

**Collaborative community networks to optimize implementation
of low barrier COVID-19 testing efforts
among diverse Latinx populations in Northern California**

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Glossary of Key Terms

CBO	Community Based Organization
CDC	Centers for Disease Control
CDCC	RADx-UP Coordination and Data Collection Center, NIH
CLIA	Clinical Laboratory Improvement Amendments
COVID-19	2019 Novel Coronavirus Disease
CWT	Community Wellness Team
FQHC	Federally Qualified Health Center
LTF	Latino Task Force
NIH	National Institutes of Health
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
RADx	Rapid Acceleration of Diagnostics Program, NIH
RADx-UP	Rapid Acceleration of Diagnostics-Underserved Populations Program, NIH
RCT	Randomized Controlled Trial
SARS-COV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SEBI	RADx-UP Social, Ethical, and Behavioral Implications Center, NIH

1. Introduction

The health and economic effects of the SARS-CoV-2 pandemic in the United States are staggering, and people of color – already heavily impacted by structural inequities – bear a disproportionate burden of COVID-19 disease. Testing is a cornerstone of stopping the spread of the virus, yet in the US testing rates remain far below target levels and current strategies are failing to reach the communities most affected. An incomplete understanding of testing barriers, and optimal strategies to mitigate these barriers among people of color, hampers the design of the scalable strategies needed to increase equity in the reach, uptake, and preventative impact of SARS CoV-2 testing throughout the US.

In California, despite initial success in limiting spread with the earliest shelter-in-place mandate in the nation, even partial attempts at easing restrictions have resulted in a surge in new cases, with the state having the highest case count in the US as of July 2020. **Latinx people, who represent 39% of the state's population, account for 58% of cases.** In our community-engaged COVID-19 research in San Francisco, testing barriers among Latinx persons include language, access, distrust of health systems, immigration concerns, and economic repercussions of a positive test. Understanding local context is critical, and there is an urgent need to define, assess, and test strategies to overcome *barriers across diverse* Latinx community settings.

Overcoming testing barriers is possible with a community-engaged research approach. Our group has extensive experience working with community partners to develop innovative approaches for HIV testing in low-income settings and for COVID-19 testing among Latinx persons. In a US census tract in San Francisco, we conducted one of the first community-based, universal SARS-CoV-2 testing studies in the US, in which we provided PCR and antibody mass testing to ~4,000 residents and non-resident workers, regardless of symptoms, reaching 60% of census tract residents over 4 days in April 2020. We found that ongoing infections were almost exclusively occurring among Latinx residents (95% of all PCR+ persons), and that risk factors for PCR-positivity included inability to shelter-in-place and maintain one's income, as well as unemployment and frontline work. In partnership with the Latino Task Force (LTF) for COVID-19, a collective of community-based organizations (CBOs) in San Francisco, we tested a high proportion of this majority Latinx-community rapidly.

We now propose to scale low-barrier COVID-19 testing for Latinx communities and evaluate retesting strategies for priority groups in Latinx communities at increased infection risk, drawing upon our experience with Latinx community-engaged COVID-19 testing research and the success of San Francisco's LTF model, as well as community-based HIV testing trials informed by behavioral economics theory.

1.1. Study Synopsis

We will evaluate community-engaged approaches to improving access and uptake of COVID-19 testing among majority Latinx communities in Northern California, and to understanding local epidemiology and factors driving the stark ethnic disparities observed in COVID-19 case rates. In **Aim 1**, we will evaluate implementation of a Latino Task Force (LTF) collaborative network across 3 counties in California (Marin, Merced and San Francisco), adapted from San Francisco's LTF model to promote locally-adapted COVID-19 test and respond initiatives in two majority-Latinx communities: one suburban (Marin) and one rural (Merced). In **Aim 2**, we will determine the population-level prevalence of active (PCR+ or BinaxNOW™ rapid antigen test-positive) SARS-CoV-2 infection, most at-risk subgroups, and attitudes and preferences of community members regarding COVID-19 testing services during baseline mass testing campaigns at the Marin and Merced sites. The campaigns will offer testing to all community residents regardless of symptoms at easily accessible venues, implemented in partnership with each site's LTF. In **Aim 3**, we will study implementation of three complementary testing strategies (a. drop-in; b. responsive; and c. spot surveillance) delivered by community partners and local, Spanish-speaking *promotoras* trained and certified to conduct FDA-authorized (EUA) BinaxNOW™ rapid COVID-19 antigen testing with confirmation by PCR of antigen test positive participants.

1.2 Background & Rationale

The SARS-CoV-2 virus pandemic has had devastating health and economic effects in the US since early 2020, with over 150,000 lives lost to date and with case rates still climbing in July 2020 due to ongoing transmission, particularly in Southern and Western states.¹ Some of the earliest COVID-19 clinical cases in the US were identified in California² and the state was the first in the nation to issue a state-wide shelter-in-place order on March 19.³ Despite early success in reducing transmission rates with these

public health measures, California leads the nation in the absolute number of cases⁴ and recent attempts to ease public health measures in the state have resulted in a resurgence of COVID-19 cases, hospitalizations and deaths.⁵ Due to this resurgence, attempts to ease public health restrictions in the state were reversed as of July 13, 2020 by Governor Newsom, as communities across the state reconsider a path forward.⁶

Robust SARS-CoV-2 testing programs are critical for communities to understand ongoing local transmission dynamics and the effectiveness of public health measures, and to develop and implement effective prevention interventions. However, testing remains inadequate to achieve these goals, particularly in historically underserved communities. As a consequence, high rates of transmission are ongoing, disproportionately affecting Latinx/Hispanic and Black/African American communities across the US that were already heavily impacted by health inequities prior to the COVID-19 pandemic.⁷ In California, Latinx people represent 39% of the state's population and a high proportion of frontline and essential workers, but account for 58% of COVID-19 cases and 46% of deaths.⁸ These stark epidemiologic disparities highlight the need to scale up testing access rapidly among Latinx communities to address the pandemic.

Though the literature on the specific factors driving ethnic disparities in SARS-CoV-2 infection is sparse, longstanding social, economic and health inequities in the US are clearly contributing to disproportionate infection rates and exacerbating COVID-19 clinical outcomes in Latinx communities. In multiple settings, pre-pandemic inequities are exacerbating and accelerating COVID-19 transmission in Latinx communities. For example, shelter-in-place orders have been untenable for many low-income Latinx workers due to employment that does not allow for remote work.^{9,10} Community-acquired infections then spread quickly within high-density households that are a consequence of dramatic increases in the cost of living (i.e. "gentrification") in many settings over the past several decades that disproportionately impact communities of color, including Northern California.¹⁰⁻¹² In addition, inequities in health insurance access (particularly in low-income, "gig" economy or "independent contractor" jobs) and health care access are factors driving relatively lower testing access and uptake among Latinx and African American communities.¹³⁻¹⁵ Without measuring, understanding and addressing the inequities driving disparate spread of COVID-19, successful, community-wide prevention efforts – an ethical imperative for our nation – will remain elusive.

Community-partnership is essential to understand and address the factors driving disparate infection rates in Latinx and African American communities and thereby ensure that testing services reach populations disproportionately affected by COVID-19. Working in partnership with San Francisco's Latino Task Force (LTF) for COVID-19, we have been conducting the ongoing *Unidos en Salud* project in San Francisco's Mission District – a historically majority-Latinx community. In April 2020, we conducted a mass SARS-CoV-2 PCR and antibody testing campaign and identified multiple barriers to testing among Latinx residents.^{10,16} During mobilization and testing, community members expressed interest in testing but noted the financial and social consequences of testing positive for SARS-CoV-2 as barriers. Financial concerns related to testing positive included challenges with loss of income during self-isolation (particularly for day laborers or undocumented workers without job security) and the impact on household members' income if having to self-quarantine. Social concerns included concern that personal data would be shared with federal immigration agencies, or that accessing testing services would represent a public charge and impact one's legal status. *With community partnership that directly addressed these barriers, we were able to engage a high proportion of census tract residents and workers.* As a result of our partnership with San Francisco's LTF, we tested 60% of tract residents, 40% of whom were Latinx, and determined that 95% of PCR-positive residents were Latinx – the majority of whom were asymptomatic, uninsured and working frontline jobs.¹⁰ Similar community-engaged models for expanding testing access are essential to effectively reach Latinx populations in other settings.

