

Welcome.

COLON CANCER **SCREENING**

made easy

[c] **cologuard®**
Rx only

INDICATIONS FOR USE

Cologuard® is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.

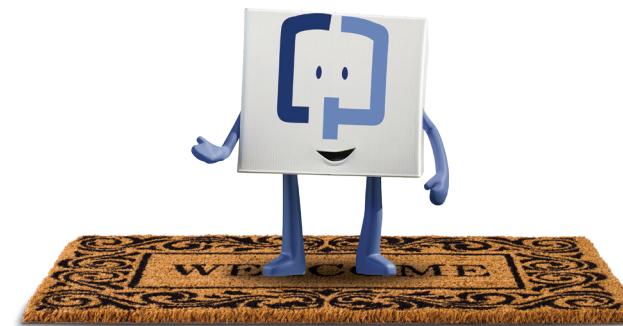
CONTRAINDICATIONS

Cologuard is intended for use with patients, age 45 years and older, at average risk who are typical candidates for CRC screening. Cologuard was not clinically evaluated for the following types of patients:

- Patients with a history of colorectal cancer, adenomas, or other related cancers.
- Patients who have had a positive result from another colorectal cancer screening method within the last 6 months.
- Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:
 - Inflammatory Bowel Disease (IBD)
 - Chronic ulcerative colitis (CUC)
 - Crohn's disease
 - Familial adenomatous polyposis (FAP)
 - Family history of colorectal cancer
- Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary nonpolyposis colorectal cancer syndrome (HNPCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis.

WARNINGS AND PRECAUTIONS

- The performance of Cologuard has been established in a cross sectional study (i.e., single point in time). Programmatic performance of Cologuard (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Performance has not been evaluated in adults who have been previously tested with Cologuard. Non-inferiority or superiority of Cologuard programmatic sensitivity as compared to other recommended screening methods for CRC and AA has not been established.
- The clinical validation studies were conducted in patients over 50 years of age. ACS Guidelines recommend screening begin at age 45. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.
- CRC screening guideline recommendations vary for persons over the age of 75. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with a healthcare provider. Cologuard test results should be interpreted with caution in older patients as the rate of false positive results increases with age.
- A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program with another recommended screening method. The screening interval for this follow-up has not been established.
- Cologuard may produce false negative or false positive results. A false positive result occurs when Cologuard produces a positive result, even though a colonoscopy will not find cancer or precancerous polyps. A false negative result occurs when Cologuard does not detect a precancerous polyp or colorectal cancer even when a colonoscopy identifies the positive result.
- Patients should not provide a sample for Cologuard if they have diarrhea or if they have blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstruation).
- To ensure the integrity of the sample, the laboratory must receive the patient specimens within 72 hours of collection. Patients should send stool samples to the laboratory according to the instructions stated in the Cologuard Patient Guide.
- Patients should be advised of the caution listed in the Cologuard Patient Guide. Patients should NOT drink the preservative liquid.
- The risks related to using the Cologuard Collection Kit are low, with no serious adverse events reported among people in a clinical trial. Patients should be careful when opening and closing the lids to avoid the risk of hand strain.



LET'S GET STARTED

Thank you for choosing Cologuard® to get screened for colorectal cancer. Use this guide to learn:

- How it's as easy as **GET. GO. GONE.**
- About your results
- About insurance

NEED ASSISTANCE?

Call our Customer Care Center at **1-844-870-8870** or watch the how-to-use video at CologuardTest.com/use.



GET

Good news! Cologuard is almost on its way.

Once your healthcare provider sends us your completed order, we'll ship a Cologuard collection kit directly to you! You'll also get a welcome call to learn more about collecting and returning your sample.

To learn more about what you can expect, visit CologuardTest.com/whatsnext.

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GO



Collecting your sample is easy. Here are a few tips!



No special prep. No need for time off. No changes to your diet or medication.



Collect your sample in the privacy of your home

(your sample should be no larger than the bottle of liquid in the kit). You should not provide a sample if you have diarrhea or blood in your urine or stool (e.g., from bleeding, hemorrhoids, bleeding cuts or wounds on hands, rectal bleeding, or menstruation).



