

Sample Collection and Handling Requirements for Assays Performed by Monogram Biosciences

	Assay Name	Drug Classes	Viral Load Requirement	Monogram Test Code	CPT Code	Specimen Requirements
COMBO PHENO + GENO	PhenoSense® GT	NRTIs, NNRTIs, PIs	≥ 500 c/mL	V7000	87900 87901 87903 87904x11	3mL frozen plasma. Draw blood in either 2 PPT or 2 lavender-top (EDTA) tubes. Centrifuge within 6 hours of collection. Spin at 1000–1200g for 10 to 15 minutes. Transfer plasma to one or more screw-cap tubes (not "pop-top" or "snap-cap"). Freeze immediately at -20°C and ship frozen.
	PhenoSense® GT Plus Integrase	NRTIs, NNRTIs, PIs, INIs	≥ 500 c/mL	M7000	87900 87901 87903 87904x14 87906	5mL frozen plasma. Draw blood in either 3 PPT or 3 lavender-top (EDTA) tubes. Centrifuge within 6 hours of collection. Spin at 1000–1200g for 10 to 15 minutes. Transfer plasma to one or more screw-cap tubes (not "pop-top" or "snap-cap"). Freeze immediately at -20°C and ship frozen.
PHENOTYPE	PhenoSense®	NRTIs, NNRTIs, PIs	≥ 500 c/mL	V3200	87903 87904x11	3mL frozen plasma. Draw blood in either 2 PPT or 2 lavender-top (EDTA) tubes. Centrifuge within 6 hours of collection. Spin at 1000–1200g for 10 to 15 minutes. Transfer plasma to one or more screw-cap tubes (not "pop-top" or "snap-cap"). Freeze immediately at -20°C and ship frozen.
	PhenoSense® Integrase	INIs	≥ 500 c/mL	S3200	87903	
	PhenoSense® Entry	Enfuvirtide	≥ 1000 c/mL	E2000	87903	
GENOTYPING	GenoSure PRIme®***	NRTIs, NNRTIs, PIs, INIs	≥ 500 c/mL	P5000	87900 87901 87906	5mL frozen plasma. Draw blood in either 3 PPT or 3 lavender-top (EDTA) tubes. Centrifuge within 6 hours of collection. Spin at 1000–1200g for 10 to 15 minutes. Transfer plasma to one or more screw-cap tubes (not "pop-top" or "snap-cap"). Freeze immediately at -20°C and ship frozen. **Note: Testing may not be successful when the viral load is < 500 copies/mL plasma. If the assay fails on the initial attempt, HIV-1 RNA quantitation will be performed. If the result is < 500 copies/mL, the viral load will be reported and the client will be billed.
	GenoSure® MG**	NRTIs, NNRTIs, PIs	≥ 500 c/mL	G5000	87900 87901	
SUPPRESSION MGMT	GenoSure Archive® DNA Sequencing	NRTIs, NNRTIs, PIs, INIs	Undetectable	R6000	87900 87901 87906	4mL lavender-top (EDTA) whole blood. Draw whole blood in 1 lavender-top (EDTA) tube. Do not centrifuge. Freeze immediately at -20°C and ship frozen. <i>Note: GenoSure Archive and Trofile DNA can be ordered together (test code D9000). Draw two 4mL EDTA tubes. HIV-1 DNA Sequencing Testing is also available for Protease-Reverse Transcriptase (test code R6200) and Integrase (test code R6400) separately. For more information please call Client Services at 1-800-777-0177.</i>
	Trofile® DNA	CCR5 Antagonist	Undetectable	E3600	87999	
TROPISM	Trofile®	CCR5 Antagonist	≥ 1000 c/mL	E3100	87999	3mL frozen plasma. Draw blood in either 2 PPT or 2 lavender-top (EDTA) tubes. Centrifuge within 6 hours of collection. Spin at 1000–1200g for 10 to 15 minutes. Transfer plasma to one or more screw-cap tubes (not "pop-top" or "snap-cap"). Freeze immediately at -20°C and ship frozen.
	Trofile® Select	CCR5 Antagonist	Use when VL unknown	E3000T	87999	Both plasma and whole blood are needed for Trofile Select. 5mL frozen plasma AND 4mL frozen whole blood from lavender-top (EDTA) tubes. Draw 4 lavender-top (EDTA) tubes. Freeze one tube immediately at -20°C. Centrifuge the other 3 tubes within 6 hours of collection. Transfer plasma to screw-cap tubes. Freeze immediately at -20°C and ship all tubes frozen.
HIV VL	HIV-1 RT-PCR Quant (Graph/Non-Graph)		N/A	V1000N (Non-Graph) V1000G (Graph)	87536@	3mL frozen plasma. Collect specimen in 2 PPT or lavender-top (EDTA) tubes. Centrifuge specimen within 6 hours of collection, remove plasma and transfer specimen to screw-cap tube. Freeze immediately at -20°C and ship frozen.
HCV	Hepatitis C Virus, Genotype(subtype)		≥ 1000 IU/mL	C1200	87902	3mL frozen plasma. Collect specimen in 2 PPT, yellow-top (ACD) tubes, or lavender-top (EDTA) tubes. Centrifuge specimen within 6 hours of collection and transfer to 2 plastic screw-cap tubes. Freeze immediately at -20°C and ship frozen.
	Hepatitis C Virus RT-PCR Quant (Graph/Non-Graph)		N/A	C1000N (Non-Graph) C1000G (Graph)	87522	3mL frozen plasma. Draw blood in 2 PPT or lavender-top (EDTA) tubes, centrifuge within 6 hours of collection. Spin at 1000–1200g for 10 to 15 minutes. Transfer plasma to one or more screw-cap tubes (not "pop-top" or "snap-cap"). Freeze immediately at -20°C and ship frozen.
	HCV GenoSure® NS3/4A (Genotype 1a / 1b)	PIs	≥ 2000 IU/mL	C5000	87900 87902	For Genotype 1 only. 2mL frozen plasma. Draw blood in 2 PPT or lavender-top (EDTA) tubes, centrifuge within 6 hours of collection. Spin at 1000–1200g for 10 to 15 minutes. Transfer plasma to one or more screw-cap tubes (not "pop-top" or "snap-cap"). Freeze immediately at -20°C and ship frozen.
	HCV NS5A Drug Resistance Assay (Genotype 1a / 1b)	NS5AIs	≥ 500 IU/mL	C6200	87900 87902	
	HCV NS5B Drug Resistance Assay (Genotype 1a / 1b)	NIs, NNIs	≥ 1000 IU/mL	C6300	87900 87902	
HCV Genotype 3 NS5A Drug Resistance Assay	NS5AIs	≥ 500 IU/mL	C6220	87900 87902	For Genotype 3 only. 2mL frozen plasma. Draw blood in 2 PPT or lavender-top (EDTA) tubes, centrifuge within 6 hours of collection. Spin at 1000–1200g for 10 to 15 minutes. Transfer plasma to one or more screw-cap tubes (not "pop-top" or "snap-cap"). Freeze immediately at -20°C and ship frozen.	

Unacceptable conditions: 1) Incorrect tube type. 2) Frozen required: Non-frozen specimens or specimens exposed to repeated freeze-thaw cycles. 3) Unlabeled specimens. @ = Subject to Medicare medical necessity guidelines. Visit www.MonogramBio.com for assay use and limitations. MG-SF-FRMS-F90699.017 10/24/2016