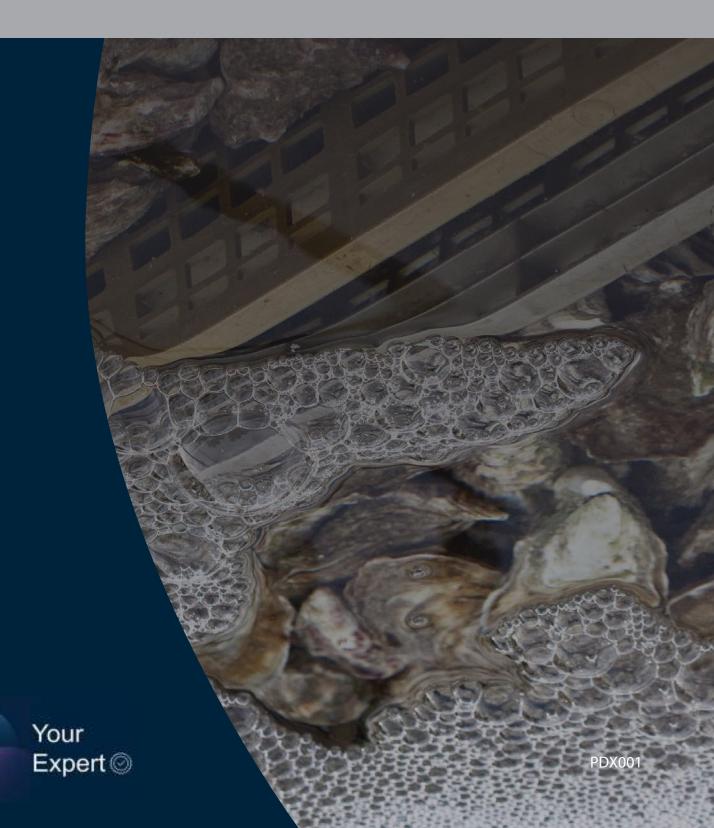
P R I M E R D E S I G N

The Importance of Norovirus Testing in Oyster Farming



In this edition of Your Expert, Primerdesign interviewed Dr Stephanie Anderson, Product Manager at Primerdesign on the development of the genesig® Easy_oys Norovirus detection workflow.



Stephanie Anderson, PhD - Product Manager at Primerdesign

Before joining Primerdesign in 2019, Steph completed a PhD where she investigated osteogenic potential of human bone cells grown on artificial implant surfaces.

Prior to her PhD Steph worked as a Research Technician at Southampton University in a developmental biology research group for seven years. After four years in R&D at Primerdesign, Steph moved into the Marketing department and became the Product Manager for Food, Water and Agriculture.

Why is it important that patients do not catch norovirus, although a common term can you explain about more about the health burden and symptoms of the disease?

Norovirus, also called the "winter vomiting bug", is a stomach bug that causes vomiting and diarrhoea. It can be very unpleasant, but usually goes away in about 2 days. Norovirus can be quite hazardous for older people or people who are immunocompromised, but for the general population, it will make you feel quite unwell and sick for a few days.

Please can you explain how you came across this unmet need for testing for norovirus in oysters?

When I moved into this role as Product Manager in June 2023, I started looking back at old opportunities to try and see if there was an area that we could grow within aquaculture. I discovered that we'd previously contacted some oyster farms about Norovirus testing, so I re-engaged and begun contacting some of the old oyster farmers. The first response I got was from Loch Fyne Oysters and they were interested in bringing testing in house. It transpired then that their current providers where they had been sending the samples out to test had just stopped offering that service. I understood that other farms would be interested in bringing testing in house because obviously there was no alternative now for them to do the testing in the UK.



What about the regulators in the industry? Have you worked with them to ensure that our offering is suitable and meets their standards?

Yes of course, the testing of Norovirus on oyster farms is regulated by the FSA and Cefas (Centre for Environment, Fisheries and Aquaculture Science), it was strongly recommended by one of the Oyster farmers, to speak with Dr. James Lowther who was the **Head Virologist at Cefas**. During my conversation with James Lowther I explained the workflow and how it worked, and the sensitivity that we thought we had at the time, and he was comfortable with how the workflow was expected to perform.



You mentioned Loch Fyne Oysters, who else did you talk to in order to develop the user requirements for this product?

I mainly worked with Othniel Oysters and Cumbrae Oysters, they used our beta kits throughout and together we monitored the performance of our kits during the winter of 2023. Based on feedback during this early phase, we developed a cross functional site study where we were working with Cefas and Bangor University to compare test results throughout the winter. The kit was modified on the feedback to ensure that it was more sensitive. We are continuously carrying out post-market surveillance to ensure that we are listening to the market and responding with product improvements to guarantee that our product is meeting our customer needs.

I understand that Norovirus is a seasonal virus responsible for the "winter vomiting bug", why is this the case? Is the virus exacerbated in different climates, and what causes fluctuations in its prevalence?

Norovirus is most prevalent in the winter, when the water is colder because the oysters don't feed as much and anything that they accumulate, they don't exude again. This is exacerbated as in Winter there is a higher prevalence of Norovirus in the human population. Heavy rainfall combined with effluent from the sewers, leads to an increase in the risk of Norovirus being present in the water that the oysters populate, leading to higher levels of bioaccumulation of Norovirus in the oysters. The higher levels of Norovirus accumulated within the oyster gut leads to increased risk to human health via consumption of oysters. Norovirus poses a lower risk during the summer months when it's warmer and the oysters are feeding regularly. It is very much a winter seasonal issue.