The box you receive is also the box you will send back with your sample. *How neat is that?* The inner bag helps contain leaks, **so please don't remove that part since it's actually glued down.**



Return your sample within 24 hours of collection according to the detailed instructions inside your kit.

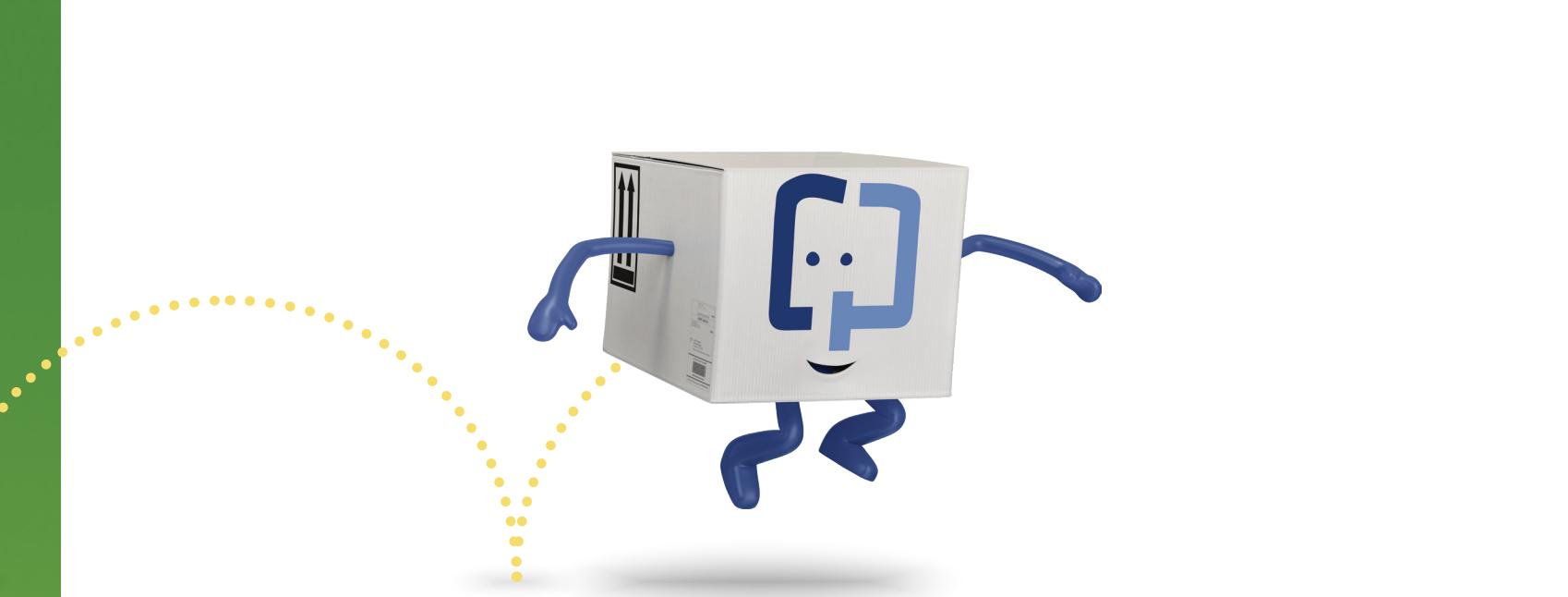
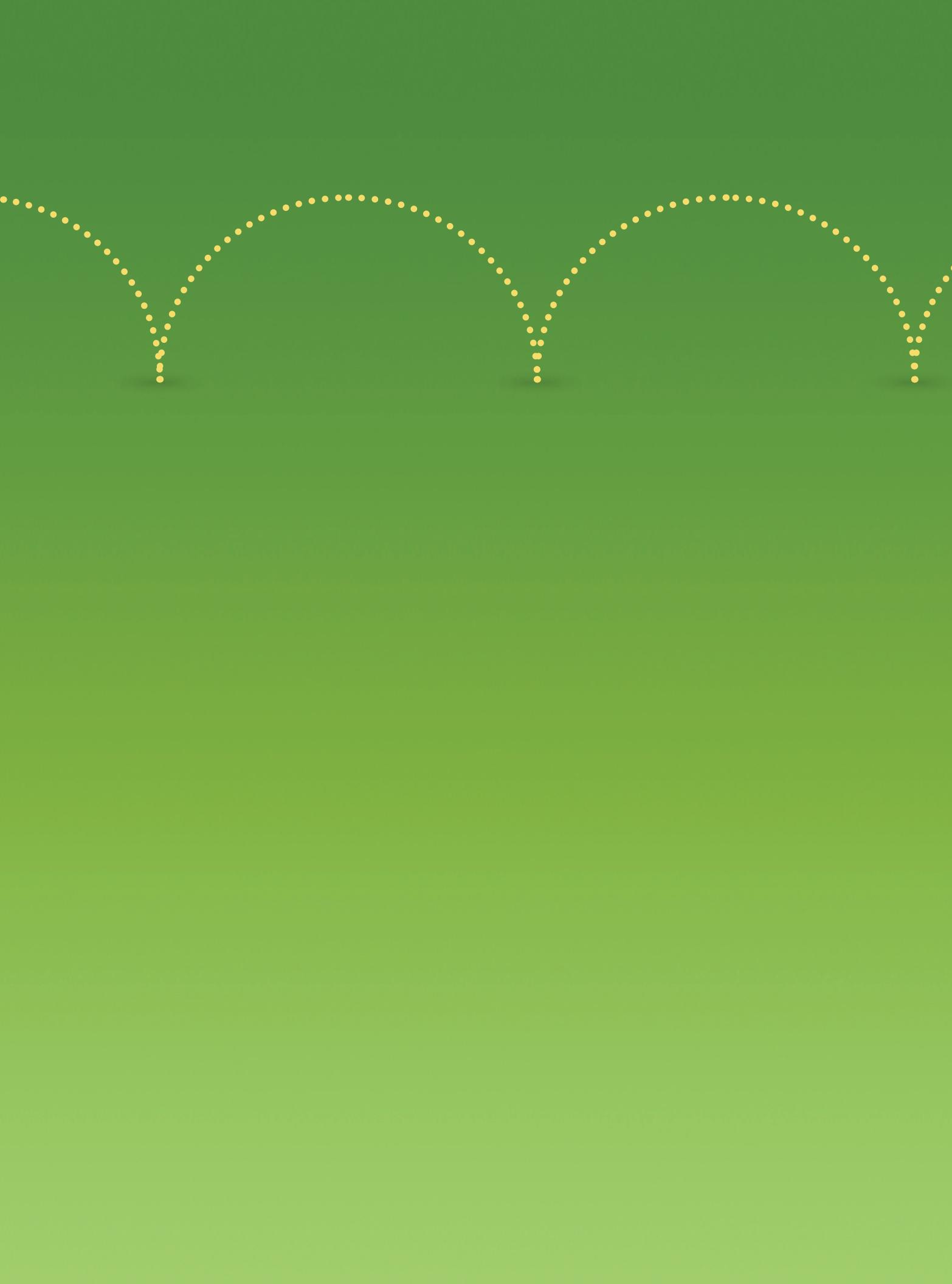
Since weekend mail may be delayed, we recommend you collect and ship your sample sometime between Monday and Thursday.



