IMMUNOREPERTOIRE WELLNESS ASSESSMENT SYSTEMS AND METHODS

BACKGROUND OF INVENTION

[0001] Diagnostic tests are currently available and performed on a regular basis to detect the presence or absence of a normal state in an individual. These tests, however, do not provide a clear assessment of the immunorepertoire in an individual or insight into how such individual's immunorepertoire is indicative of the presence or absence of wellness. A need, therefore, exists for systems and methods to provide individuals with a means of assessing and displaying their immunorepertoire in a manner that may assist with an assessment of the health of such individual.

SUMMARY

[0002] In one aspect, the present disclosure refers to a method of presenting a user's immunorepertoire profile to the user, comprising the steps of: determining at least one index for selected from the group consisting of a clonotype index, an essential index, and a diversity index to produce an immunorepertoire profile for a blood sample obtained from the user; wherein the clonotype index is obtained by performing the steps of measuring the total number of unique clonotypes from lymphocytes in the blood sample from the user and dividing the number of unique clonotypes by the number of unit reads for the blood sample; wherein the essential index is obtained by performing the steps of: (a) amplifying polynucleotides from a population of white blood cells from the blood sample of the user in a reaction mix comprising target-specific nested primers to produce a set of first amplicons, at least a portion of the target-specific nested primers comprising additional nucleotides which, during amplification, serve as a template for incorporating into the first amplicons a binding site for at least one common primer; (b) transferring a portion of the first reaction mix containing the first amplicons to a second reaction mix comprising at least one common primer; (c) amplifying, using the at least one common primer, the first amplicons to produce a set of second amplicons; (d) sequencing the second amplicons to identify CDR3 sequences in the subpopulation of white blood cells, and (e) identifying CDR3 sequences which constitute pCDR3s; (f) calculating the essential index based on the individual's pCDR3s; and (g) identifying whether the essential index is normal or abnormal, wherein a normal state is characterized by the presence of a minimum percentage of pCDR3 and an abnormal state is characterized by the absence of a minimum percentage of pCDR3; and wherein the diversity index is obtained by performing the steps of (a) amplifying polynucleotides from a population of white blood cells from the user's blood sample in a reaction mix comprising target-specific nested primers to produce a set of first amplicons, at least a portion of the target-specific nested primers comprising additional nucleotides which, during amplification, serve as a template for incorporating into the first amplicons a binding site for at least one common primer; (b) transferring a portion of the first reaction mix containing the first amplicons to a second reaction mix comprising at least one common primer; (c) amplifying, using the at least one common primer, the first amplicons to produce a set of second amplicons; (d) sequencing the second amplicons to identify V(D)J rearrangement sequences in the subpopulation of white blood cells, (e) using the identified V(D)J rearrangement sequences to quantify both the total number of cells in a population of immune system cells and the total numbers of cells within each of the clonotypes identified within the population; and (f) identifying the number of clonotypes that comprise a significant percentage of a total number of cells counted within that population, wherein a normal state is characterized by the presence of a greater variety of clonotypes represented within the significant percentage of the total number of cells and an abnormal state is characterized by the presence of a lesser number of clonotypes represented within a significant percentage of the total number of cells; and outputting information to the user pertaining to the user's immunorepertoire profile. In another aspect, the present disclosure refers to a method of presenting a user's immunorepertoire profile to the user, comprising the steps of: providing the user with a kit comprising a blood collection card, wherein the blood collection card comprises at least one blood collection area and a QR code; scanning the QR code by the user to associate the blood sample with the user's account on a software application; obtaining a set of

