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Original Research

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing for essential food production workers: evolving thinking, pilot testing, and lessons learned



RSPH

S.C. Lucan^{a, *}, S.K. Goodwin^b, M. Lozano^b, S. Pak^b, M. Freitas^b

^a Albert Einstein College of Medicine, Montefiore Health System, Bronx, NY, USA
^b Danone North America, White Plains, NY, USA

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ABSTRACT

An essential part of U.S. coronavirus disease 2019 (COVID-19) critical infrastructure is the country's foodproduction workforce. Keeping food-production workers safe during the COVID-19 pandemic has meant added workplace protections. Protection guidance came early from the Federal Government. Absent from such guidance were strategies to screen for the causative virus. Without viral screening, some food companies had outbreaks; some facilities had to close. Companies interested in viral screening had to devise their own strategies. One company devised a strategy having three main goals: (1) detecting asymptomatic infections, before opportunity for spread; (2) identifying workplace clusters, to indicate potential protection breakdowns; and (3) comparing company results to community infection rates. The company decided on pilot screenings at two U.S. production plants. Screenings involved mandatory viral testing (through reverse transcription polymerase chain reaction) and optional antibody testing (both immunoglobulins G and M). Pilot screenings showed benefits along with limitations: (1) detecting asymptomatic infections, but at questionably relevant time points; (2) identifying infection clusters, but with uncertain sites of transmission; (3) showing relatively low rates of infection, but absent details for meaningful community comparisons. Establishing a worker screening process was an enormous undertaking. Company employees had to stretch job roles and were distracted form usual responsibilities. Whether other companies would find sufficient benefits to justify similar screening is unclear. Moving forward, new Federal leadership could provide greater support for, and assistance with, worker screenings. In addition, new technologies could make future screenings more feasible and valuable. The worker screening experience from this pandemic offers learnings the next.

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Introduction

An essential part of U.S. coronavirus disease 2019 (COVID-19) critical infrastructure is the food production workforce.¹ While food production is a priority at any time, it is particularly important during a global pandemic²—especially one so strongly linked to diet-related diseases.^{3,4}

Access to food has been challenged in the time of COVID-19; food insecurity has surged from nearly three of every 10 Americans to more than four of 10.⁵ Children have been affected disproportionately^{6,7} and so have Black and Latinx populations.^{5–7} Many Americans are experiencing hunger for the first time. If food production wanes, the problem can only worsen.

To keep our food supply thriving, it is imperative to keep production workers safe. During the COVID-19 pandemic, production worker safety has meant additional protections beyond the routine: added engineering controls (e.g. ventilation, air filtration, physical barriers); new procedures (e.g. staggered work shifts, symptoms screenings, contact tracing); and extra personal safeguards (e.g. hand sanitizer, face shields, universal masking).

Early guidance about such protections came from several sources: the World Health Organization;^{8,9} the Occupational Safety and Health Administration;¹⁰ and jointly from the U.S. Department of Health and Human Services and the Centers for Disease Control



^{*} Corresponding author. Department of Family and Social Medicine, Montefiore Health System 1300 Morris Park Ave, Block Building, Room 408, Bronx, NY 10461, USA. Tel.: +718 430 3667; fax: +718 430 8645.

E-mail addresses: slucan@yahoo.com (S.C. Lucan), stephanie.goodwin@ danone.com (S.K. Goodwin), lozanomariano50@gmail.com (M. Lozano), serina. pak@danone.com (S. Pak), miguel.freitas@danone.com (M. Freitas).

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and Prevention (CDC).¹¹ However, completely lacking from early COVID-19 guidance were recommendations around an essential issue—testing for the causative virus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Some information about SARS-CoV-2 testing came from the CDC; but recommendations were limited to situations where a COVID-19 case had already been identified.¹² Other CDC testing guidance was general in nature, not specific to a food production workforce.¹³ In addition, testing to screen for asymptomatic infections was not addressed.

Without screening for asymptomatic infections, some food producers had outbreaks.^{14,15} A few facilities had to close.¹⁶ At the same time, emerging literature was making clear the problem of asymptomatic (and presymptomatic) COVID-19 spread.¹⁷

Purpose

Toward identifying asymptomatic/presymptomatic cases, one company, Danone North America, thought a worker screening strategy could be of benefit. Danone North America (from here forward, 'the company') has approximately 6000 employees across the U.S., with approximately 3000 production workers in 16 US food production facilities. In deciding to undertake a worker testing pilot, the company had several aims: first, enhancing worker safety; second, keeping plants open to produce needed food; third, generating knowledge to benefit other critical infrastructure workers—including employees at other food companies.

