CLAIMS

1. An in vitro 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 an antibody or immunoglobulin domain thereof that specifically recognizes an epitope of human ALT1, that is not recognized by rodent antibodies raised against human ATL, when the rodent antibodies are in the presence of human plasma, to form an antigen-antibody complex and detecting the complex using a 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 determined from step (i);

and wherein;

(a) the specific binding agent is a lagomorph antibody raised against human ATL1 or comprises an antigen binding part thereof, or wherein the specific binding agent recognizes the same epitope as the lagomorph antibody; and/or

(b) the epitope of ALT1 is not immunodominant; and/or

(c) the mass concentration of the ALT1 is positively correlated with ALT1 enzymatic activity; and/or

(d) the mass concentration of ALT1 is positively correlated with increasing liver disease; and/or

(e) the immunoassay detects a mass concentration of human ALT1 that is equivalent to the upper limit of normal human ALT1 enzyme activity.

2. The assay of claim 1, wherein the assay is an enzyme-linked immunosorbent (ELISA)-type or immunochromatographic-type assay or microfluidic assay.

3. The assay of claim 1 or 2, wherein the anti-human ATL1 antibody or immunoglobulin binding domain thereof is immobilised on a support.

4. The assay of claim 3, wherein the assay is an immunochromatographic-type assay and wherein the blood sample is contacted with the anti-human ATL1 antibody or immunoglobulin binding domain thereof 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 anti-human ATL1 antibody or immunoglobulin binding domain thereof which specifically binds to the human ATL1 antigen in the sample such that the antigen is captured by the antibody or immunoglobulin binding domain thereof to form a binding agent-antigen complex in the capture portion.

5. The assay of claim 4, wherein the capture portion is a test line.

6. The assay of any one of claims 1 to 5, wherein the antibody-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 provides a detectable signal that can be quantified visually or by instrument reader.

7. 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 human ALT1, and forms an ALT1-lagomorph antibody/ agent comprising an antigen binding part thereof complex, and wherein;

(a) the epitope of ALT1 is not immunodominant; and/or

(b) the mass concentration of the ALT1 is positively correlated with ALT1 enzymatic activity; and/or

(c) the mass concentration of ALT1 is positively correlated with increasing liver disease; and/or.

(d) the kit detects a mass concentration of human ALT1 that is equivalent to the upper limit of normal human ALT1 enzyme activity such as 40IU/L or equivalent to between 20 and 200IU/L human ALT1;and/or

(e) the enzymatic level of ALT1 in the sample shows a visual correlation with the intensity of the ATL1 test line in the device; and/or

(f) a control portion comprises a reference line corresponding to one or more clinically relevant amounts of ALT1, such as a line corresponding to 40IU/L ALT1.

8. A method of screening for antibody or other specific binding agents that are substantially not inhibited from antigen binding by human plasma, the method

comprising contacting antigen and a potential antibody or 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.

9. The method of claim 8, wherein the antigen is a liver enzyme, such as ALT1.

10. The kit of claim 7 further comprising reagents for assessing platelet levels.