characteristic data associated with the user, wherein the characteristic data associated with the user comprises the user's age, gender and the presence or absence of any disease; determining at least one index for selected from the group consisting of a clonotype index, an essential index, and a diversity index to produce an immunorepertoire profile for a blood sample obtained from the user; wherein the clonotype index is obtained by performing the steps of measuring the total number of unique clonotypes from lymphocytes in the blood sample from the user and dividing the number of unique clonotypes by the number of unit reads for the blood sample; wherein the essential index is obtained by performing the steps of: (a) amplifying polynucleotides from a population of white blood cells from the blood sample of the user in a reaction mix comprising target-specific nested primers to produce a set of first amplicons, at least a portion of the target-specific nested primers comprising additional nucleotides which, during amplification, serve as a template for incorporating into the first amplicons a binding site for at least one common primer; (b) transferring a portion of the first reaction mix containing the first amplicons to a second reaction mix comprising at least one common primer; (c) amplifying, using the at least one common primer, the first amplicons to produce a set of second amplicons; (d) sequencing the second amplicons to identify CDR3 sequences in the subpopulation of white blood cells, and (e) identifying CDR3 sequences which constitute pCDR3s; (f) calculating the essential index based on the individual's pCDR3s; and (g) identifying whether the essential index is normal or abnormal, wherein a normal state is characterized by the presence of a minimum percentage of pCDR3 and an abnormal state is characterized by the absence of a minimum percentage of pCDR3; and wherein the diversity index is obtained by performing the steps of (a) amplifying polynucleotides from a population of white blood cells from the user's blood sample in a reaction mix comprising target-specific nested primers to produce a set of first amplicons, at least a portion of the target-specific nested primers comprising additional nucleotides which, during amplification, serve as a template for incorporating into the first amplicons a binding site for at least one common primer; (b) transferring a portion of the first reaction mix containing the first amplicons to a second reaction mix comprising at least one common primer; (c) amplifying, using the at least one common primer, the first amplicons to produce a set of second amplicons; (d) sequencing the second amplicons to identify V(D)J rearrangement sequences in the subpopulation of white blood cells, (e) using the identified V(D)J rearrangement sequences to quantify both the total number of cells in a population of immune system cells and the total numbers of cells within each of the clonotypes identified within the population; and (f) identifying the number of clonotypes that comprise a significant percentage of a total number of cells counted within that population, wherein a normal state is characterized by the presence of a greater variety of clonotypes represented within the significant percentage of the total number of cells and an abnormal state is characterized by the presence of a lesser number of clonotypes represented within a significant percentage of the total number of cells;and outputting information to the user pertaining to the user's immunorepertoire profile using a software application. In some examples, the present disclosure relates to a method of presenting a user's immunorepertoire profile to the user, comprising the steps of: obtaining a blood sample from the user; determining at least one index for selected from the group consisting of the clonotype index, essential index, and diversity index to produce an immunorepertoire profile for the blood sample for the user; and outputting information to the user pertaining to the user's immunorepertoire profile. In some examples, the method further comprises the step of obtaining a set of characteristic data associated with the user, wherein the characteristic data associated with the user comprises the user's age and gender. In some examples, the characteristic data further comprises the presence of any disease. In some examples, the blood sample comprises whole blood. In some examples, the blood sample comprises a dried blood spot. In some examples, the method comprises the additional steps of: providing the user with a kit comprising a blood collection card, wherein the blood collection card comprises at least one blood collection area and a QR code; and scanning the QR code by the user to associate the blood sample with the user's account on a software application. In some examples, the step of outputting information to the user is performed using a software application.

CLAIMS

Now, therefore, the following is claimed:

1. A method of presenting a user's immunorepertoire profile to the user, comprising the steps of:

determining at least one index for selected from the group consisting of a clonotype index, an essential index, and a diversity index to produce an immunorepertoire profile for a blood sample obtained from the user;

wherein the clonotype index is obtained by performing the steps of measuring the total number of unique clonotypes from lymphocytes in the blood sample from the user and dividing the number of unique clonotypes by the number of unit reads for the blood sample;

wherein the essential index is obtained by performing the steps of: (a) amplifying polynucleotides from a population of white blood cells from the blood sample of the user in a reaction mix comprising target-specific nested primers to produce a set of first amplicons, at least a portion of the target-specific nested primers comprising additional nucleotides which, during amplification, serve as a template for incorporating into the first amplicons a binding site for at least one common primer; (b) transferring a portion of the first reaction mix containing the first amplicons to a second reaction mix comprising at least one common primer; (c) amplifying, using the at least one common primer, the first amplicons to produce a set of second amplicons; (d) sequencing the second amplicons to identify CDR3 sequences in the subpopulation of white blood cells, and (e) identifying CDR3 sequences which constitute pCDR3s; (f) calculating the essential index based on the individual's pCDR3s; and (g) identifying whether the essential index is normal or abnormal, wherein a normal state is characterized by the presence of a minimum percentage of pCDR3 and an abnormal state is characterized by the absence of a minimum percentage of pCDR3; and

wherein the diversity index is obtained by performing the steps of (a) amplifying polynucleotides from a population of white blood cells from the user's blood sample in a reaction mix comprising target-specific nested primers to