Despite our initial success in implementing low-barrier, high-reach COVID-19 testing in a majority-Latinx community, further research is needed on how to reproduce and scale similar community-engaged testing initiatives. Latinx community-based organizations (CBOs) with established trust due to track records of serving their communities pre-pandemic are well situated to mobilize communities and design innovative solutions to COVID-19 testing barriers. However, CBOs are now facing novel challenges, including a need to rapidly adapt to the massive social and economic upheaval of COVID-19, reconfigure their service delivery, and coordinate with public health agencies. To support CBO adaptation and accelerate SARS-CoV-2 testing implementation for Latinx communities, we propose to create organizational social networks of local Latinx CBOs across 3 sites. Social network analysis research has long observed that interpersonal *and inter-organizational* connections, can speed the spread of information and the adoption of innovative ideas.¹⁷⁻¹⁹ In this study, we aim to leverage the influence of social networks among local Latinx CBOs to speed

dissemination of innovation for COVID-19 “test and respond” initiatives by adapting the San Francisco Latino Task Force model in two underserved communities in Northern California.

Over the past two decades, advances in implementation science research have provided rigorous, validated frameworks for evaluating the effectiveness of public health and health behavior change programs. Due to the recognition that scientific advances are often limited and inequitable in their reach, a growing field of implementation science research has developed frameworks for planning and evaluating how such scientific advances can achieve greater effectiveness. The RE-AIM framework was developed to address this evidence-effectiveness gap and provides a validated framework to evaluate how the LTF model for community-engaged COVID-19 testing research can be reproduced in new settings.^{20,21} In addition, a powerful catalyst for group cohesion is working together toward a common, shared objective^{22,23} – in this case, a community mass testing campaign to understand local epidemiology and gauge community attitudes. This will serve as a platform for further engagement on optimizing standing, low-barrier testing and retesting services for priority community members, such as frontline workers, at increased risk of SARS-CoV-2 infection.

Mass testing community campaigns offer a platform to rapidly scale testing, overcome barriers to testing and reach people with asymptomatic SARS-CoV-2 infection, providing a population-level “snapshot” of local epidemiology, disparities in infection and community perceptions. Estimates of SARS-CoV-2 prevalence that rely on testing symptomatic people provide an incomplete view given the high proportion of infected persons with mild or no symptoms.^{10,24-26} Standard sampling approaches are also unlikely to reveal a complete picture of COVID-19 burden, given low response rates to survey-based research without strong community partnership and trust. Expanding testing out of health centers and offering universal testing in communities can improve understanding of SARS-CoV-2 epidemiology, including asymptomatic infections. To date, few such studies have been performed in the US, apart from congregate settings (e.g. cruise ships or nursing homes).^{27,28} Mass testing – using community campaigns and then sampling campaign non-participants²⁹ – can accelerate the process of understanding and addressing the full burden of SARS-CoV-2, including disparities in infection risk for people of color. In our April 2020 mass testing campaign in San Francisco’s Mission District, we determined that the prevalence of PCR+ SARS-CoV-2 infection among Latinx residents (3.9%) was 20-times that of non-Latinx residents (0.2%) 6-weeks into shelter-in-place. The majority of infections (52%) were asymptomatic at time of testing.¹⁰ Such data from other communities are urgently needed to accelerate implementation of low-barrier testing with broad reach to all community members.

Retesting services for essential, frontline workers are critical for ensuring safe work environments, limiting community transmission of SARS-CoV-2 and maintaining our nation’s critical infrastructure. For many Latinx people, observing “shelter-in-place” orders or working from home is not possible due to lost wages and occupation types. Latinx persons are disproportionately represented in essential, frontline jobs that have maintained critical infrastructure during the COVID-19 pandemic, such as food services, agriculture, public transportation, construction and sanitation/janitorial services. For example, California’s Central Valley produces one-quarter of our nation’s food, including 40% of fruits, nuts, and other table foods, and 8% of agricultural output.³⁰ In the San Francisco Bay Area, Latinx workers represent 22% of the workforce, but 31% of frontline workers.³¹ The ability of many non-frontline workers to work from home rests heavily on these services which puts frontline workers at increased likelihood of infection, as we have seen in cities and now with rapidly increasing infection rates among Latinx agricultural workers in the Central Valley.³² Strategies to promote regular retesting of essential frontline Latinx workers and other priority Latinx community members at increased likelihood of infection are therefore crucial. However, unlike participating in a one-time testing event, retesting requires repeated health care engagement and longitudinal behavior change via habit formation. *Optimal strategies to promote regular SARS-CoV-2 retesting in essential workers remain unknown.*

Building on low-barrier, rapid testing, there is now an opportunity to test implementation of community-responsive testing models to ensure regular access to SARS-CoV-2 testing and retesting in a dynamic (post-vaccine and delta-variant) period in which testing demand varies over time. In a post-vaccine environment, our research group has successfully developed methods and infrastructure for standing, low-barrier COVID-19 testing services at community sites based on COVID-19 mass testing campaigns and drop-in testing at standing community sites. We now have an opportunity to evaluate a novel community-responsive COVID-19 testing model (developed in collaboration with our community partners (Canal Alliance in San Rafael, Marin County and United Way-Merced in Merced County) and community member input from our Aim 1 Latino COVID-19 Collaborative) in which testing is conducted by community

health workers/advocates (known as “*promotoras*”) at community-based testing sites, to measure and respond to dynamic and evolving community testing needs in a post-vaccine era.

2. Study Objectives

Aim 1: Evaluate implementation of the Latino Task Force (LTF) model to promote COVID-19 test and respond initiatives in two majority Latinx communities with low COVID-19 testing access. We will adapt and test the reproducibility of the LTF model in two underserved communities - one suburban (Marin) and one rural (Merced) - by establishing a collaborative LTF network between San Francisco and the two communities to share best practices, advice and support. We will use the RE-AIM evaluation framework to evaluate implementation and outcomes of Latinx CBO participation, adoption and fidelity to the collaborative network intervention, and LTF network effectiveness and maintenance.

Aim 2: Determine population-level prevalence of active SARS-CoV-2 infection, most at-risk subgroups, and attitudes and preferences regarding COVID-19 testing services during low-barrier, community-based mass testing campaigns in the two Northern California study communities. In each community, we will conduct baseline, rapid, low-barrier, community-wide testing campaigns, regardless of symptoms, with follow-up home/work-place sampling of campaign non-attendees, to gather valuable data on epidemiology, most at-risk subgroups, and attitudes and preferences regarding COVID-19 testing services. These robust data will guide action on prevention messaging, testing initiatives, and future vaccine delivery.

Aim 3: Evaluate implementation of community-responsive COVID-19 testing strategies, delivered by local community health workers (“*promotoras*”) and tailored to the needs of the two study communities post-COVID-19 vaccine scale-up in Northern California. We propose to study implementation of three complementary testing strategies (a. drop-in; b. responsive; and c. spot surveillance) delivered by community partners and local, Spanish-speaking *promotoras* trained and certified to conduct FDA-authorized (EUA) BinaxNOW™ rapid COVID-19 antigen testing with confirmation by PCR of antigen test positive participants. Outcomes include: 1) testing implementation measures (RE-AIM); and 2) changes in: a) positivity over time; b) reasons for testing over time, and c) circulating SARS-CoV-2 variants detected, by the three testing strategies.

3. Study Sites & Populations

The three communities in which the LTF collaborative network will be based are in San Francisco, Marin and Merced counties, representing an urban, suburban and rural setting, respectively.

San Francisco site: San Francisco’s LTF has been active since March 2020, with successful implementation and advocacy for COVID-19 test and respond initiatives throughout the city (see Preliminary Data). Following our large-scale, mass SARS-CoV-2 testing campaign in April 2020 in the Mission District in partnership with the San Francisco LTF, community advocates from Marin and Merced counties reached out to the *Unidos en Salud* team with interest in collaboration to scale up community-based testing initiatives for their Latinx populations. However, to date, resources to facilitate and oversee a 3-site collaboration, and to organize Latinx community-led test and respond programs in Marin and Merced counties have been lacking.

Marin site: Marin county, just north of San Francisco, is a largely suburban county with some of the greatest ethnic disparities in COVID-19 case rates in California: whereas Latinx people make up 16% of the county’s population, they have accounted for 75% of COVID-19 cases. Within San Rafael, one of the largest cities in Marin and the location with the greatest number of COVID-19 cases, a predominantly (~80%) Latinx community resides in the Canal Area – a low-income neighborhood within an otherwise wealthy Bay Area county.³³ The Canal Area has been among the hardest hit communities in the Bay Area, with a high proportion of essential, frontline workers and densely populated housing units.

Merced site: Merced county, in the Central Valley of California, is a largely agricultural, rural setting, with a large population of Latinx farm and factory (e.g. canning) workers. As of late July 2020, Merced County has been considered a state COVID-19 “hot-spot” with spiking numbers of cases and deaths, with COVID-19 testing positivity at 17% compared to a state average of 7%.³⁴

4. Study Design

Table 1. Overview of proposed study aims, interventions, evaluation framework and outcomes.

