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 specific binding agent that specifically recognizes an epitope of human ALT1 even in the presence of human plasma, or recognizes an epitope of human ALT1 that is not recognized by rodent antibodies to human ATL1 in the presence of human plasma, to form an antigen-agent complex and detecting the complex using a detecting 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;

the specific binding agent is an antibody or comprises an antigen binding part thereof that recognises a human ATL1 epitope that is non-immunodominant in humans; and wherein the antibody is (a) a lagomorph antibody raised against human ATL1 or comprises an antigen binding part thereof, or (b) is an antibody or comprises an antigen binding part thereof that recognizes the same epitope as the lagomorph antibody in (a), and wherein the specific binding agent allows the immunoassay to detect 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 mass concentration of the ALT1 is positively correlated with ALT1 enzymatic activity over a clinically useful range, and wherein the mass concentration of ALT1 is positively correlated with increasing liver disease over a clinically useful range.

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

4. The assay of claim 1 or 2, wherein the anti-human ATL1 antibody or agent comprising an antigen- binding part thereof is immobilised on a support.

5. The assay of claim 4, wherein the assay is an immunochromatographic-type assay and wherein the blood sample is contacted with the anti-human ATL1 antibody or antigen 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.

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

7. The assay of any one of claims 1 to 6, wherein the antibody-antigen complex is detected using a binding agent and wherein the binding agent is an antibody or antigen-binding fragment, a 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.

8. A kit for measuring the mass concentration of ALT1 suitable for point of care to assess liver disease or function 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 portion, a sucker component, a suitable control portion and optionally a cell lysis or solubilisation portion, and (ii) a specific binding agent comprising an antibody or antigen binding part thereof that recognises an epitope of ALT1 that is not immunodominant in humans, wherein the antibody or antigen binding part thereof is (a) a lagomorph antibody or antigen binding part thereof that recognizes an epitope of human ALT1 in the presence of human plasma, and forms an ALT1-lagomorph antibody complex or an ALT1-antigen binding part thereof complex, or (b) an antibody or an antigen binding part thereof that recognizes the same epitope as the lagomorph antibody in (a).and wherein;

(c) the kit detects a mass concentration of the ALT1 positively correlated with ALT1 enzymatic activity over a clinically useful range; and

(d) the kit detects a mass concentration of ALT1 positively correlated with increasing liver disease over a clinically useful range; and

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

9. The kit of claim 8 wherein the kit detects a mass concentration of ALT1 equivalent to 40IU/L ALT.

10. The kit of claim 8 or 9, wherein the control portion comprises a reference line corresponding to a clinically relevant amount of ALT1.

11. The kit according to any one of claims 8 to 10, wherein the test portion comprises an ALT1 test line wherein, in use, the mass concentration of ALT1 or the enzymatic level of ALT in the sample provides a visual correlation with the intensity of the ATL1 test line.

12. The kit of claim 8 further comprising reagents for assessing platelet levels.