



**CLINICAL  
DIAGNOSTICS**

## **Expert BioSpecimen Sourcing**

Validation, Verification, and  
Qualification Material



**Trusted Partner and Global Supplier of Solutions to Diagnostics,  
Clinical Research and Life Science Industries for over 30 years**





## PANELS

SeraCare's portfolio of validation and qualification panels allows clinicians and researchers to assess overall assay performance. Whether generating validation data for a regulatory submission or performing assay verification in a clinical lab setting, our panel products offer a comprehensive solution to rigorously evaluate your infectious disease tests. With so many options, selecting which panel type to use and for what purpose can be daunting, especially when an ACCURUN Serological or Molecular control could also be considered. The Control and Panel Selection Guide (Table 1) will help select your best options for Method Validation, Compliance and Daily QC needs.

# VALIDATION, VERIFICATION, AND QUALIFICATION MATERIAL

## HIGHLY CHARACTERIZED

SeraCare provides a comprehensive and highly characterized set of data for all validation and qualification panels to support the demanding needs of IVD assay development. Our panels serve as valuable tools to support compliance with FDA and EU IVDR requirements for assay clearance. Our suite of products will allow you to confidently develop, challenge, troubleshoot, verify and validate your assay from initial proof of concept to production and beyond.

## LEADING SUPPLIER

Our Panels and Disease State Materials are so highly regarded that they are referenced in IVD manufacturers' package inserts, comparative test kit studies and peer-reviewed scientific journals, paving the way forward for assays' regulatory submission. Our Panels have also been referenced by the World Health Organization for comparative studies of HIV test kit performance.<sup>1</sup>

**TABLE 1: CONTROL AND PANEL SELECTION GUIDE**

|                                             | ACCURUN Serological Controls | ACCURUN Molecular Controls | AccuTrak Qualification Panels | AccuSpan Linearity Panels | AccuSet Performance Panels | AccuVert Seroconversion Panels |
|---------------------------------------------|------------------------------|----------------------------|-------------------------------|---------------------------|----------------------------|--------------------------------|
| <b>METHOD VALIDATION</b>                    |                              |                            |                               |                           |                            |                                |
| Evaluate antibody/antigen test sensitivity  | ●                            |                            |                               |                           | ●                          | ●                              |
| Evaluate nucleic acid test sensitivity      |                              | ●                          |                               | ●                         |                            |                                |
| Evaluate test specificity                   |                              |                            |                               |                           | ●                          | ●                              |
| Evaluate test precision                     | ●                            | ●                          |                               |                           |                            |                                |
| Evaluate test linearity                     |                              |                            |                               | ●                         |                            |                                |
| <b>COMPLIANCE</b>                           |                              |                            |                               |                           |                            |                                |
| Protocol training/competency                |                              |                            | ●                             |                           |                            |                                |
| Document regulatory compliance              | ●                            | ●                          | ●                             |                           | ●                          | ●                              |
| <b>DAILY QC</b>                             |                              |                            |                               |                           |                            |                                |
| Perform reagent lot acceptance              | ●                            | ●                          | ●                             |                           |                            |                                |
| Troubleshoot                                | ●                            | ●                          | ●                             | ●                         |                            |                                |
| Perform daily run control                   | ●                            | ●                          |                               |                           |                            |                                |
| Perform inter-site comparison               |                              |                            | ●                             | ●                         | ●                          |                                |
| Monitor for test interference/contamination | ●                            | ●                          |                               |                           | ●                          |                                |