produce a set of first amplicons, at least a portion of the target-specific nested primers comprising additional nucleotides which, during amplification, serve as a template for incorporating into the first amplicons a binding site for at least one common primer; (b) transferring a portion of the first reaction mix containing the first amplicons to a second reaction mix comprising at least one common primer; (c) amplifying, using the at least one common primer, the first amplicons to produce a set of second amplicons; (d) sequencing the second amplicons to identify V(D)J rearrangement sequences in the subpopulation of white blood cells, (e) using the identified V(D)J rearrangement sequences to quantify both the total number of cells in a population of immune system cells and the total numbers of cells within each of the clonotypes identified within the population; and (f) identifying the number of clonotypes that comprise a significant percentage of a total number of cells counted within that population, wherein a normal state is characterized by the presence of a greater variety of clonotypes represented within the significant percentage of the total number of cells and an abnormal state is characterized by the presence of a lesser number of clonotypes represented within a significant percentage of the total number of cells; and

outputting information to the user pertaining to the user's immunorepertoire profile.

2. The method of claim 1, further comprising the step of obtaining a set of characteristic data associated with the user, wherein the characteristic data associated with the user comprises the user's age and gender.

3. The method of claim 2, wherein the characteristic data further comprises the presence of any disease.

4. The method of claim 1, wherein the blood sample comprises whole blood.

5. The method of claim 1, wherein the blood sample comprises a dried blood spot.

6. The method of claim 5, comprising the additional steps of:

providing the user with a kit comprising a blood collection card, wherein the blood collection card comprises at least one blood collection area and a QR code; and

scanning the QR code by the user to associate the blood sample with the user's account on a software application.

7. The method of claim 1, wherein the step of outputting information to the user is performed using a software application.

8. A method of presenting a user's immunorepertoire profile to the user, comprising the steps of:

providing the user with a kit comprising a blood collection card, wherein the blood collection card comprises at least one blood collection area and a QR code;

scanning the QR code by the user to associate the blood sample with the user's account on a software application;

obtaining a set of characteristic data associated with the user, wherein the characteristic data associated with the user comprises the user's age, gender and the presence or absence of any disease;

determining at least one index for selected from the group consisting of a clonotype index, an essential index, and a diversity index to produce an immunorepertoire profile for a blood sample obtained from the user;

wherein the clonotype index is obtained by performing the steps of measuring the total number of unique clonotypes from lymphocytes in the blood sample from the user and dividing the number of unique clonotypes by the number of unit reads for the blood sample;

wherein the essential index is obtained by performing the steps of: (a) amplifying polynucleotides from a population of white blood cells from the blood sample of the user in a reaction mix comprising target-specific nested primers to produce a set of first amplicons, at least a portion of the target-specific nested primers comprising additional nucleotides which, during amplification, serve as a template for incorporating into the first amplicons a binding site for at least one common primer; (b) transferring a portion of the first reaction mix containing the

first amplicons to a second reaction mix comprising at least one common primer; (c) amplifying, using the at least one common primer, the first amplicons to produce a set of second amplicons; (d) sequencing the second amplicons to identify CDR3 sequences in the subpopulation of white blood cells, and (e) identifying CDR3 sequences which constitute pCDR3s; (f) calculating the essential index based on the individual's pCDR3s; and (g) identifying whether the essential index is normal or abnormal, wherein a normal state is characterized by the presence of a minimum percentage of pCDR3 and an abnormal state is characterized by the absence of a minimum percentage of pCDR3; and

wherein the diversity index is obtained by performing the steps of (a) amplifying polynucleotides from a population of white blood cells from the user's blood sample in a reaction mix comprising target-specific nested primers to produce a set of first amplicons, at least a portion of the target-specific nested primers comprising additional nucleotides which, during amplification, serve as a template for incorporating into the first amplicons a binding site for at least one common primer; (b) transferring a portion of the first reaction mix containing the first amplicons to a second reaction mix comprising at least one common primer; (c) amplifying, using the at least one common primer, the first amplicons to produce a set of second amplicons; (d) sequencing the second amplicons to identify V(D)J rearrangement sequences in the subpopulation of white blood cells, (e) using the identified V(D)J rearrangement sequences to quantify both the total number of cells in a population of immune system cells and the total numbers of cells within each of the clonotypes identified within the population; and (f) identifying the number of clonotypes that comprise a significant percentage of a total number of cells counted within that population, wherein a normal state is characterized by the presence of a greater variety of clonotypes represented within the significant percentage of the total number of cells and an abnormal state is characterized by the presence of a lesser number of clonotypes represented within a significant percentage of the total number of cells; and

outputting information to the user pertaining to the user's immunorepertoire profile using a software application.