ACT Monitor® +

THE BEST SOLUTION FOR REAL TIME MONITORING OF TUMOR DYNAMICS

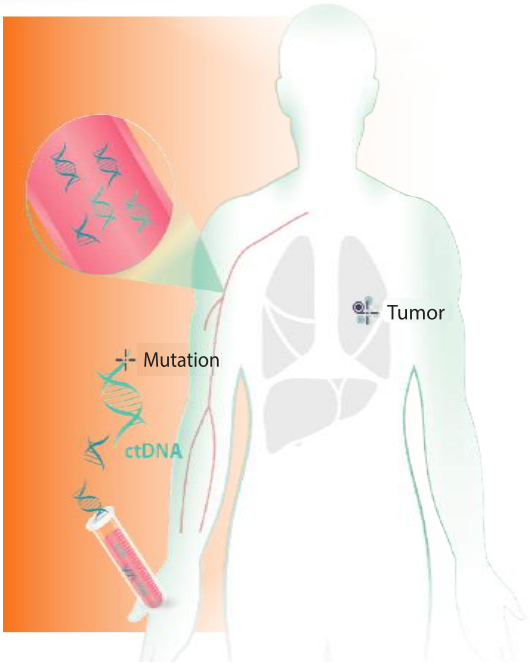
This material is intended for healthcare professionals only.

ACT GENOMICS®

ACT Monitor® +

Analysis of Circulating Tumor DNA in the Blood Stream is an Ultrasensitive Method for Cancer Monitoring

Long term monitoring is crucial in treating cancer that involves abnormal cell growth and has a high potential of drug resistance. Although cancer biomarker and image screening are widely used in cancer monitoring, both methods are plagued by false-positives/false-negatives and require large tumor size (>0.5 cm). Therefore, using a non-invasive blood drawing method for monitoring tumor dynamics has become the future trend in clinical applications.



Circulating Tumor DNA

Circulating tumor DNA (ctDNA) is fragmented DNA derived by dying tumor cells in the blood stream, and carries important tumor-related information. ctDNA can detect the occurrence of variants that are associated with drug sensitivity or resistance. Therefore, ctDNA can provide information for drug selection, assessment of treatment responses and early detection of cancer recurrence.

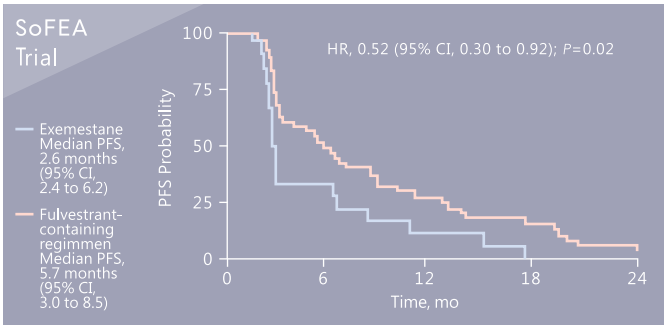
Clinical Applications of ctDNA Testing

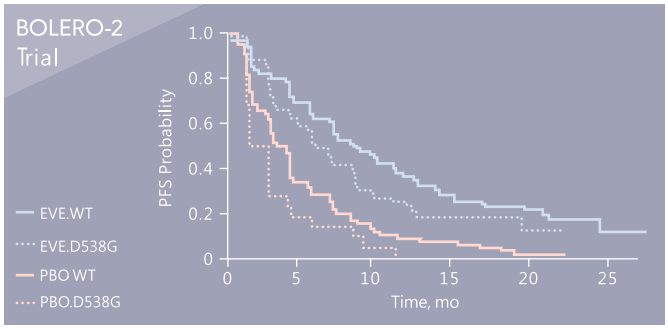
1. FDA approved ctDNA companion diagnostics for non-small cell lung cancer

In June 2016, Food and Drug Administration (FDA) approved the companion diagnostics for blood-based test in lung cancer patients, where blood of patients detected with EGFR exon 19 deletion or L858R mutations could be treated with erlotinib ; in September 2016, FDA approved the label extension of this test, where patients with EGFR T790M mutation could be treated with Osimertinib.

2. ctDNA reveals different treatment responses in patients with breast cancer

The results of the SoFEA trial indicate that detection of plasma ESR1 gene mutation shows selective sensitivity to fulvestrant-containing regimen in patients with breast cancer; the results of another trial, BOLERO-2, reveal that plasma ESR1 D538G mutations are detected in patients who may benefit from treatment with exemestane combined with everolimus.





