Wisconsin State Laboratory of Hygiene
UNIVERSITY OF WISCONSIN–MADISON

WSLH Norovirus Surveillance

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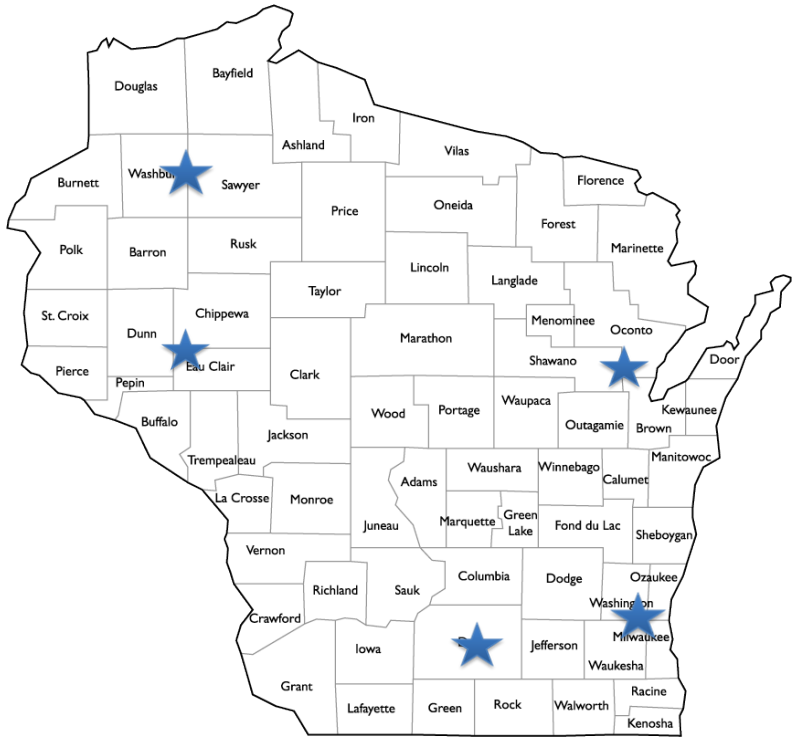
Objectives:

- Brief overview of norovirus sporadic specimens in WI
- Early BioFire false positivity (Late 2021- present)
- WI clinical labs response to BioFire’s announcement of false positivity and our data since (February 2024- current)
- Takeover of Norovirus GII.17[P17] as dominant strain

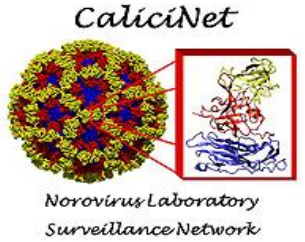
Norovirus surveillance in Wisconsin



Primary Submission Sites

- Two main types of samples for norovirus testing at WSLH: outbreak related investigations and sporadic norovirus positive samples
- WSLH receives positive norovirus samples for surveillance from clinical labs throughout the state of Wisconsin (5 primary sites and others who submit a handful of specimens a year).
- Participating labs have been part of the Wisconsin Clinical Laboratory Network prior to sending us norovirus samples and were submitting data to NREVSS on the number of norovirus positives and the number of tests they run.
- Labs were chosen based on their testing volume and geography to submit norovirus positive samples to WSLH so we could upload the demographics and sequences into CDC's CaliciNet database.
- Positive samples are tested at WSLH using the CDC Norovirus Singleplex RT-PCR assay and Norovirus polymerase-capsid typing by RT-PCR amplification of region B-C.