Aim	Intervention	Theory-guiding Intervention	Study Design / Evaluation framework	Outcomes
1	Collaborative network of LTFs	<ul style="list-style-type: none"> Dissemination of innovation Small network theory for adult learning 	RE-AIM implementation evaluation	Primary: One for each of 5 RE-AIM dimensions
2	Mass test and respond campaigns	<ul style="list-style-type: none"> Epidemiologic analysis Sampling of campaign non-participants 	<ul style="list-style-type: none"> Cross-sectional epidemiologic analyses, with census tract denominators RE-AIM implementation evaluation 	Primary: Population prevalence Secondary: Most at-risk sub-groups; community perceptions
3	Community-Responsive Testing	<ul style="list-style-type: none"> RE-AIM Implementation Framework 	Cross-sectional and longitudinal epidemiologic analyses	Primary: Testing Implementation via RE-AIM

5. Aim 1: Evaluate implementation of the Latino Task Force (LTF) model

Overview: We will leverage, adapt and test the reproducibility of San Francisco’s successful LTF model in two majority Latinx communities with low COVID-19 testing rates - one suburban (Marin) and one rural (Merced). The objective of this approach is to accelerate dissemination of innovation in COVID-19 testing strategies by establishing a “Latino COVID-19 Collaborative” (LCC) network (community-to-community) with San Francisco and the two study communities to share best practices, advice, and support. We use the RE-AIM framework^{21,35} to identify key evaluation metrics and analyze implementation outcomes of this novel collaborative network.

5.1 Recruitment & Enrollment of Study Participants

5.1.1 Recruitment

The LCC network intervention is designed to engage existing community-based organizations (CBOs) that respond to the needs of local Latinx populations within the study communities. CBOs in the selected study communities and associated counties will be eligible for network intervention participation and need not have a prior focus on health-related services.

5.1.2 Screening/Consent Process

At study start, the study team will create a comprehensive list of existing CBOs that provide services to local Latinx study populations within each of the two study communities. Study staff, led by the existing CBO partners committed to this study (**Canal Alliance** in Marin, and **United Way** in Merced) will conduct outreach over four weeks at study baseline to CBOs serving Latinx populations in each site, to join local LTFs and participate in the network intervention. All CBOs expressing interest, will be invited to an informational session via web-based conference calls at baseline.

5.1.3 Enrollment/Consent

All CBOs that express interest in participating in the Latino COVID-19 Collaborative intervention will receive a written informed consent form (provided electronically) at the completion of the informational web-based session. Study staff will review the written consent form (for e-signatures) with the group for voluntary participation in the LTF collaborative meetings, study surveys, in-depth interviews, participant observation during collaborative meetings, and focus group discussions. CBO members may have up to six weeks to consider signing the consent form and participating as part of the LTF collaborative. CBO members that wish to join at a later date may be allowed to do so; in these cases, study staff will re-review the written informed consent form, on a case-by-case basis, and obtain written consent for participation.

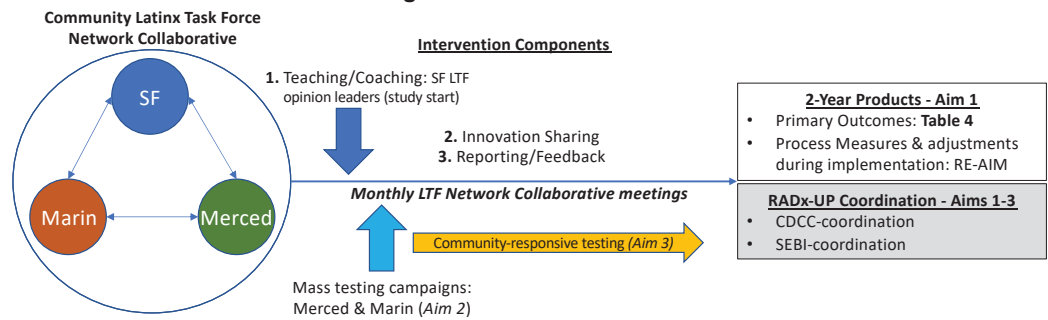
5.2 Intervention (procedures)

Intervention: At study start, we will facilitate formation of a collaborative network between members of the San Francisco LTF and key community-based organizations (CBOs) in Marin and Merced counties. CBO partners are longstanding advocates for Latinx communities and have expressed interest in working together to promote low-barrier COVID-19 testing access. The 3-site Aim 1 intervention consists of 3 key components (**Figure 1**):

1) **Teaching/Coaching:** Principles of adult learning suggest that learning occurs most efficiently through interaction and dialogue.³⁶

We therefore will conduct 3-site collaborative network teaching/coaching meetings, initiated at study start and led by two San Francisco LTF opinion leaders (“coaches”) with community COVID-19 testing mobilization/implementation

Figure 1. Aim 1 Intervention Schematic



expertise to provide an overview of LTF administrative structure, including balancing interests of multiple, existing CBOs. The rationale for this approach is that research on the link between implementation and program outcomes shows that outcomes may not be achieved by didactic training alone and that “coaching” is critical for success. Coaching can facilitate a) “buy in” from participants; b) sharing of best practices; and c) a productive environment for accountability.³⁷ In addition, adult learning models suggest that peers are the best source of knowledge to facilitate change. The objective of this intervention component is to speed the establishment of the LTF model in the Marin and Merced sites that have long-standing CBOs advocating for Latinx community members, but that do not yet have a unified LTF for COVID-19. The implementation of mass testing campaigns (Aim 2) will serve as a catalyst to unite CBOs within local LTFs at the Marin and Merced sites through joint action and visible, concrete service delivery.

2) **Innovation Sharing:** By creating a collaborative network, we enable the group to form bonds across sites and speed diffusion of innovation so that perspectives and strategies on uniting local CBOs towards a common cause – community-led COVID-19 test and respond strategies, including public health messaging – can spread within the group.³⁶ This collaborative incorporates findings from “small-world” social networks studies that suggest that creating random links between people magnifies diffusion of information in that network by rapidly reducing the average network “length” between any two individuals.³⁸ The objective of this component is to accelerate diffusion of new ideas in the small world network to overcome implementation obstacles and speed development of locally-relevant COVID-19 “test and respond” program goals.

3) **Reporting/Feedback:** In addition to sharing of best practices and dissemination of innovative solutions, accountability and feedback is important for sustainable goal achievement within the network. By creating a 3-site Latino COVID-19 Collaborative network and reconvening monthly over the 2-year study period, each collaborative has an opportunity to share progress in community mobilization efforts and planning for local COVID-19 test and respond initiatives. The study investigators will prepare summaries of data about progress and testing uptake at each site before the meeting and then the group will discuss a comparative report showing progress across all sites. The objective of this component is to provide a trusting environment where gaps or differences between sites will allow and prompt discussion of problem solving. This intervention is based conceptually on the Institute for Healthcare Improvement (IHI) Breakthrough Collaboratives Series,³⁹ but differs in notable ways such as the use of a smaller collaborative and the focus on community-based testing as an outcome.

5.2.1. Collaborative Network Meeting Procedures

Latino COVID-19 Collaborative network meetings will be held online via a web conferencing platform (e.g. Zoom) in order to allow for participation from multiple sites and to ensure social distancing and safe participation during the COVID-19 pandemic. Participants may join by phone or computer: neither computers nor WIFI are required to participate. Meetings may last up to two hours. Each meeting will be led by a collaborative network facilitator, a timekeeper (to keep the group on time) and a record keeper (to record and relay action items and other meeting highlights). Collaborative network meetings will be audio-visually recorded. Each meeting will address a specific topic, communicated at least a week in advance to the collaborative network participants. Break-out “rooms” (on web conferencing) may be used to facilitate smaller group discussions, depending on the topic or focus on community site-specific questions during any given collaborative network meeting. Meetings may be held in either Spanish or English, with translation services offered during the meeting to facilitate participation from monolingual English or Spanish speaking participants.

5.3 Measurements/Outcomes

We use RE-AIM to evaluate implementation domains of the Aim 1 intervention. We summarize the approach and provide outcome definitions, data sources and reporting timelines in **Table 2**.

Table 2: RE-AIM Implementation Evaluation Framework, Outcomes, Data Sources and Reporting Timeline for Aim 1.