What is the Norovirus workflow solution that you developed for these customers to enable this testing to be done near the oyster farms?

We built the Norovirus test for oysters around our existing genesig[®] Easy workflow, where the idea is that it is an **infield test** and **non-scientists can use it**. The workflow makes use of our q16 real-time qPCR instrument, which is small and portable with no moving parts.

The robust q16 instrument can be plugged into a car battery, and is practical for infield testing. We also adapted the extraction workflow for increased sensitivity, which is manual and makes use of magnetic beads and a magnetic rack. The goal is for the workflow footprint to be capable of fitting on a desk space at a farm or on a boat, rather than in a formal laboratory space. Offering a flexible workflow that is easy to use for customers without a science background.

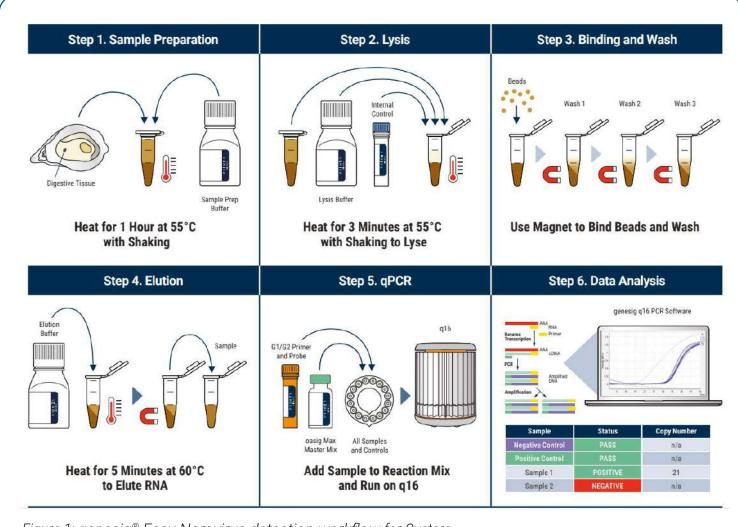


Figure 1: genesig® Easy Norovirus detection workflow for Oysters



Is the workflow adaptable with different qPCR platforms?

Yes, we could offer just the qPCR assay rather than the full workflow so customers could run the kit on their existing qPCR machine, providing they used our extraction kit. We would work with our Technical Support team to ensure compatibility.

If an oyster farmer needs to prove that a batch of oysters is tested negative for norovirus, what reports would they need to generate to show their buyers or exporters?

The q16 software provides the user with data interpretation. It reports whether the test is positive or negative and whether there has been a setup error. We have an additional customised spreadsheet that we have developed for our customers where they can add in the Cq value and it will convert that to copies per gram, giving a quantitative result. This allows a threshold to be applied to determine if they are above or below a safe limit. *This will give buyers and importers confidence in the batch of oysters and gives trust that the oyster farmers are robustly testing their products.*

How do you ensure that non-technical laboratory oyster farmers can run the workflow without much PCR or technical knowledge?

Firstly, we have a very comprehensive handbook, which describes step by step the entire workflow. We have an excellent Technical Support team that provide training to the customers. Training videos are also available to support the customer. No matter the level of our clients' expertise, we have a strong technical team who can work in partnership with the farmers and provide training at the customer site, or virtually.

How else would you explain the uniqueness of this Primerdesign Norovirus testing workflow?

It allows oyster producers to do batch release of their oysters without having to wait at least 10 days before getting results. There is an expectation for oyster producers to test, but Cefas is the only accredited testing lab in the UK. Our workflow provides customers with the opportunity to get their results by lunchtime, as the workflow only takes four hours. This means they can decide whether they need to depurate or heat treat their oysters before they can sell or export them, giving them increased confidence that they are *providing high quality products with reduced risk to human health.* "It allows oyster producers to do batch release of their oysters **without** having to wait at least **10 days** before getting results. "

How often do the oyster batches need to be tested? Is that determined by the regulators or is it determined by the farmers themselves?

The farmer's test frequency is often based on the weather. Environmental health officers will expect oyster producers to be monitoring their stocks during the Winter months. Frequency of testing will depend on the weather and how often the producers sell their product.

One of our customers is an exporter, for him it's really important to have this test because he needs to provide evidence of due diligence when he's sending oysters to Hong Kong, for example. If there is a case of suspected food poisoning, then he has proof that he has tested the oysters, it gives a real vote of confidence in their product. This will help their businesses grow because they are reassured that they are providing a high-quality product that is Norovirus free. This may lead to industry pressure for other oyster producers to follow suit.

"it gives a real vote of confidence in their product."

Is Norovirus only prevalent in oysters, what about other shellfish or foods?

Norovirus does impact other shellfish such as mussels, but as mussels are cooked it is less of a concern, oysters present a greater risk as they are eaten raw. Norovirus is also present in lettuce, but consumption of raw oysters seems to draw the most attention from consumers.

References

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Learn more about our genesig® Easy Norovirus detection workflow for Oysters



Scan the QR code to visit the Primerdesign website.



About Primerdesign

Primerdesign is an innovative company focused on the design, manufacture and supply of real-time PCR kits and reagents. Primerdesign is focused on developing improved solutions for realtime PCR.

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