

COMPOSITIONS, METHODS, AND SYSTEMS FOR DETECTING IMMUNE RESPONSE

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 63/050,526 filed July 10, 2020, which is incorporated by reference herein in its entirety.

BACKGROUND

[0002] Viral infections can cause severe diseases and even deaths. An example of the ongoing challenges presented by viral infection is the coronavirus disease of 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Vaccines or treatment options often do not exist for some existing or new viruses, or may require significant time and resources to develop. A fast and reliable test for immune response will release individuals from the constraints of physical distancing and reduce cost for public health measures.

SUMMARY

[0002a] In one aspect, provided herein is a method for detecting an immune response to a pathogen by a subject, comprising:

- i) incubating a blood sample from said subject in a container comprising an antigen and an anticoagulation agent, wherein said antigen comprises a specific T cell recognized epitope of said pathogen, and
- ii) incubating a second blood sample from said subject in a second container comprising said anticoagulation agent in (i) and not said antigen,
- iii) quantifying an amount of an immune-response analyte in said container and said second container, wherein said immune-response analyte is a nucleic acid, wherein said quantifying comprises amplifying the nucleic acid and performing nanopore sequencing,
- iv) comparing said amount of said immune-response analyte in said container and said second container to determine whether the subject has an immune response to said pathogen.

[0002b] In one aspect, provided herein is a method for detecting an immune response to a SARS-Cov2 virus by a subject, comprising:

- i) incubating a whole blood sample from said subject in a container comprising lithium heparin, glucose, an aluminum adjuvant, and a specific SARS-Cov2 antigen for at least 24 hours,
- ii) incubating a second whole blood sample from said subject in a second container comprising lithium heparin, glucose, an aluminum adjuvant, and not a SARS-Cov2 antigen, and
- iii) quantifying an amount of an IFN-gamma mRNA in said container and said second container to determine whether said subject has an immune response to said SARS-Cov2 virus,

wherein said aluminum adjuvant and said SARS-Cov2 antigen are at a ratio of 1:1 to 3:1 by weight, wherein weight of said aluminum adjuvant is as measured by weight of aluminum ion, wherein said SARS-Cov2 antigen comprises the peptide sequence of SEQ ID NO: 2.

[0003] Provided herein are point of need compositions, kits, and systems for detecting immune response to one or more pathogens, e.g. viruses, in a subject and methods for using same, as well as devices to perform methods described herein.

[0004] Provided herein, in an aspect are containers for detecting immune responses to specific pathogens by a subject. In an embodiment, provided herein is a container for detecting an immune response to a pathogen by a subject, wherein the container comprises an antigen of the pathogen and an anticoagulation agent, and wherein the antigen comprises a specific T cell recognized epitope of the pathogen.

[0005] In some embodiments, the antigen is lyophilized. In another embodiment, the antigen is in a solution.

[0006] In some embodiments, the container further comprises a sample obtained from the subject.

[0007] In some embodiments, the sample comprises PBMCs, CD8 T cells, NK cells, CD4 T cells, B cells, or any combination thereof.

[0008] In some embodiments, the sample comprises a body fluid. In some embodiments, the sample comprises saliva. In some embodiments, the sample comprises whole blood.

[0009] In some embodiments, the subject is a human.

[0010] In some embodiments, the container is used in detecting an immune response to the pathogen for a subject that exhibits symptoms of a condition associated with exposure to the pathogen. In some embodiments, the container is used in detecting an immune response to the pathogen for a subject that exhibits symptoms of a condition associated with exposure to the pathogen. The container is used in detecting an immune response to the pathogen for a subject suspected to have been exposed to the pathogen. In some embodiments, the container is used in incubating whole blood for at least 30 minutes.