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Xpress SARS-CoV-2 plus LCE009

01/2023, Edition 1 Instructions for Use

Section 1 Trademark, Patents and Copyright Statements	. 3
Section 2 Xpress SARS-CoV-2 plus	3
Section 3 Proprietary Name	. 3
Section 4 Common or Usual Name	. 3
Section 5 Intended Use	3
Section 6 Summary and Explanation	. 3
Section 7 Principle of the Procedure	
Section 8 Reagents and Instruments 8.1 Materials Provided	.4 .4
Section 9 Storage and Handling	.5
Section 10 Warnings and Precautions	. 5
10.1 General	
10.2 Samples 10.3 Assay/Reagent	
Section 11 Chemical Hazards	
Section 12 Sample Collection, Transport, and Storage	
12.1 Community Wastewater Surveillance	. 6
12.2 Targeted Wastewater Surveillance	
12.3 Wastewater Sampling Frequency 12.4 Wastewater Sample Types	
12.5 Wastewater Sample Collection	
Section 13 Procedure	
13.1 Preparing the Cartridge	
13.2 Starting the Test	
Section 14 Quality Control	11 11
Section 15 Retests	
15.1 Reasons to Repeat the Assay 15.2 Retest Procedure	
Section 16 References	
Section 17 Technical Assistance	
Section 18 Table of Symbols	
	10

Section 1 Trademark, Patents and Copyright Statements

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Section 2 Xpress SARS-CoV-2 plus

Not for Use in Diagnostic Procedures.

Section 3 Proprietary Name

Xpress SARS-CoV-2 plus

Section 4 Common or Usual Name

Xpress SARS-CoV-2 plus

Section 5 Intended Use

The Xpress SARS-CoV-2 *plus* test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in sample water and wastewater samples for water based epidemiological applications. It is not intended for human or animal testing such as nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and/or nasal wash/ aspirate samples collected from individuals suspected of COVID-19 by their healthcare provider).

Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in sample wastewater samples for communities that have multiple active positive cases in which the waste is combined and composite samples can be taken. Negative results do not preclude SARS-CoV-2 in the water samples and should not be used as the sole basis for any public health decisions. Negative results should be combined with, case counts epidemiological information, and other observations when making public health decisions.

Section 6 Summary and Explanation

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.¹ Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.²

Wastewater surveillance, the measurement of pathogen levels in wastewater, is used to evaluate community-level infection trends, augment traditional surveillance that leverages clinical tests and services (e.g., case reporting), and monitor public health interventions. Approximately 40% of persons infected with SARS-CoV-2, the virus that causes COVID-19, shed virus RNA in their stool; therefore, community-level trends in SARS-CoV-2 infections, both symptomatic and asymptomatic can be tracked through wastewater testing. ³

In nearly 80% of U.S. households, fecal waste is transported from homes to wastewater treatment plants within hours. Wastewater represents a pooled community stool sample that can provide information on infection trends in the community served by the sewer network (sewershed), which

can range in size from fewer than 2,000 to >3 million persons. Wastewater surveillance data provide information about symptomatic and asymptomatic SARS-CoV-2 infections. The accuracy of this surveillance approach is not influenced by health care access or clinical testing capacity. In addition, SARS-CoV-2 infection trends in a community can be detected in wastewater before other COVID-19 surveillance metrics, such as case reports and hospital admissions. To build sustainable national wastewater surveillance capacity, CDC focused NWSS development in four areas: 1) offering technical assistance to implementing jurisdictions; 2) creating a data portal for centralized data submission and standardized data analysis and visualization; 3) coordinating communities of practice to share best practices among health departments, public health laboratories, and utilities; and 4) building epidemiology and laboratory capacity for wastewater surveillance at health departments.³

The Xpress SARS-CoV-2 *plus* test is a molecular test that aids in the detection of SARS-CoV-2 in wastewater samples and is based on widely used nucleic acid amplification technology. The Xpress SARS-CoV-2 *plus* test contains primers and probes and internal controls used in RT-PCR for the quantitative detection of SARS-CoV-2 RNA in wastewater samples.

