



Alliance for Women's  
Health & Prevention

May 9, 2024

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee  
Center for Devices and Radiological Health  
Food and Drug Administration  
10903 New Hampshire Avenue, Building 66, Room 5214  
Silver Spring, MD 20993-0002

Docket No. FDA-2024-N-0008 - May 23<sup>rd</sup>, 2024 - Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee

Dear Esteemed Members of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee:

As an organization focused on women's preventive health, the Alliance for Women's Health and Prevention (AWHP) is deeply committed to both the prevention and early detection of cancer. **As such, we urge you to consider the potential positive health impacts of blood-based screenings for colorectal cancer as you consider approval for this innovative screening method.**

Colorectal cancer is the [second leading cause of cancer-related death](#) in the United States. In a worrying trend, colorectal cancer is [on the rise in younger adults](#), with 20% of diagnoses in 2019 in patients under 55, about double the number in 1995. Luckily, colorectal cancer can be both prevented and detected early through screening methods, namely colonoscopies and at-home fecal tests.

Regardless of these established and effective screening options, however, [1 in 3 American adults](#) are not being screened for colorectal cancer as recommended — and [75% of people](#) who die from colorectal cancer are not up to date with recommended screening. These low rates are largely due to these screening methods, given that both colonoscopies and at-home fecal tests may be unpleasant, time-consuming, or invasive.

**A blood-based screening test has the potential to fill a crucial gap in screening for colorectal cancer.** Blood-based tests could be conducted in tandem with routine bloodwork at general annual physicals or well visits, making them a convenient and easy way to increase screening for this deadly disease. An increase in screening in turn has the potential to reduce health disparities, given that Black Americans are [20% more likely](#) to get colorectal cancer and [40% more likely](#) to die from the disease.

Ultimately, blood-based screening can help achieve a singular, crucial goal: reducing deaths due to colorectal cancer. The impact of this fact cannot be understated. Given our focus on early detection, **AWHP believes that blood-based screening would bring tremendous value to the fight against colorectal cancer.** We urge your panel to leverage its position to help save lives due to a type of cancer that continues to affect far too many Americans.

Respectfully,

Millicent Gorham  
CEO, Alliance for Women's Health and Prevention