

ACT Monitor[®] +

THE BEST SOLUTION
FOR REAL TIME MONITORING
OF TUMOR DYNAMICS

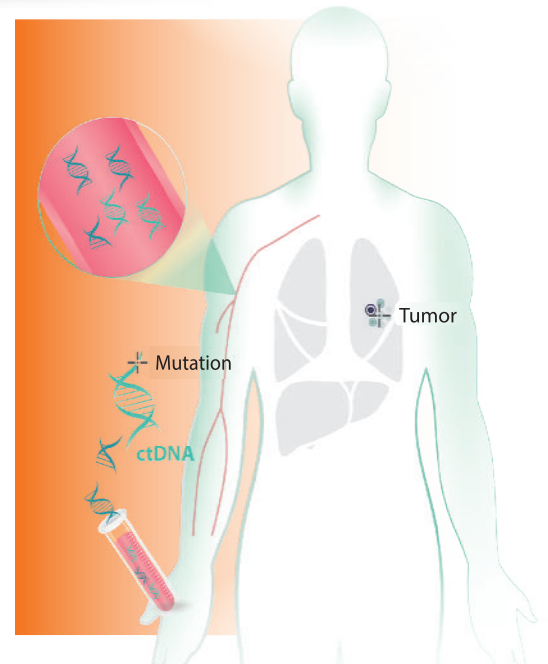


Analysis of Circulating Tumor DNA in the Blood Stream is an Ultrasensitive Method for Cancer Monitoring

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.



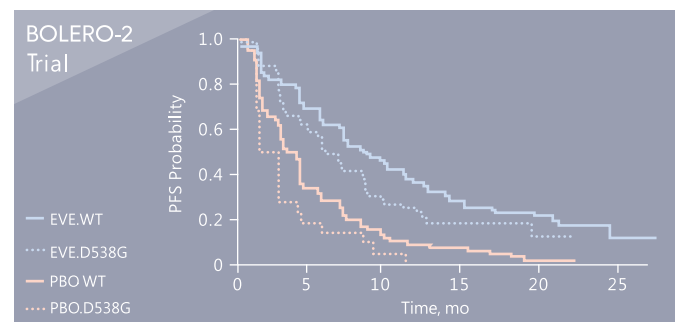
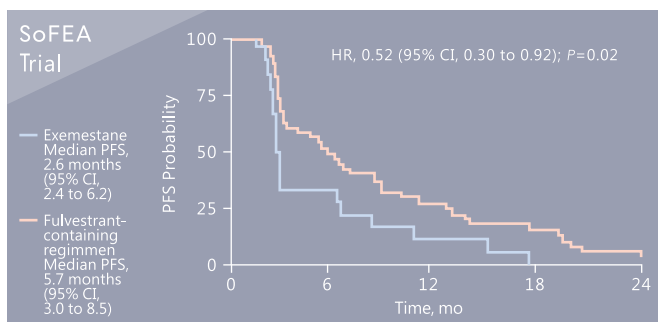
Clinical Applications of ctDNA Testing

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.



ACT Monitor® + Advantages



Applicable for different types of solid tumors

Who is suitable

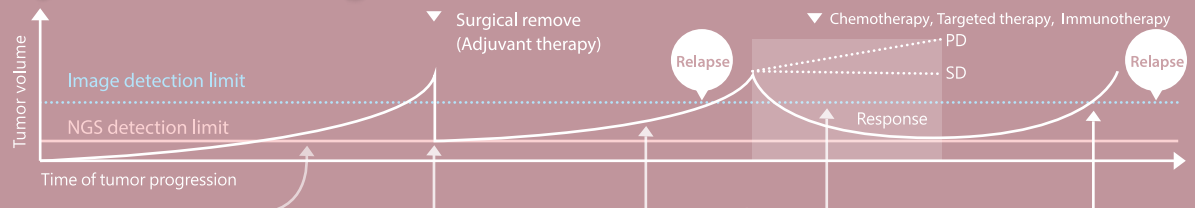
- Patients with solid tumors who
 - wish to monitor treatment response
 - have developed drug resistance
 - may be at risk of cancer recurrence
 - are unsuitable for surgery

Report provides

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

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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

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
8ml whole blood x 2 tubes
 (Please see "Specimen Preparation Instructions")

Sensitivity
0.5% variant frequency

Sequencing mean depth
>7000 X



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