In April 2020, when the company began considering SARS-CoV-2 worker screenings, the goals were essentially threefold: (1) detecting asymptomatic (or presymptomatic) infections before opportunity for spread; (2) identifying clusters of cases to indicate potential break-downs in facility protections; (3) assessing overall workplace safety by comparing company results to community rates.

Methods

While consideration was given to different SARS-CoV-2 tests, reverse transcription polymerase chain reaction (PCR)—specifically with nasopharyngeal sampling—seemed to be the emerging test standard.¹⁸ Nonetheless, for worker comfort, less invasive nasal sampling was thought to be preferable. Reassuringly, such nasal sampling seemed to have similar sensitivity.¹⁹ Regardless, with either type of sampling, in relying on a PCR-only strategy, it was recognized that SARS-CoV-2 infections could be missed.²⁰ A potential solution was thought to be add-on antibody testing.

Early thinking was that add-on antibody testing could serve three purposes: (i) capturing active but later stage infections missed by PCR; (ii) establishing who may have already been infected and how recently, and (iii) suggesting who may have some degree of protective immunity.²¹ The first and second purposes might be served by earlier-developing immunoglobulin M (IgM); the second and third purposes might be served by later-developing immunoglobulin G (IgG).^{22,23}

Given the prospect of using antibody tests along with PCR, three main screening strategies were considered; their advantages and liabilities are given in Table 1. However, PCR testing would meet Federal standards for actionable results, and it became clear that antibody testing would not.²⁴ Consequently, whereas the company could mandate all of its workers get PCR tests, it could not legally require antibody testing. In addition, given blood sampling is required for antibody tests, additional issues (related to logistics, worker comfort, information privacy, and so on) would be raised.

Company leadership ultimately decided to combine mandatory PCR screening with voluntary IgM and IgG screening. A screening pilot would be run at two U.S. food production plants. Pilot experience would inform whether repeat screening (at intervals to be determined) would be feasible or, indeed, advisable.

To proceed, the company explored three logistical options. First was purchasing testing equipment for in-house screening. However, cost, administration, and regulatory restrictions were prohibitive. The second option was partnering with local health departments. Unfortunately, government testers were not amenable to conducting screenings for private companies. In addition, health departments were focused mostly on testing only in cases of symptoms or exposures. The third option was outsourcing screening to private companies. This seemed the most viable option.

Ultimately though, there was no single 'end-to-end' solution. For specimen collection, processing, and reporting, worker screening would require a multipartner approach. Building the approach would necessitate job role stretch; food company employees would have to make assessments in unfamiliar areas-for example, related to laboratory medicine and clinical epidemiology. More than 10 laboratories and testing companies were investigated. The best combination of price, experience, credibility, and logistical feasibility seemed to be a solution involving a laboratory support service working side by side with a hospital laboratory. A medical staffing company would facilitate on-site testing. A partnering physician would provide the necessary medical orders. The food company's human resources department would help coordinate on-site administration, shipping of samples, and confidential reporting of results. In communicating plans to company workers, SARS-CoV-2 testing was framed as an added measure to support workplace safety.

Outcomes

The worker screening pilot occurred at two U.S. production plants: City of Industry, CA (COI), and Fort Worth, TX (FW). Testing in COI occurred during July 21–23; testing in FW occurred during August 25–27 (Fig. 1).

Only after pilot testing was completed did company leadership recognize an omission in their employee communication: There was no mention of sharing screening results externally. To publish pilot findings, a retrospective, voluntary, op-in consent form was designed by company attorneys. The consent form noted that individual results would be deidentified.

In COI, 70% of 347 workers provided consent to share findings; in FW, 86% of 219 workers provided consent to share findings. Fig. 1 shows test results for workers giving consent (of note, for considerations of representativeness, including data from workers who declined consent would not have meaningfully changed reported findings).

Detecting asymptomatic infections

At each pilot site, a single asymptomatic worker tested PCR positive (Fig. 1). At COI, the PCR-positive individual was among the 81.5% of workers who agreed to antibody testing. At FW, the PCR-positive individual declined antibody testing.