CaliciNet Surveillance Network

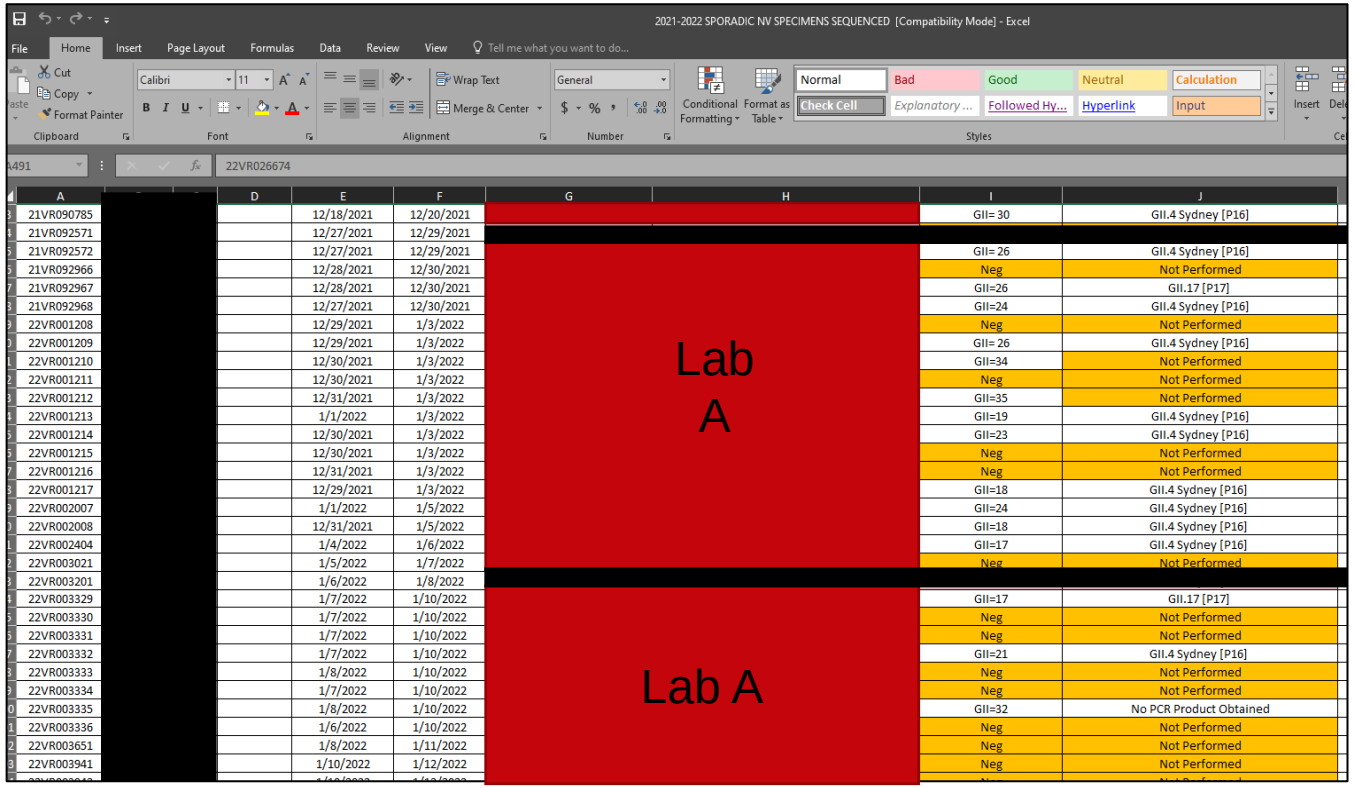


- CaliciNet is the “National norovirus outbreak surveillance network of public health laboratories in the United States, coordinated by CDC.”
- WSLH is a CaliciNet certified laboratory- we provide in-state outbreak and sporadic data, and we are also an outbreak support center for a handful of states for Norovirus genotyping
- Focuses on outbreaks and individual (sporadic) cases of norovirus
- The CaliciNet database includes genetic sequences of norovirus strains and basic epidemiologic data from outbreaks

Norovirus Biofire false positivity

A noticeable trend at Lab A

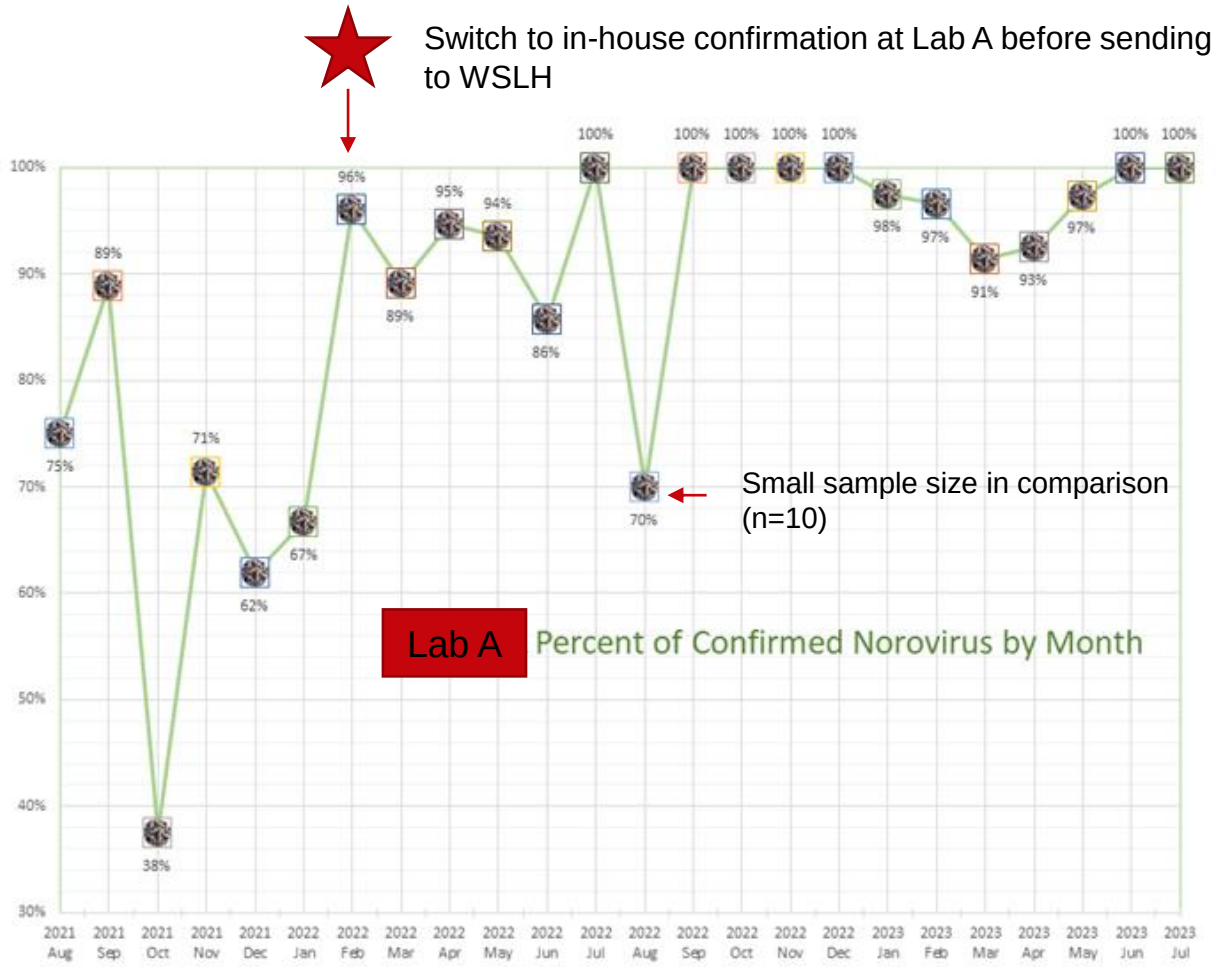
- Late 2021- very early 2022 we were starting to see a noticeable decrease in confirmation from a submitting lab, Lab A.
- To the right is a screenshot of our sporadic specimen log from specimens collected from 12/18/2021 to 1/10/2022.
- We highlight specimens orange that we will not be genotyping because they were negative on RT-PCR or if they had a ct over 30.
- It became noticeable that we were seeing a decline in confirmation by the amount of samples that were negative from this submitting lab.