Section 7 Principle of the Procedure

The Xpress SARS-CoV-2 *plus* test provides quantitative results using an automated extraction and analysis of the SARS-CoV-2 virus. The Xpert SARS-CoV-2 test is performed on GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the *GeneXpert Dx System Operator Manual*.

The Xpress SARS-CoV-2 *plus* test includes reagents for the detection of RNA from SARS-CoV-2 in wastewater samples. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The wastewater sample is collected and homogenized and 300 uL is placed into the sample chamber of the Xpress SARS-CoV-2 *plus* cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

Section 8 Reagents and Instruments

8.1 Materials Provided

The Xpress SARS-CoV-2 *plus* kit contains sufficient reagents to process 10 samples or quality control samples. The kit contains the following:

Xpress SARS-CoV-2 plus Cartridges with Integrated Reaction Tubes	10
Bead 1, Bead 2, and Bead 3 (freeze-dried)	1 of each per cartridge
Lysis Reagent	1.5 mL per cartridge
Binding Reagent	1.5 mL per cartridge

Wash buffer	0.5 mL per cartridge
Elution Reagent	3.0 mL per cartridge
Disposable Transfer Pipettes	12 per kit
Flyer	1 per kit
Directions to locate the Product Insert on https://www.hach.com. To download	

 Directions to locate the Product Insert on https://www.hach.com. To download the Instructions for Use (IFU) or ADF, visit https://www.hach.com, search LCE009, and click on **Downloads**.

Note: Safety Data Sheets (SDS) are available at https://www.hach.com.

Note: The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

Section 9 Storage and Handling

- · Store the Xpress SARS-CoV-2 plus cartridges at 2-28 °C.
- · Do not open a cartridge lid until you are ready to perform testing

Section 10 Warnings and Precautions

10.1 General

- · For wastewater analysis use.
- Performance characteristics of this test have been established with water and wastewater samples only. This system is not intended for use for human or animal testing.
- Treat all wastewater samples and used cartridges as biological specimens.
- Follow safety procedures set by your institution for working with chemicals and handling wastewater samples.
- Consult your institution's environmental waste personnel on proper disposal of used cartridges, which may contain amplified material. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions should check the hazardous waste disposal requirements within their respective countries.
- Refer to the GeneXpert Dx System Operator Manual for additional errors and warnings while operating the instrument.

10.2 Samples

 Maintain proper storage conditions during sample transport to ensure the integrity of the sample (see Sample Collection, Transport, and Storage on page 6). Sample stability under shipping conditions other than those recommended has not been evaluated. It is recommended to follow the CDC guidelines for sample collection and storage.

10.3 Assay/Reagent

- Do not open the Xpress SARS-CoV-2 plus cartridge lid except when adding wastewater sample.
- · Do not use a cartridge that has been dropped after removing it from the packaging.
- Do not shake the cartridge. Shaking or dropping the cartridge after opening the cartridge lid may yield non-determinate results.
- Do not place the sample ID label on the cartridge lid or on the barcode label on the cartridge.

- Do not use a cartridge with a damaged barcode label.
- · Do not use a cartridge that has a damaged reaction tube.
- Each single-use Xpress SARS-CoV-2 plus cartridge is used to process one test. Do not reuse
 processed cartridges.
- Each single-use disposable pipette is used to transfer one sample. Do not reuse disposable pipettes.
- Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.
- · Wear clean lab coats and gloves. Change gloves between the handling of each sample.
- In the event of a spill of the wastewater sample or controls, wear gloves and absorb the spill with
 paper towels. Then, thoroughly clean the contaminated area with a 10% freshly prepared
 household chlorine bleach. Allow a minimum of two minutes of contact time. Ensure the work area
 is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry
 completely before proceeding. Or, follow your institution's standard procedures for a contamination
 or spill event. For equipment, follow the manufacturer's recommendations for decontamination of
 equipment.
- Wastewater samples, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Section 11 Chemical Hazards

Consult the Safety Data Sheet (SDS).