Antibody testing for COI's PCR-positive worker produced an indeterminant IgM result. Another COI worker (who tested PCR negative) also had indeterminant IgM. Indeterminant results introduced uncertainty to test interpretation. However, due to the additional potential for false positives or false negatives (both for PCR and for antibody tests), even definitive results could have multiple meanings (Table 2).

Presuming all test results were true results (i.e. no false positives, no false negatives), any non-negative IgM (IgM positive or IgM indeterminant) could represent recent infection (Table 2). Thus, at COI, the number of asymptomatic infected workers could have been as high as seven (Fig. 1); at FW, the number could have

Table 1

Worker screening strategies, advantages, and liabilities.

Strategy	Advantages	Liabilities
Strategy 1:		
No worker screening (instead, diagnostic testing only in instances of symptoms or likely exposure) ^a	 No direct financial costs No logistics to coordinate No need for worker buy-in 	 Potential monetary losses related to missed cases (if avoidable, spread through production plant leads to sick workers, absenteeism, and production line or whole plant shut down) Potential logistical challenges from production adjustments (if there is need to compensate for workers who have otherwise preventable absences) Potential loss of workforce morale (fear and anxiety if what could have been detectable asymptomatic cases spread disease throughout the plant; perceived inattention to worker safety) Limited understanding of how much of a problem COVID-19 is for the company workforce
Strategy 2: Mandatory screening with diagnostic tests ^b	 Reduced potential for monetary losses related to missed cases, worker transmission, absenteeism, and production line or whole plant shut down Reduced potential for logistical challenges related to absentee-related production adjustments Potential boost in workforce morale due to perceived attention to worker safety 	 Substantial financial outlay for testing Substantial logistics to coordinate near-simultaneous testing for entire plants' workforces⁶ Some worker buy-in needed (concerns for privacy of personal health information and possible physical discomfort from a sampling procedure) High risk of inaccurate results (false positives and, to a lesser degree, false negatives) No information on prior infection (still limited understanding of how much of a problem COVID-19 is for the company workforce)
Strategy 3: Mandatory screening with diagnostic tests ^b + Voluntary screening with antibody tests ^d	 Same advantages as for strategy 2 but with potentially greater perceived attention to worker safety Information on prior infection with better understanding of COVID-19 burden for the company workforce 	• Other than somewhat better understanding of scope of prior infection, same liabilities as for strategy 2 but each liability to a greater degree.

^a Devote resources to risk mitigation and harm reduction interventions: proper ventilation; air filtration; physical barriers; distance-maximizing workspace renovations; enhanced cleaning and disinfecting routines; new hygiene protocols; additional personal protective equipment; daily symptom screening; robust contact tracing; and so on. ^b Among diagnostic tests considered were those detecting vial nucleic acid, such as reverse transcription polymerase chain reaction (PCR), and those detecting viral antigens.

^c Three logistical options were considered: (1) purchasing testing equipment for in-house screening; (2) partnering with local health departments; and (3) outsourcing to one or more outside company/laboratory.

^d Antibody tests would not meet standards for mandatory testing; according to guidelines issued by the Equal Employment Opportunity Commission, to be mandated, tests must have actionable results.

been as high as four (counting the worker who tested PCR positive but who declined antibody testing). Nonetheless, any asymptomatic infections detected by IgM would necessarily be 'longer established' as opposed to 'newly acquired' (Table 2). Once IgM starts to emerge, the chance of contagiousness might be small; the window for preventing spread to other workers might have already passed. In other words, while the pilot may have detected a few cases of asymptomatic infection, the net benefit of removing later detected cases from production plants would be unclear.

Only in FW (where the PCR-positive individual did not have antibody testing), is it possible that case removal could have substantively reduced the chance of SARS-CoV-2 spread. Based on PCR testing alone though, it is not possible to know if the individual was early or late in infection.

Identifying workplace clusters

The combination of results for PCR, IgM, and IgG can reflect infection at a specific stage (Table 2). If workers at the same stage share a job location and/or shift, the implication could be a work-place 'cluster.'

