

ACCUSET[™]

HIV Verification Starter Packs

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

LGC SeraCare's **AccuSet™ HIV Verification Panels** consist of naturally occurring human plasma samples that mimic patient specimens on laboratory instrumentation. Our panels include highly 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 HIV Verification Panels to provide you with options for onboarding both molecular and serological HIV assays based on your laboratory's specific verification requirements:

0800-0538 • AccuSet™ HIV Verification Panel 1

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

TARGET ASSAYS: ROCHE AND ABBOTT

- Molecular assays
 - Roche 6800/8800
 - Abbott Alinity M
- Serology assays
 - Perkin Elmer HIV-1 p24 Ag
 - Abbott Architect & Alinity s HIV Ab/Ag Combo
 - Roche Elecsys
 - Bio-Rad GS HIV-2 EIA
 - Aviog HIV-1
 - Inno-LIA HIV-1/2 Score

0800-0579 • AccuSet™ HIV Verification Panel 2

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

TARGET ASSAYS: ROCHE AND ABBOTT

- Serology Assays
 - Perkin Elmer HIV-1 p24 Ag
 - Abbott Architect & Alinity s HIV Ab/Ag Combo
 - Roche Elecsys
 - Bio-Rad GS HIV-2 EIA
 - Aviog HIV-1
 - Inno-LIA HIV-1/2 Score

APPLICATIONS



CLINICAL LABORATORIES

Installing a new HIV 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™ HIV 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 HIV Verification Panel-1 Serology laboratories can choose either or both HIV Verification Panels
Panel members categorized by multiple assays & HIV analytes	MULTIPURPOSE Our panels can be used to perform verification various HIV assays • Molecular OR Serology based assays • HIV-1 RNA, HIV p24 Ag, HIV Ag/Ab, HIV-1 Ab, HIV-2 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 HIV 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

HIV PANEL PRODUCTS

AccuSpan™ HIV-1 RNA Linearity Panel

- Effectively challenges assay performance at defined intervals to ensure consistency throughout the entire reportable range
- Utilize our HIV-1 RNA Linearity Panel to fulfill CLIA's reportable range requirement during assay verification and simultaneously establish the linear range of your quantitative assay

AccuSet™ HIV Worldwide Performance Panel

- Naturally occurring plasma samples collected worldwide from individual donors positive for HIV infection of varying genotypes and countries of origin
- Validate or verify HIV genotyping assay
- · Great tool to evaluate assay specificity

ACCURUN® HIV-1 MOLECULAR & SEROLOGY POSITIVE CONTROLS

ACCURUN 315 Series HIV-1 RNA Control ACCURUN 106 Series HIV-1 Ag 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