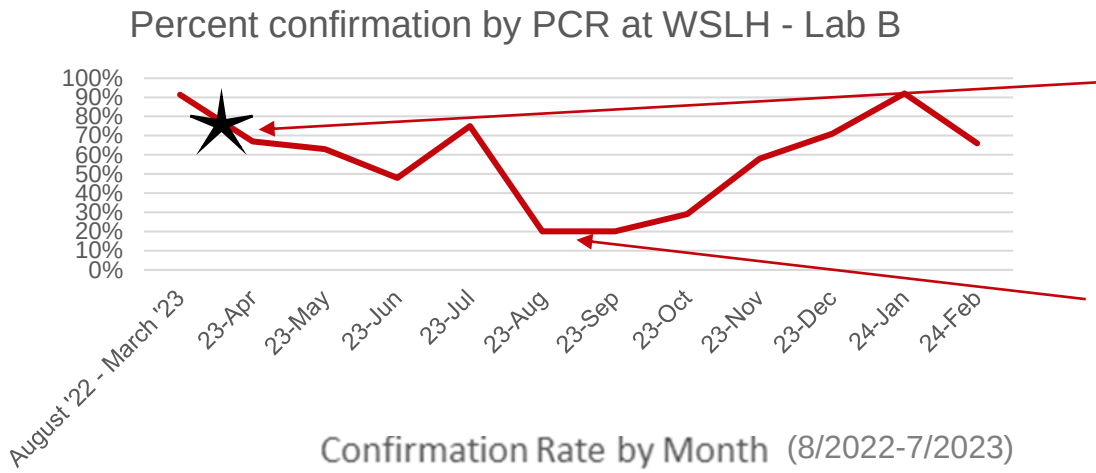
	A	D	E	F	I	J
2	21VR090785		12/18/2021	12/20/2021	GII= 30	GII.4 Sydney [P16]
4	21VR092571		12/27/2021	12/29/2021		
5	21VR092572		12/27/2021	12/29/2021	GII= 26	GII.4 Sydney [P16]
6	21VR092966		12/28/2021	12/30/2021	Neg	Not Performed
7	21VR092967		12/28/2021	12/30/2021	GII=26	GII.17 [P17]
8	21VR092968		12/27/2021	12/30/2021	GII=24	GII.4 Sydney [P16]
9	22VR001208		12/29/2021	1/3/2022	Neg	Not Performed
10	22VR001209		12/29/2021	1/3/2022	GII= 26	GII.4 Sydney [P16]
11	22VR001210		12/30/2021	1/3/2022	GII=34	Not Performed
12	22VR001211		12/30/2021	1/3/2022	Neg	Not Performed
13	22VR001212		12/31/2021	1/3/2022	GII=35	Not Performed
14	22VR001213		1/1/2022	1/3/2022	GII=19	GII.4 Sydney [P16]
15	22VR001214		12/30/2021	1/3/2022	GII=23	GII.4 Sydney [P16]
16	22VR001215		12/30/2021	1/3/2022	Neg	Not Performed
17	22VR001216		12/31/2021	1/3/2022	Neg	Not Performed
18	22VR001217		12/29/2021	1/3/2022	GII=18	GII.4 Sydney [P16]
19	22VR002007		1/1/2022	1/5/2022	GII=24	GII.4 Sydney [P16]
20	22VR002008		12/31/2021	1/5/2022	GII=18	GII.4 Sydney [P16]
21	22VR002404		1/4/2022	1/6/2022	GII=17	GII.4 Sydney [P16]
22	22VR003021		1/5/2022	1/7/2022	Neg	Not Performed
23	22VR003201		1/6/2022	1/8/2022		
24	22VR003329		1/7/2022	1/10/2022	GII=17	GII.17 [P17]
25	22VR003330		1/7/2022	1/10/2022	Neg	Not Performed
26	22VR003331		1/7/2022	1/10/2022	Neg	Not Performed
27	22VR003332		1/7/2022	1/10/2022	GII=21	GII.4 Sydney [P16]
28	22VR003333		1/8/2022	1/10/2022	Neg	Not Performed
29	22VR003334		1/7/2022	1/10/2022	Neg	Not Performed
30	22VR003335		1/8/2022	1/10/2022	GII=32	No PCR Product Obtained
31	22VR003336		1/6/2022	1/10/2022	Neg	Not Performed
32	22VR003651		1/8/2022	1/11/2022	Neg	Not Performed
33	22VR003941		1/10/2022	1/12/2022	Neg	Not Performed