1. FDA. (2016). FDA grants Roche label extension for the cobas EGFR mutation test for use with plasma as a companion diagnostic for Tagrisso.
2. Fribbens, C., et al. (2016). Plasma ESR1 mutations and the treatment of estrogen receptor-positive advanced breast cancer. Journal of Clinical Oncology, 34(25), 2961–2968.
3. Chandarlapaty, S., et al. (2016). Prevalence of ESR1 mutations in cell-free DNA and outcomes with endocrine therapy in BOLERO-2. JAMA Oncology, 2(10), 1310–1315

ACT Monitor® + Advantages

Applicable for different types of solid tumors

Who is suitable

Patients with solid tumors who

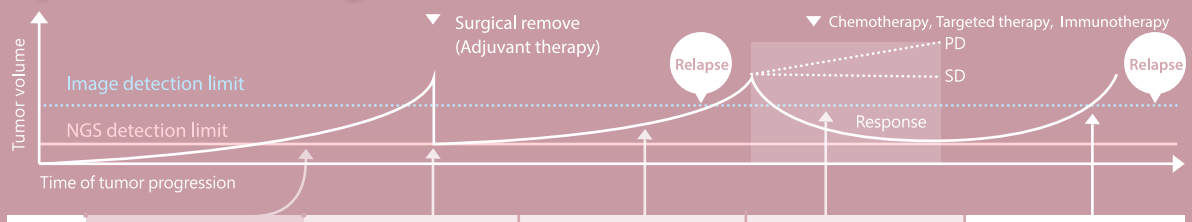
- wish to monitor treatment response
- have developed drug resistance
- may be at risk of cancer recurrence
- are unsuitable for surgery

Report provides

- Single nucleotide variation (SNV) and small insertion / deletion (InDel) alterations
- Genetic information for drug resistance or sensitivity

ACT Monitor® +

1 Dynamic Monitoring of Tumor Mutations



Application	Early cancer detection	Minimal residual disease detection	Disease recurrence detection	Treatment response evaluation	Drug resistant mutation detection
Principle	Detecting ctDNA for early screening, used as a reference for regular follow-up	Detecting ctDNA after surgery, used as a reference for disease management	Multiple sampling of ctDNA testing over time enables long term disease monitoring	Monitoring the ctDNA level for clinical evaluation of cancer treatment	Detecting drug resistant or sensitivity related mutation in ctDNA
Evidence	Awaiting	Compelling clinical evidence	Compelling clinical evidence	Compelling clinical evidence	FDA approved companion diagnostics for ctDNA testing

Annu Rev Med. 2021 Jan 27:72:399-413. Clin Oncol (R Coll Radiol). 2020 Oct;32(10):626-631.

2 Multiple Specialized Tests Suitable for Various Cancers

Specifically designed for various cancers, and is capable of detecting common variants in different cancers such as lung, breast and colorectal cancers.

3 Variant Detection

Detects single nucleotide variations (SNVs) and small insertion deletions (InDels).

4 Short Turnaround Time of 10 Working Days

Professional and expeditious procedure provides immediate monitoring of genetic alterations and drug resistance/sensitivity information.

Specification

	ACT Monitor® Lung	ACT Monitor® Breast	ACT Monitor® Colon	ACT Monitor® +			
Gene list	*ALK* *BRAF* *CDKN2A* *CTNNB1* *EGFR* *ERBB2* *KRAS* *MET* *PIK3CA* *TP53* *U2AF*	*AKT1* *CCND1* *CDH1* *ERBB2* *ESR1* *FGFR1* *GATA3* *PIK3CA* *PTEN* *TP53*	*AKT1* *BRAF* *CDKN2A* *CTNNB1* *EGFR* *FBXW7* *IDH1* *IDH2* *KRAS* *NRAS* *PIK3CA* *SMAD4* *TP53*	*ABL1* *AKT1* *ALK* *APC* *ATM* *BRAF* *CDH1* *CDKN2A* *CSF1R* *CTNNB1* *EGFR* *ERBB2* *ERBB4*	*EZH2* *FBXW7* *FGFR1* *FGFR2* *FGFR3* *FLT3* *GNA11* *GNAQ* *GNAS* *HNF1A* *HRAS* *IDH1* *IDH2*	*JAK2* *JAK3* *KDR* *KIT* *KRAS* *MET* *MLH1* *MPL* *NOTCH1* *NPM1* *NRAS* *PDGFRA* *PIK3CA*	*PTEN* *PTPN11* *RB1* *RET* *SMAD4* *SMARCB1* *SMO* *SRC* *STK11* *TP53* *VHL*
Total	11	10	13	50			

Specimen

8 ml whole blood x 2 tubes

(Please see "Specimen Preparation Instructions")

Limit of Detection

VAF ≥ **0.2%** (for hotspots);
VAF ≥ **0.5%** (for non-hotspots)

Sequencing mean depth

>7,000 X

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

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