PACIFIC DIAGNOSTIC LABORATORIES Guiding Health™

Gastrointestinal (GI) Panel by PCR LAB8729:

- **Medical Device Recall FILMARRAY BIOFIRE Norovirus**
- **CMS Local Coverage Limitations**

March 27, 2024

This notification is to inform you of a medical device recall for the GI Panel by PCR (LAB8729) test as well as provide information on the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) for this test.

Medical Device Recall	Increased Risk of False Positive Norovirus Results with the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel.
Reimbursement Restrictions	CMS Local Coverage Determinations (LCD) ARTICLE ID: A58720 • *Authorizing/ordering provider specialty guidelines* • *Patient immune status guidelines* • *ICD10 Codes from BOTH Group 2 and Group 7 required*

MEDICAL DEVICE RECALL - INCREASED RISK OF FALSE POSITIVE NOROVIRUS RESULTS

If Norovirus is detected, the following comment is applied to the result:

"The test vendor has identified a potential increased false positive Norovirus on the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel. If a positive Norovirus result is inconsistent with clinical presentation, the positive Norovirus result should be confirmed using another method. Please contact the laboratory."

MEDICARE BILLING & CODING - CMS LOCAL COVERAGE DETERMINATION ARTICLE A58720

The following is information from the CMS Article A58720 on the place of service, ordering provider, patient immune status, and ICD10 coding needed when ordering the GI Panel by PCR. Please note, this is only part of the full text provided in the CMS Article A58720.

For Expanded (>5 pathogens) GI Panels the following additional conditions apply:

1. Testing is billed according to 1 of the following:
   (a) Places of service (POS) 19 (Off Campus – Outpatient Hospital), 21 (Inpatient Hospital), 22 (On Campus – Outpatient Hospital), 23 (Emergency Room – Hospital), OR
   (b) The test is ordered as follows (for healthcare POS other than the POS listed in 1(a)):
   (1) **For immune-competent beneficiaries**, the test must be ordered by an Infectious Disease Specialist or 1 of the following: Pulmonologist (for the RP and PNP panels) or Gastroenterologist (for the GI panels) who is diagnosing and treating the beneficiary.
   (2) **For immune-compromised beneficiaries**, the test must be ordered by a clinician specialist in 1 of the following: Infectious Diseases, Oncology, Transplant (for any panel), Pulmonologist (for the RP and PNP panels), or Gastroenterologist (for the GI panels) who is diagnosing and treating the beneficiary.
   (3) Regarding (1) and (2), An exception may be made in geographic locations where the specialist(s) cannot be reasonably reached by the beneficiary, and the ordering provider is located closer to the beneficiary's place of

PACIFIC DIAGNOSTIC LABORATORIES Guiding Health™

Gastrointestinal (GI) Panel by PCR LAB8729

▪ CMS Local Coverage Limitations (continued)

residence than the nearest specialist. We would generally expect that beneficiaries for whom the test is ordered under this exception to be living in rural locations, islands, or some other location where access to care is limited.

(4) **An ICD-10 diagnosis code from Group 7* must be on the claim, *in addition to* the sign or symptom (from Group 2* for which there is suspicion of gastrointestinal illness in order to bill for the GI panels.** See the specific instructions in Group 7*****. The exception to this is testing that is performed as part of a pre-transplant evaluation of an immune-compromised beneficiary, regardless of the presence of symptoms. In such cases, clear documentation of the pre-transplant evaluation must accompany the claim.

*****ICD10 Code listings for Group 7 and Group 2 including specific instructions for Group 7 are available on the CMS Article website: Article - Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (A58720) (cms.gov)

ICD10 CODING/DIAGNOSIS CODING REMINDER: The ordering provider is solely responsibility for assigning diagnosis (codes). PDL does not – through this information or otherwise – recommend any diagnosis codes. PDL will submit to Medicare only the diagnosis (codes) provided to PDL by the ordering provider and/or his/her authorized staff.

TECHNICAL CONTACT: Weiliang (William) Xie Ph.D., MLS(ASCP)MB
PDL Microbiology Technical Specialist
Phone: 805-879-8100 Email: wxie@sbch.org

GI PANEL BY PCR (LAB8729)		
MEDICAL NECESSITY CODING ALERT: LOCAL COVERAGE DETERMINATION (LCD) ARTICLE A58720		
PANEL INCLUDES:	BACTERIA • *Campylobacter (C. jejuni/C. coli/*C. *upsaliensis*) • *Plesiomonas shigelloides** • *Salmonella** • *Yersinia enterocolitica** • *Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae)** • *Vibrio cholerae** VIRUSES • Adenovirus F40/41 • Astrovirus • Norovirus GI/GII • Rotavirus A • Sapovirus (I, II, IV, and V)	DIARRHEAGENIC E. COLI/SHIGELLA • *Enteroaggregative E. coli* (EAEC) • *Enteropathogenic E. coli* (EPEC) • *Enterotoxigenic E. coli* (ETEC) *lt/st* • *Shiga-like toxin-producing E. coli* (STEC) *stx1/stx2** • *E. coli O157** • *Shigella/Enteroinvasive E. coli* (EIEC)* PARASITES • *Cryptosporidium* • *Cyclospora cayetanensis* • *Entamoeba histolytica* • *Giardia lamblia*
REFLEX TESTS **Reflex confirmation testing required; additional charges will apply.*	**If DETECTED:**	**CONFIRMATION TEST REFLEXED:**
	Plesiomonas shigelloides	Stool culture
	Salmonella	Stool culture if isolated send to Public Health
	Shigella/Enteroinvasive E. coli (EIEC)	Stool culture
	Shiga-like E. coli (STEC) *stx1/stx2*	Send to Public Health
	Shiga-like E. coli (STEC) *stx1/stx2* and *E. coli 0157*	Send to Public Health
	Vibrio cholerae detected another *Vibrio sp.*, not *V. cholera*, may also be present	*Vibrio* culture
	Vibrio species (not *V. cholerae*)	*Vibrio* culture
	Yersinia enterocolitica	*Yersinia* culture