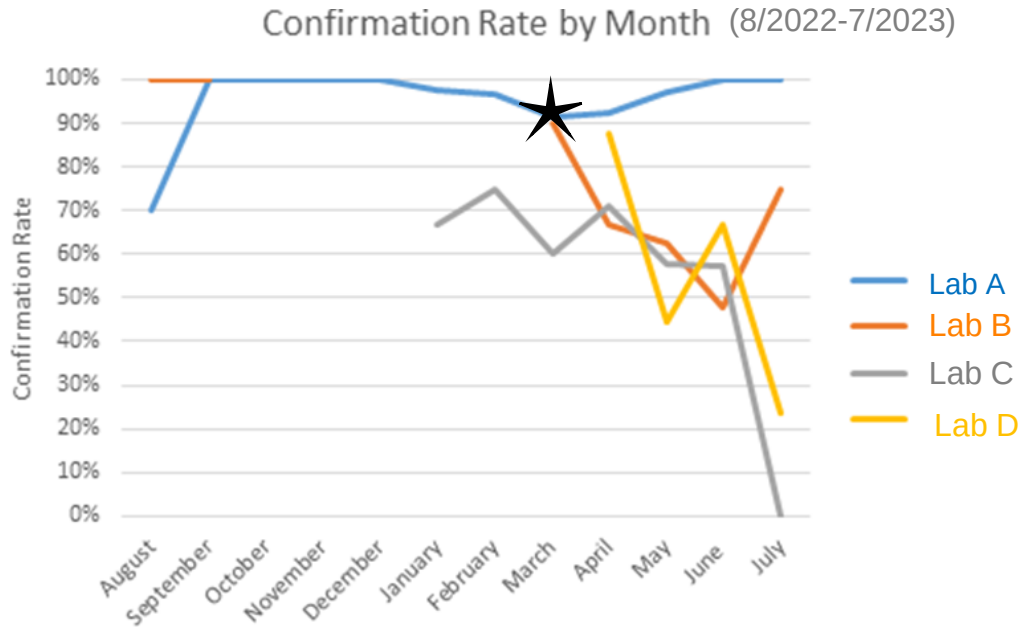
WSLH and Lab A response to low confirmation rates

- We tested a handful of Lab A's specimens on our BioFire instrument, and they were also negative.
- Our director talked to the lab director at the performing lab to inform them of our decreased confirmation.
- Lab A did some internal testing and then started performing confirmatory testing on the Cepheid for any BioFire positives starting in February 2022.



