

MLS Laboratory Update: BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Recall due to Increased Risk of False Positive Norovirus results

January 31st, 2024

Purpose of this Message:

To inform clinical laboratories of a recall issued by bioMerieux on 1/29/2024 regarding an elevated incidence of false positive Norovirus results from BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel.

Action Item:

- Please review the recall notice (FSCA 5812) for the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel.
- In cases where a positive Norovirus result appears inconsistent with clinical presentation, please refer the specimen to your send out reference lab for confirmation using alternative detection methods.
- If the confirmation result is discrepant from initial result using the BioFire, report the findings directly to bioMerieux technical support team at biofiresupport@biomerieux.com or via telephone by dialing 1-800-735-6544 and selecting option 5 for Product Technical Support.

Background:

Norovirus is the leading causes of vomiting and diarrhea from acute gastroenteritis with most Norovirus outbreaks in the US occurring in November to April. The CDC, along with other state Public Health Laboratories (PHL) including MDH PHL, have expressed concerns regarding an unusual surge in Norovirus positivity detected by the BIOFIRE®, coupled with a low concordance rate observed with alternative detection methods.

On 1/29/24 bioMerieux released a recall notice for the BIOFIRE® FILMARRAY® GI Panel, necessitating appropriate follow-up actions.

Additional Information:

- Norovirus is NOT a reportable disease under the Minnesota Reportable Disease Rule. Laboratories are not required to send specimens to MDH PHL.

- According to bioMerieux, there is no indication of cross-reactivity with the remaining organisms on the GI panel that would result in a false positive at this time.

Questions: Please contact: Jisun Haan, Ph.D, jisun.haan@state.mn.us, 651-201-5041

Thank you for your attention to this matter.

Jisun Haan, Ph.D
Enterics Unit Supervisor
Public Health Laboratory, Minnesota Department of Health
Phone: 651-201-5041
jisun.haan@state.mn.us

THIS IS AN UPDATE FROM THE MINNESOTA DEPARTMENT OF HEALTH – PUBLIC HEALTH LABORATORY (MDH-PHL) AND THE MINNESOTA LABORATORY SYSTEM (MLS). THIS MESSAGE IS BEING SENT TO MLS LABORATORY CONTACTS SERVING MINNESOTA RESIDENTS. YOU ARE NOT REQUIRED TO REPLY TO THIS MESSAGE.

PLEASE FORWARD THIS TO ALL APPROPRIATE PERSONNEL WITHIN YOUR INSTITUTION AND HEALTH SYSTEM

THE CONTENT OF THIS MESSAGE IS INTENDED FOR PUBLIC HEALTH AND HEALTH CARE PERSONNEL AND RESPONSE PARTNERS WHO HAVE A NEED TO KNOW THE INFORMATION TO PERFORM THEIR DUTIES. IT IS FOR OFFICIAL USE ONLY. DO NOT DISTRIBUTE BEYOND THE INTENDED RECIPIENT GROUPS AS DESCRIBED IN THIS MESSAGE.

Minnesota Laboratory System
Minnesota Department of Health, Public Health Laboratory
601 Robert St. N, St. Paul, MN 55164-0899
651-201-5200
health.mnlabsystem@state.mn.us
www.health.state.mn.us/diseases/idlab/mls/index.html

To obtain this information in a different format, call: 651-201-5200.