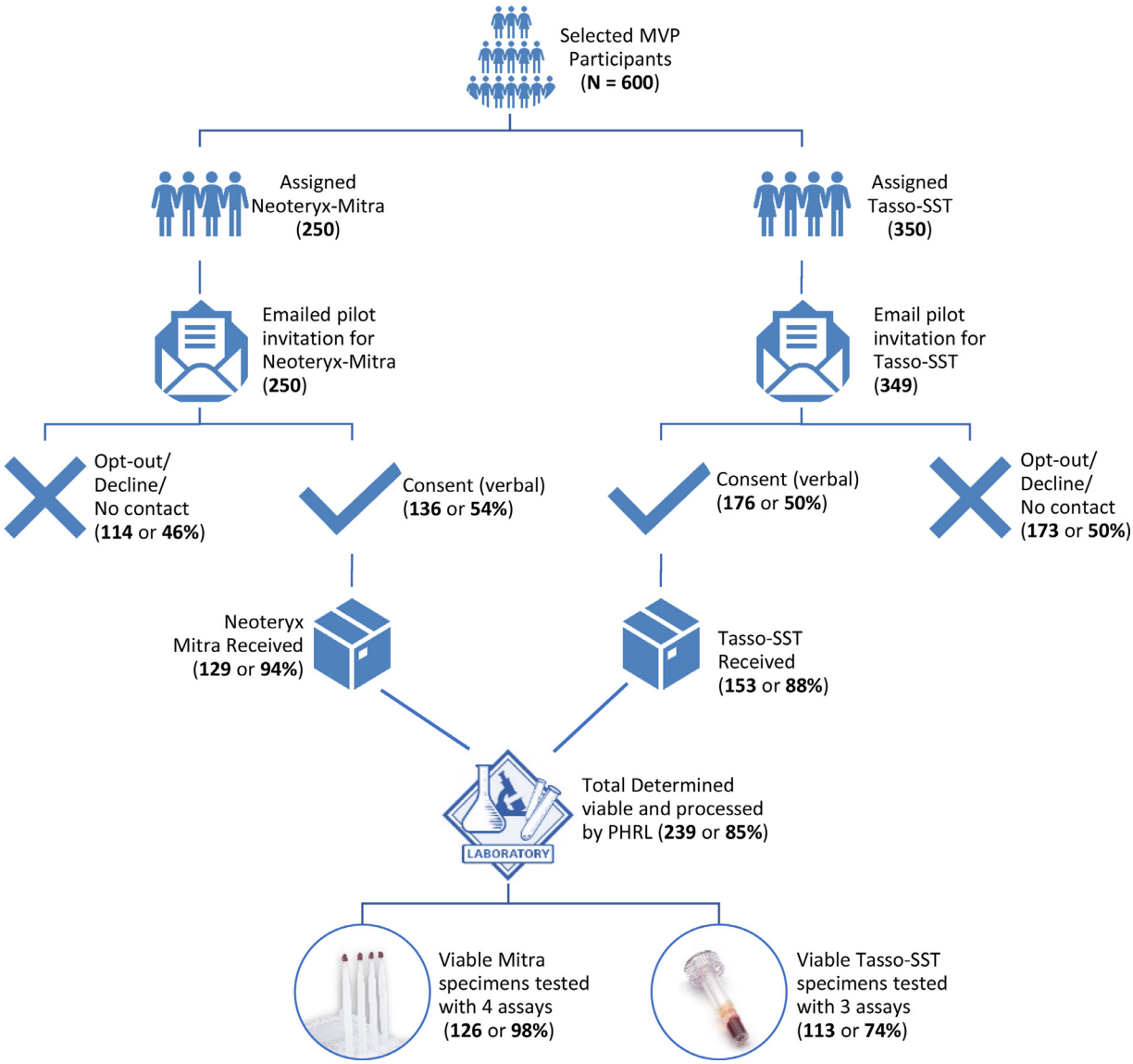

Fig. 1. Pilot study workflow.

