# 3X

The 5-year relative survival rate for common cancers is at least **3X** higher for cancers detected at an early stage than at a late stage.[c]

**SCAN HERE** for more clinician resources about cancer screening and MCED tests, including local community resources that can help increase access to screening.

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[a]The cancer screenings included in this survey were breast, cervical, colorectal, lung, oral, prostate, skin, and testicular cancer; [b]Based on NCI-reported data, the cancer types in which early detection has led to improved patient outcomes include anal, bladder, breast, cervical, colorectal, esophageal, kidney, liver, lung, pancreatic, prostate, skin, stomach, and uterine cancers. Current data suggest that stage of ovarian cancer at diagnosis does not impact mortality rates; [c]Based on colorectal, lung, prostate, and female breast cancers diagnosed from 2011 to 2017 and follow-up of patients through December 31, 2017.

Menon U, et al. *Lancet*. 2021;397(10290):2182–2193; National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) Program. https://seer.cancer.gov/statfacts/html/all.html.

INTEGRITAS COMMUNICATIONS

Montefiore Einstein

# POTENTIAL WORKFLOW FOR MCED TESTING

MCED testing should be used to **complement** recommended screening approaches to identify cancers they do not cover, **NOT** in place of current screening.

1. **Assess Patient Eligibility**
2. **Pretest Counseling** → **Order MCED Test for Interested Patients**
3. **MCED Test Processing**
   - Patient blood sample sent to test manufacturer → Results delivered via portal within 2 weeks of sample receipt by lab
4. **Patient Notification**
   - **A. "NO CANCER SIGNAL DETECTED"** — Patient notified and additional health screenings discussed as needed
   - → **B. "CANCER SIGNAL DETECTED"** — Diagnostic results and next steps discussed with patient

## SUGGESTED INITIAL DIAGNOSTIC STEPS FOLLOWING A "CANCER DETECTED" RESULT[a]

| CANCER SIGNAL ORIGIN PREDICTION | PROPOSED FIRST-LINE PROCEDURES | |
|---|---|---|
| Multiple myeloma | Blood workup including peripheral blood smear, CBC with differential; chemistry tests including creatinine clearance, protein electrophoresis of blood/urine | |
| Upper GI (esophagus, stomach) | Blood Work | Endoscopy |
| Colorectal | | Colonoscopy |
| Head and neck | | Physical exam, fiber optic exam, U/S, CT or MRI with contrast, PET-CT |
| Pancreas, gallbladder | | CT abdomen with IV contrast, MRCP, GI referral |
| Ovary | | CA-125 analysis, abdominal/pelvic exam, U/S (preferred) |
| Lung | | CT chest with or without IV contrast |
| Liver, bile duct | | U/S, CT, GI referral |
| Breast | | Diagnostic mammography with U/S (MRI if mammography screening within last 3 months) |
| Lymphoid neoplasm | | CT (neck, chest, abdomen, pelvis) with IV contrast, PET-CT |
| Indeterminate | | CT (neck, chest, abdomen, pelvis) with IV contrast, PET-CT |

CBC, complete blood count; GI, gastrointestinal; IV, intravenous; MRCP, magnetic resonance cholangiopancreatography; MRI, magnetic resonance imaging; PET-CT, positron emission tomography-CT; U/S, ultrasound.

[a]There currently are no guidelines for follow-up testing after a "cancer signal detected" MCED test result. This is not a comprehensive list of cancer signals returned but includes suggested initial diagnostic steps to consider for many common cancer signals identified. Adapted from: Fearrington FW, et al. *Oral Oncol*. 2024;152:106809; Funston G, et al. *PLoS Med*. 2020;17(10):e1003295; Nadauld LD, et al. *Cancers* (Basel). 2021;13(14):3501.

# CANCER SCREENING
## *A CLINICIAN REFERENCE GUIDE*

**40%** of Americans will be diagnosed with cancer in their **LIFETIME**.

**2M+** **MORE THAN 2 MILLION** new cases of cancer will be diagnosed this year.

**70%** of Americans are **NOT UP TO DATE** on at least 1 routine cancer screening.[a]

## EARLY CANCER DETECTION MAY LEAD TO BETTER OUTCOMES[b]

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# DID YOU KNOW?

ONLY **25%** of cancers are detected by a screening test.

