Case Study | 12th May 2022

Retrospective Biomarker Analysis Performed To Measure Tumor-infiltrating CD39+ CD8+ T Cells in metastatic Renal Cell Carcinoma

Robustness, IHC Capabilities And Scientist To Scientist Collaboration

The Case

A biotech conducted a phase II study to analyze the percent expression of CD8+ mRCC tumor samples. This secondary endpoint was done by means of IHC simplex method and chromogenic detection through Cerba Research labs.

After garnering CD8+ data, there was a strong scientific interest in retrospectively assessing tumor-infiltrating CD39+ CD8+ in mRCC.

Of note, high tumor-infiltrating CD39+ CD8+ T cells may indicate poor prognosis in RCC.[1]

The Challenges

Develop an IHC protocol that will permit the assessment of tumor-infiltrating CD39+ CD8+ in mRCC.

Use the same CD8 antibody for the supplemental assay, ie IHC simplex automated with chromogenic detection vs IHC multiplex with fluorescence detection.

While harmonizing technics and data.

How we responded

Facilitate protocol transfer from simplex to multiplex thanks to more than 8 IHC automaton available in our Cerba Research lab.

Our validation process, including image analysis, allowed for robust data accuracy.

We also responded to the challenge by ensuring harmonization.

And used our robust image analysis capabilities to accurately assess CD39 and CD8 positivity.

Top Takeaways

Robustness of our validation process to go from IHC simplex to multiplex, with an average reproducibility of 13.8% for CD8+ and 11.7% for CD39+ expression, and average repeatability of 6.8% for CD8+ and 4.34% for CD39+.

Reliability and reproducibility of our data from simplex to multiplex with a simplex/multiplex ratio of 0.7 for CD8+ and 0.9 for CD39+.

Access to a wide range of IHC technologies to respond to your prospective and retrospective biomarker analysis needs.

Build a trusting relationship between Cerba Research and the sponsor through scientist to scientist collaboration, communication, and state of the art reports.

Timeline

Dec 27th ‘19
Start of validation of multiplex protocol

Feb 18th ‘20
Samples received & End of validation of multiplex protocol

Jun 5th ‘20
Experimental phase end

Jun 29th ‘20
Draft report edition

Sep 15th ‘20
Final report

Cerba Research Data In-house

[1] Qi et al. Cancer Immunol Immunother 2020;69(8):1565-76; mRCC=metastatic renal cell carcinoma; IHC=immunohistochemistry

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