# Analytical performance and initial clinical validation of a functional ex vivo platform for the prediction of response to immune checkpoint inhibitors in solid tumors

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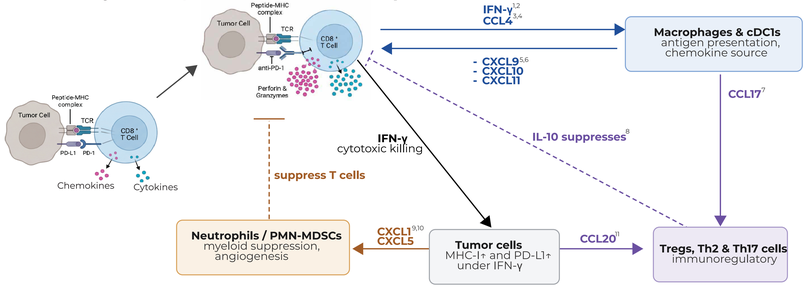
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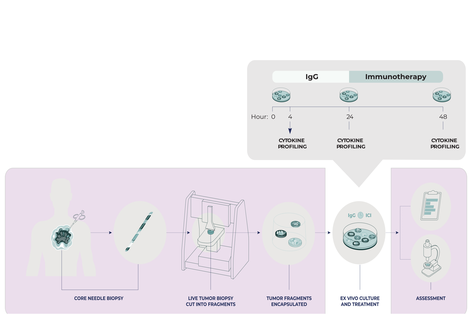
## Introduction

- Immune checkpoint inhibitors (ICIs) provide durable benefit in a subset of patients; however, FDA-approved biomarkers have limited predictive value
- Functional ex vivo profiling has emerged as a promising approach for improving response prediction
- Existing ex vivo approaches are generally limited to large tissue specimens from surgical resections and require evaluation at specialized centers
- Here we report the analytical performance and initial clinical validation of an ex vivo platform capable of predicting ICI response from core needle biopsies (CNBs) collected across diverse clinical settings

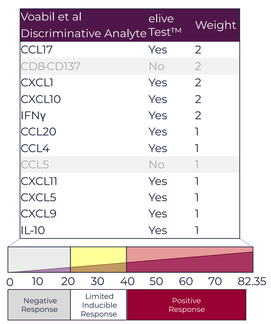
### Role of cytokines/chemokines in ICI response




## Methods




| Voabil et al Discriminative Analyte | elive Test™ | Weight |
|---|---|---|
| CCL17 | Yes | 2 |
| CD8:CD137 | No | 2 |
| CXCL1 | Yes | 2 |
| CXCL10 | Yes | 2 |
| IFNγ | Yes | 2 |
| CCL20 | Yes | 1 |
| CCL4 | Yes | 1 |
| CCL5 | No | 1 |
| CXCL11 | Yes | 1 |
| CXCL5 | Yes | 1 |
| CXCL9 | Yes | 1 |
| IL-10 | Yes | 1 |




Diagnostic CNBs were collected from patients enrolled in prospective observational studies (NCT05478538, NCT05520099, NCT06349642, or NCT07327489) under Institutional Review Board-approved protocols with informed consent. CNBs were shipped overnight and cut into live tumor fragments (LTFs) of 300 µm thickness using an automated sectioning device; cutting performance was validated across clinically relevant needle gauges (12-20G, N = 20 biopsies) against predefined acceptance criteria. LTFs were encapsulated in hydrogel and treated sequentially for 24 hours each with immunoglobulin G (IgG)-control and ICI (αPD-1, αPD-L1, αPD-1+αCTLA-4, or αPD-L1+αCTLA-4). Cytokine quantification was performed on conditioned media collected at 4, 24, and 48 hours by multiplexed bead-based immunoassay (Luminex). Precision and sensitivity of cytokine measurements were assessed to characterize analytical performance. Cytokine concentrations from IgG- and ICI-treated conditions were converted to cytokine production rates. For each cytokine, the delta in production rate (ICI minus IgG) was calculated. Delta values were transformed via quantile normalization and scored using a modified algorithm based on Voabil et al. to assign a binary elive Test™ response call.[12] LTFs were fixed at culture initiation and completion (days 0 and 3), processed for hematoxylin and eosin (H&E) staining, and reviewed by a pathologist for preservation of tissue architecture and immune cells. For clinical validation, concordance between ex vivo response and clinical response was evaluated in patients receiving matched ICI therapy. Clinical outcomes (best overall response [BOR], progression-free survival [PFS]) were obtained from treating-site records; concordance was defined as elive-predicted responders achieving disease control (Complete Response [CR]/Partial Response [PR]/Stable Disease [SD]) and predicted nonresponders experiencing PD. PFS was estimated by the Kaplan-Meier method.

