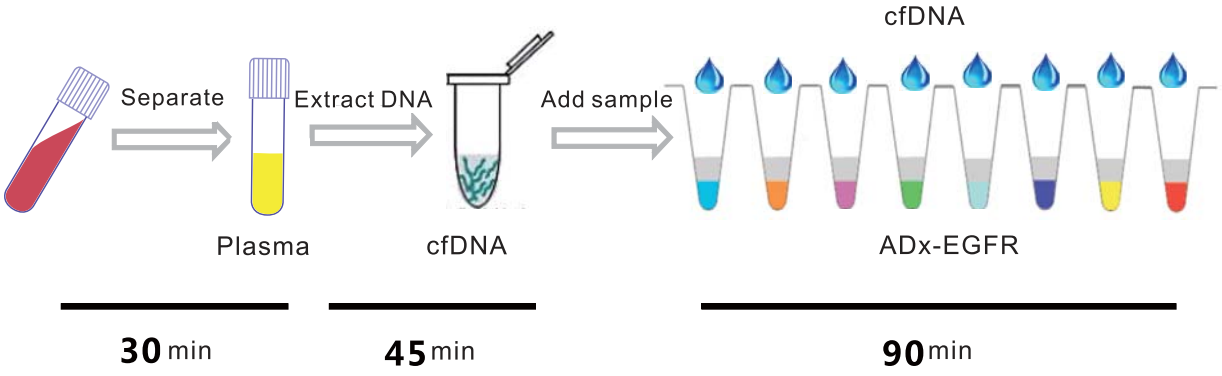
AmoyDx® *EGFR* Plasma Testing

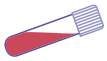
EGFR blood testing provides NSCLC patients with unavailable or insufficient tumor tissue the opportunity to benefit from personalized treatment

In 2013, AmoyDx EGFR 29 Mutations Detection Kit was approved for blood testing by CFDA (China FDA).

AmoyDx EGFR plasma testing procedure:



AmoyDx® Cell -free DNA Protection Vacuum Tube



- 10 mL blood collection tube for stabilization of cell-free plasma DNA
- Contains cell-free DNA protection reagent
- Whole blood collected are stable for 7 days at 4~25 ℃

AmoyDx® Circulating DNA Kit

- For isolation of cell-free DNA from serum, plasma and pleural effusion
- 4 mL sample → 30~100 µL elution
- High DNA yield and purity
- Simple procedure (< 1.5 hrs)

AmoyDx® EGFR 29 Mutations Detecion Kit

- Detect 29 mutations including T790M in the EGFR gene
- Detects 1% mutant allele
- Positive and negative controls
- External and internal controls

Intended Use: CFDA approved for clinical use in China and CE marked for IVD use in Europe.

AmoyDx®

Better Life with AmoyDx

High concordance rate of AmoyDx EGFR detection in blood compared with matched tissue

Qiagen-cfDNA kit + ADx-ARMS

Tissue				
Plasma		+	-	Total
	+	27	0	27
	-	13	46	59
	Total	40	46	86
Sensitivity		67.5%		
Specificity		100%		

References: Xiaoqing Liu. *et al*. J Clin Pathol 2013

ADx-cfDNA kit + ADx-ARMS

Tissue				
Plasma		+	-	Total
	+	22	0	22
	-	9	25	34
	Total	31	25	56
Sensitivity		71%		
Specificity		100%		

References: Real world data from 5 Chinese hospitals, 2015

EGFR blood testing can predict efficacy of EGFR-TKI

EGFR mutation status predict efficiency of EGFR-TKIs treatment in advanced NSCLC

Clinical Study FASTACT II

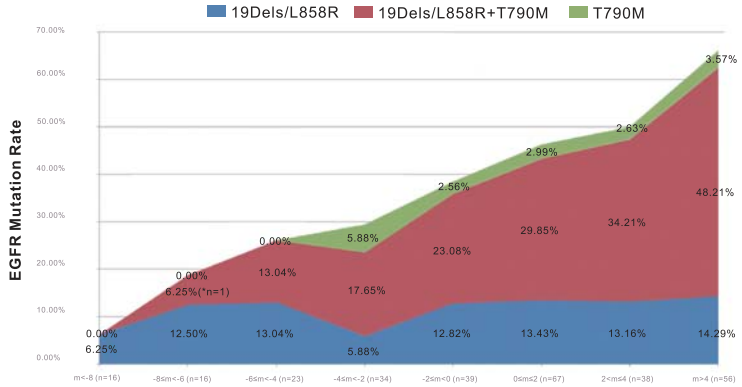
Positive and negative predictive values for EGFR activating mut were 93% (68/73) and 86% (130/151) respectively.

	Combination of E & C *	Chemotherapy	HR	P
PFS (month)				
EGFR mut (plasma)	13.8	6.1	0.21	0.0001
Wild type (plasma)	6.7	6	0.8	0.06
OS (month)				
EGFR mut (plasma)	32.4	19	0.51	0.0035
Wild type (plasma)	16.1	13.3	0.89	0.39

* Combination of E & C: combination of Erlotinib and chemotherapy
Reference: Mok T, *et al*. 2013 ASCO Abstract 8021.

EGFR mutation status monitor drug resistance of EGFR-TKIs treatment in NSCLC

T790M ctDNA can be detected in plasma before and after PD and represents a potential poor prognostic factor



Reference: D Zheng, et al. 2015 ASCO Abstract 8080

AmoyDx®

Tel: (86) 592-680-6835 (86) 592-680-6322 Fax: (86) 592-680-6839

Add: 39 Dingshan Road, Haicang District, Xiamen 361027, China