Lab B and the others started to follow

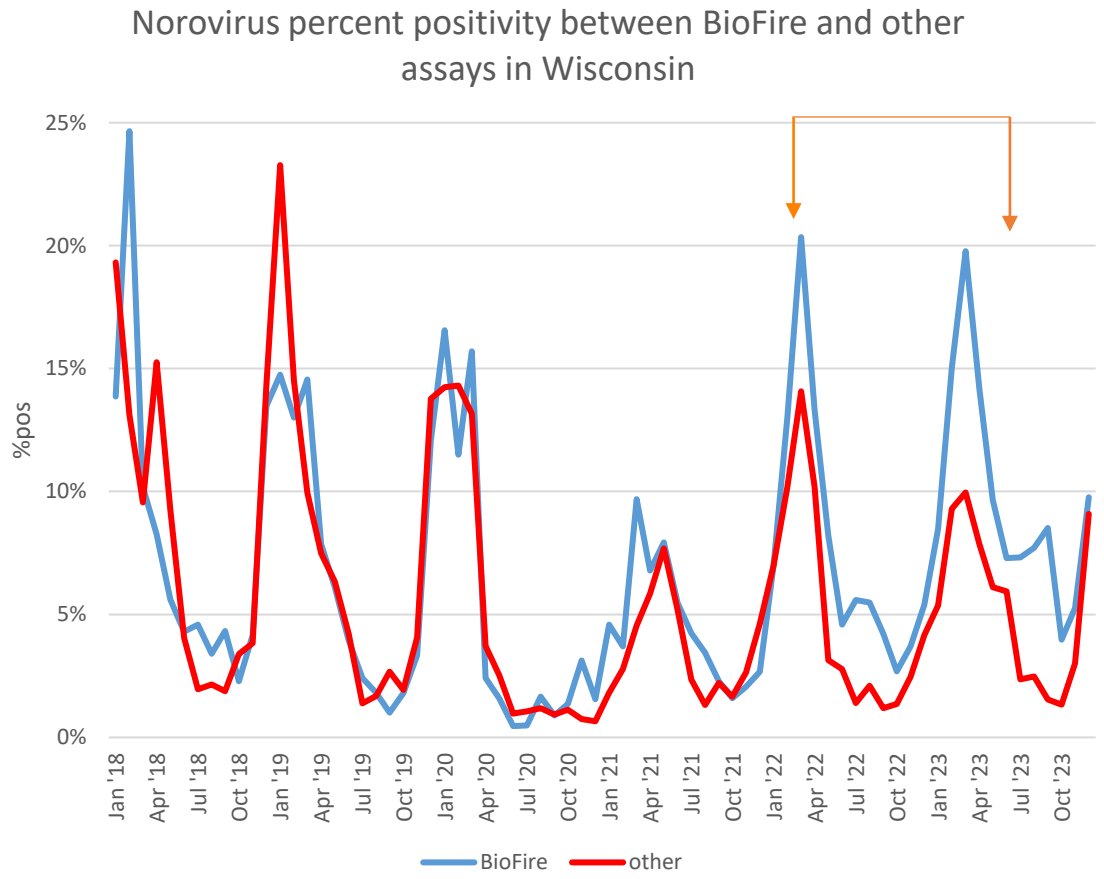




- In April of 2023, Lab B switched from testing their Enteric specimens on the Verigene to the BioFire.
- Prior to switch, Lab B had an average of 90%+ confirmation, in August and September they had their lowest confirmation at 20% of samples.
- Increase in percent confirmation in winter of 2023-2024 most likely due to higher prevalence in the community. Lower percent confirmation is seen in months with lower prevalence.
- Since this seemed to be more than a one lab situation at this point, we looked at our data with our most frequently submitting labs, and it was clear that this was a common theme.

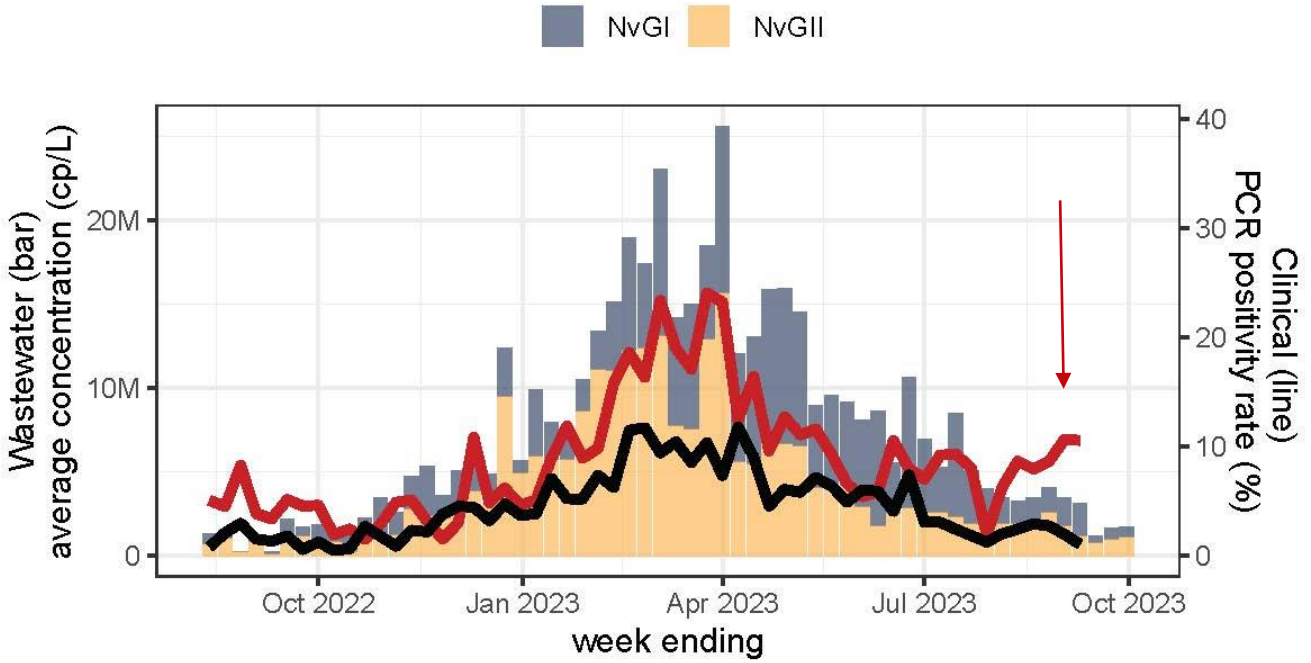
Additional statewide comparison

- NREVSS reported data from labs were compared
- Percent positivity was compared between BioFire positive samples and samples that were tested on other platforms in Wisconsin.
- Percent positivity in samples tested on BioFire compared to other platforms seemed to start having a heightened gap in 2022 with a much larger gap in 2023.