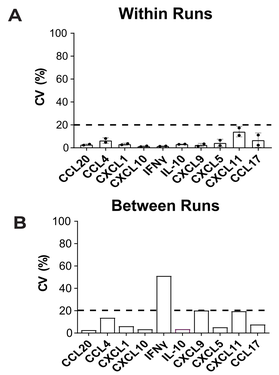
## Results

### 1 Automated sectioning of CNBs meets all predefined acceptance criteria

| ACCEPTANCE CRITERION | RESULT | MET |
|---|---|---|
| **Biopsies processed** Section CNBs across gauges (12G, 18G, 20G) | **20/20** biopsies processed successfully | ✓ |
| **Slice yield** ≥75% yield | **20/20** achieved ≥75% — 12G **97%** \| 18G **100%** \| 20G **104%** | ✓ |
| **Processing time** ≤1 hour per biopsy | **8.5 min** average per biopsy | ✓ |
| **Slice thickness** 200–400 µm | **260 µm** average; all within 200–400 µm | ✓ |

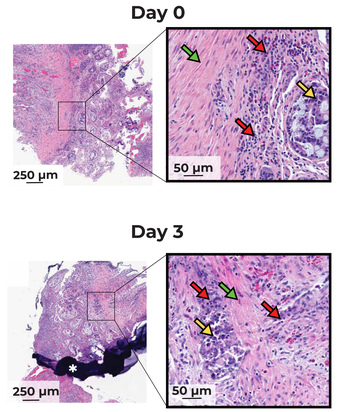
Analytical validation of the automated cutting process for CNBs across clinically relevant needle gauges (12G, 18G, and 20G; N = 20 biopsies). For each performance characteristic, the predefined acceptance criterion (center) is shown with the observed result (right). Average processing time excludes embedding.

### 2 elive Test is repeatable and reproducible



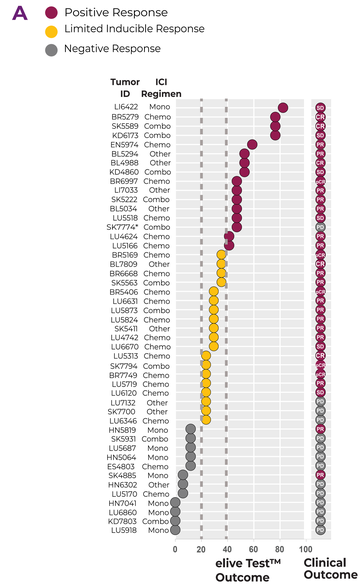

Precision was assessed using peripheral blood mononuclear cells for all 10 reported analytes, with a predefined acceptance criterion of ≤20 CV (%, dotted line). **A.** Within-run precision (repeatability): CV of replicate measurements within a single run for each analyte. Bars indicate mean CV; points represent highest and lowest CV; error bars represent SD. All analytes met the ≤20% criterion in accepted runs. **B.** Between-run precision: CV across independent runs (N=4; spanning 2 operators). Eight of 10 analytes met the criterion; CXCL9 (20.2%) and IFN-γ (51.1%) exceeded it.

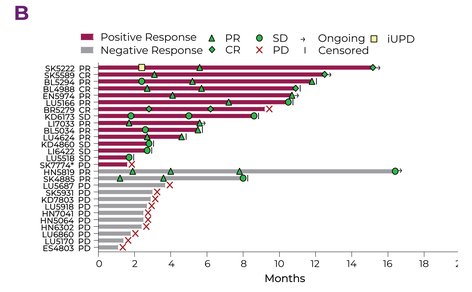
### 3 elive Test maintains immune cells through 3 days of culture