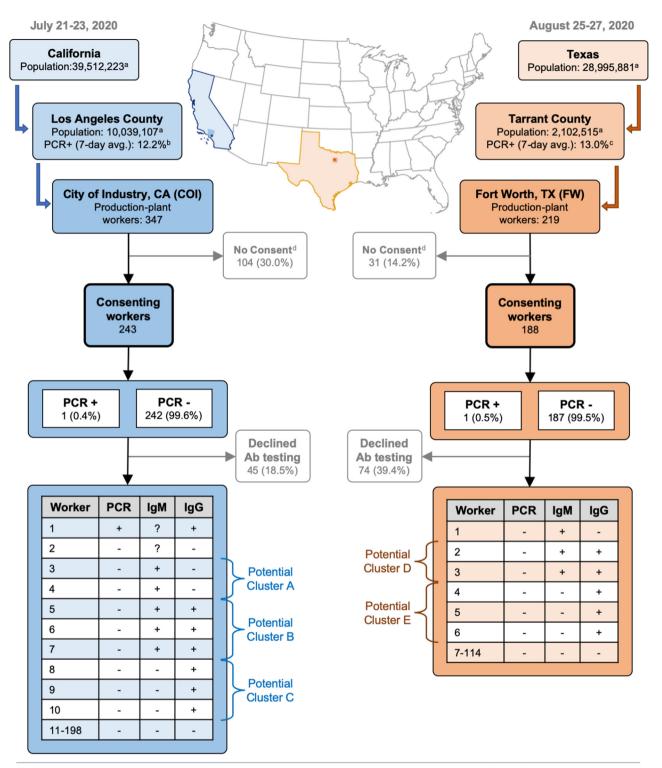
Potential clusters are shown in Fig. 1. Other than 'triple negative' (PCR negative, IgM negative, and IgG negative, seen in 95.0% of workers at COI and 94.7% of workers at FW), no combination of test

results occurred in more than three workers at either site. In all cases of any shared non-negative results, workers in potential clusters had different job locations and/or shifts. In no instance was there a true 'cluster' suggesting breakdown in facility protections. In addition, as revealed by contact tracing, some concordant testing workers lived in the same household or had social connections outside of work.

Comparing company results with community rates

To compare pilot plant results with rates of disease in surrounding communities, company employees obtained 7-day rolling averages of community SARS-CoV-2 positivity. Averages were available for each county where pilot sites were located—Los Angeles County for the COI plant and Tarrant County for the FW plant. The 7-day average in Los Angeles County was 12.2%; the 7-day average in Tarrant County, TX, was 13.0% (Fig. 1).

Applying county percentages to pilot site consenting worker populations, the expected number of positives in COI would have been 30; the expected number of positives in FW would have been 24. Applying the percentages to only antibody-tested workers, the numbers would have been 24 and 15, respectively. Actual pilot plant positives were much fewer. For antibody-tested workers,



+ = positive test result, - = negative test result, ? = indeterminant test result (including "quantity not sufficient"). PCR = reverse transcriptase polymerase chain reaction. PCR tests were mandated for all employees. Antibody tests were voluntary.

^a U.S. Census Bureau <u>https://www.census.gov/</u>

^b Los Angeles County Department of Health (data from 7/23/20) <u>http://publichealth.lacounty.gov/media/Coronavirus/</u>

^c Texas Health and Human Services (data from 8/27/20) <u>https://hhs.texas.gov/services/health/coronavirus-covid-19</u>

^d Consent to share results was not tied to test positivity

Fig. 1. Pilot SARS-CoV-2 screening at two U.S. production plants, summer 2020.

