

Molecular Hepatitis Testing Quick Reference Guide

Test Name	N ^o	Specimen Requirement Transfer serum or plasma to a polypropylene screw-cap tube and freeze. Ship frozen screw-cap transport tube or frozen PPT [™] tube.	Use/Limitations
Hepatitis C Virus (HCV), Quantitative, Real-time PCR	550080 550070*	2.5 mL serum or plasma Collect specimen in gel-barrier, lavender-top (EDTA), or PPT tube. Centrifuge specimen within 24 hours of collection. Plasma from a PPT can be frozen and shipped in situ.	Confirm an active hepatitis infection. Determine the number of international units (IU) of hepatitis C virus (HCV) RNA per milliliter in serum or plasma in known HCV-positive patients. The quantifiable range of the assay is 15 IU/mL to 100,000,000 IU/mL.
Hepatitis C Virus (HCV) Genotyping, Nonreflex	550475	3 mL serum or plasma Collect specimen in gel-barrier, yellow-top (ACD), lavender-top (EDTA) or PPT tube. Do not use green-top (heparin) tubes. Centrifuge specimen within 6 hours of collection. Centrifuge PPT within six hours and freeze .	This test allows for the genotyping of the six major HCV types and their most common subtypes. This procedure may not be successful when the HCV viral load is <1000 IU/mL in serum/plasma.
Hepatitis C Virus (HCV), Quantitative, RNA PCR (Nongraphical) With Reflex to Genotyping	550090 550100*	3 mL serum or plasma Collect specimen in gel-barrier, lavender-top (EDTA), or PPT tube. Centrifuge specimen within 24 hours of collection. Plasma from a PPT can be frozen and shipped in situ.	Quantitation of hepatitis C virus with reflex to HCV genotype if viral load is >1000 IU/mL. The quantifiable range of the assay is 15 IU/mL to 100,000,000 IU/mL.
Hepatitis C Virus (HCV) GenoSure [®] NS3/4A	550540	3 mL plasma Collect specimen in two lavender-top (EDTA) tubes or two PPT tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze . Please indicate the patient's HCV genotype (1a or 1b) on the test request form.	Detect resistance in HCV to direct-acting antiviral agents. This procedure may not be successful when the viral load is <2000 IU/mL plasma. This assay requires an HCV genotype of either 1a or 1b. Detects Q80K polymorphism.
Hepatitis C Virus (HCV), Quantitative, RNA PCR (Nongraphical) With Reflex to Hepatitis C Virus (HCV) GenoSure [®] NS3/4A	550072 550066*	6 mL plasma Collect specimen in PPT or lavender-top (EDTA) tube. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze . Please indicate the patient's HCV genotype (1a or 1b) on the test request form.	Quantitation of hepatitis C virus with reflex to HCV GenoSure(R) NS3/4A if viral load is >2000 IU/mL. The HCV real-time PCR assay has a quantitative range of 15 IU/mL to 100,000,000 IU/mL. This assay requires an HCV genotype 1a or 1b. Detects Q80K polymorphism.
Hepatitis C Virus (HCV) Genotyping With 1a Subtype Reflex to Hepatitis C Virus (HCV) GenoSure [®] NS3/4A	550555	3 mL serum or plasma Collect specimen in two PPTs, gel-barrier tubes, yellow-top (ACD) tubes, or lavender-top (EDTA) tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze .	Genotyping of the six major HCV types and their most common subtypes. Assessment of drug susceptibility by nucleic acid sequencing of a patient's hepatitis C virus (HCV) to the NS3/4A protease inhibitors. Detects Q80K polymorphism. The HCV GenoSure(R) NS3/4A assay is only validated for samples with HCV Viral Load >2000 IU/mL.
Hepatitis C Virus (HCV) NS5A Drug Resistance Assay	550325	2 mL plasma (preferred) or serum Collect specimen in two PPT, gel-barrier, or lavender-top (EDTA) tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze . Please indicate the patient's HCV genotype (1a or 1b) on the test request form.	Assessment of drug susceptibility by nucleic acid sequencing of a patient's hepatitis C virus (HCV) to the NS5A inhibitors. This procedure may not be successful when the HCV viral load is <500 IU/mL plasma. This assay requires an HCV genotype of either 1a or 1b.
Hepatitis C Virus (HCV), Quantitative, RNA PCR (Nongraphical) With Reflex to Hepatitis C Virus (HCV) NS5A Drug Resistance Assay	550349 550333*	4 mL plasma (preferred) or serum Collect specimen in two PPT, gel-barrier, or lavender-top (EDTA) tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze . Please indicate the patient's HCV genotype (1a or 1b) on the test request form.	Quantification of HCV with reflex to HCV NS5A Drug Resistance Assay (at additional charge) if ≥ 500 IU/mL. The HCV real-time PCR assay has a quantitative range of 15 IU/mL to 100,000,000 IU/mL. This assay requires an HCV genotype of either 1a or 1b.
Hepatitis C Virus (HCV) Genotyping With 1a Subtype Reflex to Hepatitis C Virus (HCV) NS5A Drug Resistance Assay	550615	3 mL plasma (preferred) or serum Collect specimen in two PPT tubes, gel-barrier tubes, yellow-top (ACD) tubes, or lavender-top (EDTA) tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze .	Genotyping of the six major HCV types and their most common subtypes. Assessment of drug susceptibility by nucleic acid sequencing of a patient's hepatitis C virus (HCV) to the NS5A inhibitors. Detects resistance-associated variants at positions 28, 30, 31 and 93 in genotype 1a HCV. The HCV genotype determination may not be successful when the HCV viral load is <1000 IU/mL serum/plasma. The HCV NS5A drug resistance assay will only be performed when the HCV genotype is 1a.
Hepatitis C Virus (HCV) GT1a NS5A Profile	550705	4 mL plasma (preferred) or serum Collect specimen in two PPT tubes, gel-barrier tubes, yellow-top (ACD) tubes, or lavender-top (EDTA) tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze .	The HCV GT1a NS5A profile is intended for baseline determination of HCV viral load, HCV genotype and HCV NS5A drug resistance in patients with documented HCV infection and HCV genotype 1a.