You'll get a detailed Cologuard® Patient Guide with step-by-step instructions in your kit. If you like how-to-use videos, you're in luck! Visit CologuardTest.com/use.

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GONE

Return me within 24 hours! Follow these simple steps.

1 Fill out your labels

It's very important to write your name exactly as it's written on the shipping label. Be sure to write your DOB, date and time you collect your sample, too. Accurate labeling helps our lab team deliver your result as quickly as possible.

2 Attach your labels

After filling out the labels, firmly attach them to the sample container lid and tube.

3 Ship your sample

Put your labeled sample in the box. The shipping labels are already on the box. You can ship it from any UPS location, or schedule a pickup at cologuardtest.com/pickupmykit or by calling 1-800-PICKUPS. **No shipping payment required!**

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GET TO KNOW YOUR RESULTS

Once we receive your kit, our lab will test your sample right away and have a result typically within two weeks. We'll send the results to your healthcare provider who will follow up and discuss with you shortly after. But for now, here's a quick overview of what to expect.



POSITIVE RESULT

- A positive result means the test detected abnormal DNA and/or blood that could be caused by precancer or cancer in the colon.
- Any positive result should be followed by a colonoscopy.
- False positives do occur. A false positive result occurs when Cologuard produces a positive result, even though a colonoscopy will not find cancer or precancerous polyps.



NEGATIVE RESULT

- A negative result means the test did not detect abnormal DNA and/or blood that could be caused by precancer or cancer in the colon.
- Plan to get screened again at a time that your healthcare provider recommends. The American Cancer Society recommends repeating Cologuard every 3 years following a negative result.
- False negatives do occur. A false negative result occurs when Cologuard does not detect a precancerous polyp or colorectal cancer even when a colonoscopy identifies the positive result.

NEED ASSISTANCE?

Call our Customer Care Center at **1-844-870-8870** or watch the how-to-use video at CologuardTest.com/use.



WE'VE GOT YOU COVERED

Cologuard is covered by Medicare and most major insurers.

Cologuard is covered by Medicare and Medicare Advantage with no co-pay or deductible for eligible patients ages 50-85.

Nationwide, more than 94% of Cologuard patients have no out-of-pocket cost for screening.

- Based on the Affordable Care Act, Cologuard should be covered by most private insurers with no co-pay or deductible for eligible patients (ages 50-75; at average risk for colon cancer; without symptoms).

Currently, ~74% of Cologuard patients 45-49 have no out-of-pocket cost for screening.

- Many national and regional payers have begun paying for CRC screening at 45. Exact Sciences continues to work with payers to expand coverage and access for patients ages 45-49.

Patient Support

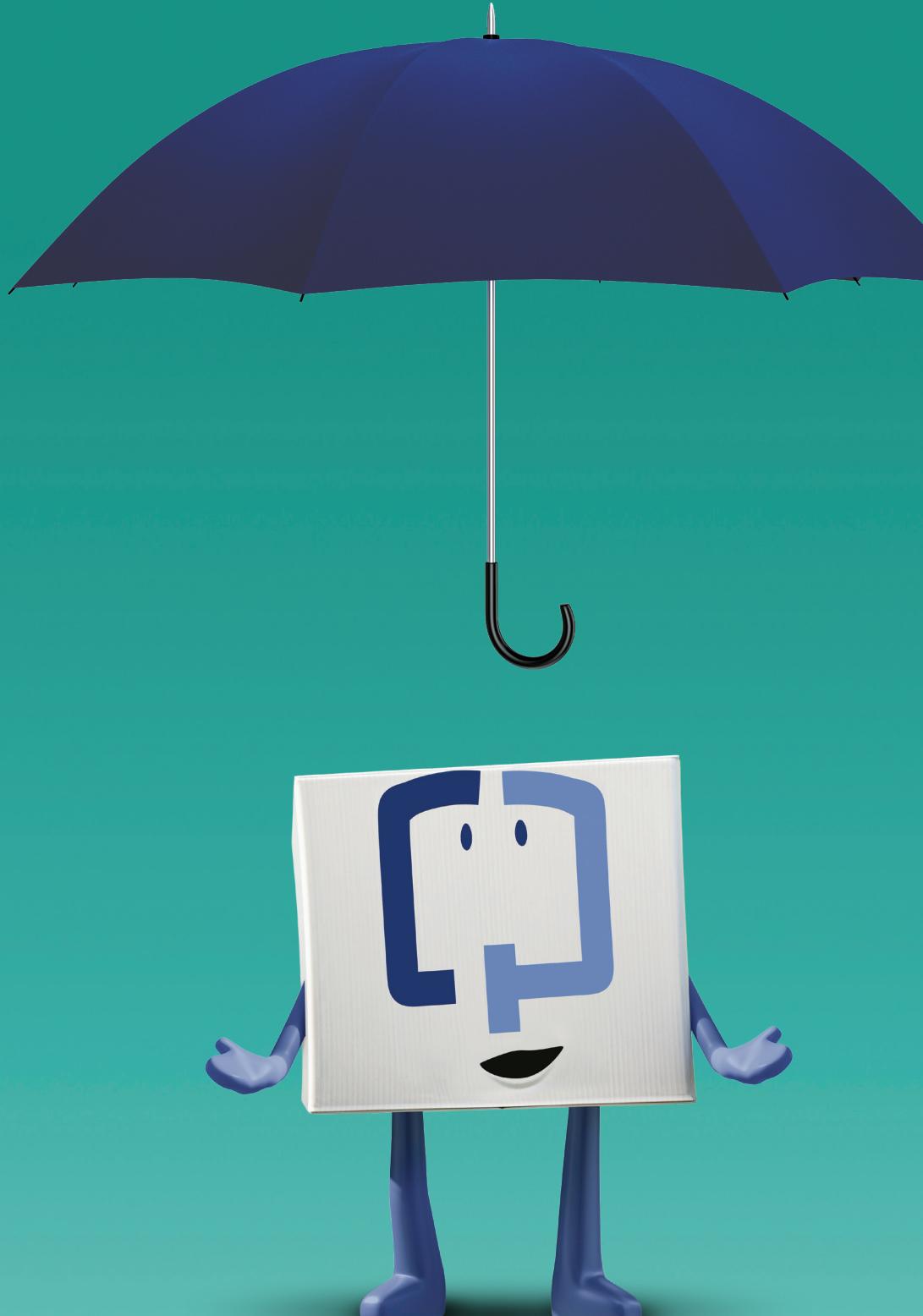
Exceptions for coverage may apply; only your insurer can confirm how Cologuard would be covered for you. Our team of specialists can help you contact your insurer and ask the right questions – please call us at 1-844-870-8870.