Hercules, CA) nucleocapsid (NC) total Ab, Alinity i SARS-CoV-2 IgG (NC IgG) and AdviseDx SARS-CoV-2 IgG II (Spike IgG) (Abbott Diagnostics, Abbott Park, IL) according to manufacturer instructions.

3. Results

3.1. Goal 1: determine feasibility of at-home blood specimen collection for scalability purposes

Of those invited, 52% of MVP Participants consented to participate and 90% of pilot participants returned a viable (sufficient quantity and quality) specimen. The consent rate was slightly higher for Mitra compared to Tasso (54% vs 50%). Viable specimens, defined as sufficient volume to conduct at least one SARS-CoV-2 antibody assay, received for Mitra was 98% compared to 74% for Tasso. This is discussed further in the *Goal 2* section below. See Fig. 1 for consent and specimen rates per device.

Though there was effectively no difference in age and gender, median income was 4% higher for those who verbally consented to participate compared to those invited to join the pilot. Similarly, the demographics were slightly different between those invited to participate and those who consented, becoming slightly less diverse moving from 83% White to 88% White, and from 4% to 2.6% Hispanic. Some slight shifts in geographic region representation occurred with a West/Pacific 2% increase and South 2% decrease, with those in urban settings decreasing by 2% while those in rural settings stayed steady at an estimated 25% of all recruited and consented participants. The COVID-19 diagnosis rate decreased slightly from 30% to 27% and COVID-19 fully vaccinated rate increased from 16% to 27%, with the unvaccinated rate slightly decreasing from 65% to 61%. See Table 2 for comparison of demographic, COVID-19 diagnosis, and COVID-19 vaccination status, between invited and consented participants.

Further analysis to compare those who consented to participate to those who provided a viable specimen (by either collection device) showed no major difference in mean age, gender, and race and ethnicity. A larger proportion of Tasso-SST users who returned a viable specimen either had been vaccinated (at least 1 dose) or had evidence of a COVID-19 diagnosis. See Table 3 for demographics, COVID-19 diagnosis, and COVID-19 vaccination status for consented participants and those returning viable specimens.

Additionally, participants rated their experience using their assigned self-collection device via a feedback form included in kits. In total, 95% of pilot participants that returned a specimen provided feedback. Generally, participants found both devices easy to use, rating the Mitra and Tasso-SST devices equally on average as 4.4 on a 1-5 scale (Table 1).

3.2. Goal 2: test the feasibility of low volume capillary blood for SARS-CoV-2 antibody detection

As shown in Fig. 1, viable samples were received from 98% and 74% of those participants who were sent Mitra or Tasso-SST collection devices, respectively. The average time from self-collection to receipt at the laboratory was 3.6 days (range 1−23 days, N = 235 participants that completed a feedback form with their specimen date of collection). Twenty-five percent of received Tasso-SST samples either had no blood volume or insufficient volume (< 4 uL) to perform 1 or more COVID-19 antibody assays. Since each assay had different volume requirements (see Table 4), low volume Tasso-SST samples required prioritization of which assay(s) could be performed. Because of the eluent volume used during Mitra processing, all but 1 Mitra samples had sufficient volume for testing with all assays.

The Abbott IgG II assay had the highest sensitivity across both devices (87% Mitra and 98% Tasso-SST) for detecting known COVID infection and/or vaccination. Semiquantitative results ranged from 0 to 5123.5 AU/mL for Mitra samples (N = 65) and 1.8−50,000 AU/mL for Tasso-SST samples (N = 51). InBios IgG assay with the Tasso-SST had the best combination of sensitivity (97%) and specificity (80%) detecting known COVID-19 infection and/or vaccination, see more details in Table 4. Stratification into COVID-19 Infection Only and Vaccinated Only groups display the difference between the spike protein assays and nucleocapsid assays, see Table 5 for more details. The sensitivity remains high in both groups and both devices for the InBios Spike IgG and Abbott Spike IgG II assays. However, the sensitivity in the Vaccinated Only group drops sharply to 3% (Neoteryx Mitra) and 9% (Tasso-SST) for the BioRad NC assay and to 0% (Neoteryx Mitra) and 8% (Tasso-SST) for the Abbot NC IgG assay. Additionally, it should be noted that 1mL of eluent buffer was used to process 120 uL of whole blood from Mitra tips, resulting in an 8-fold reduced starting dilution of all whole blood samples. Since serum represents approximately 55% of whole blood, an additional 1.8-fold dilution is required when considering whole blood as the tested medium. Sample dilution may have contributed to reduced sensitivity results seen with Mitra tip whole blood.