Table 2

Complexity in interpretation	of screening results-	-with resultant uncertainty for action.
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Test r	Test results ^a		Presumed meaning	Implication – action	Select alternative possibilities	Alt. implications – actions
PCR	lgM	IgG	(one interpretation)	(if meaning were certain)	(illustrative, not exhaustive, list)	(if Alt. possibility were certain)
+	-	-	• New active infection detected before antibodies start to develop	 Possibly contagious remove from production plant for 10-day self-isolation 	 False-positive PCR^b(more likely than a true positive when disease prevalence is low) 	• Healthy – continue working ^c
					 Inconsequential true positive (residual viral debris from distant infection for which antibodies never developed or for which antibodies have already declined) 	Recovered and no risk to others workers – continue working
+	+	-	• Recent infection detected just as antibodies start to develop	 May no longer be contagious to be safe, remove from plant but for <10 days of self- isolation^d 	• New active infection along with false-positive IgM ^e	 Possibly contagious – remove from plant for 10-day self- isolation
+	+	+	• Late-stage infection	 Likely no longer contagious – may continue to work 	• New active infection along with false-positive IgM/IgG ^e	 Possibly contagious – remove from plant for 10-day self- isolation
+	?	+	• Later-stage infection with declining IgM	 Likely no longer contagious – may continue to work 	• Recent active infection with emerging IgM and false-positive IgG ^e	 Possibly contagious – to be safe, remove from plant for <10 days of self-isolation^d
+	-	+	• Very late-stage infection	 Likely no longer contagious – may continue to work 	 Recent active infection along with false-positive IgG^e Inconsequential persistent carriage of virus from distant infection 	 Possibly contagious – remove from plant for 10-day self- isolation Recovered – continue working
-	?	_	Laboratory error	• Healthy – continue working	 False-negative PCR; early new infection just starting to produce detectable antibodies 	 May no longer be contagious – to be safe, remove from plant for <10 days of self-isolation^d
-	+	_	• Recent infection with early viral clearance	 Quickly recovered and no longer a risk to others workers – continue working 	 False-negative PCR; current infection with recent initiation of antibody production 	• May no longer be contagious – to be safe, remove from plant for <10 days of self-isolation ^d
-	+	+	• Somewhat later infection with viral clearance	 Recovered and not a risk to others workers – continue working 	• False-positive IgM/IgG ^e	• Possibly never exposed to SARS- CoV-2 – continue working
-	-	+	• Distant past infection	Long recovered – continue working	 New infection with false-negative PCR along with false-positive IgG^e 	 Possibly contagious – remove from plant for 10-day self- isolation
_	_	-	• Never infected with SARS-CoV-2	• Healthy – continue working	 Distant past infection with complete viral clearance and antibodies already declined New infection with false-negative PCR 	 Recovered and not a risk to others workers – continue working Possibly contagious – remove from plant for 10-day self- isolation

+ = positive test result, - = negative test result, ? = indeterminant test result (including 'quantity not sufficient'), Alt. = alternative. Rows shaded gray are possible scenarios

not realized at either site of the pilot trial; pilot-trial results are shown in Fig. 1.

^a Example combinations of test results; technically, both PCR and IgG could also have indeterminant results, adding more possible combinations.

^b For example, due to cross-contamination during specimen collection, shipping, or aliquoting.

^c 'Healthy – continue working' is always an alternative possibility given any/all positive tests results could be false positives.

^d Exact duration of self-isolation would not be defined by CDC guidance; company would have to decide what is most reasonable.

^e For example, due to other circulating human beta coronaviruses.

even if liberally allowing any non-negative test result to count as a case, COI had only 10 cases; FW had only six cases (Fig. 1). Results provided reassurance about workplace safety.

Lessons learned

The company's pilot experience demonstrated the potential value of screening asymptomatic production plant workers. Lessons learned include those related to the three SARS-CoV-2 testing goals and to the prospect of conducting worker screenings in the first place.

Detecting asymptomatic infections

Identifying asymptomatic infections—particularly those having real potential to spread disease—is not straightforward. For instance, PCR positivity could mean active infection. However, it could also indicate past infection currently posing no infectious risk.^{24,25} Antibody results would presumably help differentiate. However, if antibody results are indeterminant (as occurred at one pilot site), the situation would remain ambiguous. However, if positive IgG could suggest active infection entering convalescence, it could also indicate a long-past infection unrelated to the current situation. In addition, perhaps especially in the setting of indeterminant IgM, a positive IgG could be a false positive (e.g. from previous infection with a non-SARS-CoV-2 coronavirus).²⁶

False positives are a concern with PCR testing as well. In fact, in low-prevalence populations (seemingly the case at both pilot sites), false positives would be more likely than true positives.²⁷ The implication of false positive results could be the unnecessary

Even in cases of true positives (even for actively contagious asymptomatic infection), one-time or infrequent testing may provide limited benefit. For instance, with a weekly testing strategy, some variation of the following scenario would be possible: at the time of sample collection, a worker has a new infection with virus below the level of detection; after sample collection, the worker becomes contagious; the worker then spreads virus for several days until the next round of testing. Rather than screening asymptomatic workers as an additional strategy to keep virus out, companies might do better to invest in strategies to prevent spread when virus enters.

Identifying workplace clusters

The real value of even one-time screening for asymptomatic workers might be in identifying workplace clusters. Concordance between PCR, IgM, and IgG results can identify groupings of workers at similar stages of infection. Grouping by shift, job role, or functional area could suggest areas of concern within a production plant. A preponderance of triple-negative results (as in the current pilot) would, in particular, be reassuring about no important breaches in workplace protections.