### KEY

- Best choice
- Can be used, other product may work better

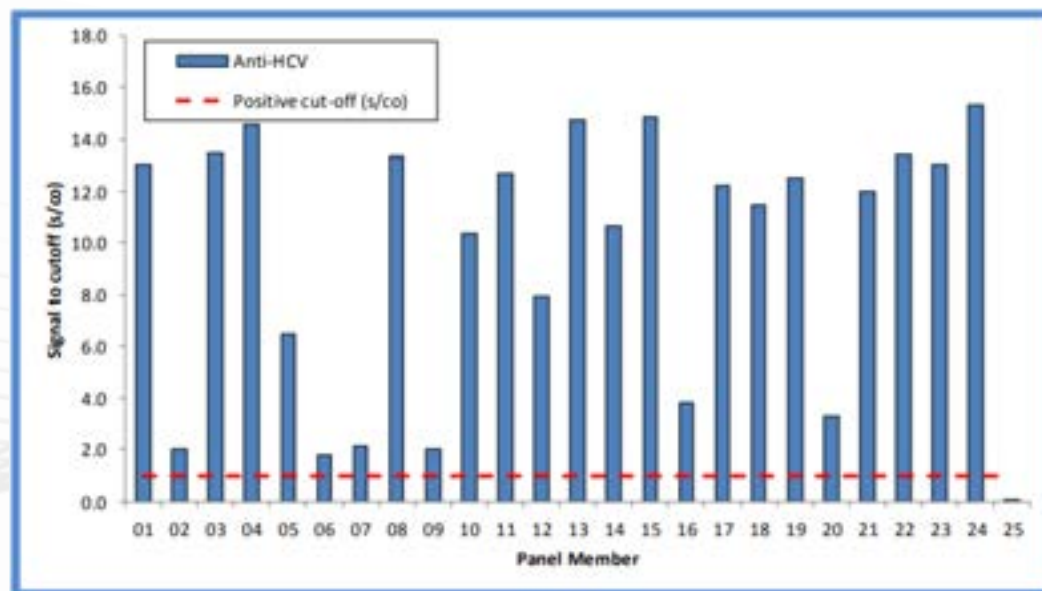
1. WHO (2015) HIV Assays: Lab Performance and Other Operational Characteristics. Report 18. Rapid Diagnostic Tests ([https://www.who.int/diagnostics\\_laboratory/evaluations/hiv/en/](https://www.who.int/diagnostics_laboratory/evaluations/hiv/en/))

## INTEGRATE WITH ACCURUN® CONTROLS

Validating and qualifying your assay throughout its development is a necessary and time-consuming process. SeraCare's panels make that job easier. Consider also incorporating SeraCare's ACCURUN Controls to your quality control workflow so that once you've completed your assay validation, ACCURUN Controls will reassure you that your assay is running at optimal performance.

## PERFORMANCE PANELS

AccuSet™ Performance Panels consist of naturally occurring plasma samples collected from multiple donors of varied analyte concentrations, genotypes and/or demographic diversity. Panel members are characterized by disease markers across multiple test methods and platforms to provide comparative data sets for your evaluation. This allows you to benchmark your assay's performance against other industry leading manufacturers. Use our performance panels to evaluate assay specificity, sensitivity, and reproducibility throughout assay development and validation.



**FIGURE 1: EXAMPLE OF PERFORMANCE DATA FROM THE ACCUSET™ HCV PERFORMANCE PANEL TESTED FOR ANTI-HCV ON THE ABBOTT ARCHITECT TEST METHOD.**

SERACARE  
DEVELOPED THE  
INDUSTRY'S FIRST  
SEROCONVERSION  
PANELS BACK IN  
THE 1980'S.

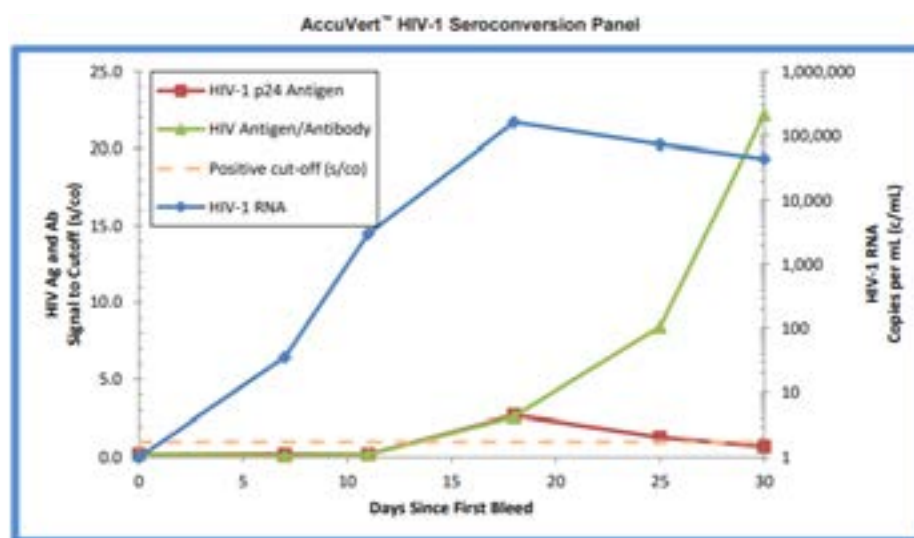
## QUALIFICATION PANELS

AccuTrak™ Qualification Panels are consistently manufactured from human plasma or serum positive for disease state analytes with confirmed reactivity in serological, molecular, or genotype assays. AccuTrak™ Qualification Panels are designed as a reliable, consistent, cost-effective solution for your assay's QC program. These panels are well-suited for troubleshooting and lot change evaluations. They also serve as an excellent source of affordable reference materials for personnel training on new and existing equipment.