Section 12 Sample Collection, Transport, and Storage

Proper sample collection, storage, and transport are critical to the performance of this test. Inadequate sample collection, improper sample handling and/or transport may yield a false result. It is important to follow the CDC guidelines for proper sample collection and storage: https://www.cdc.gov/healthywater/surveillance/wastewater-surveillance/developing-a-wastewatersurveillance-sampling-strategy.html

Sampling Safety

Standard practices associated with wastewater treatment plant operations should be followed to protect wastewater workers from SARS-CoV-2. These standard practices can include engineering and administrative controls, handwashing, specific safe work practices, and personal protective equipment⁴ normally required when handling untreated wastewater. Beyond CDC recommendations for how to protect against COVID-19, no additional COVID-19–specific protections are recommended for workers managing wastewater, including those at wastewater treatment facilities.⁴

Storage

Never store samples at temperatures higher than refrigeration (4 °C). Refrigerate samples during the collection process. If possible, process samples within 24 hours of collection, as effective actionable wastewater surveillance relies on rapid data collection. Remaining samples can be frozen at -70 °C for archiving. Avoid more than one freeze-thaw cycle. Preliminary data have shown potential loss of signal following freezing.

Shipping

When sending samples to laboratories, CDC recommends packing samples with cold packs (4 °C) and using same-day or overnight shipping. Package and ship samples as Category B infectious substance (UN 3373), in accordance with the U.S. Department of Transportation's Hazardous Materials Regulations and the International Air Transport Association Dangerous Goods Regulations.

12.1 Community Wastewater Surveillance

Sampling wastewater for SARS-CoV-2 as it enters a treatment plant (referred to as untreated influent) is used to evaluate trends in infection within the community contributing water to the sewer system. Select the number of treatment plants for community-level wastewater disease surveillance

based on the public health data needs in the region and availability of resources. COVID-19 rates and trends in the community, distribution of the population, and characteristics of the sewer system may also influence your selection.

Wastewater treatment plants may be selected for community wastewater surveillance to:

- · Cover a certain percentage of the population.
- Provide data on communities at higher risk for COVID-19 or at increased risk for severe illness from COVID-19.
- Provide data on communities where timely COVID-19 clinical testing is underutilized or unavailable.
- Represent several sewer sheds that serve a larger interconnected population, such as in dense urban areas.

Prior to selecting a wastewater treatment plant for community wastewater surveillance, it is critical to consult with wastewater engineers and utility managers to understand:

- · Geographic area and population served by the utility
- · Relative contribution of the types of waste inputs (industrial, commercial, residential)
- Operating factors that could influence the detection of SARS-CoV-2 (e.g., pre-treatment of
 incoming wastewater or diversion of wastewater to adjust flow upstream of the sampling site)
- · Available sampling locations at the treatment plant
- Utility capacity for sample collection, documentation, and shipping
- Availability of utility meta-data needed for public health interpretation (e.g., influent flow measurements, chemical/physical water quality measurements, service area shapefile)

12.2 Targeted Wastewater Surveillance

Targeted wastewater surveillance⁵ entails sampling wastewater from upstream in the wastewater network (e.g., lift stations, interceptors, manholes). Targeted wastewater surveillance may provide a better understanding of how SARS-CoV-2 infections are distributed within a sewer shed. However, there are currently little data demonstrating the application of this approach.

