

# **Xpert<sup>®</sup> Norovirus**

Fast and accurate identification and differentiation of norovirus genogroup I and genogroup II in as soon as 57 minutes\*



#### The Need<sup>1,2</sup>

- Norovirus is highly contagious and is the most common cause of acute gastroenteritis worldwide
- Globally, an estimated 685 million cases of norovirus are seen annually, including 200 million cases amongst children under 5
- Norovirus causes an estimated 200,000 deaths per year, including 50,000 child deaths
- Every year, this virus is estimated to cost \$60 billion worldwide due to healthcare costs and lost productivity
- Norovirus outbreaks in healthcare institutions require immediate implementation of infection control measures to avoid ward closures

## The Solution

- **Xpert Norovirus** detects genotype I (GI) and genotype II (GII), which are responsible for the majority of infections
- **Xpert Norovirus** provides **fast and actionable results** for clinicians when it is needed most, to timely set up infection control initiative and optimized bed and patient management to reduce the spread of infection<sup>3</sup>
- On-demand identification supports **outbreak management** enabling fast contact tracing to manage onward transmission<sup>4</sup>

## The Impact

Fast and accurate PCR testing with Xpert Norovirus greatly improves time to result compared to other PCR tests, allowing healthcare professionals to quickly identify, isolate and appropriately manage patients, helping prevent spread<sup>3</sup>:

- 89% decrease in turnaround time (22 h versus 2.4 h) $^{\rm 5}$
- 66% reduction in unnecessary isolation<sup>6</sup>
- \$320,209<sup>^</sup> savings by preventing bed closures and unnecessary isolation<sup>6</sup>

2 Norovirus introduction. WHO. https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/norovirus. Accessed November 22, 2023

4 Salmona M, et al. Laboratory-based strategy using a new marketed polymerase chain reaction assay to manage diarrheic episodes among patients from rehabilitation and longterm care facilities. Am J Infect Control. 2016 Jun 1;44(6):716-8

5 Henningsson AJ, Nilsson Bowers A, Nordgren J, Quttineh M, Matussek A, Haglund S. Rapid diagnosis of acute norovirus-associated gastroenteritis: evaluation of the Xpert Norovirus assay and its implementation as a 24/7 service in three hospitals in Jönköping County, Sweden. Eur J Clin Microbiol Infect Dis. 2017 Oct;36(10):1867-1871

6 Lyer S, et al. Comparative Evaluation 2 Commercial Norovirus Real-time PCR assays for Hospital Outbreak Management. Federation of Infection society p192 11th-14th Nov. 2013

\* 57 minutes with early assay termination for positive results

\* Exchange rate December 08, 2023: 1\$ = 0,79£

<sup>1</sup> Norovirus Burden and trends, CDC https://www.cdc.gov/norovirus/burden.html#worldwide. Accessed November 22, 2023

<sup>3</sup> Cleary O, et al. Evaluation of the Xpert Norovirus assay for the rapid detection of norovirus genogroups I and II in faecal specimens within a routine laboratory setting. British Journal of Biomedical Science. 2017 Dec:74(3):144-147

#### **Xpert<sup>®</sup> Norovirus**

Product Reference Sheet — US-IVD & CE-IVD

Test Reagent Kit	Xpert Norovirus	
Catalog Number	<b>US-IVD</b> GXNOV-10	<b>CE-IVD</b> GXNOV-CE-10
Technology	Real-time RT-PCR	
Targets	GI, GII	
Batch or On-Demand	On-demand	
Minimum Batch Size	1	
Sample Type	Raw or unpreserved unformed stool	
Sample Extraction	Automated/Integrated	
Precision Pipetting	Not required	
ТАТ	88 minutes (57 minutes with EAT*)	
Control: Process	Sample Processing Control (PCC)	
Controls: Probe Function/Detection	Probe Check Control (SPC)	
	GI	GII
РРА	100%	98.5%
NPA	99.6%	98.8%
Sample Stability	2–8 °C for 2 days Room temperature 20-30°C for 24 hours	
Kit Storage	2–28 °C	
<b>Commercial Controls</b>	Refer to Package Insert or Contact Cepheid Technical Support	

Xpert Norovirus Package Insert n° 301-2440, Rev. H March 2023 CE-IVD. *In Vitro* Diagnostic Medical Device. Not available in all countries. Not available in the United States

Xpert Norovirus Package Insert n° 301-2441, Rev. D November 2019 US-IVD. For *In Vitro* Diagnostic Use. Not available in all countries

#### \* 57 minutes with early assay termination for positive results.

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