Intervention: LTF Network	Implementation Primary Outcomes	Outcome Measurement & Data Sources	Reporting Timeline
Reach	% of baseline, active Latinx CBOs participating in local LTFs in Marin and Merced.	LTF CBO participants	Within 4 weeks of study start
Effectiveness	Extent to which local LTFs meet their pre-specified, baseline goals for community-based test and response initiatives	Baseline and follow-up LTF participant surveys & in-depth interviews (IDIs)	Within 18 months of study start
Adoption	Proportion of CBO members participating in quarterly collaborative network meetings	LTF collaborative network meeting attendance logs	Every 6-month reporting
Implementation	Fidelity to collaborative intervention: a) 3-site meetings occurring on schedule; b) completion of mid- and end-of-study LTF network reports; c) sharing of ideas/proposals; d) follow through on collaborative action items and engaged participation from all 3 sites.	CBO participant surveys and network participant observation reports and focus group discussions (FGDs)	End of Month 18 time point
Maintenance	Ongoing LTF meetings held across 3-site network post-intervention period	Post-network collaborative surveys	End of year 2

5.3.1. Measurement Procedures

Aim 1 Collaborative Network Surveys:

a) **Baseline:** Study research assistants will provide all participants in the collaborative network with a baseline survey prior to the first collaborative network meeting. Surveys will be available in both English and Spanish, and may be self-administered online (via REDCap) or, if a participant prefers, administered by a study staff member online or via phone call or socially distanced outdoor interview. The baseline survey is estimated to take between 20-30 minutes, on average, to complete, depending on the level of detail participants provide in the open-ended questions.

b) **Follow-up:** Study research assistants will provide all Aim 1 participants, regardless of attendance at collaborative network meetings, with an Aim 1 mid-point and end of study survey, to understand participant perceptions and views on effectiveness of the collaborative network in meeting the participant or their organization's baseline goals for community-based COVID-19 test and response initiatives in their communities. Similar to baseline, follow-up surveys will be available in both English and Spanish, and may be self-administered (via REDCap) or, if a participant prefers, administered by a study staff member online or via phone call or socially distanced outdoor interview. The follow-up surveys are estimated to take between 20-30 minutes, on average, to complete, depending on the level of detail participants provide in the open-ended questions.

c) **Post-collaborative network survey:** Six months following completion of Aim 1 study activities, study staff will administer a post-network collaborative survey to all Aim 1 participants that will seek to understand maintenance of collaboration: i.e. the extent to which collaborative activities continue within each community (in Marin and Merced counties) and cross-county, between collaborative network members. The post-baseline survey will be available in both English and Spanish, and may be self-administered (via REDCap) or, if a participant prefers, administered by a study staff member online or via phone call or socially distanced outdoor interview. This survey is estimated to take between 10-15 minutes.

Aim 1 In-depth Interviews (IDIs): Study staff will invite a random sample of collaborative network participants to participate in in-depth interviews over the course of the study period, with a goal of conducting roughly one-third of IDIs within 3-months of study baseline, one-third from 3-9 months into the study, and one-third in the final 3-6 months of the study (see Aim 1 Schedule of Evaluations). Exact timing of the IDIs will depend on participant availability. IDIs will be conducted by bilingual study staff (Spanish/English) in the language of the participant's preference, and audio recorded. IDIs are estimated to take between 1-2 hours per interview, and study staff administering the IDIs will use an interview guide.

Participant Observation: Collaborative network meetings will be audio/visual recorded using Zoom (or other electronic teleconference platforms made available by UCSF). Network meetings will be scheduled monthly,

with the option to increase (up to weekly) or decrease meeting frequency (to every 2-3 months), depending on ongoing study field activities (e.g. Aim 2 testing events).

5.3.2. Aim 1 Schedule of Evaluations

	Baseline	Collaborative Network Meetings*	Aim 1 mid-point (6-9 months post-baseline)	End of study (15-18 months post-baseline)	6 months Post Aim 1 study activities
Latino COVID-19 Collaborative (LCC) Network Surveys	◆		◆	◆	
In-depth interviews (IDI)	◆		◆	◆	
Participant Observation		◆			
LCC Attendance Logs		◆			
Post-LCC Network Study					◆

*Planned as monthly, with the option to increase (up to weekly) or decrease meeting frequency (to every 2-3 months), depending on ongoing study field activities (e.g. Aim 2 testing events).

5.4 Analysis

The primary objective is to evaluate the impact of adapting the LTF model via a collaborative network intervention to promote an effective implementation strategy for community-based, low barrier COVID-19 test and respond initiatives. We will use RE-AIM to guide the implementation evaluation analysis, with primary outcomes for each domain shown in **Table 2** (above).

Qualitative Analyses:

IDs and Participant observation recordings (from zoom meeting audio) will be reviewed by the study investigators and study staff: IDI facilitators will be engaged to participate in coding and interpretation of data in collaboration the co-investigators. Team members will prepare and load IDI transcripts (translated if needed) into appropriate software (such as Atlas.ti) for coding and interpretation. An initial analytical code list will be defined on the basis of theory and initial empirical data, with iterative refinement as new data are loaded. At defined stages of the analysis process, codes and definitions will be refined or expanded as needed. In team meetings, members will discuss coding of rich or difficult segments of text to achieve consensus. Code query reports will be generated to explain patterns and identify emergent themes in the IDI and participant observation data.

5.5 Sample Size & Accrual

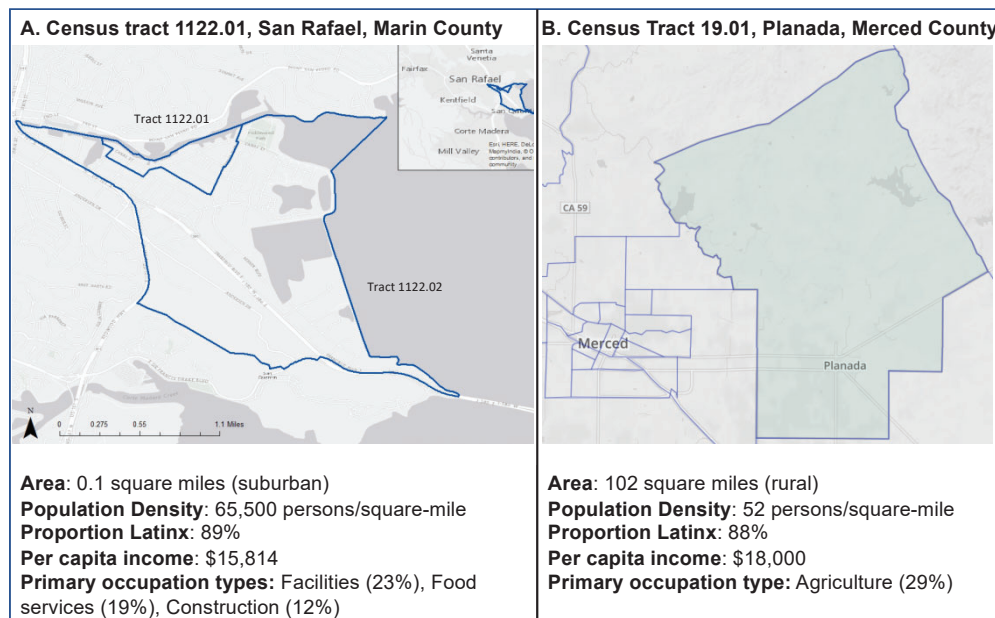
The possible maximum sample size will be based on the number of persons from participating CBOs that wish to participate in the LTF collaborative. Based on our experience in the San Francisco LTF, we anticipate approximately 50 participants in the LTF collaborative at each study site (in Marin and Merced counties), for a total of 100 participants in Aim 1.

6. Aim 2: Low-barrier, community-based mass testing campaigns

Aim 2: Determine population-level prevalence of active SARS-CoV-2 infection, most at-risk subgroups, and attitudes and preferences regarding COVID-19 testing services during low-barrier, community-based mass testing campaigns in the two Northern California study communities.

Overview: In each community, we will conduct baseline, rapid, low-barrier, community-wide testing campaigns, regardless of symptoms, with follow-up sampling of campaign non-attendees, to gather valuable, community-wide data on epidemiology (point prevalence of PCR-positive or rapid antigen test-positive persons, regardless of symptoms), most at-risk subgroups, and community attitudes and preferences regarding COVID-19 “test and respond” services. Through mass, community-based SARS-CoV-2 testing, we will obtain robust data to guide action on prevention messaging, long-term testing and retesting initiatives, isolation and quarantine support.

Figure 2. Community maps for mass testing campaigns in Marin (A) and Merced (B) counties.



6.1 Study Populations

Working in collaboration with partner CBOs in Marin and Merced counties, we have identified one majority-Latinx community in each county for implementation of rapid, 4-6-day, mass testing campaigns designed to reach and test the majority of residents. In Marin, we will conduct the baseline mass testing campaign in US census tract 1122.01 in San Rafael within a majority Latinx sub-urban community referred to as the “Canal Area,” with a population size of 8,175 persons, and demographics shown (Figure 2).⁴⁰ In Merced, we will conduct the baseline campaign in census tract 19.01, in the Planada community (population size of 5,298).