What does the wastewater show?

- On the graph, the yellow and gray indicate wastewater concentration of GI and GII positives in Wisconsin
- The red line indicates BioFire positivity rate and the black line indicates positivity rate of samples tested on other platforms.
- The wastewater data suggests that even in times where there is lower prevalence in the community, BioFire positives stayed relatively elevated. It also shows that BioFire positivity remained at a higher level than other testing platforms.



- **Red- BioFire PCR Positivity Rate**
- **Black- Other platform Positivity Rate**

BioMeriux announcement and WSLH data since

January 26th, 2024 BioFire released their recall due to increased risk of false positives

IMPORTANT:

URGENT: MEDICAL DEVICE RECALL

BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel – Ref. Number: RFIT-ASY-0116 & RFIT-ASY-0104

FSCA 5812 – Increased Risk of False Positive Norovirus Results with the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel

January 26, 2024

To the attention of the Laboratory Director

bioMérieux Reference: FSCA 5812

Table 1 - Affected Product

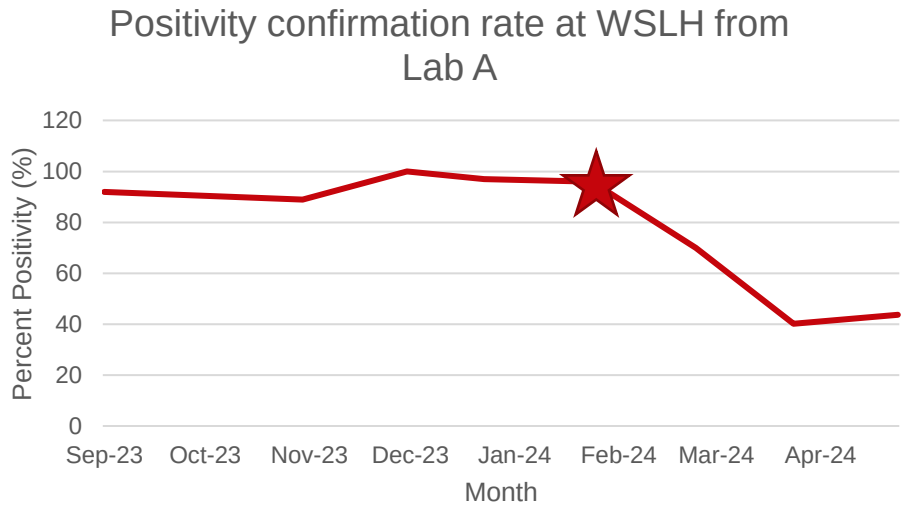
Product Name	Reference #	Kit Lot #	Expiration Date
BIOFIRE GI Panel	RFIT-ASY-0116 (30-pack) RFIT-ASY-0104 (6-pack)	N/A – All lot numbers	N/A – All unexpired product

Dear bioMérieux Customer,

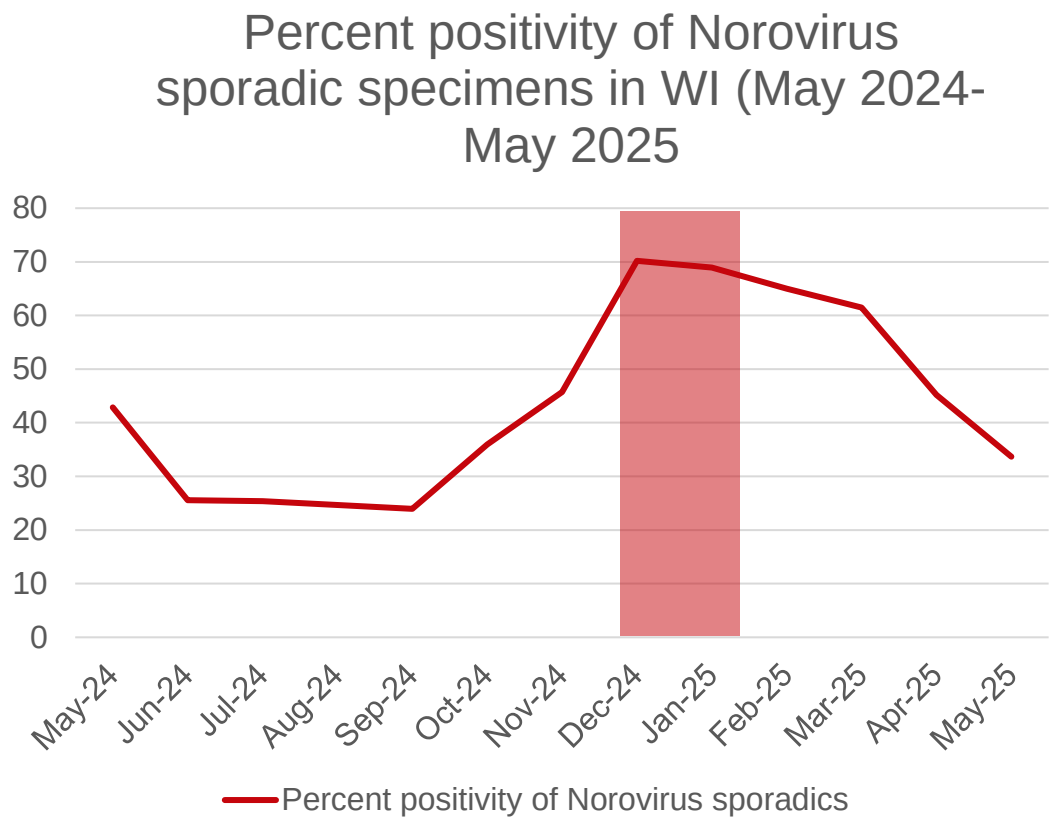
The purpose of this letter is to inform you of a product recall (correction) involving the **BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel** (part number: **RFIT-ASY-0116** and **RFIT-ASY-0104**). bioMérieux has identified a potential signal of increased false positive Norovirus results when using the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel. **All unexpired product is potentially impacted.**

