Connecting patients everywhere to precision oncology

Oncomine Dx Express Test (CE-IVD)

Genomic profiling in precision oncology is transforming cancer care for your patients. But long waiting periods for biomarker test results from the laboratory can delay therapy decisions. However, now with the new Ion Torrent™ Oncomine™ Dx Express Test, laboratories will be able to:

- Generate clinically relevant biomarker results in as little as 24 hours
- Integrate molecular biomarker profiling, including *EGFR, BRAF, KRAS, ERBB2, ALK, ROS1, RET, MET,* and *NTRK1/2/3*, among others, with PD-L1 results, into one complete report
- Match biomarker results to approved therapies, guidelines, and clinical trials
- Provide results for even small samples, thereby limiting the need for re-biopsy

The Oncomine Dx Express Test is based on amplicon technology requiring the lowest sample input compared to hybrid capture–based next-generation sequencing (NGS). A recent real-world study of 31,101 patient samples demonstrated that 94.2% of the samples were successfully tested with amplicon-based technology, hence increasing access to precision oncology[1] (Figure 1).

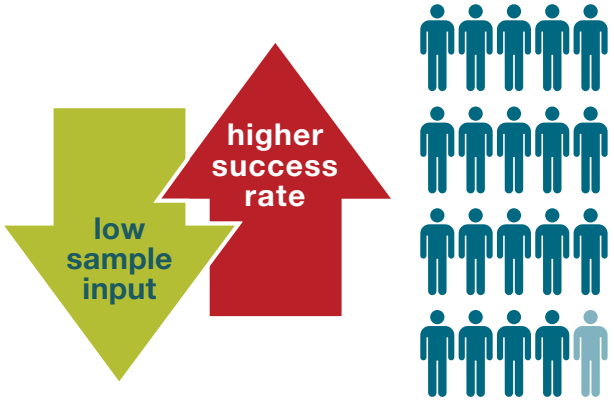
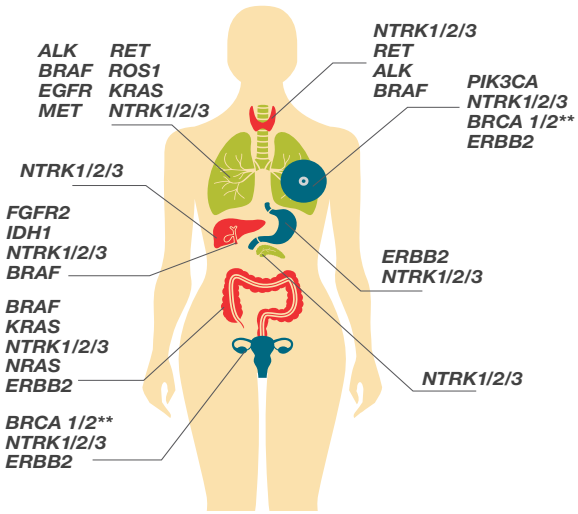


Figure 1. Amplicon-based NGS offers best-in-class sample input requirements resulting in higher patient sample success rates[1].

The Oncomine Dx Express Test covers 100% of the clinical routine biomarkers in non-small cell lung cancer (NSCLC) and the majority of clinical routine biomarkers for other solid tumors per ESCAT* Tier I[2]



The importance of timely biomarker results

In the absence of molecular data, chemotherapy and/or immunotherapy (IO) can be indicated for NSCLC patients, while some could be eligible for targeted therapy. Findings from the Integra Connect database analysis of 525 patients with stage 4 NSCLC harboring actionable oncogenic drivers suggest that treatment outcomes were significantly compromised in patients (n=141) who initiated treatment before their genomic profiling results were reported, compared to patients (n=384) who initiated treatment after receiving their genomic profiling results[3] (Figures 2 and 3).

The Oncomine Dx Express Test can deliver results in as little as 24 hours, allowing the laboratory to integrate molecular biomarker results with immunohistochemistry results such as PD-L1.

In a recent multicentric performance evaluation study, 6 clinical laboratories were able to generate results with the Oncomine Dx Express Test on average of 18.3 hours from nucleic acid to report[4].