4. Discussion

MVP Participants are comfortable using either of these devices as evidenced from their consent rate for this additional blood specimen, the rate of returned specimens, and their overall feedback on ease of use. From a Veteran perspective, each group evaluated the ease of use of each device similarly (Table 1). This is particularly interesting, as on average the Veteran population age in this study was 68 (ages ranged from 30 to 89 years old, N = 312), and in general older Veterans tend to face more health challenges than the non-Veteran population within the same age range [9]. This means that despite being an older population, likely with a higher percentage of health issues, participants were able to use either collection device successfully. Blood collected from either device was able to detect SARS-CoV-2 nucleocapsid and spike IgG antibodies using different commercially available assays although with varied sensitivity and specificity. It was determined that 98% Mitra specimens were deemed viable for assay testing compared to 76% Tasso-SST (Fig. 1). However, assays performed on Mitra samples resulted in lower sensitivity due to the dilution factor. Despite having less Tasso-SST samples deemed viable,

Table 1
Participant feedback on devices.

AT-HOME PILOT - FEEDBACK FORM RESULTS Total Responses	NEOTERYX AVG RATING 120 (95%)	TASSO AVG RATING 148 (95%)
1. How was your experience receiving and opening the kit?	4.5	4.6
2. How easy was the at-home collection kit instructions to understand and follow?	4.2	4.5
3. How easy was the specimen collection device to use?	4.3	4.4
4. How easy were the mailing return instructions to follow?	4.6	4.4
5. How was your overall experience receiving the kit, using the collection device, and returning your specimen to MVP?	4.5	4.4
Overall Average Rating	4.4	4.4

Table 2
Pilot invited vs consented participants: age, income, demographics, and COVID-19 diagnosis and COVID-19 vaccination status.

	Emailed for recruitment (*N* = 599)		Consented (*N* = 312)	
	Mean	Std	Mean	Std
Age at pilot consent[a]	68.2	10.9	68.7	10.1
	Median	**IQR**	**Median**	**IQR**
Income	$32,456	$13,000 - $51,060	$33,876	$13,284 - $52,075
N missing income data	66	31		
	N	**%**	***N***	**%**
Gender				
Male	537	89.65	280	89.74
Female	62	10.35	32	10.26
Unknown	0	0.00	0	0.00
Race				
American Indian/Alaska Native	2	0.33	2	0.64
Asian	7	1.17	1	0.32
Black/African American	54	9.02	18	5.77
Native Hawaiian/Other Pacific Islander	1	0.17	0	0.00
White	498	83.14	275	88.14
Multiple	25	4.17	11	3.53
Other	9	1.50	2	0.64
Unknown	3	0.50	3	0.96
Ethnicity				
Hispanic or Latino	24	4.01	8	2.56
Not Hispanic or Latino	571	95.33	302	96.79
Unknown	4	0.67	2	0.64
Region				
Northeast	69	11.52	35	11.22
South	264	44.07	131	41.99
Midwest	108	18.03	57	18.27
West/Pacific	157	26.21	89	28.53
Other[b]	1	0.17	0	0.00
Rurality				
Rural	148	24.71	80	25.64
Urban	444	74.12	227	72.76
Highly Urban	7	1.17	5	1.6
COVID diagnosis[c]	182	30.38	85	27.24
COVID vaccination status[d]				
Not vaccinated	392	65.44	190	60.90
Partially vaccinated (1 dose)	99	16.53	30	9.62
Fully vaccinated (2 doses)	98	16.36	85	27.24
Missing[e]	10	1.67	7	2.24

