

Population surveillance for SARS-CoV-2

Overview of SARS-CoV-2 surveillance testing

As the SARS-CoV-2 global crisis continues, the need for routine surveillance testing strategies for SARS-CoV-2 infection has emerged as a necessity to monitor for population-level occurrence. This shift to large-scale surveillance of populations allows for the ability to assess local infection rates and trends.

Challenges to implementing surveillance testing

Tools for surveillance testing research have broadened over time. Through this crisis, many established and new technologies have been used to develop SARS-CoV-2 tests, although the majority of available methods are based on qPCR technology. So how do these emerging technologies stack up against the more established methods? How can you determine the most effective method for surveillance testing? This overview is a primer on how these testing modalities compare in capabilities and may fit into a large-scale, high-frequency surveillance testing strategy.

Critical considerations for population surveillance strategies

Surveillance for SARS-CoV-2 includes ongoing systematic activities, including collection, analysis, and interpretation of data that are essential to planning, implementing, and informing public policies and guidelines. Surveillance testing is used to gain information at a population level rather than an individual level, and results of surveillance testing can be returned in aggregate to the requesting institution. Surveillance testing may sample a certain percentage of a specific population to monitor for increasing or decreasing prevalence and to determine

the population effect from community interventions such as social distancing. When assessing available test technologies for surveillance applications, the following considerations should be addressed to decide the best solution for your needs:

- **Importance of analytical sensitivity**—The analytical sensitivity of an assay will influence the required frequency of surveillance testing. Methods that are less analytically sensitive may require more frequent testing of a population, which will increase the cost and operational complexity of a surveillance strategy.
- **Frequency of testing and impact on volume**—Testing at higher frequency will require large-scale testing throughput capacity. The testing technology will need to effectively accommodate the required capacity throughput in the most efficient, cost-effective manner.
- **Sample types and impact on compliance, cost of collection, staffing requirements, and test validity**—Sample types such as saliva allow for flexibility in collection methods. This consideration has a significant impact on operating and material costs.
- **Time-to-result requirement**—How quickly are the data needed: nearly immediately vs. 4–24 hr turnaround time? What is an acceptable time frame, which often needs to be weighed with trade-offs in analytical sensitivity and scalability for volume?
- **Cost**—The initial economic assessment of a surveillance program may focus on just the cost of the test, but the true all-in costs across the complete workflow—from sample collection to result—should be evaluated. To understand your true all-in costs, be sure to evaluate costs across the complete workflow.

Testing modalities for the SARS-CoV-2 market

	Real-time PCR (qPCR)	Direct-to-PCR assay	Loop-mediated isothermal application (LAMP)**	On-site PCR	Rapid antigen detection test (RADT)
Research sample type	NP, MT, NS, OP, NA, BAL	Raw saliva	NS	NP, MT, NS, OP, NA, BAL	NP, NS
Analytical sensitivity	20 GCE/mL (normal)–250 GCE/mL*	1,000–10,000 GCE/mL	1,000–10,000 GCE/mL	1,000–5,000 GCE/mL	~1 million GCE/mL
Scalability: fit for large-scale, high-frequency testing (8 hr shift)	<ul style="list-style-type: none"> High fit—384-well plate processivity Single-instrument output—<2,500 samples 	<ul style="list-style-type: none"> High fit—384-well plate processivity Single-instrument output—<3,700 samples 	<ul style="list-style-type: none"> Moderate fit—plate processivity is lab-developed, no commercially competitive/scalable options available Low fit—instrument is of single reaction Single-instrument output—<16 samples a day 	<ul style="list-style-type: none"> Low fit—instrument is of single reaction Single-instrument output—<16 samples a day 	<ul style="list-style-type: none"> Low fit—instrument is of single reaction Single-instrument output—<32 samples a day
Cost per sample (not market price)	\$12–25	\$6–17	\$5–50	\$25–60	\$5–20
Turnaround time (TAT)	1.25 hr	~1 hr	0.5 hr	0.5 hr	0.25–0.5 hr
Target	2–3 targets	2–3 targets	1 target	1–2 targets	1–2 protein targets
Control	Positive and negative controls, some assays have human control	Positive and negative controls; RNase P for sample quality verification	No multiplexed controls—controls require separate wells	Positive and negative controls (no human control)	No positive or negative control (no human control)

Sample collection types include nasopharyngeal (NP), nasal swabs (NS), bronchoalveolar lavage (BAL), nasopharyngeal aspirate (NA), oropharyngeal (OP), and mid-turbinate (MT).

Data based on publicly available information from suppliers and manufacturers.

* GCE/mL—genome copy equivalents per milliliter of specimen

** Risk of lab contamination—Since LAMP generates many amplicons, there is a risk of permanent lab-site contamination.

Analytical sensitivity table

Gold-standard qPCR: 20–250 GCE/mL
Direct-to-PCR: 1,000–10,000 GCE/mL
LAMP: 1,000–10,000 GCE/mL
Rapid antigen test: ~1 million GCE/mL

While each test technology has a key role to play in the global response to SARS-CoV-2, population surveillance requires research tools that can handle not only high volumes but also high frequency. Once the key requirements are defined, one can determine the surveillance testing technology that best fits. A testing model that is fast, cost-effective, and easy to implement and operate is likely to be the cornerstone to a successful surveillance testing program.

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