* Includes graphical report

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Hepatitis C Virus (HCV) Genotype 3 NS5A Drug Resistance Assay	550603	2 mL plasma (preferred) or serum Collect specimen in two lavender-top (EDTA), gel-barrier, or PPT tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze.	Assessment of drug susceptibility by nucleic acid sequencing of a patient's hepatitis C virus (HCV) to the NS5A inhibitors. Assay should be used for patients with documented HCV genotype 3. This procedure may not be successful when the HCV viral load is <500 IU/mL plasma. This assay requires an HCV genotype of 3.
Hepatitis C Virus (HCV) NS5B Drug Resistance Assay	550505	2 mL plasma (preferred) or serum Collect specimen in two PPT, gel-barrier, or lavender-top (EDTA) tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze . Please indicate the patient's HCV genotype (1a or 1b) on the test request form.	Assessment of drug susceptibility by nucleic acid sequencing of a patient's hepatitis C virus (HCV) to the NS5B inhibitors. This procedure may not be successful when the HCV viral load is <1000 IU/mL plasma. This assay requires an HCV genotype of either 1a or 1b.
Hepatitis C Virus (HCV), Quantitative, RNA PCR (Nongraphical) With Reflex to Hepatitis C Virus (HCV) NS5B Drug Resistance Assay	550577 550554*	4 mL plasma (preferred) or serum Collect specimen in two PPT, gel-barrier, or lavender-top (EDTA) tubes. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection. Centrifuge PPT within six hours and freeze . Please indicate the patient's HCV genotype (1a or 1b) on the test request form.	Quantification of HCV with reflex to HCV NS5B Drug Resistance Assay (at additional charge) if ≥ 1000 IU/mL. The HCV real-time PCR assay has a quantitative range of 15 IU/mL to 100,000,000 IU/mL. This assay requires an HCV genotype of either 1a or 1b.

Hepatitis C Virus (HCV) continued

Test Name	N°	Specimen Requirement	Use/Limitations
		Specimen Requirement	
Hepatitis B Virus (HBV), Quantitative, DNA Real-time PCR, Cobas® TaqMan® (Nongraphical)	551610 551620*	2.5 mL plasma and serum Collect specimen in gel-barrier, lavender-top (EDTA), or PPT tube. Centrifuge specimen within 24 hours of collection. Plasma from a PPT can be frozen and shipped in situ.	The HBV quantitative real-time PCR assay has a quantitative range of 10 to 1,000,000,000 IU/mL.
Hepatitis B Virus (HBV) Genotype	551710	1.2 mL plasma and serum Collect specimen in gel-barrier, yellow-top (ACD), lavender-top (EDTA) or PPT tube. Centrifuge specimen within six hours of collection.	The HBV Genotype assay classifies the virus present in the sample into 1 of 8 recognized genotypes (A-H) via sequence analysis of the DNA polymerase gene. Disease progression and response to therapy may be influenced by genotype. In addition, the HBV Genotype assay identifies and reports sequence polymorphisms in the basal core promotor (BCP) and coding regions of the HBV Precore gene that result in either decreased levels, or complete absence, of HBeAg expression in chronically infected patients. This assay may not be successful when the HBV viral load is <500 IU/mL.
Hepatitis B Virus (HBV) DNA Quantitative Real-time PCR With Reflex to HBV Genotype	551722	3 mL plasma and serum Collect specimen in red-top, gel-barrier, lavender-top (EDTA) or PPT tube. Do not use green-top (heparin) or yellow-top (ACD) tube. Centrifuge specimen within six hours of collection.	This test quantitates HBV DNA in serum or plasma with reflex to HBV genotype if ≥ 500 IU/mL is detected. The quantitative test has a range of 10 IU/mL to 1,000,000,000 IU/mL.
Hepatitis B Virus (HBV) Genotype Plus Drug Resistance	551750	1.2 mL plasma and serum Collect specimen in gel-barrier, yellow-top (ACD), lavender-top (EDTA) or PPT tube. Centrifuge specimen within six hours of collection.	Data generated in the genotyping assay is subsequently analyzed for mutations in the reverse transcriptase gene of HBV associated with resistance to therapeutic agents, and if identified an interpretation of their clinical significance provided. This assay may not be successful when the HBV viral load is <500 IU/mL.
Hepatitis B Virus (HBV) DNA Quantitative Real-time PCR with Reflex to HBV Genotype Plus Drug Resistance	551735	3 mL plasma and serum Collect specimen in red-top, gel-barrier, lavender-top (EDTA) or PPT tube. Do not use green-top (heparin) or yellow-top (ACD) tube. Centrifuge specimen within six hours of collection.	This test quantitates HBV DNA in serum or plasma with reflex to HBV Genotype if ≥500 IU/mL is detected. The quantitative test has a range of 10 IU/mL to 1,000,000,000 IU/mL.

Hepatitis B Virus (HBV)

* Includes graphical report
To avoid delays in turnaround time when requesting multiple tests on frozen samples, **please submit separate frozen specimens for each test requested.**
For additional test information, including specimen requirements, CPT coding and RUO/IUO status, **consult the Online Test Menu at www.LabCorp.com.**

For more information, please contact your local account representative.