## WHAT IS A MULTI-CANCER EARLY DETECTION (MCED) TEST?

- An MCED test is a simple blood test that can detect from 2 to at least 50 different types of cancer, depending on the test
- The MCED tests that are currently available and in late-stage development analyze cell-free DNA (cfDNA) that is shed by tumors
- MCED tests can identify cancer and its tissue of origin by analyzing methylation patterns of cfDNA
- MCED testing has the potential to reduce or increase screening disparities
- Only 1 MCED test, Galleri, is currently available but it is not FDA approved

**ADDING AN MCED TEST TO ROUTINE SCREENING HAS THE POTENTIAL TO FIND 3X AS MANY CANCERS AS ROUTINE SCREENING ALONE.**

## USPSTF RECOMMENDATIONS FOR SCREENING ASYMPTOMATIC PATIENTS

| CANCER | PROPOSED FIRST-LINE PROCEDURES | CRITERIA | YEAR PUBLISHED |
|---|---|---|---|
| Breast | Biennial screening mammography | Women aged 40-74 years | 2024 |
| Cervical | Cervical cytology every 3 years | Women aged 21-29 years | 2018; update in progress |
| | Cervical cytology every 3 years **OR** hrHPV every 5 years **OR** hrHPV + cervical cytology every 5 years | Women aged 30-65 years | |
| Colorectal | • Stool-based testing<br>» Annual FIT or high-sensitivity guaiac-based testing<br>» sDNA-FIT every 1-3 years<br>• Colonoscopy every 10 years<br>• CT colonography every 5 years<br>• Flexible sigmoidoscopy<br>» Every 5 years<br>» Every 10 years + annual FIT | • All aged 45-75 years<br>• Certain populations aged 76-85 years | 2021 |
| Lung | Annual LDCT | All aged 50-80 years with ≥20 pack year history of smoking and currently smoke or quit within the past 15 years | 2021 |
| Prostate | PSA testing | Men aged 55-69 years when elected with shared decision-making | 2018; update in progress |

CT, computed tomography; FIT, fecal immunochemical test; hrHPV, high-risk human papillomavirus; LDCT, low-dose CT; PSA, prostate-specific antigen; sDNA-FIT, stool DNA test with FIT; USPSTF, United States Preventive Services Task Force.

## ELIGIBILITY FOR MCED SCREENING

### WHO IS ELIGIBLE

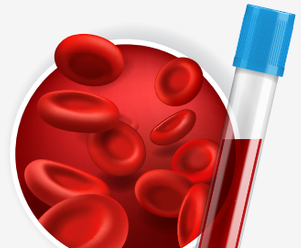
- Age ≥50 years
- Family or personal history of cancer
- Known genetic mutations

### WHO IS NOT ELIGIBLE

- Pediatric populations (<21 years)
- Pregnant patients
- Patients with active cancer diagnosis or treated for cancer in last 3 years

### FACTORS THAT INCREASE CANCER RISK

- Alcohol use
- Tobacco use
- Exposure to cancer-causing substances (eg, fire smoke, tobacco smoke, radiation, sunlight)
- Immunosuppression
- Infectious agents (eg, viruses, parasites)
- Overweight/obesity



## CRITERIA TO EVALUATE CANCER SCREENING TESTS

| CRITERIA | WHY IMPORTANT |
|---|---|
| High Specificity | To minimize false-positives and thereby reduce unnecessary workup, overdiagnosis, and overtreatment |
| High Sensitivity | To detect early tumors that may be curable by surgery |
| High Positive Predictive Value (PPV) | To reduce unnecessary workup, overdiagnosis, and overtreatment |
| High Negative Predictive Value (NPV) | To reduce the probability of missing potentially curable tumors |
| Ability to Localize Site of Tumor | To focus follow-on diagnostic interventions and minimize testing (eg, imaging) to localize the cancer signal origin (CSO) |

| HOW DO MCED TESTS COMPARE? | |
|---|---|
| PPV | Low-dose CT: 3.8% |
| | Mammography: 4.4% |
| | Cologuard®: 2.6% |
| | Currently-available MCED test: 43.1% |

## THE CURRENTLY AVAILABLE MCED TEST DEMONSTRATED

**88%** accuracy of CSO identification in clinical trials.