## Multi-modal blood-based colorectal cancer screening is a viable colorectal cancer screening option – a prospective study

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### **Disclosures**

Paloma Peinado

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# Background



- Despite the availability of multiple colorectal cancer (CRC) screening options, about one-third of individuals are not up to date with CRC screening<sup>1,2</sup>
  - Screening adherence rates have remained below ٠ the 80% target set forth by leading health care organizations
- A blood-based CRC screening test with optimized sensitivity and specificity may improve screening adherenće<sup>3</sup>



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# **Background: Blood-based CRC screening test**



- The blood-based test integrates genomics and epigenomics yielding high sensitivity and specificity for CRC detection
- Multi-modal analyses integrated to yield a final "abnormal" or "normal" result<sup>2</sup>

- Retrospective studies of a multimodal bloodbased test in individuals with early-stage CRC have yielded promising results:
  - In a previously reported case-cohort study, this blood-based test demonstrated 91% CRC sensitivity at 94% specificity<sup>1</sup>
- However, no prospective studies in screened populations have been completed
- We aimed to evaluate the performance of this blood-based colorectal neoplasia test in a prospective study of individuals presenting for colonoscopy



1. Kim, et al (2021). Journal of Clinical Oncology 39, no. 15\_suppl (May 20, 2021) 3536-3536.2. Guardant Health, Redwood City, California; Bloodbasedscreening.com

# Methods: Clinical Cohort

Age 45 – 84 years

Undergoing colonoscopy

#### Exclusion:

- History of any malignancy, including CRC
- Colonoscopy in last 9 years
- Known Hereditary Predisposition to CRC



 Real world, prospective, observational study of adults undergoing colonoscopy at one of four hospitals in Spain

- Enrollment target: n = 600 individuals
- <u>Colonoscopy results</u> categorized based on most advanced finding:
  - Colorectal Cancer
  - Advanced Adenoma
  - Non-advanced adenoma/negative colonoscopy
  - Not evaluable

Whole blood sample collected prior to colonoscopy

- <u>Primary analysis</u>: Correlate blood-based test results with colonoscopy findings:
  - Colorectal cancer
  - Non-advanced adenoma/negative



# **Cohort Demographics**

At the time of analysis, 93% (n=557) of individuals had a complete colonoscopy and a blood sample analyzed



Indication for Colonoscopy

Other

MAY 21-24 | SAN DIEGO, CA

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**Positive Family** 

History

#### @DDWMeeting | #DDW2022

AA: advanced adenoma; FIT: fecal immunohistochemical test; FOBT: fecal occult blood test

# **Results: Sensitivity and Specificity**

#### At 90% Specificity, CRC sensitivity was 100%

![](_page_6_Figure_2.jpeg)

- No differences in sensitivity or specificity based on the indication for colonoscopy.
- Specificity did not differ when restricting the analysis to only those with negative colonoscopy (excluding the non-advanced adenoma).

![](_page_6_Picture_5.jpeg)

## **Results: Sensitivity and Specificity**

#### At 90% Specificity, CRC sensitivity was 100%

![](_page_7_Figure_2.jpeg)

#### At 95% Specificity, CRC sensitivity was 88%

![](_page_7_Figure_4.jpeg)

# **Strengths and Limitations**

### Strengths:

- Prospective study conducted at multiple institutions
- "All-comers" population
- First prospective evaluation of this blood-based test in individuals undergoing colonoscopy

### Limitations:

- Given this is a real-world analysis, referral patterns were based on national guidance in Spain, leading to a higher proportion of individuals presenting with "symptomatic" disease
- Few cases limit ability for subgroup analyses

![](_page_8_Picture_8.jpeg)

# **Conclusions:**

- In this real-world, prospective study of individuals eligible for colonoscopy, sensitivity and specificity of the multi-modal bloodbased test reaches thresholds consistent with available stool-based screening options.
- Analysis of the full cohort is ongoing, as is one-year clinical follow-up.
- The reported performance, combined with a more acceptable mode of testing suggests that **this multi-modal blood-based test may be a viable CRC screening option.**
- An updated version of this multi-modal test has been validated for clinical use and is undergoing further clinical validation (ECLIPSE; NCT04136002).

![](_page_9_Picture_5.jpeg)

## Acknowledgements

![](_page_10_Picture_1.jpeg)

- Healthy individuals undergoing CRC screening who consented to this research
- Study teams at HM Hospitales
- Collaborators at Guardant Health

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![](_page_10_Picture_6.jpeg)