[a] Defined as age at pilot consent date for consented participants or age as of February 1, 2021 for individuals without a pilot consent date.
[b] The "Other" region contains international bases.
[c] Restricted to positive COVID test from EHR or self-reported COVID diagnosis before pilot consent date or before February 1, 2021 for individuals without a pilot consent date.
[d] Vaccination status as of pilot consent date for consented participants or February 1, 2021 for individuals without a pilot consent date.
[e] Missing vaccination status is a result of the vaccine records being flagged as "Potentially Erroneous."

it was found that the Tasso-SST combined with the InBios Spike IgG assay provided the highest combination of sensitivity and specificity.

Recent studies have shown that DBS can be used to detect SARS-CoV-2 IgG antibodies with laboratory-derived assays or EuroImmun IgG assay and results compared favorably to venous blood serum results after phlebotomy [4,5]. Venous collected blood was compared to capillary collected blood using Microvette 100 capillary tubes and DBS in 39 participants and demonstrated > 94% concordance among the collection methods for SARS-CoV-2 antibodies using the Omega Diagnostics COVID-19 IgG ELISA [10]. Mitra tips were evaluated by Whitcombe et al., in a simulation study where 19 previously collected whole blood samples were compared to serum and found very high correlation among several SARS-CoV-2 antibody assays [11]. Kalish et al, utilized self-collected Mitra tips in a large SARS-CoV-2 antibody seroprevalence study in over 9000 US subjects [6], determining a much larger spread of COVID-19 than originally estimated due to mild/asymptomatic cases that were not diagnosed. One recent study used serum from the Tasso-SST device to determine COVID-19 IgG antibody status among over 2000 college students with the

Table 3
Consented participants and specimens received with sufficient volume by device type: age, gender, race, and COVID-19 diagnosis and vaccination status.

	Consented (*N* = 312)	Neoteryx mitra returned, viable specimen (*N* = 126)	Tasso-SST returned, viable specimen (*N* = 113)
Age at pilot consent[a]	68.7 (10.1)	69.7 (10.1)	66.5 (10.7)
Male (Gender)[b]	280 (89.7%)	113 (89.7%)	100 (88.5%)
White (Race)[b]	275 (88.1%)	109 (86.5%)	100 (88.5%)
COVID-19 diagnosis[b,c]	85 (27.2%)	26 (20.6%)	36 (31.9%)
Vaccinated for COVID-19[b,d]	115 (36.9%)	38 (30.2%)	46 (40.7%)

[a] Mean (Standard Deviation).
[b] *N*(%).
[c] Defined as a positive COVID test from electronic health record or self-reported COVID diagnosis from survey, before pilot consent date.
[d] Defined as having received at least 1 COVID-19 vaccine dose, before pilot consent date.

Table 4
Assay sensitivity and specificity by device type.

		Neoteryx mitra (N = 126)[a]		Tasso-SST (N = 113)[a]	
		Antibody positive	Antibody negative	Antibody positive	Antibody negative
InBios Spike IgG (4 uL)[c]	COVID-19 Dx and/or vaccinated[d]	35	23	63	2
	No COVID-19 Dx/not vaccinated	8	60	5	20
	Sensitivity	0.60		0.97	
	Specificity	0.88		0.80	
BioRad (Total NC[b] Ab) (15 uL)	COVID-19 Dx and/or vaccinated	19	39	30	37
	No COVID-19 Dx/not vaccinated	4	64	3	42
	Sensitivity	0.33		0.45	
	Specificity	0.94		0.93	
Abbott NC[b] IgG (125 uL)	COVID-19 Dx and/or vaccinated	11	47	14	27
	No COVID-19 Dx/not vaccinated	2	66	3	29
	Sensitivity	0.19		0.34	
	Specificity	0.97		0.91	
Abbott Spike IgG II (125 uL)	COVID-19 Dx and/or vaccinated	46	7	47	1
	No COVID-19 Dx/not vaccinated	9	4	5	0
	Sensitivity	0.87		0.98	
	Specificity	0.31		0.00	

[a] Due to volume restrictions, not all samples were tested for all assays.
[b] NC = nucleocapsid.
[c] Sample volume required for assay.
[d] Defined as a positive COVID test from EHR or self-reported COVID diagnosis from survey, or having received at least 1 dose before pilot consent date.
Some subjects may have had COVID-19 infection and were not tested.