Comparing company results with community rates

Unfortunately, unlike workplace screenings where testing represents a full census, community testing is not generally population representative. Rather, community testing is likely to overrepresent symptomatic disease—and, thus, overestimate prevalence. In addition, age-sex distributions for tested community members likely differ from age-sex distributions for production plant workers. To account for differences, standardization by age-sex categories is one approach.²⁸ But age- and sex-specific strata for community rates are not generally available. Another approach, using linear regression, is to correlate asymptomatic worker prevalence with weekly community incidence rates.²⁹ Such an approach, however, is only meaningful with more than two data points—that is, more than two pilot sites (it is always possible to draw a perfect line between two points, even if correlation is actually poor).

The bottom line is that without additional data—that is, doing worker screenings at a greater number of production plants or having further details about community data—it is not possible to meaningfully compare worker results with population results. Such realities complicate the design of any test-and-response algorithm, as attempted by the company before starting the screening pilot (Appendix - Figure).

Final thoughts

For any company, implementing a worker screening strategy could be an enormous undertaking. Beyond sizable financial outlays for sampling, processing, and results delivery, there are monetary costs related to shifting job roles; in figuring out testing complexity, some company employees will necessarily be distracted from their usual responsibilities. Productivity may suffer. The potential costs (and benefits) of a screening program need to be weighed against the potential costs (and benefits) of not screening (Table 1).

If companies do decide to screen, paper-strip antigen tests could be a 'game changer.' Such tests would allow for cheap, rapid, frequent (even daily) testing without need for a processing laboratory.³⁰ The tests could be performed by workers themselves, and while having lower sensitivity than PCR-based assays, greater testing frequency would help ensure fewer missed cases.³⁰ In addition, positive results would more definitively suggest actual contagiousness rather than inconsequential past infection.³⁰

Another 'game changer' is vaccination. As of this writing, two COVID-19 vaccines have just received emergency use authorization. Essential food workers will be prioritized for receipt.³¹ A vaccinated workforce changes the calculus about the value of asymptomatic worker screening—at least until the emergence of the next pandemic.

For any future pandemic, the same issues will inevitably arise again. In what has been described as a 'leadership vacuum' for COVID-19,³² testing was neither prioritized nor coordinated; individual companies were largely left to fend for themselves. Hopefully, under a new administration, government will place greater importance on testing—particularly testing of critical infrastructure workers.

In the interim, individual companies will continue to have to determine whether asymptomatic worker screening makes sense. The decision will continue to be one of consequence. Critical infrastructure workers are critical for a reason. Screening may not be essential but food production is.

Author statements

Acknowledegments

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Ethical approval

This described SARS-CoV-2 testing pilot was deemed to be quality improvement and not human subject research. The testing pilot was overseen by executive leadership at Danone North America. There was oversight input from company attorneys, human resources, and an external medical consultant. For workers participating in the pilot trial, agreement to publish deidentified data came through voluntary, written, opt-in informed consent. The consent process was approved by executive leadership; there was input from company attorneys, human resources, and an external medical consultant. The project was exempt from IRB review.

Funding

Funding for the SARS-CoV-2 testing pilot, including financial support for this publication, came entirely from Danone North America. The company funded the initiative as part of broader investments related to COVID-19. Internally, the goal was ensuring worker safety and undisrupted food production. Externally, the goal is to help other critical infrastructure businesses, including other food companies.

Competing interests

S.C.L. was a paid consultant for Danone North America. In addition, he has served on the Scientific and Nutritional Advisory Board of Epicure. He has accepted honoraria for speaking at Epicure national meetings. S.C.L. has also served as a paid consultant for researchers at Georgetown University. S.K.G., S.P., M.L., and M.F. were all paid employees of Danone North America during the planning of the SARS-CoV-2 testing pilot, during pilot testing, and at the time of drafting of this article. M.L. has since left Danone North America.

Author contributions

S.C.L. reviewed relevant literature, contributed to project planning, and participated in data analyses. He co-conceived this article. He drafted the initial manuscript, including tables and figures. S.K.G. contributed to literature review, project planning, and data analyses. She also assisted with manuscript writing. M.L. and S.K. each participated in project planning and data analyses. Along with M.L., M.F. oversaw conduct of the project. In addition, M.F. assisted with literature review, project planning, data analyses, and manuscript writing. All authors contributed revisions to the final article.

Appendix A. Supplementary data

Supplementary figure for this article can be found online at https://doi.org/10.1016/j.puhe.2021.06.014.

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