

AccuSet™

HCV Verification Starter Packs

Ready-to-use panels designed to fulfill CLIA's Performance Specifications for assay verification

SeraCare's AccuSet[™] HCV Verification Panels consist of naturally occurring plasma samples that mimic patient specimens on laboratory instrumentation. Our panels include characterized mixed-titer samples that will allow you to efficiently onboard your new assays. We provide the tools you need to easily meet CLIA's performance specifications so that you can verify your test system and start reporting patient results.

PRODUCT SPECIFICATIONS

We offer two HCV Verification Panels to provide you with options for onboarding both molecular and serological HCV assays based on your laboratory's specific verification requirements:

0810-0325 AccuSet™ HCV Verification Panel 1

- √ 20 HCV members x 1.5mL fill
- √ Natural, undiluted plasma samples
- ✓ Molecular and Serology focused

TARGET ASSAYS: ROCHE AND ABBOTT

- Molecular assays
 Serology assays

 - Roche 6800/8800 Abbott Alinity M
- - Abbott Architect HCV Ag
 - Abbott Architect HCV Ab
 - Abbott Alinity s HCV Ab
 - Roche Elecsys
 - Inno-LIA HCV Score

0810-0304 • AccuSet™ HCV Verification Panel 2

- √ 20 HCV members x 1.0mL fill
- ✓ Natural, undiluted plasma samples
- √ Serology focused

TARGET ASSAYS: ROCHE AND ABBOTT

- Serology Assays
- Abbott Architect HCV Ag
- Abbott Architect HCV Ab
- Abbott Alinity s HCV Ab
- Roche Elecsvs
- Inno-LIA HCV Score

APPLICATIONS



CLINICAL LABORATORIES

Installing a new HCV test method and performing assay verification

Performing smaller verifications after software updates or instrument maintenance

Monitoring assay performance

Testing for operator proficiency

Assay comparability studies



IVD MANUFACTURERS

Customer instrument / assay launch support

Evaluating assay performance during development

Performing assay validation

Troubleshooting test methods



AccuSet™ HCV VERIFICATION PANEL FEATURES AND BENEFITS

FEATURE	BENEFIT
Panel members are natural, undiluted plasma samples	CONFIDENCE Specimens mimic patient samples on diagnostic instrumentation & are ideal samples for performing assay verification
Offering two different Verification Panels	FLEXIBILITY You have the option of 20 samples or 40 samples depending on your verification protocol • Molecular laboratories will utilize HCV Verification Panel-1 • Serology laboratories can choose either or both HCV Verification Panels
Panel members categorized by multiple assays & HCV analytes	MULTIPURPOSE Our panels can be used to perform verification various HCV assays • Molecular OR Serology based assays • HCV RNA, HCV Ag, HCV Ab
Comprehensive data sheet with established values on test methods from leading IVD manufacturers	EFFICIENT Save time and money by alleviating the need to source and characterize your own materials No time wasted on characterizing your own samples on instrumentation No need to reconstitute samples
Panel members are diverse & have a wide variety of HCV concentrations	STREAMLINED Customers can fulfill CLIA's verification requirements with our Verification Panels
Higher sample fill volumes	PRACTICAL Allows for testing multiple replicates on most laboratory assays

OUR COMPLEMENTARY PRODUCTS TO COMPLETE ASSAY ONBOARDING

HCV PANEL PRODUCTS

AccuSpan™ HCV RNA Linearity Panel

- Effectively challenges assay performance at defined intervals to ensure consistency throughout the entire reportable range
- Utilize our HCV RNA Linearity Panel to fulfill CLIA's reportable range requirement during assay verification and simultaneously establish the linear range of your quantitative assay

AccuSet™ HCV Worldwide Performance Panel

- Naturally occurring plasma samples collected worldwide from individual donors positive for HCV genotypes 1-6 with varying subtypes
- · Validate or verify HCV genotyping assay
- · Great tool to evaluate assay specificity

ACCURUN® HCV MOLECULAR POSITIVE CONTROLS

ACCURUN 305 Series HCV RNA Control

- Great tools to verify the precision of an assay
- Once assay verification is complete, you can immediately start performing quality control using our ACCURUN products
- Starting off with a well-designed QC program will allow you to continue to monitor assay performance and effectively detect any assay variability
- A consistent and reliable source of QC material; helps maintain compliance and meet regulatory commitments

ALSO AVAILABLE:

NEW AccuSet™ HIV Verification Panel

Download our new product sheet to learn more **2**



TO LEARN MORE ABOUT HCV REFERENCE MATERIALS OR OUR CUSTOM CAPABILITIES