What happened in WI after the recall?

- Due to cost, Lab A stopped confirming their positive samples with Cepheid when the recall was issued.
- Their confirmed rate at WSLH dramatically decreased when they started to submit to us samples that have only been tested on BioFire.



Current WSLH Biofire Data



- Percent confirmation still seems reduced for norovirus specimens
- The highest confirmation rate for sporadic norovirus specimens was during peak season, when norovirus prevalence was high in the community.
- For the month of May 2025, only about 1/3 of samples received confirmed positive at WSLH

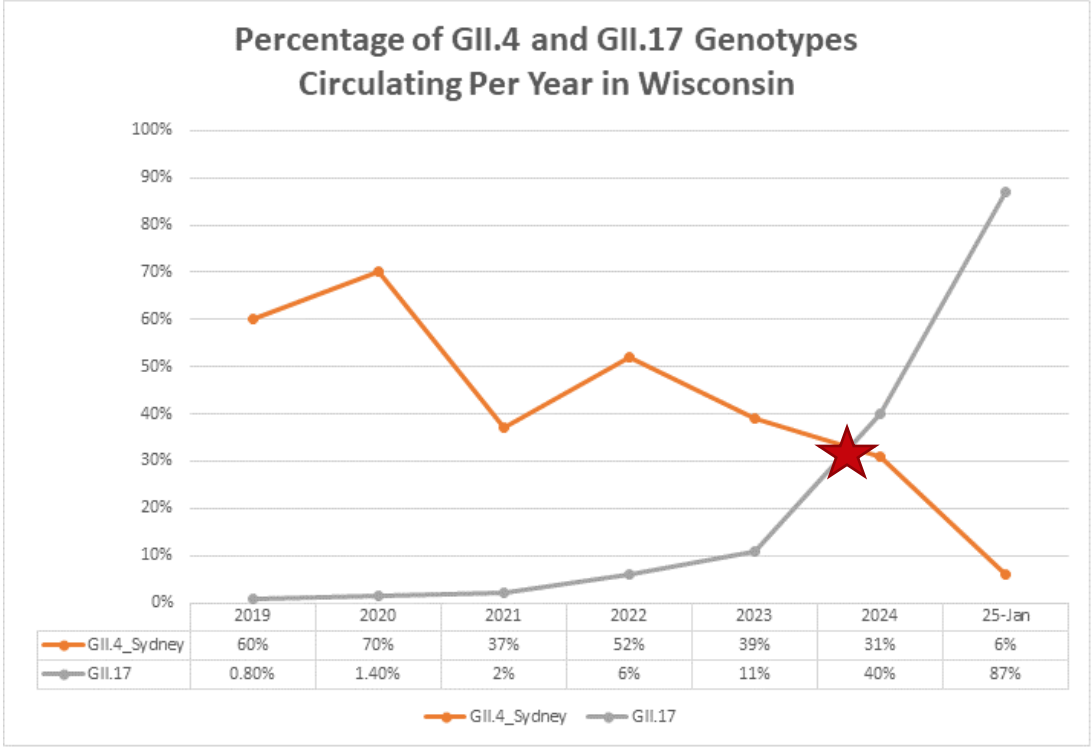
Takeaways from WSLH BioFire data

- We started seeing decrease in confirmation at WSLH on BioFire positive samples late 2021
- WSLH is continuing to see decreased confirmation of norovirus sporadic specimens run on the Biofire
- Biofire positivity does seem to have a better confirmation rate when norovirus prevalence is high in the community but remains at a higher positivity rate than other testing platforms and than wastewater data during the off-season (low prevalence).