Exact Sciences estimate based on historical patient billing as of October 1, 2019. Rate of coverage varies by state and region. Exceptions for coverage may apply, only your insurer can confirm how Cologuard would be covered for you.

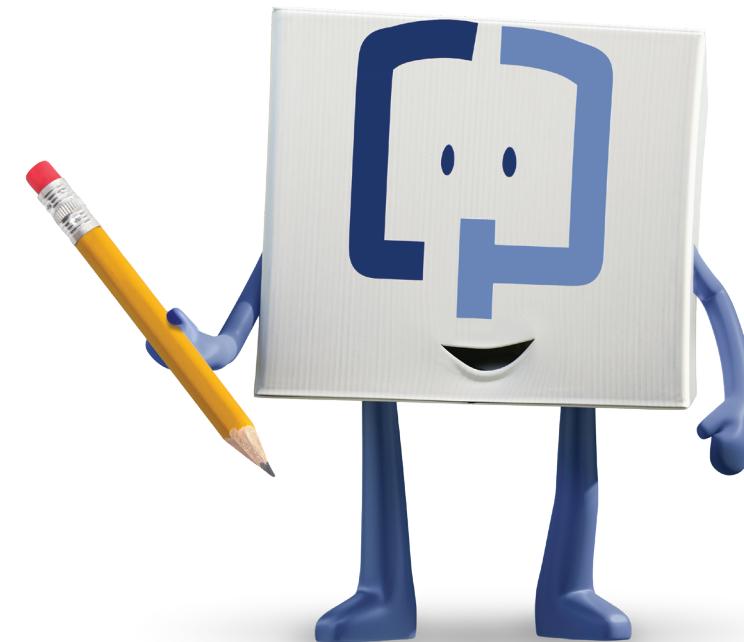
Learn more at CologuardTest.com/insurance.

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A REMINDER TO STAY ON TRACK!

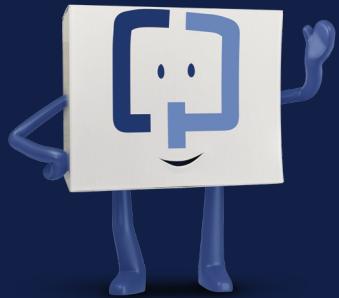


Use this magnet to get your sample out the door within 24 hours of collection by writing down important dates.

NEED ASSISTANCE?

Call our Customer Care Center at **1-844-870-8870** or
watch the how-to-use video at CologuardTest.com/use.

See you soon!



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1-844-870-8870

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For more helpful information, visit CologuardTest.com

 **cologuard**[®]
Rx only

EXACT
SCIENCES