Crystal Digital PCR® Operational Qualification (OQ) Solutions

Taking digital PCR to the next level with Crystal Digital PCR® technology

Stilla Technologies' Crystal Digital PCR® technology for absolute quantification of nucleic acids is based on cutting-edge microfluidic technology that integrates the digital PCR process in a single consumable, reducing hands-on time and interaction.

Crystal Digital PCR® technology provides the complete workflow for digital PCR and is designed to provide a sensitive, robust, fast, and easy-to-use solution.

Importance of routine qualification of Crystal Digital PCR® systems to exploit the full potential of Crystal Digital PCR®

Any Crystal Digital PCR® system installation starts with a full Installation Qualification (IQ) and Operational Qualification (OQ) performed by a qualified Stilla Technologies expert to ensure optimal conditions for the precise and highly sensitive dPCR quantification.

Routine OQ verifies that laboratory instruments meet specified operating criteria across the entire system lifetime. The close monitoring of equipment compliance to operating specifications helps identify possible effects due to external factors before spending valuable time and risking any impact on sample data.

Figure 1. The naica® IQ/OQ Kit, a ready-to-use kit for the OQ of Crystal Digital PCR® systems.

The naica® IQ/OQ Kit, the tool for routine OQ for Crystal Digital PCR®

Routine OQ procedures of the naica® system and Nio™+ can be performed using the **naica® IQ/OQ Kit**, a ready-to-use OQ solution to gather the required documented verification that the naica® system and Nio™+ is fully functioning according to its specifications to ensure stable analysis.

Experience a streamlined, routine OQ solution with the naica® IQ/OQ Kit for a wide range of key nucleic acid detection and quantification applications.

Figure 2. Simple OQ workflow of Crystal Digital PCR® systems with the naica® IQ/OQ Kit, a full OQ solution from reaction preparation to reporting of OQ results.

The naica® IQ/OQ Kit can be included in your OQ routine process in compliance to global standards and country-specific regulations. OQ with the naica® IQ/OQ Kit is ideal for the monitoring of the naica® system and Nio™+ on a periodic basis in accordance with established Standard Operating Procedures (SOPs).

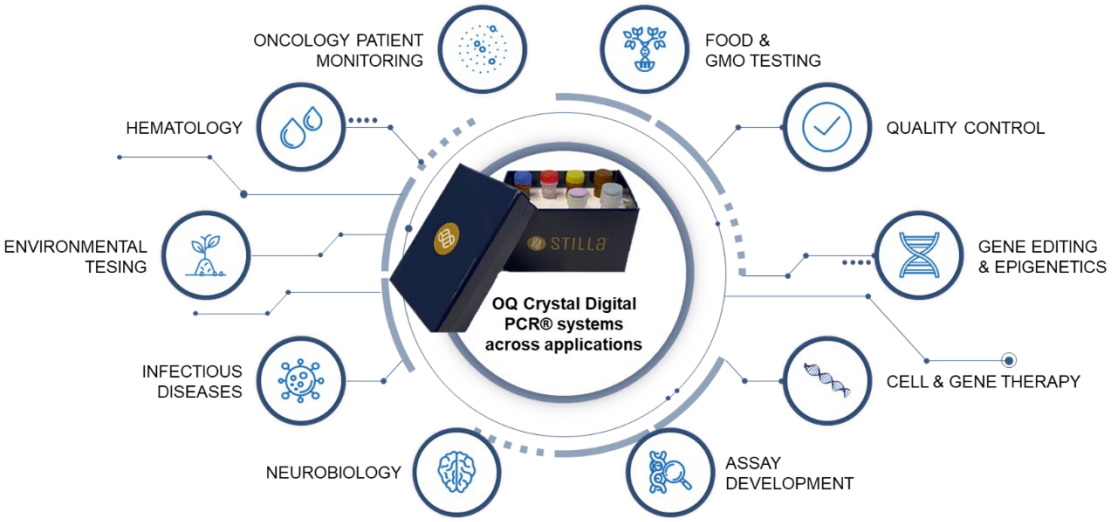

Figure 3. The naica® IQ/OQ Kit is a streamlined routine OQ solution for a wide range of key nucleic acid detection and quantification applications.

For compliance with Food and Drug Administration's regulations on Good Laboratory Practices (GLP), as well as Good Manufacturing Practices (GMP), the naica® IQ/OQ Kit can be used in combination with naica® system Pro software, which provides the necessary features to comply with Title 21 of the U.S. Code of Federal Regulations Part 11 (21 CFR Part 11)*.

Stilla Technologies helps maximize the effectiveness of routine OQ protocols with the naica® IQ/OQ Kit.

Ordering information

To find out more about Crystal Digital PCR® OQ capabilities and how they can help you achieve your laboratory compliance goals, contact your local Stilla® representative.

Product Name	Part Number	System Compatibility	Product Size Format
naica® IQ/OQ Kit	R30001	naica® system with the Sapphire Chip Nio™+ with the Ruby Chip	24 Sapphire Chip reactions *(2 naica® system OQ)* 96 Ruby Chip reactions *(1 Nio™+ OQ)*

**Instrument's owner is responsible for ensuring that the OQ process is adequate to meet its applicable regulation and certification requirements.*