When deciding whether targeted wastewater surveillance would be useful for public health action, it is important to consider the following:

- SARS-CoV-2 RNA concentrations are more variable upstream from the wastewater treatment plant than at the plant intake because upstream wastewater has had less time to mix and contains feces from fewer people.
- Access to sewer lines serving only the intended target population may require infrastructure alterations or may not be possible.
- Depending on the size of the target population, conducting effective targeted wastewater surveillance may be more costly and logistically challenging than case surveillance.

12.3 Wastewater Sampling Frequency

Wastewater sampling frequency depends on how the data will be used for public health and the prevalence of COVID-19 in the community. With sufficient testing frequency, wastewater testing may be used to track trends over time. Single samples or very infrequent (e.g., monthly) sampling will likely not be informative for establishing trends, but could be used for establishing presence of COVID-19 in a community.

If the goal of wastewater surveillance is to screen for the presence of SARS-CoV-2 in wastewater, sampling once per week may be adequate. If the goal is early indication of infection trends, at least three sampling points are needed within a trend period of interest for surveillance. There are little data available describing how rapidly wastewater concentrations may change under various epidemic scenarios.

Consider the following when determining sample frequency at a specific location:

 A minimum of three samples is required to detect wastewater trends over time. The time between consecutive wastewater samples determines the minimum length of time over which a trend may be detected. For example, if samples are collected twice per week, 8 days is the minimum timespan over which a trend can be confirmed.

- Laboratory testing capacity and supply chain shortages may limit the maximum sampling frequency.
- One-time sampling will not provide actionable data beyond presence of SARS-CoV-2 infection within the sewer shed.

12.4 Wastewater Sample Types

Sample type is an important consideration for collecting representative samples and will depend on the sample collection location and factors specific to the wastewater treatment plant. Closely consult with treatment plant staff to determine appropriate sample types that will best represent the target population. Samples should be collected at locations that precede addition of chemicals or mixing of waste streams at the wastewater treatment plant. The two wastewater surveillance sample types are untreated wastewater and primary sludge.

- 1. Untreated wastewater: Untreated wastewater includes waste from household or building use (e.g., toilets, showers, sinks), which contains human fecal waste, as well as waste from non-household sources (e.g., rainwater, industrial use). Untreated wastewater may be sampled from wastewater treatment plant influent (prior to primary treatment) or upstream in the wastewater collection network. Changes in SARS-CoV-2 RNA concentrations in wastewater samples collected from wastewater treatment plant influent influent have been shown to correlate with trends in reported cases. In most cases, untreated wastewater will likely require concentration⁶ prior to RNA extraction. The number of infections needed to detect the virus in wastewater without concentration is difficult to determine because it depends on both the method detection limit and the amount of virus in feces, for which there are few data.
- 2. Primary sludge: Primary sludge comprises suspended solids that settle out of wastewater during the first solids removal ("sedimentation") process at a wastewater treatment plant. Primary sludge is distinct from secondary sludge following primary treatment. Do not use secondary sludge for wastewater surveillance. Changes in SARS-CoV-2 RNA concentrations in primary sludge samples have been shown to correlate with trends in reported cases. An advantage of primary sludge samples compared to untreated wastewater is that SARS-CoV-2 concentrates in sludge, which reduces the sample volume required to detect the virus and may eliminate the need to concentration in sludge is not well characterized. Sludge samples may also present challenges that must be evaluated for each wastewater treatment plant, such as chemicals added at the treatment plant, increased concentrations of compounds that can interfere with laboratory methods, or the addition of recycled waste streams from other parts of the treatment plant.

Selecting a Sample Type

Untreated wastewater and primary sludge are both acceptable community wastewater surveillance sample types. For upstream targeted wastewater surveillance, only untreated wastewater samples are available. If laboratory methods are available, sludge sampling is recommended to evaluate infection presence within a sewer shed with few known case patients because the virus will be more concentrated in sludge. Untreated wastewater samples are recommended when wastewater treatment plants apply disinfectant before sludge can be sampled, sludge testing demonstrates high assay inhibition or poor virus recovery, or solids residence time within the primary clarifier is unknown.