6.2 Recruitment & Enrollment of Study Participants

6.2.1 Recruitment. We will work in partnership with local Latino COVID-19 Collaboratives (LCCs: established in Aim 1) from each of the two (Marin and Merced county) study sites to identify easily accessible and familiar community locations as testing venues and mobilize community members to participate in testing via local Spanish media, social media, and flyer distribution, as well as other local LCC-proposed mobilization methods.

6.2.2 Eligibility Criteria

Inclusion criteria:

1. Current resident of study area or non-resident worker in study area;
2. Age ≥ 2 years;
3. Able to provide verbal consent (if age >18 years) or parent/guardian consent (if age 2-17 years, with verbal assent if age 7-17 years) to participate.

Exclusion criteria: 1. Unable to provide consent; 2. Non-current resident or worker in study area.

6.2.3 Enrollment/Consent

During community mobilization activities and at testing sites on campaign days, we will utilize existing software for pre- or on-site registration, respectively, and we will obtain verbal consent for participation in the mass testing campaigns.

6.3 Mass testing campaign procedures

6.3.1 Survey The survey, adapted from our Mission testing survey, will gather data from participants on symptoms, co-morbidities, prior COVID-19 testing or diagnosis, and attitudes and preferences regarding prevention messaging, testing and retesting services, post-testing needs (e.g. isolation, quarantine, and workplace notification), and future vaccine delivery. Survey data will be captured by staff on handheld tablet computers during pre-test evaluation, or by secure, online pre-registration that participants may complete on their own devices (smartphone, tablet or computer) prior to or on the day of testing. The Aim 2 survey will be

available in both Spanish or English (depending on participant preference). The survey is estimated to take 10-15 minutes to complete.

6.3.2 Mass SARS-CoV-2 testing campaigns: Over 4-14-day community-based mass testing campaigns, we will offer walk-up and/or drive-through testing at accessible outdoor community-based venues using validated procedures from our Mission testing campaign.¹⁰ Campaign capacity is designed to test >1,000 people/day, and the UCSF lab is prepared to process >1,000 FDA-authorized tests daily with <72-hour turnaround time.

a) Specimen collection for mass testing campaigns: Following the study questionnaire, study staff will obtain staff-collected swabs for SARS-CoV-2 virus (by PCR of viral RNA or by Abbott BinaxNOW™ rapid antigen test kit) testing, regardless of symptoms. Study staff will collect nasal (anterior nares) swabs. Specimen collection will be facilitated by outdoor or in-vehicle sampling, *one household at a time*, with isolation masks worn by participants immediately before and after swabbing, to minimize any close contact between participants and study staff. Study staff will wear personal protective equipment (PPE) throughout any close contact with participants for providing sterile swabs and accepting used swabs (self-collection) or while swabbing the patient (study staff collection).

b) Laboratory testing: SARS-CoV-2 virus testing by a CLIA certified polymerase chain reaction (PCR) amplification of viral RNA and/or by Abbott BinaxNOW™ rapid antigen testing will be performed on all upper respiratory tract specimens collected, regardless of symptoms reported by participants. All SARS-CoV-2 virus isolates obtained (applicable only when PCR used, but not BinaxNOW™) during population screening in Aims 1 and 2 will be sequenced and analyzed at UCSF and the Chan-Zuckerberg Biohub (CLIAHub). Pairwise genetic distances between viral isolates will be analyzed in conjunction with epidemiologic data including timing and location of infection to obtain inference on transmission patterns. Deidentified viral sequence data will be uploaded to public databases such as GISAID.

6.3.3 Sampling of campaign non-participants (“post-campaign outreach” testing): To improve accuracy of prevalence estimates and better understand barriers to testing, we will offer a brief telephone survey and COVID-19 testing (“post-campaign outreach” testing) to a random sample of 100-200 campaign non-participants (using census and geospatial data of non-participating households) at each site. Testing will be conducted at an outdoor community-based location or at the home, per the participant’s preference. Study team members will either call or visit homes of event non-attendees (wearing a mask and eye shield) and invite (by direct knock/ring at the door, phone call, SMS text or email) an adult (≥18 years) household member to complete a brief survey and participate in COVID-19 testing. Oral consent will be obtained prior to the brief telephone survey to provide information about the survey. For participants who opt to participate in outdoor SARS-CoV-2 testing at a community-based location or at home, we will use informed consent using similar procedures to the mass testing campaigns.

a) COVID-19 Testing for sampling of campaign non-participants (“post-campaign outreach” testing): As with the mass testing campaigns, we will offer testing with Abbott BinaxNOW™ rapid antigen test kit testing, regardless of symptoms. On March 31, 2021 Abbott BinaxNOW™ received an Emergency Use Authorization from the FDA for use in asymptomatic and symptomatic persons and for home use.^{41,42} Specimens will be obtained via observed, outdoor and distanced self-collection. For self-collection: study staff will first provide verbal instruction with educational aids to assist in instruction, and then provide a sterile swab and collection kit for each participant. Participants will be asked to perform the swabs in view of the study staff, whenever possible, and to hand collected swabs back to study staff. We will also conduct confirmatory testing with a CLIA-certified PCR.

b) Drop-In COVID-19 Testing: During implementation and after completion of post-campaign outreach testing, we will continue to offer COVID-19 testing services provided at community sites and days/hours chosen by our community partners. As with our mass testing campaigns and post-event testing, we will offer testing with Abbott BinaxNOW™ rapid antigen test kit testing, regardless of symptoms. For drop-in COVID-19 testing, we will provide testing under a California Department of Public Health (CDPH) CLIA-Waiver program to which our community partners (Canal Alliance in Marin County and United Way-Merced in Merced County) have already successfully applied. Specimens will be obtained via observed, outdoor and distanced self-collection by study staff or CDPH-trained community health workers (*promotoras*). For self-collection: study staff will first provide verbal instruction with educational aids to assist in instruction, and then provide sterile swabs and collection kit for each participant. Participants will be asked to perform the swabs in view of the study staff, whenever

possible, and to hand collected swabs back to study staff. We will also conduct confirmatory testing with a CLIA-certified PCR test provided by the CDPH (Valencia Branch Laboratory).

6.3.4 Response for COVID-19-positive persons

i) Individual results reporting will be provided as follows: Results will be directly reported from the lab to the study-associated (Primarybio) encrypted record management platform and then delivered electronically and securely via SMS or email. We will also provide participants access to a secure phone hotline to retrieve their results for those without SMS or internet access, or those who prefer to use a phone system. Study staff will also call all participants with a positive SARS-CoV-2 PCR or BinaxNOW™ test (**hereafter referred to as COVID-19-positive persons**) to disclose the positive result and to provide counseling and guidance on isolation and quarantine. Study staff will log all disclosure calls into the study associated (Primarybio) encrypted record management platform, which links to Redcap. At the time of disclosure, all participants with a positive SARS-CoV2 test will also be offered additional services to support isolation and quarantine (see Community Wellness Team, below). Usual Department of Public Health case investigation and contact tracing will occur per the county Department of Public Health's local practice, whether testing is offered by PCR or BinaxNOW™ rapid antigen tests.

ii) Community Wellness Team: Building on the Test to Care Model developed in our *Unidos en Salud* studies,¹⁶ we will provide community health worker-led longitudinal wrap-around services (symptom and wellness checks, linkage to financial assistance and social service programs, food delivery, and linkage to primary care) to support isolation and quarantine. We will leverage services that our community partners (United Way and Canal Alliance) are already providing.

6.3.5 Post-campaign evaluation: Within 4-weeks of each site's baseline mass testing campaign, we will convene a follow-up meeting of the LTF collaborative network (Aim 1) to review de-identified data from the campaign, review and discuss interpretation of survey and testing results in transparent "reports back" (**Table 3**, below).

6.4 Measurements/Outcomes

1. Epidemiologic measures: The Aim 2 **primary outcome** is the estimated, baseline point prevalence of active (PCR-positive or BinaxNOW™ rapid antigen-positive) SARS-CoV-2 infection for each of the two study communities, adjusting for both assay test characteristics and for response, accounting for both participation in the mass testing campaign and successful contact and testing of non-attendees sampled for home/work-based follow up. We will compare prevalence estimates by ethnic groups, with Latinx ethnicity as the primary group of interest, and identify demographic and socio-economic factors associated with greater likelihood of COVID-19-positivity, stratified by ethnicity. Socio-economic risk factors of interest will include occupation type, household income, household density, ability to work from home and maintain one's income, mobility/migration, use of public transport, and reported work environment. We will sequence SARS-CoV-2 virus isolates to characterize strain diversity and transmission patterns and compare differences in strain diversity between suburban and rural sites.

