

SmartNorovirus

Rapid Detection of Norovirus GI & GII
in convenient bead format



CE IVD In vitro diagnostic medical device

defining molecular diagnostics

“Having all the reagents in one kit has simplified processing and eliminates the need to pipette small volumes and therefore potentially introduce operator error. The software that accompanies the new kit is also more user friendly, making it easier to distinguish between Genogroups. I feel that the new kit will make a positive impact on our laboratory testing”.

Kay Capaldi

*Chief BMS Virology, Medical Microbiology
St. George's Healthcare NHS Trust*



The Problem

Noroviruses are increasingly recognized as one of the most important enteric pathogens and the most common cause of non-bacterial gastroenteritis. Currently available test methods are not sensitive or convenient enough for Norovirus detection.

- EIA is not sensitive enough¹
- Difficult to culture in the lab
- Environmentally stable²
- Resistant to most cleaning agents²
- Causes outbreaks leading to temporary closures of affected institutions³

The Solution

Rapid and accurate identification of Norovirus infection is a critical part of effective infection control. Cepheid's SmartNorovirus delivers both with convenience.

- Result available in less than 3 hours
- Easy to use bead format maximizes result consistency
- Provides flexible testing capability
- All reagents needed are included in the kit

Analytical Sensitivity

The Limit of Detection (LOD) was determined by analyzing six different concentration levels in 24 replicates/level. Probit analysis was used to calculate the LOD concentrations.

SMARTNOROVIRUS LIMIT OF DETECTION (LOD)

	LOD 95%*		95% Confidence Interval	
	(copies/ μ l)	(copies/PCR)	(copies/ μ l)	(copies/PCR)
Norovirus GI	10	50	7.2 – 18	36 – 90
Norovirus GII	98	490	87.2 – 122	436 – 608

* Limit of Detection (LOD) is defined as the titer level where 95% of all replicates are determined positive

Inclusivity & Exclusivity

SmartNorovirus detects the majority of the Norovirus GI and GII sequences published in GeneBank, with no cross reactivity obtained for over 25 most common organisms found in the human gastrointestinal system.

Flexible & Expandable

Cepheid's SmartCycler® instrument is the only random-access, modular real-time PCR instrument on the market with up to 96 sites that can each run a different protocol. Test 16 different protocols simultaneously in one instrument, or up to 96 different protocols with six instruments. Because all sites are calibrated optically and thermally, every site will perform the same when programmed to run identical protocols. Installation of the SmartCycler System is plug-and-play, and system expansion only requires an additional USB connection.



The Cepheid advantage: Comprehensive Norovirus testing solution.

SmartNorovirus offers your laboratory the only comprehensive solution for Norovirus testing.

SmartNorovirus: Ultimate Flexibility

- Standardizes testing, producing highly accurate results
- Fits perfectly into the workflow of busy molecular laboratories
- Random access provides testing flexibility



ORDERING INFORMATION

SmartNorovirus. Catalog No. SCN-CE-40
(40 tests)

References:

1. Gray et al., Clinical and Vaccine Immunology 2007
2. Duizer E, Bijkerk P, Rockx B, De Groot A, Twisk F, Koopmans M. Inactivation of caliciviruses. Appl Environ Microbiol 2004;70(8):4538-43.
3. Lopman et al., Clinical Infectious Disease 2004

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Practice of the patented polymerase chain reaction (PCR) process requires a license. The SmartCycler® System is an authorized thermal cycler and may be used with PCR licenses available from Applied Biosystems. Its use with authorized reagents also provides a limited PCR license in accordance with the label rights accompanying such reagents. Purchase of this instrument does not convey any right to practice the 5' nuclease assay or any of the other real-time methods covered by patents owned or controlled by Roche or Applied Biosystems. Cepheid's SmartCycler® System is a licensed real-time thermal cycler under Applera's European Patent No. EP 0 872 562, Japanese Patent No. JP 3136129 and patents pending, for all fields including human *in vitro* diagnostics except for diagnosis and monitoring of HIV and HCV infections. This product is made using components and licensed by Eppendorf AG. The purchase price of this product includes limited, nontransferable rights to use only this amount of the product to practice the method for reversible inhibition of thermostable polymerase as claimed in U.S. Patent No. 6,667,165.

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