

CLAIMS:

1. An immunoassay suitable for point of care to assess liver disease or function,
said assay comprising:
 - (i) contacting a blood sample from a human subject with a specific binding agent that recognizes an epitope of ALT1, that is not recognized by rodent antibodies when the rodent antibodies are in the presence of human plasma, to form an antigen-binding agent complex and detecting the complex using a second or further binding agent linked to or comprising a detectable reporter; and
 - (ii) detecting liver disease or liver function in the subject contingent upon the mass concentration of ALT1 in the sample.
2. The assay of claim 1 wherein the specific binding agent is a lagomorph antibody or comprises an antigen binding part thereof, or wherein the specific binding agent recognizes the same epitope as the rabbit antibody.
3. The assay of claim 1 or 2 wherein the mass concentration of the ALT1 is positively correlated with ALT1 enzymatic activity.
4. The assay of any one of claims 1 to 3 wherein the mass concentration of ALT1 is positively correlated with increasing liver disease.
5. The assay of any one of claims 1 to 4 wherein the binding agent is an antibody or comprises an immunoglobulin domain thereof.
6. The assay of one of claim 1 to 5 wherein the assay is an enzyme-linked immunosorbent (ELISA)-type or immunochromatographic-type assay or microfluidic assay and the binding agent is immobilised on a support.
7. The assay of claim 6, wherein the assay is an immunochromatographic-type assay and wherein the blood sample is contacted with the binding agent by applying the blood sample to a sample portion of an immunochromatographic device wherein the device sample portion is operably connected to a spaced capture portion of the device and whereby the components of the sample flow from the device sample portion to and

through the device capture portion, and wherein one capture portion comprises the binding agent which specifically binds to the antigen in the sample such that the antigen is captured by the binding agent to form a binding agent-antigen complex in the capture portion.

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8. The assay of any one of claims 1 to 7 wherein the antigen complex is detected using a binding agent such as an antibody or antigen-binding fragment, ligand or affimer that specifically binds the antigen and directly or indirectly provide a detectable signal that can be quantified visually or by instrument reader.

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9. The assay of any one of claims 7-8 wherein the capture portion is a test line.

10. A kit for measuring the mass concentration of ALT1 comprising (i) a chromatographic device comprising a porous membrane, or a microfluidic device, operably connected to a sample portion, one or more capture (test) portions, and optionally one or more of the following; a conjugate (detection marker) portion, a sucker component, a suitable control portion and optionally a cell lysis or solubilisation portion, and (ii) a lagomorph antibody or an agent comprising the antigen binding part thereof that recognizes an epitope of ALT1, and forms an ALT1-lagomorph antibody/antibody/antigen binding part complex, and (iii) optionally instructions for using the device to determine liver function.

11. The kit of claim 10 wherein the device is chromatographic device comprising a porous membrane suitable for reverse or lateral flow immunochromatographic formats.

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12. A kit for measuring the mass concentration of ALT1 comprising (i) a chromatographic device comprising a porous membrane, or a microfluidic device, operably connected to a sample portion, one or more capture (test) portions, and optionally one or more of the following; a conjugate (detection marker) portion, a sucker component, a suitable control portion and optionally a cell lysis or solubilisation portion, and (ii) a lagomorph antibody or an agent comprising the antigen binding part thereof that recognizes an epitope of ALT1, and forms an ALT1-lagomorph antibody/antibody/antigen binding part complex, and (iii) optionally instructions for using the device to determine liver function.

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13. The method of claim 12, wherein the method is able to detect a mass concentration of human ALT1 that is equivalent to 40 IU/L ALT1 or equivalent to between 20 and 200 IU/L ALT1.

5 14. A method of screening for antibody or other specific binding agents that are substantially not inhibited from antigen binding by plasma, the method comprising contacting antigen and a potential antigen binding agent in the presence of different concentrations of plasma to determine whether the binding agent can bind the antigen in the presence of plasma.

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15. The method of claim 14, wherein the antigen is a liver enzyme such as ALT1.

16. An immunoassay suitable for point of care to assess liver disease or liver function, said assay comprising:

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(i) contacting a blood sample from a human subject with a specific binding agent that recognizes an epitope of a liver enzyme or a metabolite thereof, that is not recognized by rodent/mouse antibodies when the rodent antibodies are in the presence of human plasma, to form an antigen-binding agent complex and detecting the complex using a second binding agent linked to a detectable reporter; and

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(ii) detecting liver disease or function in the subject contingent upon the mass concentration of liver enzyme or metabolite thereof in the sample.

25 17. The assay of claim 16 wherein the specific binding agent is a lagomorph antibody or comprises an antigen binding part thereof, or wherein the specific binding agent recognizes the same epitope as the lagomorph antibody.

18. The assay of claim 16 or 17 wherein the mass concentration of the liver enzyme is positively correlated with the liver enzyme enzymatic activity.

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19. The assay of any one of claims 16 to 18 wherein the mass concentration of liver enzyme is positively correlated with increasing liver disease.

35 20. The assay of any one of claims 16 to 19 wherein the binding agent is an antibody or comprises an immunoglobulin domain thereof.

21. The assay of one of claim 16 to 20 wherein the assay is an enzyme-linked immunosorbent (ELISA)-type or immunochromatographic-type assay, or microfluidic assay and the binding agent is immobilised on a support.
- 5 22. The assay of any one of claims 1 to 9 or 16 to 21 or the method of claim 12 or 13 or the kit of claim 10 or 11 wherein the assay or method or kit further comprises assessing or includes reagents for assessing platelet levels to determine a liver enzyme:platelet ratio index as described herein as a measure of liver fibrosis in the subject.