Neither Nor or Norovirus GI/GII?

P0330

Good Consensus in International EQA Pilot Study for Norovirus Antigen Detection

Heidi Berghäll*, Kati Luiro, Kristel Virtanen, Jonna Pelanti
Labquality EQAS, Aurevia, Helsinki, Finland
*heidi.berghall@aurevia.com

Background

Norovirus, a common cause of gastroenteritis primarily transmitted through the faecal-oral route, is highly contagious and outbreaks can have widespread effects, particularly in enclosed environments such as nursing homes and hospitals. The preferred diagnostic methods for norovirus testing focus on detecting viral RNA using highly sensitive RT-qPCR assays, however, rapid norovirus antigen detection tests are also commonly used. Labquality EQAS by Aurevia has developed a new external quality assessment (EQA) scheme for norovirus antigen detection. This study presents the successful results of the pilot study performed in 2024.

Materials & methods

The layout of this pilot study followed the traditional EQA process described in the figure below.

Registration for EQA pilot study	Distribution of identical sample sets to participants	Analysis of samples	Result processing and reporting to participants
EQA is an essential part of the quality assurance of a clinical laboratory / POCT site. EQA in addition to internal quality control helps to ensure that tests are performed accurately.	In EQA, identical sample sets are distributed to the participants. The expected results of each sample is unknown to the participants in EQA schemes.	EQA samples are to be handled according to the instructions and analysed as patient samples using the test. The participants report their results to the EQA provider.	The results are processed and evaluated by the EQA provider after round closing. The participating sites should take appropriate actions if needed according to their quality management system.
In this study: • 63 participants • 8 countries • Clinical laboratories and POCT sites	Novel EQA material dessicated to samples swabs to be eluted in test buffer: • S001 negative • S002 Norovirus GII positive (containing recombinant GII.4 protein) • S003 Norovirus GI positive (containing recombinant GI.1 protein)	Participants reported their qualitative results, genogroup, and test methods in and test methods in the Labquality EQAS electronic platform LabScala. 17 different tests were used among the participants in the pilot study.	Results were processed in LabScala and evaluated by the EQA Coordinator. Individual and summary reports with peer group comparison were provided to all participants together with a final report letter.
Schedule: Registration period closed in August 2024.	Sample shipments in September 2024.	Pilot round result reporting closed in October 2024.	Pilot round final reports published in November 2024.

Results

Of the 63 registered pilot participants, 56 testing sites reported all together 57 qualitative results analysed using 17 different commercial tests. The response rate was 89%. The overall success rate was 96% (100% for negative sample S001, 95% for GII positive sample S002, and 93% for GI positive sample S003), (Figure 1).

Most tests used by the participants of this pilot study were based on lateral flow immunochromatography and designed for single or multi-analyte testing. Some tests distinguished between norovirus genogroups GI and GII (Table 1), but not all participants reported the genogroups (data not shown). Genogrouping was reported in 36/57 results; three participants reported the incorrect genogroup for the GII positive sample S002 whereas two reported the incorrect genogroup and two reported a negative result for the GI positive sample S003 (Figure 2). One participants had most likely mixed up the positive samples resulting in incorrect results. According to the sample manufacturer, the viral load was lower in the GI positive sample, possibly explaining the two false-negative results.

	No. of participants	No. of responding participants	Response rate
Norovirus, antigen detection – Pilot, 1-2024	63	56	89%

▼ Summary

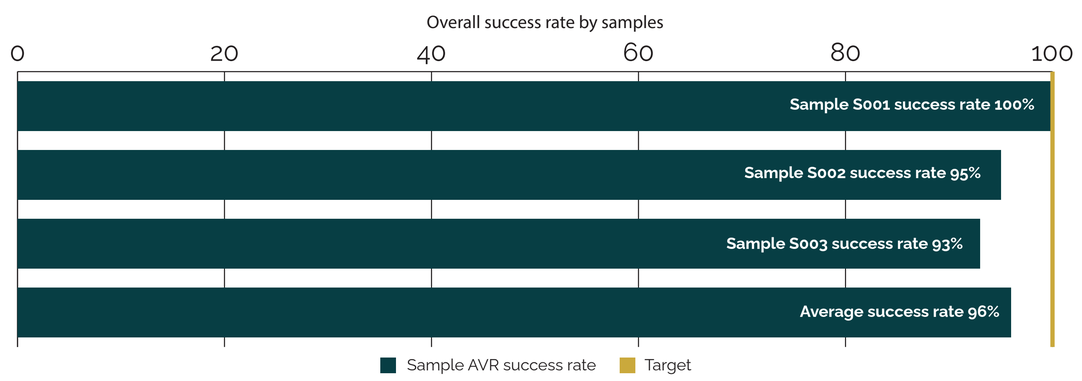

Figure 1. The overall success rate was 96% (100% for negative sample S001, 95% for GII positive sample S002, and 93% for GI positive sample S003). The response rate was 89%.

