PRECISION for medicine

PRECISION epiontisid℠

CASE STUDY

Noninvasive Immunophenotyping via Dried Blood Spots and Nasal Swabs Using Epiontis ID™: Evaluating COVID-19 Disease Course and Measuring SARS-CoV-2 Vaccine Response

Situation

Monitoring the status of the immune system is a critical activity both in the development of therapeutics that can modulate the immune system and in understanding infectious disease like acute COVID-19 infection. However, performing immune monitoring typically requires a blood draw, which can be difficult on patients, and limits the ability to perform immune monitoring in point-of-case or home environments. The ability to perform immune monitoring assays on noninvasively obtained samples has benefits to patients in clinical trials, and could help to consistently and reliably predict disease course or vaccine efficacy, especially in the SARS-CoV-2 pandemic.

Challenges

While flow cytometry is a well-established, widely studied method of quantifying and typing immune cell populations, its technical requirement for fresh samples means that flow cytometry is unsuitable for immune monitoring in situations where it is impractical to collect blood draws. It would therefore be ideal to have available an immune monitoring assay technology that utilizes accessible sample matrices, such as dried blood spots or nasopharyngeal swabs.

Solution

Precision for Medicine's proprietary Epiontis ID™ is an epigenetic-based cell counting technology that utilizes differences in the methylation status of specific gene loci to distinguish target immune cell types from other cell populations. Importantly, Epiontis ID can be applied to multiple matrices, such as fresh, frozen, or paper-spotted dried blood and other bodily fluids or tissues.

In this study, Precision for Medicine collaborated with investigators from the University General Hospital of Valencia in Spain and University Hospitals of the Ruhr-University Bochum in Germany to assess the clinical utility of epigenetic-based cell counting fornon-invasive immune monitoring related to COVID-19.

While flow cytometry is a well-established, widely studied method of quantifying and typing immune cell populations, its technical requirement for fresh samples creates logistical challenges, especially in a pandemic setting

Epiontis ID was used to perform immunophenotyping on:

- Whole blood and nasopharyngeal swab samples collected from unvaccinated patients hospitalized with COVID-19 and healthy controls to identify potential predictors of COVID-19 disease course. Various cell populations—including CD3, CD4, CD8, and regulatory T cells; natural killer (NK) cells; and naïve and memory B cells—were quantified using existing immune cell-type specific epigenetic assays
- Dried blood spots collected from healthy subjects before and at multiple timepoints after SARS-CoV-2 booster vaccination to assess immune cell population changes associated with vaccine response. Epigenetic immune cell counting was performed for CD3 T cells, CCR7+, CTLA4+, TIGIT+, B cells, memory B cells, and IgM+ B cells

Results

This study showed that epigenetic immunophenotyping can be performed not only in venous whole blood, but also in nasopharyngeal swabs or dried blood spots that can be collected in a point-of-care or at-home setting by untrained individuals. Results from epigenetic immunophenotyping may be useful for predicting disease course or vaccination response in the ongoing SARS-CoV-2 pandemic.

Epiontis ID of whole blood and nasopharyngeal swab samples showed significantly lower CD3 T cell counts in patients compared with controls (see Figure 1).

Among unvaccinated patients hospitalized with COVID-19, high CD3 T cell count and higher lymphocyte-to-neutrophil ratio (LNR) were associated with more favorable clinical outcomes (see Figure 2). Epiontis ID of dried blood spots showed T cell responses as early as 6 hours after booster vaccination. CD3 T cells, CCR7+ cells, and TIGIT+ cells all decreased post-vaccination, with the most significant reduction in TIGIT+ cells (see Figure 3).

For more information on how Epiontis ID can be an ideal solution for immune monitoring in research and in clinical trials, please visit epiontis.com, or to learn more about all of Precision for Medicine's therapeutic development solutions, visit precisionformedicine.com.

Figure 1. Low CD3 T cells in whole blood and nasopharyngeal swab samples from patients with COVID-19

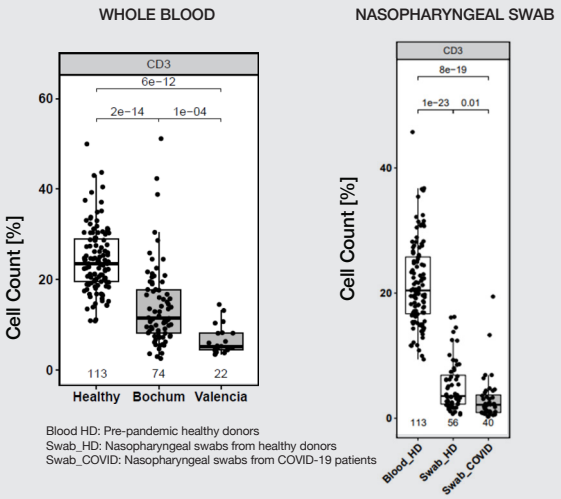

Figure 2. CD3 T cells and lymphocyte-to-neutrophil ratio as prognostic markers for COVID-19 disease course

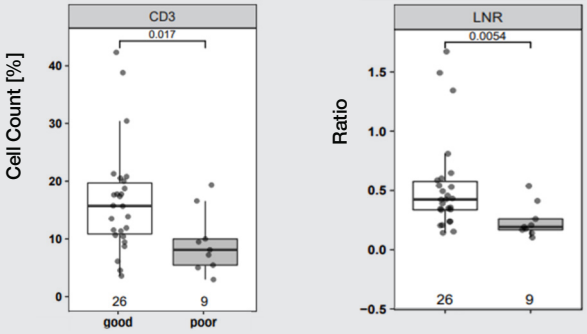

Figure 3. Decreases in immune cells subsets post—SARS-CoV-2 booster vaccination