Hepatitis C Virus (HCV) NS5A Drug Resistance by Sequencing

Last Literature Review: October 2025 Last Update: December 2025

Hepatitis C is a common cause of viral hepatitis and can progress to chronic hepatitis, which can result in liver failure, cirrhosis, or hepatocellular carcinoma if undiagnosed and untreated.[1] Before initiating treatment with select NS5A inhibitors, hepatitis C virus (HCV) genotype and subtype testing is recommended. This test sequences NS5A codons 20-101 for HCV genotypes 1a and 1b and reports resistance-associated substitutions to ledipasvir, elbasvir, ombitasvir, daclatasvir, velpatasvir, and pibrentasvir.

Featured ARUP Testing

Hepatitis C Virus (HCV) NS5A Drug Resistance by Sequencing 2014139

Method: Polymerase Chain Reaction (PCR)/Sequencing

Order before initiating treatment with NS5A inhibitors. Do not order before molecular confirmation of positive HCV screen and confirmation of genotype 1a or 1b.

Test Interpretation

Limitations

- Specimens with viral loads <3.4 log or 2,500 IU/mL may fail to amplify, thus producing an indeterminate result.
- Testing may not be successful if the HCV RNA genotype is not 1a or 1b.
- Variants in viral subpopulations less than 20% of the total may not be detected.

Evaluated Mutations

HCV Genotype 1a						
Variant	**Ledipasvir**	**Elbasvir**	**Ombitasvir**	**Daclatasvir**	**Velpatasvir**	**Pibrentasvir**
K24E[2]	NP	NP	NP	NP	NP	NP
K24T[3]	NP	NP	NP	NP	NP	NP
K24R[4,5,6,7]	Poss	NP	NP	Poss	NP	NP
K24N[4,7]	Poss	NP	NP	NP	NP	NP
K24G[4,7]	Poss	NP	NP	NP	NP	NP
M28S[4]	NP	Poss	NP	NP	NP	NP
M28T[4,5,6,7,8,9,10,11,12,13,14]	Pred	Pred	Poss	Poss	Poss	NP
M28V[4,5,6,8,9,10,11,15]	Poss	Poss	Poss	Poss	Poss	NP
M28G[4,5,7,12]	Pred	Pred	NP	NP	Poss	Poss
M28A[4,5,7,8,9,12,14]	Pred	Pred	Poss	Poss	Poss	Poss
P29Q[16]	NP	NP	NP	NP	NP	Poss
P29R[16]	NP	NP	NP	NP	NP	Poss
Q30D[4,12,17]	NP	Pred	NP	Poss	NP	Poss
Q30E[4,5,7,8,9,10,11,12,13]	Pred	Pred	Poss	Poss	Poss	NP
Q30G[4,7,12]	Pred	Pred	NP	Poss	NP	NP
Q30H[4,5,7,8,9,10,11,12,13,14,15,18]	Pred	Pred	Poss	Poss	Poss	NP
Q30K[4,5,7,8,12,13]	Pred	Pred	Poss	Poss	Poss	Poss

Variant	Ledipasvir	Elbasvir	Ombitasvir	Daclatasvir	Velpatasvir	Pibrentasvir
Q30L[4,5,7,8,12,13]	Poss	Pred	Poss	Poss	Poss	NP
Q30N[4,13,19,20,21,22]	Poss	NP	NP	Poss	Poss	Poss
Q30S[19]	Poss	NP	NP	NP	NP	NP
Q30R[4,5,7,8,9,10,11,12,13,14,18]	Pred	Pred	Poss	Poss	Poss	Poss
Q30P[23]	NP	NP	NP	NP	NP	NP
Q30Y[4,5]	Poss	Poss	Poss	Poss	NP	NP
Q30T[4,7,21,24,25,26,27]	Poss	Poss	NP	Poss	NP	NP
L31V[4,5,7,8,9,10,11,12,13,14]	Pred	Pred	Poss	Poss	Pred	NP
L31C[28]	NP	NP	NP	Poss	NP	NP
L31R[29]	NP	NP	NP	Poss	NP	NP
L31I[4,7,13]	Poss	Poss	NP	Poss	Poss	NP
L31M[4,5,7,8,9,10,11,12,13,14,15,18]	Pred	Pred	Poss	Poss	Pred	Poss
L31P[5]	Poss	NP	NP	NP	NP	NP
L31F[4,9,11,12,15]	Poss	Pred	Poss	Poss	Poss	NP
P32L[4,7,12,13]	Pred	NP	Poss	Poss	Poss	NP
P32S[12]	Pred	NP	NP	NP	NP	NP
S38C[30]	Poss	NP	NP	NP	NP	NP
S38F[4,5,7]	Poss	NP	NP	NP	NP	NP
H58R[31]	NP	NP	NP	NP	NP	NP
H58P[16,29,32,33,34,35]	Poss	NP	Poss	Poss	NP	NP
H58D[4,5,7,9,10,12,13]	Pred	Pred	Poss	Poss	Poss	Poss
H58C[36]	NP	NP	NP	NP	NP	NP
A92E[37,38]	NP	NP	NP	NP	NP	NP
A92V[39]	NP	NP	NP	NP	NP	NP
A92T[4,7,9]	Poss	NP	NP	Poss	NP	NP
A92P[27]	NP	NP	NP	Poss	NP	NP
A92K[4,9,40,41]	NP	NP	NP	Poss	Poss	NP
Y93A[42]	NP	NP	NP	NP	Poss	NP
Y93C[4,5,7,8,9,10,11,12,13,14,15]	Pred	Pred	Poss	Poss	Poss	NP
Y93D[17,43]	NP	NP	NP	NP	NP	Poss
Y93F[4,7,8,13,15]	Poss	NP	Poss	Poss	NP	Poss
Y93G[3]	NP	NP	NP	Poss	NP	NP
Y93H[4,5,7,8,9,10,11,12,13,14,15,18]	Pred	Pred	Poss	Poss	Pred	Poss
Y93L[4,44]	NP	NP	Poss	NP	Poss	NP
Y93N[4,5,7,8,9,10,11,12,13,14,15]	Pred	Pred	Poss	Poss	Pred	Poss