Norovirus GII.17[P17] takeover

Norovirus GII.17[P17] – a new dominant strain

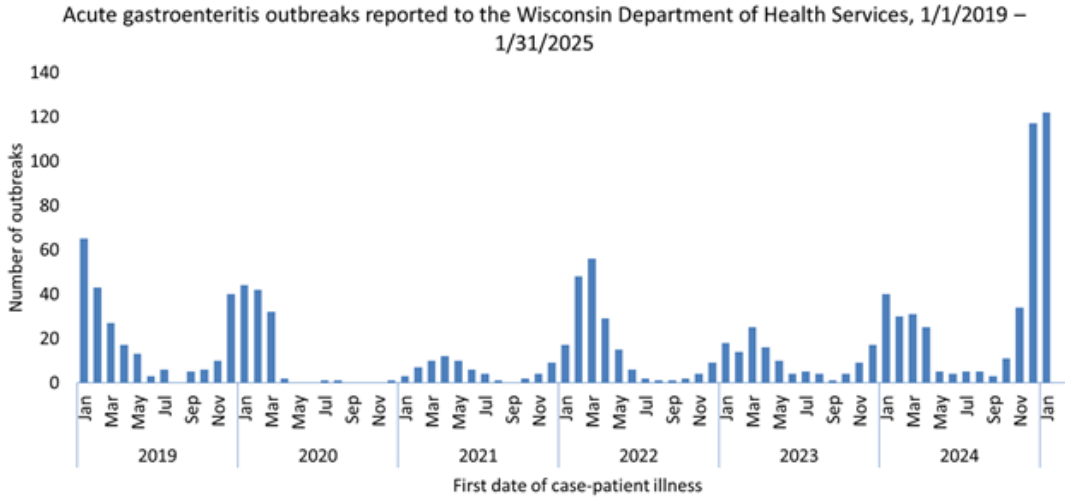
- According to CDC, Norovirus GII.17 outbreaks in the United States increased from <10% during the 2022-23 to 75% of outbreaks during the 2024-25 season.
- In WI, our data supports national data with GII.17 genotypes becoming more prominent than GII.4 strains, which had been dominant for about a decade.

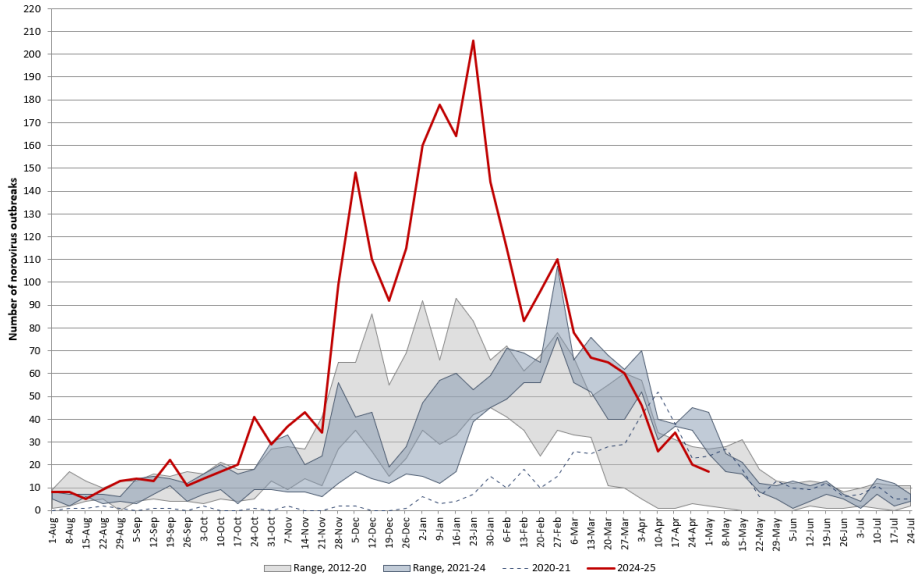


	2019	2020	2021	2022	2023	2024	25-Jan
GII.4_Sydney	60%	70%	37%	52%	39%	31%	6%
GII.17	0.80%	1.40%	2%	6%	11%	40%	87%

New strain leads to a robust Norovirus Season

- With the change in dominant strain, we saw a more robust norovirus season
- In WI, reported acute gastroenteritis outbreaks were about three-fold higher than the same time frames the previous years
- Nationally, from August 2024- May 7th 2025, there were 2,571 norovirus outbreaks reported by NoroSTAT-participating states. During the same period of the 2023-2024 season, there were 1,358 norovirus outbreaks reported.
- The graph to the right shows the national levels of norovirus outbreaks since 2012. The red line indicating the most recent season.





Acknowledgements

- I would like to thank:
  - The submitting laboratories in Wisconsin. We would not have our robust data if we did not receive as many sporadic norovirus samples as they send us.
  - Wisconsin Department of Public Health
  - CDC- CaliciNet and Norovirus group
  - WSLH- EHD Wastewater team. Thanks to Adelaide Roguet and Devin Everett for the dPCR data.
  - Dr. Al Bateman, Wisconsin State Laboratory of Hygiene - Communicable Disease Director
  - Dr. Matthew Martin, APHL LLS Fellow. Thank you Matt for data management of Wisconsin Norovirus testing platforms and their percent positivity.
  - WSLH Specimen Receiving, Data Entry, and Virology staff
  - Tim Davis, Microbiologist III, Wisconsin State Laboratory of Hygiene