

Early Access Program - For Research Use Only

EAP SUBJECT

 Name: Jane Doe
 MRN: ABC12345
 DOB: 3/2/1976
 Sex: Female

SPECIMEN

 Specimen ID: 5279
 Biopsy Type: CNB
 Specimen Site: Liver
 Collected: 7/8/2025
 Received: 7/10/2025

ORDERING PHYSICIAN

 Name: Dr. Nick Patera
 Facility: Upstairs Clinic
 Phone: 123-456-7890

THERAPY TESTED

anti-PD-1 biosimilar


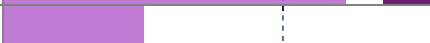




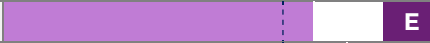



INTERPRETATION

Positive for inducible response with anti-PD-1 treatment

PATHOLOGIST COMMENTARY

An ex vivo inducible immune response was observed in the subject derived tumor sample following anti-PD-1 treatment. This response pattern has been associated with clinical response to immune checkpoint therapy in previous studies [1] [2].

RESULTS FOR ANTI-PD-1 BIOSIMILAR

Analyte	Control Phase	Treatment Phase	Delta Change	Response Profile
CCL17	1.33	3.18	1.85	
CXCL11	4.56	7.19	2.64	
CXCL5	513.57	1096.02	582.45	
CXCL9	211.43	159.27	-52.15	
CCL20	3.71	5.19	1.48	
CCL4	29.91	28.32	-1.59	
CXCL1	41.62	101.12	59.50	
CXCL10	83.75	366.88	283.13	
IFN-gamma	1.51	10.98	9.46	
IL-10	6.48	17.67	11.19	

Response Threshold

DEFINITIONS

Control Phase	Baseline cytokine production (pg/mL*hr) under IgG administration
Treatment Phase	Cytokine production (pg/mL*hr) in response to tested therapeutic
Delta Change	Increase (or decrease) of cytokine production between treatment and control phases
Response Profile	Cytokine delta change as a percentile of training data
E Elevated	Cytokine level exceeds the analyte threshold for induced response during the treatment phase. See PATHOLOGIST COMMENTARY for comprehensive interpretation.

Josh Routh

 Josh Routh, MD
 DIGITAL SIGNATURE: 07/11/2025 15:45 CDT

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METHODOLOGY

Fresh tumor biopsies are processed into live tumor fragments and encapsulated in a hydrogel matrix to maintain the tumor microenvironment. Fragments undergo a sequential treatment incubation where they are treated with IgG (control phase) followed by a specific therapeutic agent or biosimilar (treatment phase) to simulate the expected in-vivo treatment conditions. Supernatant is collected at the end of each phase and tested for a panel of relevant cytokines using a bead-based multiplex assay. This information is used to calculate the change in cytokine production rate. A board-certified pathologist reviews the results and provides an overall interpretation of the response pattern in the context of the therapeutic agent tested.

LIMITATIONS

This assay is designed to assess ex vivo cytokine responses following short-term treatment of intact tumor fragments and does not fully recapitulate the complexity of in-vivo immune dynamics, including systemic factors, immune cell trafficking, and pharmacokinetics. Cytokine release is measured in a controlled microenvironment and may be influenced by factors such as tumor content, tumor viability, baseline inflammation, and tumor-intrinsic immune suppression. Observed responses may not directly predict clinical outcomes. Results during the Early Access Period (EAP) are intended for research use only and are not to be used for clinical purposes. Repeat testing or alternative assays may be warranted in cases of borderline or inconsistent results.

SUPPORT SERVICES

For questions specific to the test report and measurements, email us at elive@elephaslabs.com or call (608) 622 - 7954.

DISCLAIMER

This report and its results do not promise or guarantee the use of a particular treatment will be effective or helpful in the treatment of disease or conditions in any patient. Results during the EAP are intended for research use only and are not to be used for clinical purposes. All clinical decisions about a patient, including the final selection of treatment, should be determined by physician discretion using other diagnostic data.

This test has been developed and validated as a laboratory developed test (LDT) by Elephas Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This laboratory is certified by the Clinical Laboratory Improvement Amendments (CLIA #52D2333937) to perform high complexity clinical laboratory testing.

REFERENCES

1. Ramasubramanian TS, Adstamongkonkul P, Scribano CM, et al. A live tumor fragment platform to assess immunotherapy response in core needle biopsies while addressing challenges of tumor heterogeneity. *J Transl Med.* 2026;24(1):18. doi:10.1186/s12967-025-07378-2
2. Voabil P, de Bruijn M, Roelofsen LM, et al. An ex vivo tumor fragment platform to dissect response to PD-1 blockade in cancer. *Nature medicine.* 2021;27(7):1250-1261. doi:10.1038/s41591-021-01398-3