Bio-Rad Laboratories, Inc.

Sapphire Chip for the naica System

Instructions for Use

February 2026

For research use only. Not for use in diagnostic procedures.

Contents

Purpose

This document provides information and instructions for using the Sapphire Chip with the naica™ System and is intended for laboratory personnel who are trained to perform digital PCR (dPCR) procedures.

Intended Product Use

The Sapphire Chip is a four-chamber cartridge that is used with the naica System, which is a high-resolution dPCR droplet generation and analysis system. Samples added to the Sapphire Chip chambers are partitioned to generate water-in-oil droplets for detection of nucleic acids. For optimal results, you must ensure the following:

- Strict compliance with the information and instructions in this document
- Appropriate collection, transport, storage, and sample processing; *improper handling and operation will cause inaccurate results*

Figure 1 Sapphire Chip

Important: The naica System and its associated components are intended for research use only (RUO). Do not use them for diagnostic procedures. Laboratory personnel and other users must complete all required training before using the systems referenced herein.

About the Sapphire Chip

Sapphire Chip consumables are packed in specific well-sealed shipping boxes. Each box contains four plastic trays of three chips each, for a total of 12 chips per box. Each chip is pre-loaded with proprietary oil and closed with flat white and blue caps. Figure 1 illustrates the Sapphire Chip layout of four chambers (A, B, C, and D). Each chamber has one inlet (white caps) and one outlet (blue caps). Sapphire Chip consumables are identified with a unique serial number (Chip ID) that can be scanned using a barcode reader. You can also write directly on the sticker.

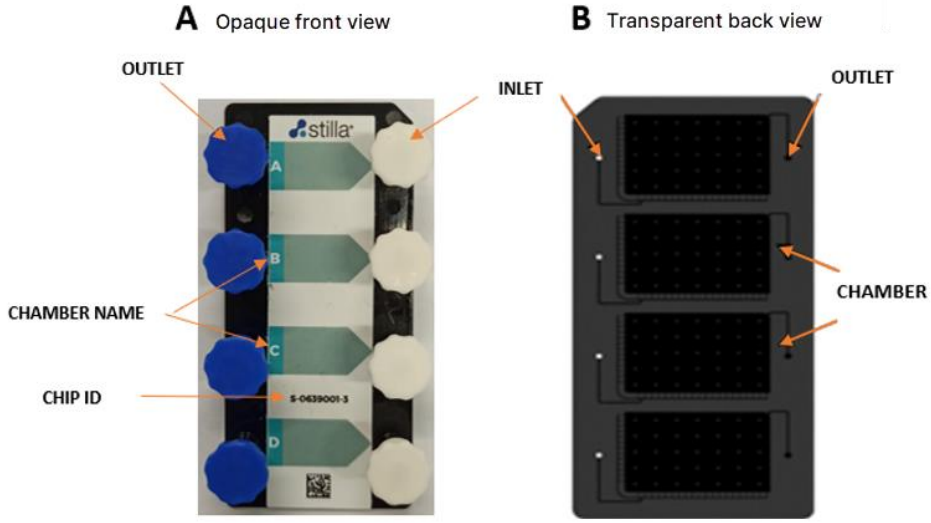

Figure 1 Sapphire Chip components

Table 1 Sapphire Chip specifications

Capacity	Up to 4 samples per chip
Input volume	25 µL/chamber
Dynamic range[1]	~ 5,0 log
Droplets per sample	12 900 – 25 800 [2]
Average droplet volume	~ 0,62 nL [2]
LOD min (95%)[1]	Down to 0,20 cp/µL [2]
LOD max (95%)[1]	Up to 13.000 cp/µL [2]
Altitude	Operating at max. 1000m above sea level
naica System compatibility	Geode, Prism3, Prism6

Use and Safety Requirements

Safety Precautions and Recommendations

Important: Before using this product, review the Sapphire Chip Safety Data Sheet (SDS) and comply with all specified requirements, hazard statements, and environmental precautions to ensure personal, operational, and environmental safety. You can download the document after logging into bio-rad.com or you can contact Bio-Rad™ Technical Support.