Variant	Ledipasvir	Elbasvir	Ombitasvir	Daclatasvir	Velpatasvir	Pibrentasvir
Y93R[4,13]	NP	NP	NP	NP	Poss	NP
Y93S[4,5,7,12,13]	Pred	Pred	Poss	Poss	Poss	NP
Y93T[4,29]	NP	NP	NP	Poss	Poss	NP
Y93W[4,13]	NP	NP	NP	NP	Poss	NP

HCV Genotype 1b						
Variant	Ledipasvir	Elbasvir	Ombitasvir	Daclatasvir	Velpatasvir	Pibrentasvir
Q24K[4,36,45]	NP	NP	NP	NP	Poss	Poss
L28A[39,45]	NP	Poss	NP	NP	NP	NP
L28M[4,5,34,45,46,47,48,49]	Poss	Poss	Poss	Poss	Poss	NP
L28T[4,5,17,36,45,50,51]	Poss	Poss	Poss	Poss	NP	NP
L28V[5]	NP	NP	Poss	NP	NP	NP
P29del[10]	NP	NP	NP	Poss	NP	NP
P29S[5,10,45]	NP	NP	NP	Poss	NP	NP
R30H[4,5,45]	Poss	NP	NP	Poss	NP	NP
R30E[2,46]	NP	NP	NP	Poss	NP	NP
R30G[5,45]	NP	NP	NP	Poss	NP	NP
R30Q[4,5,45]	NP	Poss	Poss	Poss	NP	NP
R30P[5,45]	NP	NP	NP	Poss	NP	NP
R30S[4,45]	NP	NP	NP	NP	Poss	NP
L31M[4,5,7,8,10,13,15,45,52]	Poss	Poss	Poss	Poss	Poss	NP
L31F[4,5,8,15,45,50]	Poss	Poss	Poss	Poss	Poss	NP
L31H[53]	NP	NP	NP	Poss	NP	NP
L31P[54]	NP	NP	NP	NP	NP	NP
L31W[4,45,54,55,56]	NP	NP	NP	Poss	NP	NP
L31V[4,5,7,8,10,13,14,45,50]	Pred	Poss	Poss	Poss	Poss	NP
L31S[54]	NP	NP	NP	NP	NP	NP
L31R[54]	NP	NP	NP	Poss	NP	NP
L31I[4,5,7,8,14,45]	Poss	Poss	NP	Poss	Poss	NP
P32F[5,45]	NP	NP	NP	Poss	NP	NP
P32L[5,7,45]	Poss	NP	NP	Poss	NP	NP
P32S[45]	NP	NP	NP	NP	NP	NP
P32del[5,36,45,57,58]	Poss	Poss	Poss	Poss	Poss	Poss
Q54Y[5]	NP	NP	NP	Poss	NP	NP
Q54H[5,29,34]	NP	NP	NP	Poss	NP	NP

Variant	Ledipasvir	Elbasvir	Ombitasvir	Daclatasvir	Velpatasvir	Pibrentasvir
P58A[4,45]	NP	NP	NP	Poss	NP	NP
P58S[4,5,17,45,50,59,60]	Poss	NP	Poss	Poss	NP	NP
P58R[4,27,45]	NP	NP	NP	NP	Poss	NP
P58L[4,11,45]	NP	NP	Poss	Poss	NP	NP
P58T[4,45]	NP	NP	NP	NP	Poss	NP
P58D[4,7,45,61]	Poss	NP	NP	NP	NP	NP
Q62D[5,45]	NP	NP	NP	Poss	NP	NP
*Q62R*cite[62,63]	NP	NP	NP	Poss	NP	NP
A92E[36,45,50,64]	Poss	NP	NP	Poss	NP	NP
A92V[36,45,50,65]	NP	NP	Poss	NP	NP	NP
A92T[4,45]	Poss	NP	Poss	NP	NP	NP
A92K[4,7,41,45,48,61]	Poss	Poss	NP	Poss	Poss	NP
Y93C[4,8,13,45]	Poss	NP	NP	Poss	Poss	NP
Y93H[4,5,7,8,10,13,14,45,50]	Pred	Pred	Poss	Poss	Poss	NP
Y93I[4]	NP	NP	NP	Poss	NP	NP
Y93L[16]	NP	NP	NP	NP	NP	NP
Y93N[4,5,13,45,50,61,62]	NP	NP	Poss	Poss	Poss	NP
Y93R[4,45]	NP	NP	NP	Poss	Poss	NP
Y93S[4,13,36,45,66]	Poss	NP	Poss	NP	Poss	NP
Y93T[4,45]	NP	NP	NP	NP	Poss	NP
Y93W[67]	NP	NP	NP	NP	NP	NP

NP, resistance not predicted; Poss, possible resistance; Pred, predicted resistance

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