2. Clinical outcomes: We will perform post-testing follow-up over two weeks for all COVID-19-positive persons identified to provide support in coordination with the clinical response and community wellness teams, to properly classify symptom status (i.e. proportion asymptomatic, pre-symptomatic and symptomatic PCR+ or BinaxNOW™ rapid antigen+ infections) and to ascertain proportion of infections requiring medical care and hospitalization post-diagnosis.

3. Beliefs and Preferences re: COVID-19 testing: During pre-testing registration, we will systematically perform surveys to ascertain community member beliefs and attitudes regarding COVID-19 infection and public health prevention measures, as well as preferences and concerns regarding COVID-19 test and response services. Domains of interest will include beliefs regarding SARS-CoV-2 transmission, natural history of infection, and effectiveness of prevention measures, attitudes regarding stay-at-home measures, social distancing, mask use and public health messaging, preferences regarding low barrier COVID-19 testing access and modalities, and concerns regarding accessing testing, self-isolation, quarantine and potential future vaccines.

4. **Testing implementation outcomes:** We will measure and assess mass testing campaign implementation outcomes using the RE-AIM implementation framework (**Table 3**), with primary outcomes of mobilization goals met (*reach*); testing coverage (*effectiveness*); reasons for campaign participation or non-participation in the sample reached for home/work-place testing (*adoption*); timeliness of campaign and results reporting (*implementation*), and the proportion of eligible, priority residents engaging in (Aim 3) community-responsive testing (*maintenance*).

5. **Drop-In Testing measures:** For participants who access drop-in, community-based testing, we will measure reasons for testing in a post-vaccination context, symptoms, and self-reported vaccination status.

6.4.1 Aim 2 Schedule of Evaluations

Aim 2: Community-based Testing Events	Study Timepoint				
	Prior to Mass Testing Campaign	Mass Testing Campaign		Post-campaign outreach testing & Drop-In Testing	<= 4-weeks Post-campaign
		Pre-test (on-site at campaign)	Testing/Post-test		
Testing site identification	◆				
Community mobilization	◆	◆			
Pre-registration	◆	◆			
Pre-testing survey		◆		◆	
SARS-CoV-2 PCR or BinaxNOW™ rapid antigen testing (anterior nares swab)			◆	◆	
Individual Results Reporting			◆	◆	
Community Wellness Team (CWT) support			◆	◆	
Latino COVID-19 Collaborative (LCC) network post-campaign evaluation					◆

Table 3. RE-AIM Implementation Evaluation Framework, Outcomes, Data Sources and Reporting Timeline for Aim 2.

Intervention: Mass Testing Campaign	Implementation Primary Outcomes	Outcome Measurement & Data Sources	Reporting Timeline
Reach	% of participants reporting exposure to pre-campaign mobilization messaging	Campaign-day pre-test and post-campaign outreach testing surveys	Within 6 months of study start
Effectiveness	Latinx resident testing coverage. <i>Secondary:</i> SARS-CoV-2 positivity and % asymptomatic positives	<i>Numerator:</i> testing participants from study census tract; <i>Denominator:</i> estimated residents in study census tract	Within 9 months of study start
Adoption	Reasons for campaign participation & non-participation	Campaign pre-test surveys and post-campaign outreach testing surveys	Within 9 months of study start
Implementation	Campaign delivered within pre-specified timeline <i>Secondary:</i> Test results reported to participants within 72 hours	Campaign dates vs. pre-specified timeline; <i>Secondary:</i> digital confirmation of receipt of results	Within 6 months of study start
Maintenance	Proportion of eligible priority Latinx residents engaging in Aim 3 community-responsive testing activities	Aim 3 testing uptake	Within 12 months of study start

6.5 Analysis

1. **Prevalence of active (PCR+ or BinaxNOW™ rapid Ag+) SARS-CoV-2 infection:** The Aim 2 **primary outcome** will be the prevalence of SARS-CoV-2 among tract residents, estimated using the two-stage sampling design based on i) prevalence of infection among residents tested at the campaign; and, ii) prevalence of infection among non-attendees who were sampled and reached for testing at home/work.^{43,44} Inverse weights will be used to correct for both known re-sampling probability and for non-response. Estimates will be further adjusted for PCR or BinaxNOW™ assay characteristics, with 95% confidence intervals will be based on a non-parametric bootstrap approach,¹⁰ extended to reflect the two-stage sampling design. Non-

resident workers will be considered as a secondary subgroup of interest. While exact precision achieved will depend on underlying prevalence, campaign uptake, and response among re-sampled non-attendees, this design is anticipated to result in highly precise estimates (for example, if underlying prevalence is 8%, 2500 PCR results should yield a confidence interval width of <3%).

2. **Determination of priority sub-groups** at increased likelihood of acquiring SARS-CoV-2 infection: Univariate and multivariate risk factors on an absolute and relative scale will be calculated using both parametric approaches (logistic and log linear models) and non-parametric approaches incorporating machine learning (collaborative targeted maximum likelihood incorporating Super Learner),^{45,46} both incorporating sampling weights to reflect the two stage design. Participant addresses will be used to create geospatial maps (using a Gaussian kernel density method)⁴⁷ and for hotspot detection using SaTScan.^{48,49}

3. **Analysis of beliefs, attitudes & preferences** for testing will be assessed by quantitative pre-test and post-campaign outreach testing surveys, stratified by suburban vs. rural site, and by those tested at the campaign vs. those reached for testing at home/work using appropriate statistical tests to identify response trends. We will also assess changes in reasons for testing over time among drop-in testing participants.

6.6 Sample Size & Accrual

The total population of the study sites is 13,473 persons (8,175 in San Rafael, and 5,298 in census tract 19.01 in Merced County), with an estimated additional 500-700 persons who work (but do not reside) in the study setting, for an estimated total of approximately 14,000 eligible persons. If we reach 80% coverage (inclusive of sampling of non-participants), we anticipate testing approximately 11,200 persons in Aim 2 mass testing.

7. Aim 3: Implementation of community-responsive COVID-19 testing strategies.

Aim 3: Evaluate implementation of community-responsive COVID-19 testing strategies, delivered by local community health workers ("*promotoras*") and tailored to the needs of the two study communities post-COVID-19 vaccine scale-up in Northern California.

Overview. We will study implementation of three complementary testing strategies (a. drop-in; b. responsive ["as needed"] testing; and c. spot surveillance) delivered by study staff and local, Spanish-speaking *promotoras* trained and certified to conduct FDA-authorized (EUA) BinaxNOW™ rapid COVID-19 antigen testing with confirmation by PCR of antigen test positive participants. **Outcomes** include: 1) testing implementation measures (RE-AIM); and 2) changes in: a) positivity over time; b) reasons for testing over time, and c) circulating SARS-CoV-2 variants detected, by the three testing strategies.

7.1 Study Design

We will evaluate testing implementation and conduct epidemiologic analyses in study census tracts (the same study communities from Aims 1 and 2) using a RE-AIM implementation evaluation framework of the community-responsive testing model (**Figure 3**).

7.2 Recruitment & Enrollment of Study Participants

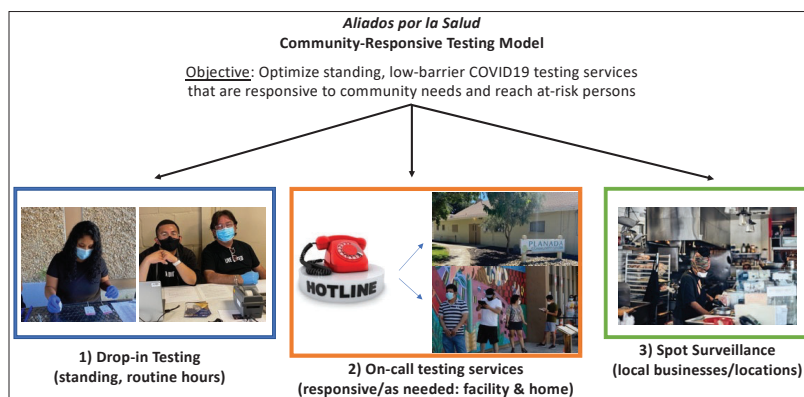
7.2.1 Recruitment

We will work in partnership with local Latino COVID-19 Collaboratives (LCCs: established in Aim 1) from each of the two (Marin and Merced County) study sites to conduct community mobilization and outreach education for community members. The goals of community mobilization and outreach include: a) providing up-to-date information on COVID-19 testing services we offer locally and b) gathering continuous community member input on the types of COVID-19 testing services needed locally.

7.2.2 Eligibility Criteria

1. Current resident of study area or non-resident worker or visitor in study area
2. Age ≥ 2 years

Figure 3. Aim 3 Community-Responsive Testing Model



3. Able to provide verbal consent (if age ≥ 18 years) or parent/guardian consent (if age 2-17 years, with verbal assent if age 7-17 years) to participate.