Note the following hazard and precautionary statements:

H413: Might cause long lasting harmful effects to aquatic life.

P273: Avoid release to the environment.

P501: Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable.

[1] Analytical specifications are assay-dependent; values are theoretical, calculated from the droplet size and droplet volume

[2] naica Multiplex ddPCR™ Mix and naica ddPCR Mix

Good Laboratory Practices

- Do not eat, drink or smoke when using this product.
- Always wear appropriate personal protection equipment for handling this product - lab coat, disposable gloves, and appropriate eye/face protection are required. Whenever needed, wear additional personal protection equipment.
- Contaminated work clothing should be removed immediately and not be allowed out of the workplace until decontaminated. Change disposable gloves frequently and to prevent cross-contamination.
- Prevent release of oil or oil-contaminated components into the environment. • Before breaks and after work, always wash your hands.
- All materials of human origin are to be treated as potentially infectious. Handle samples based on Standard and Universal Precautions, following local, regional, and national guidelines (such as Biosafety in Microbiological and Biomedical Laboratories). Dispose of all samples according to biohazardous and medical waste management regulations.
- Handle with general biosafety laboratory ventilation.

Consumables Required but Not Provided

The consumables listed below are required, but not provided with the Sapphire Chips:

- Reagents or consumables for nucleic acid purification
- Standard consumables and equipment for PCR mix preparation
- Assay-specific digital PCR reagents, primers and probes

  Note: For more details about the recommended master mixes for the naica System, refer to the Geode User Manual available at naica System Product Page.
- DigiKey ACL Staticide antistatic wetted wipes (DigiKey catalog no. ST1059-ND SW12)
- Kimtech Kimwipes, 1 ply, 4.4 in x 8.2 in (114 mm x 213 mm); *available from general suppliers*.

The products referenced herein are intended for professional use in a laboratory environment only. You must

- Ensure proper training on all instruments before use.
- Before each experiment, follow manufacturer instructions and perform quality control checks.
- Operate in accordance with regulations for PCR gene amplification laboratories.

Sapphire Chip Handling Requirements

- Handle the Sapphire Chip with caution. Do NOT shake.
- Hold the Sapphire Chip by the edges to avoid any marks on the chamber.
  - Do NOT touch the back side of the Sapphire Chip, as this can compromise further analysis.
  - Do NOT hold the Sapphire Chip by the blue caps.
- Carry the chips in the plastic packaging (blister) provided or on a Petri dish lined with a Precision Wipe.
- Avoid contact with hair, hands, clothes, and everything that might accumulate static energy.
- Hold the chips by the white caps and transfer them from the Geode thermal cycler directly to the Prism3 or Prism6 instrument. Touch the Prism3 or Prism6 tray holder to discharge it before removing the chips from the Geode.

- Handle the Sapphire Chip with the flat inlet port caps (blue) and white vented Sapphire Chip PCR caps pointing upwards.

Sapphire Chip Storage Requirements

- If the Sapphire Chip package is delivered upside down, the chips are still usable, provided the packaging (including the pouch) is not damaged. Keep the boxes in an upright position for one hour before using the Sapphire Chip.
- If the Sapphire Chip packaging appears damaged, contact Bio-Rad Technical Support before using the product.
- Keep the shipping box upright in a clean area, at room temperature (15° C to 25° C).
- Store the Sapphire Chip in the original packaging and keep away from strong bases, strong alkali, and oxidizing agents.
- Use the Sapphire Chip before the expiration date stated on the Sapphire Chip shipping box.

Disposal Requirements

Dispose of all package components and contaminated materials appropriately and in accordance with all pertinent regulations.

