

Date: 7 February 2017

From: Dr Kitty Croxson, Virology/Immunology, LabPlus, ADHB

Subject: **Hepatitis C NS5A resistance testing**

LabPlus is now offering NS5A resistance testing for patients who have failed direct acting antiviral (DAA) therapy for hepatitis C, genotype 1a.

Resistance of HCV to DAAs is related to the nucleotide substitutions emerging during replication. Full resistance depends on the number and type of Resistance-Associated Substitutions (RASs) acquired.

We perform NS5A 1a analysis using Sanger sequencing of an informative fragment of the NS5A gene.

RAS for patients who have failed virologic treatment is assessed for the following codons :

Related nucleotide substitution:

M28T
Q30E / H / R
L31M / V
P32L
H58D
Y93C / H / N

Related Drug Resistance:

Ledipasvir (LDV)
Daclatasvir (DCV)
Ombitasvir (OMV)
Elbasvir (EBR)

The requirements for test acceptance are:

- 1. 5ml of serum or EDTA plasma.***
- 2. The request **MUST** state that the patient has failed a regimen containing an NS5A inhibitor (i.e. either VIEKIRA PAK, HARVONI, ZEPATIER or generic daclatasvir plus sofosbuvir. (list drugs)***
- 3. A recent (within past month) HepC viral load result is required.***
- 4. A recent (within past month) HepC genotyping result is required.***

Final cost has not been set, but likely to retail at \$330 approx.