Exclusion criteria: 1. Unable to provide consent

7.2.3 Enrollment/Consent

For persons who meet the eligibility criteria, study staff will obtain verbal consent and proceed to the study survey and COVID-19 testing.

7.3 Procedures

7.3.1 Testing Modalities & Procedures

1) **COVID-19 Testing Modalities:** We will offer testing with Abbott BinaxNOW™ rapid antigen test kit testing, regardless of symptoms, with confirmatory PCR testing (see below), using a community-responsive testing model (**Figure 3**) focused on three testing modalities:

- a) **Drop-in testing at community sites:** This testing modality will ensure regular access to low barrier, no appointment, free testing at well-known community locations and at regular days/times. Drop-in testing days/times may range from bimonthly or weekly, to a more frequent schedule (e.g., 2-3 times/week) based on testing demand as well as surges in COVID-19 or other respiratory viruses with similar symptoms (e.g., influenza or other upper respiratory viruses during the winter months).
- b) **Responsive (“as needed”) testing within communities:** This testing modality will be offered to accommodate those who have unexpected/unplanned needs for testing (e.g., sudden onset symptoms, work or childcare requirement; unexpected exposures to a contact, etc.) that are not met in a sufficiently timely manner by drop-in testing days/times. Study staff will work with our community partners, including members of the LCC (Aim 1), to offer a range of options for rapid access to community-based testing, including: i) same-day appointments for testing at local sites; ii) provision of home test kits for self-use with instructions on use and interpreting results; and iii) referral to a local network of *promotoras* (community health workers/volunteers) for same-day access to home-test kits.
- c) **Surveillance testing events at high-risk workplaces and locations within each community:** This testing modality aims to evaluate circulating SARS-CoV-2 strains, including emerging variants, among both symptomatic and asymptomatic persons at high-risk of COVID-19 exposure, independent of vaccination status. Unlike “passive” drop-in testing and as-needed testing that are driven by demand from persons seeking testing, surveillance activities aim to provide active outreach and screening to persons who may not be seeking testing on their own. Working with our community partners, we will identify local businesses and/or community gathering sites to offer surveillance testing. Examples of surveillance sites include “mom and pop” shops (in the Canal), local farms (in Planada) and Latinx migrant worker gathering or housing sites.

2) **COVID-19 Testing Procedures:** Similar to the drop-in testing procedures described for Aim 2 (above), we will provide testing under a California Department of Public Health (CDPH) CLIA-Waiver program in which our community partners (Canal Alliance in Marin County and United Way-Merced in Merced County) are already successfully participating. For drop-in testing and as-needed testing at local sites, and surveillance testing, specimens will be obtained via outdoor and distanced self-collection, observed by study staff or CDPH-trained community health workers (*promotoras*). For young children aged 2-4 years of age, or persons who cannot self-swab (due to disability or other self-reported challenges), trained study staff wearing personal protective equipment (PPE: including gown, gloves, N95 respirators and eye protection [face shield or goggles]) may perform anterior nares swabbing via outdoor collection.

2a) **Observed self-collection:** study staff will first provide verbal instruction with educational aids to assist in instruction, and then provide sterile swabs and collection kit for each participant. Participants will be asked to perform the swabs in view of the study staff, whenever possible, and to hand collected swabs back to study staff. We will also conduct confirmatory testing with a CLIA-certified PCR test provided by the CDPH (Valencia Branch Laboratory).

2b) **Home-testing:** i) **Access:** For “as needed” testing in which home test kits may be provided, our study staff or *promotoras* will provide free access (subsidized by the project) to BinaxNOW rapid antigen self-use home-test kits (FDA authorized and now available over the counter [OTC]⁵⁰), along with verbal and/or written instructions, or access to online instructions, on how to use the test kits. Eligible participants will have an option for delivery of home-based self-test kits by *promotoras* or

arrange pick up at pre-designated community-based sites (including the Canal Alliance offices in San Rafael, CA or the Planada Community Center in Planada, CA). ii) *Testing*: Participants will be provided instruction on how to self-register in the PrimaryBio system and perform self-collection and processing of OTC BinaxNow tests per the package inserts, supplemented with simplified instructions on how to use the test kits. Per participant preference, the study staff or *promotoras* can offer (1) real-time coaching on sample collection, processing tests, test interpretation, and registering and recording data in PrimaryBio, (2) remote or in-person review of tests and result interpretation. After the results of the self-test are obtained, they can be verified by our study staff or *promotoras* either remotely/virtually or in-person by having the self-tester place the processed results outside of their door for inspection and documentation of processed results by study staff or *promotoras*. Participants also have the option to obtain over-the-counter self-tests for home use without sharing results or registering in the PrimaryBio system.

7.3.2 Surveys

a) Time of testing surveys: At the time of testing, for each modality, staff will administer or provide access to an online Aim 3 survey. Surveys will be available in both English and Spanish and may be self-administered online (via REDCap) or administered by a study staff member online or via phone call or socially distanced outdoor interview. The testing survey is estimated to take between 10-15 minutes, on average, to complete, and will include questions about demographics, health, occupation, socioeconomic, and school attendance of participants and people in their households or work environments, as well as perceptions of COVID-19 services and factors that facilitate or create barriers to testing. Immediately after completing testing procedures, we will also offer a brief post-test satisfaction survey to adults (≥ 18 years old) who tested.

b) In-depth interviews (IDI): We will contact a random sample of 20 participants from each of the three study modalities, for up to a year post-testing, to ask for voluntary participation in a phone, web-based audio/video call or in-person (socially distanced) interview about participants' experiences with our community-responsive testing model. This voluntary interview will be audio-recorded and led by a trained study staff member using a standardized IDI interview guide. The interview guide will be developed by study investigators based on lessons learned from Aims 1 and 2. IDIs are estimated to take up to 60 minutes to complete.

7.3.3 Post-Testing Support

We will report COVID-19 test results and provide post-test support as described for Aim 2 (see Section: 6.3.4 Response for COVID-19-positive persons). In brief, for a) Guidance on isolation and quarantine: After tests are complete for any given modality, study staff or *promotoras* will provide the appropriate recommendations on isolation and quarantine and repeat testing. b) Linkage to resources: The study staff will also assess needs for financial support and linkage to health insurance and primary care, as described in Aim 2 (Section 6.3.4).

7.4 Measurements/Outcomes

Primary Outcome - Implementation Outcomes: We will measure and assess community-responsive testing implementation using the RE-AIM implementation framework (**Table 4**), with primary outcomes: of mobilization goals met (*reach*); testing coverage (*effectiveness*); reasons for choosing a given testing modality (*adoption*); fidelity to the three testing modalities and adaptation in response to community feedback via LCCs and Aim 3 testing surveys (*implementation*), and the extent to which these modalities are adopted by local County departments of public health, following initiation of our project (*maintenance*).

Secondary Outcomes include changes in testing metrics over one year (including who is testing positive, reasons for testing, characteristics of breakthrough infections, and variants), and COVID-19 vaccine uptake among unvaccinated persons who access study testing sites.

Table 4. RE-AIM Implementation Evaluation Framework, Outcomes, Data Sources and Reporting Timeline for Aim 3.

Intervention: Community- Responsive Testing	Implementation Primary Outcomes	Outcome Measurement & Data Sources	Reporting Timeline
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Reach	% of participants testing with Aim 3 modalities reporting exposure to pre-campaign mobilization messaging	Aim 3 Pre-test surveys	Within 12 months of study start
Effectiveness	<ul style="list-style-type: none"> Latinx resident testing coverage. <i>Secondary</i>: SARS-CoV-2 positivity and % asymptomatic positives, % of testers who identify as Latinx 	<i>Numerator</i> : testing participants from study census tract; <i>Denominator</i> : estimated residents in study census tract	Within 12 months of study start
Adoption	Number of <i>promotoras</i> who provide testing services in each community: absolute number and proportion among all <i>promotoras</i> trained	Staff testing attendance records and study training logs	Within 12 months of study start
Implementation	<ul style="list-style-type: none"> Acceptability and feasibility of testing at each modality among <i>promotoras</i> (who were enrolled as Aim 1 participants) Fidelity to testing modality delivery (process measures) Adaptation in response to community feedback via LCCs (Aim 1) and Aim 3 pre-test and post-test surveys 	<ul style="list-style-type: none"> <i>Promotora</i> surveys Testing Modality-based logs, including: <ol style="list-style-type: none"> 1) Number of calls by <i>promotoras</i> for Tech support during testing delivery; 2) time spent by <i>promotora</i> coaching test use (home testing); 3) Number of home visits; 4) Top tech or test challenges 	Within 6 months of study start
Maintenance	Proportion of eligible priority Latinx residents engaging in Aim 3 community-responsive testing activities	Aim 3 testing uptake	Within 12 months of study start

7.5 Analysis

For each implementation outcome within the RE-AIM framework (**Table 4**), we will compare reach, effectiveness, adoption, implementation and maintenance, by testing modality. We will also evaluate implementation outcome metrics over time, and by secular trends (e.g. in relationship to surges in COVID-19 diagnoses, and other upper respiratory virus diagnoses [obtained via publicly available respiratory virus reporting], by County) to evaluate implementation responsiveness to community input and changes in COVID-19 testing demand. Lastly, we will describe changes in: a) positivity over time; b) reasons for testing over time, c) proportion in asymptomatic persons testing, and d) circulating SARS-CoV-2 variants detected, by the three testing strategies, to evaluate how these metrics vary by testing modality.