12.5 Wastewater Sample Collection

Collection Methods

1. Grab: Grab samples can be collected rapidly and do not require automated equipment. However, grab samples may be less representative of community fecal contributions than composite samples. For untreated wastewater and sludge, grab samples represent a single moment in time and are highly influenced by daily fluctuations in wastewater flow and composition. At the treatment plant level, grab samples may provide similar concentrations to composite samples if the proportion of the community that is infected is sufficiently high. However, at this time, the

minimum proportion of the community that needs to be infected for grab and composite samples to be similar is unknown.

2. Composite: Composite samples are collected by pooling multiple grab samples at a specified frequency over a set time period – typically 24 hours for wastewater surveillance. You can collect composite samples of untreated wastewater manually or using automated samplers with refrigeration capacity that collect flow-weighted samples (e.g., one sub-sample per 200,000 gallons of flow). Continuous composite samplers (versus flow-weighted) may improve how representative the sample is of the community contributing to the sewer. Composite samples are considered more representative of community fecal contributions than grab samples.

Selecting a Sample Volume

The volume of sample to collect will depend on the sample type (wastewater or sludge). A 1 liter (L) composite wastewater sample or 100 milliliter (ml) grab sludge sample volume should be adequate for testing. The maximum amount of sludge solids that may be directly extracted is typically around 2 grams. The remaining sample volume (if any) can be used for repeat measurement or to assess biological variability.

The volume of sample that is concentrated and quantified will determine the lowest amount of SARS-CoV-2 RNA that can be detected. Concentrating more than 1 L of wastewater may result in poor recovery or viral signal inhibition. If using grab samples, consult with wastewater treatment plant staff to collect representative samples that capture peak times of human fecal loading and to understand the solids residence time for sludge.

Section 13 Procedure

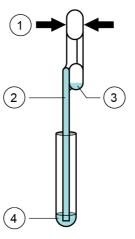
13.1 Preparing the Cartridge

Important: Start the test within 30 minutes of adding the sample to the cartridge.

Note: The preferred sampling strategy is to use a composite sample, allow the solids to settle, and pipette the sample from the top 1/3 of the sample volume. See Wastewater Sample Collection on page 8 for information on composite samples.

- 1. Remove a cartridge from the package.
- 2. Check the sample container is closed.
- 3. Mix the sample by inverting the sample container 5 times. Let the sample sit for at least two minutes. Open the cap on the sample container.
- 4. Open the cartridge lid.
- 5. Remove the transfer pipette from the wrapper.
- 6. Squeeze the top bulb of the transfer pipette **completely until the top bulb is completely flat**. While continuing to hold the bulb, place the pipette tip in the top 1/3 of the sample within the sample container (see Figure 1).

Figure 1 Transfer Pipette



1 Squeeze here	3 Overflow Reservoir Bulb
2 Pipette	4 Sample

- Release the top bulb of the pipette to fill the pipette before removing from the tube. After filling
 pipette, excess sample will be seen in the overflow reservoir bulb of the pipette (see Figure 1).
 Check that the pipette does not contain bubbles.
- 8. To transfer the sample to the cartridge, squeeze the top bulb of the transfer pipette completely again to empty the contents of the pipette ($300 \ \mu$ L) into the large opening (Sample Chamber) in the cartridge shown in Figure 2. Dispose of the used pipette.

Figure 2 Xpress SARS-CoV-2 plus Cartridge (Top View)



9. Close the cartridge lid.

13.2 Starting the Test

Note: Before you start the test, make sure that the system contains modules with GeneXpert Dx software version 4.7b or higher and that the Xpress SARS-CoV-2 plus Assay Definition File is imported into the software.

This section lists the default steps to operate the GeneXpert Instrument System. For detailed instructions, see the *GeneXpert Dx System Operator Manual*.

Note: The steps you follow may be different if the system administrator has changed the default workflow of the system.