Important: As stated in the SDS, this product can cause long-lasting harmful effects to aquatic life. Do NOT release it into the environment. You must dispose of waste oil, or items contaminated by waste oil, as special or hazardous waste. You must dispose of waste that is considered biohazardous according to the requirements applicable to your laboratory or location.

To recycle cardboard packaging, follow the requirements applicable to your laboratory or location.

Preventing DNA Contamination

Due to the extraordinary sensitivity of most Taq polymerases, exogenous DNA amplification can occur and ruin an entire experiment (Kwok and Higuchi, 1989). Since many sources of contamination exist (such as cross-contamination and previous PCR amplification) compliance with a strict set of protocols, combined with some precautions, is essential. To limit DNA contamination, the following conventional recommendations for PCR should be followed (not exhaustive):

- Keep areas separate and use dedicated equipment and supplies for sample preparation, dPCR setup, dPCR amplification, and dPCR product analysis.
- Wear a clean lab coat and gloves during each step of the experiment.
- Clean laboratory benches and equipment periodically with water/ethanol, or (depending on the application) with DNase/RNase. To prevent negative contamination, avoid cleaning agent aerosols. For the naica System instruments, refer to the respective user manuals for cleaning instructions.

  Important: Bleach is not recommended but if its use is unavoidable, ensure thorough rinsing after the bleach treatment.
- Keep tubes capped between uses.
- After vortexing, centrifuge tubes to limit aerosols.
- Include a “no template control” (NTC) to monitor potential contaminants.
- **Note:** You can aliquot some reagents to prevent contamination and concurrently reduce repetitive freeze/thaw cycles that might affect their efficiency.

Loading the Sapphire Chip

Input material for the Crystal Digital PCR™ workflow includes extracted nucleic acid. The purity of the extracted sample might vary, depending on the raw material and the implemented extraction protocol. You should perform validation tests to select a compatible extraction protocol for optimal performance of Crystal Digital PCR.

DNA samples with ≥10 kb average length (such as genomic DNA) should be fragmented by restriction digestion. Care must be taken to use restriction enzymes that do not cut within the amplified sequence.

Important: To prevent oil evaporation in the Sapphire Chip, do not load more than three Sapphire Chip consumables at a time.

To load a Sapphire Chip

1. Open the package and remove one Sapphire Chip. The chip is pre-loaded with proprietary PCR oil and closed with flat caps.

   Important: Keep each Sapphire Chip in the plastic blister to protect the Sapphire Chip from scratches and dust particles. You can also use the plastic blister to transport the Sapphire Chip consumables. When less than 3 chips are needed and the plastic blister cannot be used, lay a Precision Wipe on the bench to protect the Sapphire Chip from scratches and dust particles while loading.

2. To apply the antistatic coating:
   a. Open a pouch of the pre-wetted antistatic wipe (ACL Staticide).
   b. Wrap the antistatic wipe around a finger and thoroughly wipe the underside and the edges of one Sapphire Chip to fully coat it with the antistatic treatment.
   c. Lift the Sapphire Chip to visually verify that the entire bottom surface of the Sapphire Chip has been fully covered with anti-static solution. Do not turn the Sapphire Chip upside down.
   d. After applying the antistatic treatment, wipe off any excess with a Precision Wipe (Kimtech Science, reference 7552).
   e. If the antistatic wipe appears to be dried out, take a new antistatic wipe to prepare additional chips. You can use one ACL Staticide antistatic wipe for up to three chips, provided they are processed one directly after another.
   f. Place the Sapphire Chip back in the plastic blister and repeat the steps to apply the antistatic treatment to the next chip.
3. Disconnect the white flat inlet caps from the inlets of the Sapphire Chip:
   a. Twist the cap a quarter(¼) of a turn in any direction. The cap should loosen for easy removal.
   b. Discard the white flat inlet caps (see Figure 2 on the following page).