Ask your laboratory for fast NGS, so you and your patients don't have to wait weeks for results

* ESCAT: ESMO scale for clinical actionability of molecular biomarkers,
** *BRCA1/2* are not covered by the Oncomine Dx Express Test

References

1. Tomlins SA, et al. (2021) *JCO Precis Oncol* 5:1312–1324.
2. Mateo J et al. (2018) *Ann Oncol* 29:1895 -1902.
3. Smith R, et al. (2022) *J Clin Oncol* 40, suppl 16; abstr 1530.
4. Hofman P, Removing Barriers to Enable Routine NGS Testing, European Lung Cancer Conference – Symposium, March 31, 2022, virtual.

Table 1. The Oncomine Dx Express Test gene list

Deletions, insertions, and substitutions		Copy number alterations	Gene fusions and splicing variants
AKT1	*IDH1*	*AR*	*ALK*
AKT2	*IDH2*	*EGFR*	*AR*
AKT3	*KEAP1*	*ERBB2*	*BRAF*
ALK	*KIT*	*ERBB3*	*EGFR*
AR	*KRAS*	*FGFR1*	*ESR1*
ARAF	*MAP2K1*	*FGFR2*	*FGFR1*
BRAF	*MAP2K2*	*FGFR3*	*FGFR2*
CDK4	*MET*	*KRAS*	*FGFR3*
CHEK2	*NRAS*	*MET*	*MET*
CTNNB1	*NTRK1*	*PIK3CA*	*NRG1*
EGFR	*NTRK2*		*NTRK1*
ERBB2	*NTRK3*		*NTRK2*
ERBB3	*PDGFRA*		*NTRK3*
ERBB4	*PIK3CA*		*NUTM1*
ESR1	*PTEN*		*RET*
FGFR1	*RAF1*		*ROS1*
FGFR2	*RET*		*RSPO2*
FGFR3	*ROS1*		*RSPO3*
FGFR4	*STK11*		
FLT3	*TP53*		
GNAS	*HRAS*		

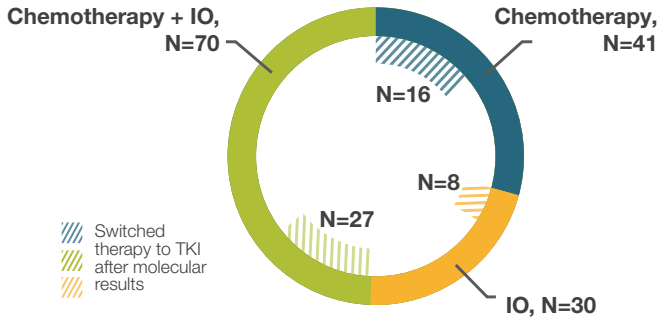


Figure 2. 51 out of 141 (36%) patients switched to TKI therapy after molecular test results were available.

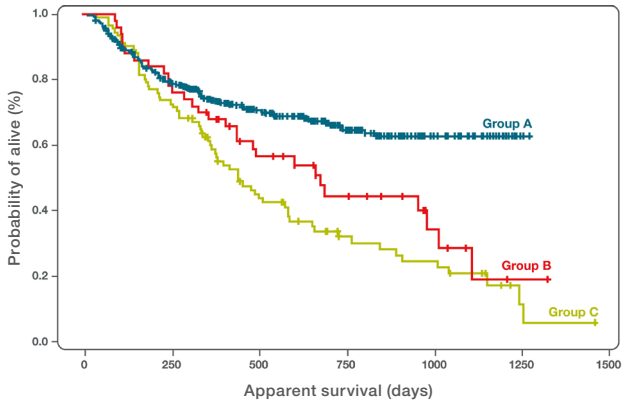


Figure 3. Group B (n=51), who switched to TKI treatment within 35 days, demonstrated a median apparent survival (AS) of 672 days. Group C (n=90), who did not switch demonstrated a median AS of 435 days. A median AS was not reached for Group A (control group, n=384) because survival extended beyond the data cut-off date in more than half of patients.

Learn more at **oncomine.com/express-test**