- 1. Turn on the GeneXpert Instrument System:
 - First turn on the instrument, and then turn on the computer. Log into the Windows operating system. The GeneXpert software may launch automatically or may require double- clicking on the GeneXpert Dx shortcut icon on the Windows[®] desktop.
- 2. Log on to the System software. The login screen appears. Type your user name and password.
- 3. In the GeneXpert System window, click Create Test.
- 4. Scan or type in the Sample ID (optional). If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is shown on the left side of the View Results window and is associated with the test result.
- Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is shown on the left side of the View Results window and is associated with the test result.
- Scan the barcode on the Xpress SARS-CoV-2 *plus* cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Reagent Lot ID, Cartridge SN, Expiration Date and Selected Assay.

Note: If the barcode on the Xpress SARS-CoV-2 plus cartridge does not scan, then repeat the test with a new cartridge.

- Click Start Test if Auto-Submit is not enabled. In the dialog box that appears, type your password, if required.
 - **a.** Locate the module with the blinking green light, open the instrument module door and load the cartridge.
 - **b.** Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off and the door will unlock. Remove the cartridge.
 - c. Dispose of used cartridges in the appropriate sample waste containers according to your institution's standard practices.

Note: Do not turn off or unplug the instruments while a test is in progress. Turning off or unplugging the GeneXpert instrument or computer will stop the test.

Section 14 Quality Control

14.1 Internal Controls

Each cartridge includes a Sample Processing Control (SPC) and Probe Check Control (PCC).

Sample Processing Control (SPC) – Ensures that the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.

Probe Check Control (PCC) – Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the validated acceptance criteria.

Section 15 Retests

15.1 Reasons to Repeat the Assay

If any of the test results mentioned below occur, repeat the test once according to instructions in Retest Procedure on page 12.

• An **INVALID** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.

- An ERROR result could be due to, but not limited to, Probe Check Control failure, system component failure, no sample added, or the maximum pressure limits were exceeded.
- A NO RESULT indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress, or a power failure occurred.

If an External Control fails to perform as expected, repeat external control test.

15.2 Retest Procedure

To retest a non-determinate result (**INVALID**, **NO RESULT**, or **ERROR**), or a **PRESUMPTIVE POS** result, use a new cartridge.

Use the leftover sample from the original specimen transport medium tube or new external control tube.

- 1. Put on a clean pair of gloves. Obtain a new Xpress SARS-CoV-2 *plus* cartridge and a new transfer pipette.
- 2. Check the specimen transport tube or external control tube is closed.
- 3. Mix the sample by rapidly inverting the specimen transport medium tube or external control tube. Open the cap on the specimen transport tube or external control tube.
- 4. Open the cartridge lid.
- 5. Using a clean transfer pipette (supplied), transfer sample (one draw) to the sample chamber with the large opening in the cartridge.
- 6. Close the cartridge lid.

Section 16 References

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- Wastewater Surveillance Testing Methods. Centers for Disease Control and Prevention. January 26, 2022. https://www.cdc.gov/healthywater/surveillance/wastewater-surveillance/testingmethods.html.

Section 17 Technical Assistance

Hach Company should be the first point of contact for Technical Support. Before contacting Technical Support, collect the following information:

- Product name
- · Lot number of kit
- · Serial number of instrument
- · Error messages (if any)
- · Software version and, if applicable, Computer Service Tag Number

Region	Telephone	Email
US	+ 1 800 227 4224	techhelp@hach.com
EU	+ 33 563 825 319	techsupport-eu@hach.com

Section 18 Table of Symbols

Symbol	Meaning
REF	Catalog number
LOT	Batch code
	Manufacturer
<u>(čć</u>)	Country of manufacture
∑∑	Contains sufficient for <i>n</i> tests
CONTROL	Control
	Expiration date
C	Temperature limitation
\mathbf{A}	Biological risks



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