Table 5
Assay by device type and COVID-19 diagnosis and vaccination

		Tasso-SST (N = 113)[a]			Neoteryx mitra (N = 126)[a]		
		Antibody positive	Antibody negative	Sensitivity	Antibody positive	Antibody negative	Sensitivity
InBios Spike IgG (4 uL)[c]	COVID-19 Dx and vaccinated[d]	5	1	0.83	13	0	1.00
	COVID-19 Dx only	11	9	0.55	18	2	0.90
	vaccinated only	19	13	0.59	32	0	1.00
BioRad (Total NC[b] Ab) (15 uL)	COVID-19 Dx and vaccinated	4	2	0.67	11	3	0.79
	COVID-19 Dx only	14	6	0.70	16	5	0.76
	vaccinated only	1	31	0.03	3	29	0.09
Abbott NC[b] IgG (30 uL≤ x<125 uL)	COVID-19 Dx and vaccinated	4	2	0.67	5	1	0.83
	COVID-19 Dx only	7	13	0.35	7	4	0.64
	vaccinated only	0	32	0.00	2	22	0.08
Abbot Spike IgG II (30 uL≤ x<125 uL)	COVID-19 Dx and vaccinated	5	0	1.00	8	0	1.00
	COVID-19 Dx only	14	4	0.78	12	1	0.92
	vaccinated only	27	3	0.90	27	0	1.00

[a]Due to volume restrictions, not all samples were tested for all assays.
[b]NC = nucleocapsid.
[c]Sample volume required for assay.
[d]Defined as a positive COVID test from EHR or self-reported COVID diagnosis from survey, or having received at least 1 dose before pilot consent date.
Some subjects may have had COVID-19 infection and were not tested.

Abbott Architect IgG NC assay and a laboratory developed COVID-19 antibody test [7], demonstrating feasibility of this collection approach for large-scale seroprevalence studies. To our knowledge, no studies have been performed directly comparing the performance of Mitra and Tasso-SST collected samples for SARS-CoV-2 antibodies from the same subjects. But in general, capillary collected blood (either liquid or dried) compares favorably to venous collected blood for SARS-CoV-2 antibody testing.

Our study has several limitations. Only 1 collection device was given to each participant, so no intra-participant testing comparison of devices or assays was possible, and no venous blood was obtained to use as a gold standard. Varied timing of sample collection related to time since COVID-19 infection, receipt of 1 or 2 dose of COVID-19 vaccine, unknown COVID-19 infection or vaccination status among some participants could have affected COVID-19 antibody test results. Other than the BioRad total antibody test, no COVID-19 specific IgM assays were studied. Blood samples were not collected by standard phlebotomy, so assay performance could not be assessed using serum according to the package insert. Finally, variability in Tasso-SST collection volume limited some samples from being tested with all assays, and Mitra whole blood dilution may have affected sensitivity/specificity comparison across assays.

In summary, we have demonstrated the feasibility of self-collected capillary blood samples for SARS-CoV-2 antibody detection. Antibody assay performance varied among assays and collection devices. Additional testing is planned with a new collection device called Tasso+ (Tasso Plus) to address the volume variability associated with Tasso-SST, as well as additional analysis of COVID antibodies at multiple points in time to optimize use of these assays to further our understanding of Veteran's experience with COVID-19 infection and vaccination. The ability for Veterans to self-perform antibody testing may offer valuable insight into how diagnostic testing can occur at-home more broadly in the general population, both in response to the COVID-19 pandemic and beyond.

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Data availability

Data will not be made available in order to comply with current VA privacy regulations.

The views expressed in this work are those of the authors and does not represent the views of the Department of Veterans Affairs or the United States Government.

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Declaration of competing interests

The authors report no conflicts of interest relevant to this article.

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