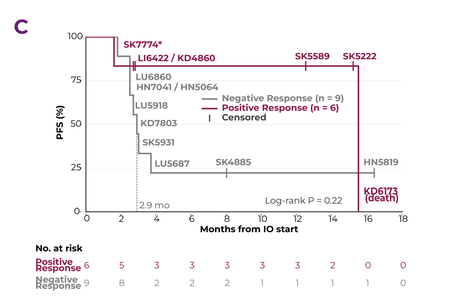



Representative H&E-stained sections of LTFs from the same colorectal cancer tumor biopsy specimen at culture initiation (Day 0, top) and assay completion (Day 3, bottom). Left: whole-fragment sections (scale bar, 250 µm); right: magnified regions (boxed; scale bar, 50 µm). Green arrows, stroma with organized pink collagenous fibroblastic bundles; red arrows, lymphocytes; yellow arrows, tumor cells. *elive Gel

### 4 elive Test is concordant with clinical response to ICI treatment in 89% of patients




**A.** elive Test and accompanying clinical response for specimens and patients in a Validation Cohort show 25 of 28 patients with clinical outcomes that are concordant with elive Test Prediction (excluding patients in the limited inducible group). **B.** Swimmer plot showing time to progression and clinical course for each patient, stratified by predicted responders and nonresponders. Symbols denote best overall response. **C.** PFS from the time of ICI initiation, comparing elive-predicted responders with nonresponders. Median PFS for nonresponders was 2.9 months; median PFS for responders was not reached. CR = complete response, pCR = complete pathological response, PR = partial response, SD = stable disease and PD = progressive disease, iUPD = immune unconfirmed progressive disease. Specimens with pCR after neoadjuvant therapy (BR6997, BR5169, BR5406, BR7749, SK7794) are not shown in B or C. Limited Inducible specimens are shown in A only. Tumor types: BL, bladder; BR, breast; EN, endometrial; ES, esophageal; HN, head and neck; KD, kidney; LI, liver; LU, lung; SK, skin. *SK7774 assessment by the elive index algorithm results in a negative response. See Braun et al for algorithm.[13]

## Conclusions

- elive Test is an ex vivo LTF platform that is scalable and readily translatable to clinical settings
- elive Test exhibits strong analytical performance
- Results are 89% concordant with patient clinical response to ICI therapy

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## Acknowledgments

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## References

1. Castro F, Cardoso AP, Gonçalves RM, Serre K, Oliveira MJ. *Front Immunol.* 2018;9:847.
2. Garcia-Diaz A, Shin DS, Moreno BH, et al. *Cell Rep.* 2017;19(6):1189-1201.
3. Spranger S, Bao R, Gajewski TF. *Nature.* 2015;523(7559):231-235.
4. Böttcher JP, Reis e Sousa C. *Trends Cancer.* 2018;4(11):784-792.
5. House IG, Savas P, Lai J, et al. *Clin Cancer Res.* 2020;26(2):487-504.
6. Chow MT, Ozga AJ, Servis RL, et al. *Immunity.* 2019;50(6):1498-1512.e5.
7. Yoshie O, Matsushima K. *Int Immunol.* 2015;27(1):11-20.
8. Ouyang W, O'Garra A. *Immunity.* 2019;50(4):871-891.
9. Highfill SL, Cui Y, Giles AJ, et al. *Sci Transl Med.* 2014;6(237):237ra67. doi:10.1126/scitranslmed.3007974
10. Veglia F, Sanseviero E, Gabrilovich DI. *Nat Rev Immunol.* 2021;21(8):485-498.
11. Kadomoto S, Izumi K, Mizokami A. *Int J Mol Sci.* 2020;21(15):5186. doi:10.3390/ijms21155186
12. Voabil P, de Bruijn M, Roelofsen LM, et al. *Nat Med.* 2021;27(7):1250-1261.
13. Braun D, Dana N, Hernan HR, et al. *Cell Rep Med.* Published online October 15, 2026. doi:10.1016/j.xcrm.2026.103114
14. Ribas A, Wolchok JD. *Science.* 2018;359(6382):1350-1355.
15. Sharpe AH, Pauken KE. *Nat Rev* Immunol. 2018;18(3):153-167.
16. Tokunaga R, Zhang W, Naseem M, et al. *Cancer Treat Rev.* 2018;63:40-47.
17. Ramasubramanian TS, Adstamongkonkul P, Scribano CM, et al. *J Transl Med.* 2026;24(1):18.doi:10.1186/s12967-025-07378-2