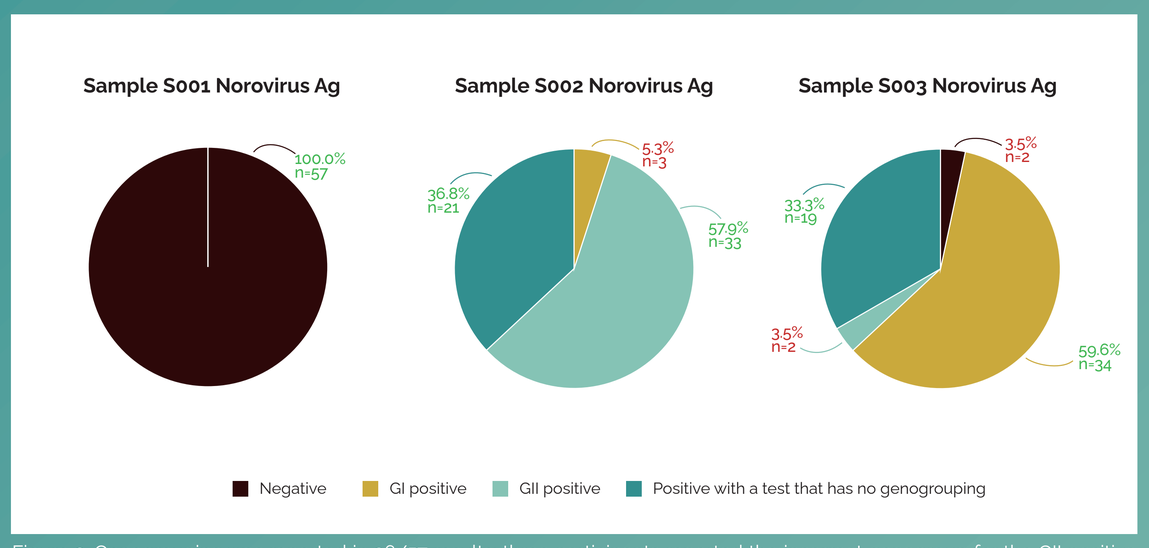

Figure 2. Genogrouping was reported in 36/57 results; three participants reported the incorrect genogroup for the GII positive sample S002 whereas two reported the incorrect genogroup and two reported a negative result for the GI positive sample S003. Correct results are indicated with green, incorrect results indicated in red. One participant had most likely mixed up the positive samples.

Conclusion

- The results of this EQA pilot study were excellent with a 96% over all success rate.
- The reported results confirm homogeneity, stability and suitability of the sample material for different norovirus antigen tests.
- While EQA is mandatory for ISO 15189 accredited laboratories, few POCT sites are accredited and only few countries have national regulations for EQA participation. To enhance patient safety, also POCT sites should implement adequate quality assurance routines.
- The new EQA scheme presented in this study facilitates EQA participation.

Tests that distinguish Norovirus GI and GII (10 tests)	Tests that do not distinguish Norovirus GI and GII (7 tests)
ACRO BIOTECH Norovirus Rapid Test Cassette	Abbott Bioline Norovirus
ACRO BIOTECH Norovirus, Rotavirus and Adenovirus Combo Rapid Test Cassette	Biosynex IMMUNOQUICK NOROTADENO
ArcDia mariPOC Gastro	CerTest Biotec Norovirus one step card test
Biosynex IMMUNOQUICK NOROVIRUS	CerTest Biotec Rota-Adeno-Astro-Noro one step combo card test
HANGZHOU ALLTEST BIOTECH Norovirus Rapid Test	CerTest Biotec Rotavirus+ Adenovirus+ Norovirus one step combo card test
Meridian Bioscience Immunocard STAT! Rota-Adeno-Noro2	R-Biopharm RIDAQUICK Norovirus
nal von minden NADAL Norovirus GI/GII Test	R-Biopharm RIDASCREEN Norovirus 3rd Generation (immunoassay)
R-Biopharm RidaQuick Rota/Adeno/Noro Combi	Servibio Adeno-Rota-Noro 1/2 Color
SD Biosensor STANDARD F Norovirus Ag Plus FIA	

Table 1. Tests used by the participants in this pilot study.

Labquality EQAS by Aurevia

Aurevia | Kumpulantie 15, FI-00520 Helsinki, Finland
+358 9 8566 8200 | info@aurevia.com | **aurevia.com**