8. Human Subjects

8.1 Risks to Human Subjects

The primary risks to study participation include: i) inadvertent disclosure of health information, including past medical history or SARS-CoV-2 infection status; ii) discomfort during upper respiratory tract swabbing (Aims 2 and 3); iii) risk of exposure to SARS-CoV-2 from leaving one's home and participating in study activities.

8.2 Adequacy of Protection against risks

1) **Consent**: Voluntary, informed consent will be obtained from all participants, or their parent/guardian if a participant is 2-17 years of age. The consent process will be offered in English and Spanish. In [Aim 1](#) we will obtain written informed consent electronically, and in [Aims 2 and 3](#) we will obtain verbal informed consent to minimize close contact, handling and exchange of pens/study documents by participants and study staff. Study staff will document verbal consent for each participant. A community member will not be permitted to participate without providing verbal consent.

2) **Privacy**: During surveys, all participants will have the option to share health information or other private information during survey questionnaires by either speaking or written/digital communication (to avoid inadvertent disclosure). Questionnaires administered verbally will be distanced from neighbors, passersby, or other household members (if desired by the participant) to avoid inadvertent disclosure.

3) **Data Security**: Study staff will collect all field electronic data (Aims 2 and 3) on password encrypted devices. Any paper data collection forms, if necessary, will be data entered into a digital form, with paper forms stored in secure, locked offices at UCSF. Data will be stored in a secure cloud or on encrypted computers.

4) *Specimen Collection*: Upper respiratory tract swabbing may potentially cause mild discomfort, and rarely may cause mild nose bleeding or elicit a gag reflex. However, nasal, nasopharyngeal and throat swabs are commonly collected in outpatient settings, including self-collection, with minimal risk.

5) *Biosafety*: SARS-CoV-2 virus is easily transmitted from person-to-person through infected respiratory droplets/airborne droplet nuclei via sneezing, coughing, talking, singing or through handling fomites recently contaminated by infected droplets. In order to minimize any risk to participants or study staff, we will take the following precautions:

a) **Participants**:

Aim 1: We will conduct web-based monthly meetings for the 3-site LTF Network Collaborative, with any in-person meetings taking place in socially distanced (ideally outdoor) spaces with participants using isolation masks.

Aims 2 and 3: To minimize risk to participants from study staff, interviews and specimen collection will take place outdoors or with a participant in a vehicle with staff outdoors, and study staff will wear respirators (to eliminate any staff-generated droplet exposure to participants), eye protection (face shield or goggles), new gloves for each participant, and gowns, with handwashing or alcohol-based hand disinfectant use between each participant encounter. Verbal consent will be obtained by study staff to minimize direct contact between participants and staff, and social distancing will be maintained when feasible. During home- and work-place testing visits for mass testing campaign non-participants, study staff will wear PPE and encourage the use of observed self-collected swabs outdoors and away from other household or workplace members. All mass testing participants who do not have their own respiratory isolation face masks will be provided masks by study staff to wear throughout campaign participation, apart from swab collection.

Aims 2 and 3: The Community Wellness Team providing home support services for COVID-19-positive persons identified in Aim 2 (mass testing campaigns, post-campaign surveys and drop-in testing participants) and Aim 3 (community-responsive testing approach) will be provided PPE and infection control training according to CDC guidelines⁵¹ by our research team, including our infectious diseases physicians, prior to home visits with regular refresher trainings throughout the study period.

b) Study staff: To minimize risk to study staff from potentially SARS-CoV-2 virus infected participants, all participants (regardless of symptoms) will be asked to wear masks during the encounter except during upper airway swabbing. Study staff performing upper airway swabbing will wear personal protective equipment (PPE), including respirators (e.g. N95 masks), disposable gowns and gloves, and goggles or face shields for eye protection, and all swab supervision will take place with the staff member outdoors. Study staff will wear isolation masks at all times during work related activities and participant interactions, apart from upper airway swabbing when full PPE will be worn (as above). Used PPE will be disposed of according to UCSF hospital policy or local FQHC clinic policy, as appropriate.

Regarding study field staff PPE changes: Staff will change disposable gloves between each patient interaction, with handwashing or alcohol-based hand disinfectant use between each participant encounter. Staff performing upper airway swabbing will wear one N95 respirator, face shield and gown throughout the day, with donning and doffing training and oversight offered daily. PPE that is contaminated by visible droplets (e.g. participant sneezes or coughs on the PPE) will be disposed of and replaced or disinfected after that participant's encounter. Well-maintained (not soiled or wet) PPE may be disinfected for subsequent re-use the next day, following established protocols. Study staff will use disinfectant solution and paper towels or wipes to clean any equipment that is touched by study participants after each participant encounter.

c) Study laboratory staff: The BinaxNOW™ rapid antigen test is FDA-authorized (Emergency Use Authorization) for point-of-care use: both as a professional-use test or an over the counter, non-prescription self-use test.⁵⁰ All swabs (apart from over-the-counter self-test kit swabs provided to participants for self-use) will be placed by study staff in biohazard bags for safe transport to our study laboratory for SARS-CoV-2 virus testing in a biosafe environment (for PCR or NAAT testing) or to our study facilities for safe disposal (for used BinaxNOW™ rapid antigen test kits). For health care worker collected PCR testing, all swabs will be placed by study staff or participants into viral transport media (DNA/RNA Shield to inactivate virus and preserve RNA stability: inactivating the virus and stabilizing

RNA for analysis) immediately after collection. Observed self-collect swabs will be placed as a dry swab in a plastic vial per standard procedure prior to handling by study staff for point-of-care (or near point-of-care) testing. All swabs will be placed by study staff in biohazard bags, for safe transport to our study laboratory or the California DPH laboratory (Valencia Branch Lab) for SARS-CoV-2 virus testing in a biosafe environment (for PCR testing) or to our study facilities for safe disposal (for used BinaxNOW™ rapid antigen test kits).

8.3 Institutional Review Board Approval

Approval from the UCSF institutional review board will be obtained prior to initiation of study activities. All study staff are required to undergo training in human subjects' research, and for the Aim 3 trial, training in good clinical practice (GCP).

8.4 Potential benefits of the proposed research to the participants and others

Study participants may benefit by learning their SARS-CoV-2 infection status (Aims 2-3), learning about SARS-CoV-2 transmission, COVID-19 and prevention measures (all Aims), and by gaining increased access to testing (free of charge) and to health care personnel after diagnosis and during the course of COVID-19 disease (Aims 2 and 3). The benefits for the community may include increased access and engagement in SARS-CoV-2 testing and prevention, the potential for reduced transmission due to increased testing, as well as gaining a better understanding of local epidemiology in majority Latinx communities.

8.5. Importance of knowledge to be gained

The minimal risk in this study is far outweighed by the importance of the knowledge to be gained. The data collected will provide urgently needed and rigorous data on how to accelerate community-led efforts to address COVID-19 testing and prevention, COVID-19 testing implementation in heavily impacted communities with majority-Latinx populations, SARS-CoV-2 epidemiology in a range of settings (suburban and rural) and among priority sub-groups within the study communities (including frontline, essential workers), and improved understanding of SARS-CoV-2 transmission dynamics – including ascertainment of asymptomatic and mild infections that go undiagnosed at health facilities – collected at a population level in both a suburban and rural context. SARS-CoV-2 PCR test and BinaxNOW™ rapid antigen test results will be shared with Departments of Public Health in Marin and Merced counties, consistent with lab requirements for reporting SARS-CoV-2 infections, augmenting testing data for the two public health departments. Study data will also be shared with the RADx-UP CDCC, providing valuable data from Latinx communities in California – the state with the largest absolute number of cases in the US – in line with the RADx-UP initiative's objectives.

9. Publication of Research Findings

The findings from this study may be published in a medical journal. No individual identities will be used in any reports or publications resulting from the study. The researchers will publish results of the study in accordance with NIH and UCSF guidelines.

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