

PRODUCT INFORMATION

Product SKU	HCV LOD
Product Name	HCV LOD
Kit Lot Number	20012405
Source Material	Inactivated HCV
Date of Expiration	2021-12-31
Base Matrix	True EDTA Plasma
Preservative	ProClin® 300
Fill Volume	1.0 mL
Storage Temperature	-70°C or Below
Regulatory Status	For In Vitro Diagnostic Use
Traceability	4 th WHO International Standard (06/102)
Testing Platform	Roche cobas® 6800/8800 HCV Assay

This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

TESTING DATA

Lot Number	Product Description	Target Concentration	Testing Results	Quantity
20012405	HCV LOD	15 IU/mL	Pass (≥ 95% detection rate)	10 Vials

Bioburden Testing Results	
Acceptance Criteria: Less than 10 CFU/mL	Pass

APPROVAL

Quality Assurance	Date
	11 Nov 20

Manufactured By: Exact Diagnostics, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107
For assistance and reordering, contact Exact Diagnostics at 817.989.9262