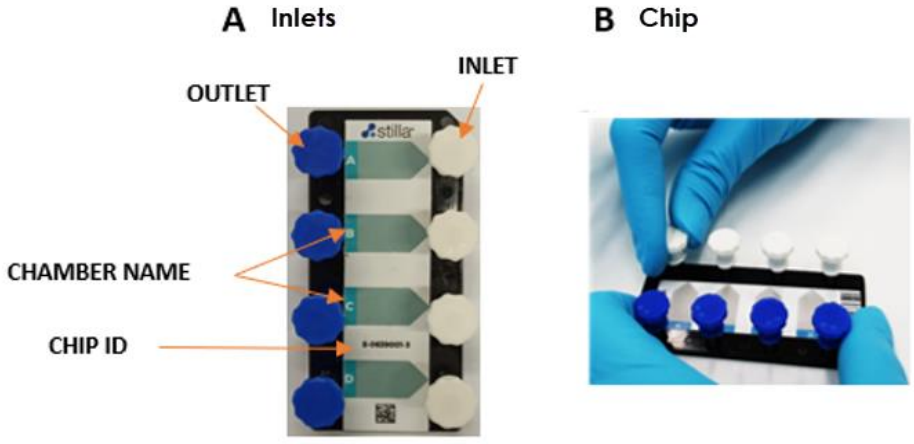

Figure 2 Flat cap display

4. Pipette 25 µL of reaction mix into each inlet.
   a. During pipetting, the reaction mix stays above the oil phase. Do not insert the tip in the oil phase.
   b. Change pipette tips after each pipetting step.

5. Place one tall white vented Sapphire Chip PCR cap on top of each inlet.
   a. Tighten the tall white vented Sapphire Chip PCR cap enough to avoid disconnection from the inlets (Figure 3).
   b. For Sapphire Chip chambers that will be empty during an experiment, disconnect the white flat caps from the chamber inlets and place one tall white vented Sapphire Chip PCR cap on each inlet.

      Note: Do **not** select unused chambers for reading in the Crystal Reader software.

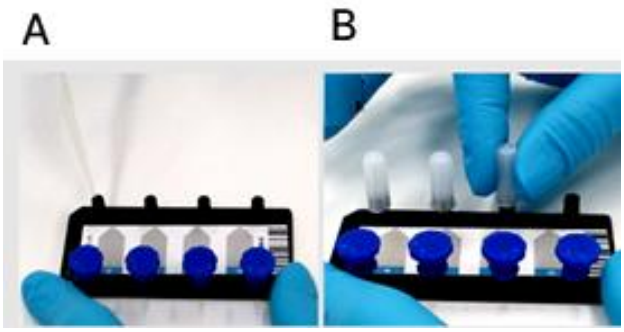

Figure 3 A) add the PCR reaction mix and B) tall white cap on unused chamber inlet

6. To transfer Sapphire Chips to the Geode, hold each chip by the tall white vented PCR caps and then place the chip in the plastic blister or a Petri dish containing a Precision Wipe.

   For subsequent steps on, refer to the Geode User Manual available from the naica System Product Page.

Symbols Lexicon

The following symbols appear on the product label.

 Manufacturer	 Distributor	 Catalog Number
 Batch Code	 Use By Date	 Temperature Limit
 If package is damaged, DO NOT USE; see Instructions for Use	 Consult Instructions for Use	 Keep Dry
 Do Not Reuse	 Contains Sufficient for Test	 This Way Up

Product Ordering Information

Catalog No.	Product Reference No.	Product Description
12025259	C14012	Sapphire Chip

Revision History

Release Date	SAP DIR and Version	Description
February 2026	10000255609 Ver A	Reformat/edit document using Bio-Rad branding

Bio-Rad Technical Support

The Bio-Rad Technical Support department in the U.S. is open Monday through Friday, 5:00 AM to 5:00 PM, Pacific time.

Phone: 1-800-424-6723, option 2
Email: Support@bio-rad.com (U.S./Canada Only)

For technical assistance outside the U.S. and Canada, contact your local technical support office or click the Contact Us link at bio-rad.com.

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