Provider Education

Occult blood testing and DRE specimens

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This document provides education to providers on the limitations and appropriate use of fecal occult blood testing (FOBT). Specifically, it addresses specimens collected via digital rectal examination (DRE).

Digital rectal exam specimens not appropriate for occult blood testing:

- **High risk of false positives**: DRE frequently causes rectal mucosal trauma or minor bleeding during the exam, which can result in misleading positive results unrelated to GI pathology. False positive results can lead to **unnecessary follow-up** such as colonoscopy.
- **DRE collection is not validated for fecal occult blood testing:** Occult blood testing is only validated and CLIA-waived for spontaneously passed stool specimens. Use of samples obtained during a digital rectal exam (DRE) falls outside the intended use of the assay and compromises result accuracy.

Best practices and guidelines:

- FOBT (guaiac or FIT) is only validated for **spontaneously passed stool**, not for DRE-obtained samples.
- **Several published studies** found significantly higher false-positive FOBT rates when DRE stool was used versus spontaneously passed stool.
- **American College of Gastroenterology (ACG)** and **US Multi-Society Task Force on Colorectal Cancer** both discourage the use of DRE for occult blood screening.
- **CLSI guidelines** specify that proper stool collection is critical for test accuracy.

Key takeaways for providers:

- Only submit a stool that the patient has passed naturally. **Not** a DRE collected specimen.
- Using DRE for FOBT increases risk of false positives and unnecessary procedures.
- If a stool cannot be collected during the visit, supply a home collection kit and have the patient return the specimen.
- For FOBT **cards distributed to ERs and other units**. Do **NOT** apply a DRE-derived sample directly to the card and return it for development. The lab has no metadata about the sampling method, the true source is unknown, yet DRE-derived cards often enter testing.
- FOBT is a screening tool and not diagnostic. Results should be interpreted within clinical context.

By standardizing this approach across the system, we can improve test accuracy, reduce provider confusion, and minimize unnecessary procedures driven by false-positive results. This will also support consistency in messaging to providers across all EDs and affiliate sites.

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References:

1. **US Multi-Society Task Force (ASGE/ACG/AGA) consensus on FOBT (2017)**: Explicitly **recommends against using in-office DRE stool** for fecal tests; advises using **spontaneously passed stool** only, with the rationale and data summarized.
2. **Annals of Internal Medicine (Collins JF, Lieberman DA, et al., 2005)**: **single DRE-obtained FOBT** is a **poor screening method**; negative results don't lower odds of advanced neoplasia; home multi-sample testing or other screening is required.
3. **CMS eCQM (CMS130 v13, 2025)**: quality measure guidance: **"Do not count" FOBTs performed in an office setting or on a **DRE-collected** sample for CRC screening.
4. **American Cancer Society (2025, patient-facing guidance)**: an **FOBT done during a DRE is not adequate** for proper screening; testing should be done at home on stool samples.
5. **US Multi-society task force FIT paper (detail within)**: notes **higher positivity and lower PPV** when using DRE-obtained samples vs passed stool; concludes programs should **not rely on DRE samples**.