**TABLE 2: AVAILABLE ANALYTES BY PANEL**

| ANALYTES/TARGETS | ACCUSPAN<br>LINEARITY PANELS | ACCUVERT<br>SEROCONVERSION PANELS | ACCUSET<br>PERFORMANCE PANELS | ACCUTRAK<br>QUALIFICATION PANELS |
|------------------|------------------------------|-----------------------------------|-------------------------------|----------------------------------|
| Babesia          |                              |                                   | ●                             |                                  |
| BKV              | ●                            |                                   |                               |                                  |
| Chagas           |                              | ●                                 | ●                             |                                  |
| CMV              | ●                            | ●                                 | ●                             | ●                                |
| CT/NG            |                              |                                   |                               | ●                                |
| Dengue           |                              |                                   | ●                             |                                  |
| EBV              | ●                            |                                   | ●                             |                                  |
| HAV              |                              | ●                                 | ●                             |                                  |
| HBV              | ●                            | ●                                 | ●                             | ●                                |
| HCV              | ●                            | ●                                 | ●                             | ●                                |
| HEV              |                              |                                   | ●                             |                                  |
| HIV              | ●                            | ●                                 | ●                             | ●                                |
| HPV              |                              |                                   |                               | ●                                |
| HSV              |                              |                                   | ●                             |                                  |
| HTLV             |                              |                                   | ●                             | ●                                |
| Lyme             |                              |                                   | ●                             |                                  |
| Rubella          |                              |                                   | ●                             |                                  |
| Syphilis         |                              | ●                                 | ●                             | ●                                |
| Toxoplasmosis    |                              |                                   | ●                             |                                  |
| TV/MG            |                              |                                   |                               | ●                                |
| West Nile        |                              | ●                                 |                               |                                  |
| Zika             | ●                            |                                   | ●                             |                                  |
| SARS-CoV-2       |                              | ●                                 | ●                             |                                  |





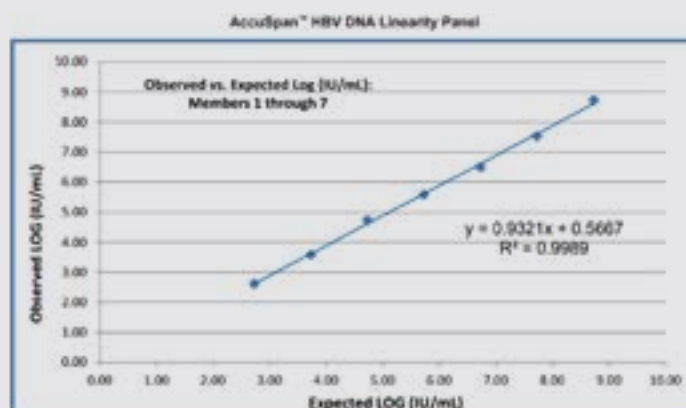
**FIGURE 2: THIS GRAPH DEMONSTRATES THE EVOLUTION OF HIV MARKERS IN EARLY INFECTION FROM OUR ACCUVERT™ HIV-1 SEROCONVERSION PANEL 0600-0272.**

## SEROCONVERSION PANELS

AccuVert™ Seroconversion Panels consist of naturally occurring plasma samples collected from a single donor during the development and progression of infection and subsequent immune response. Each seroconversion panel represents a unique donor and is characterized across multiple test methods and platforms to provide comparative data sets for each analyte. These rare panels are ideal for confirming that an assay can detect disease in patient samples at different stages of infection, and are required for regulatory submissions in some regions. Seroconversion panels are manufactured in a cGMP facility to ensure each batch provides consistent, reliable material to challenge your assay during its development.

## LINEARITY PANELS

AccuSpan™ Linearity Panels consist of serially diluted samples from high-titer recombinant, cultured or naturally occurring whole viruses that span the entire or partial analytical range of an assay for a given analyte. Panel members are calibrated against the latest WHO international standards for informational purposes and to ensure traceability. Linearity Panels can be used in assay verification procedures, operator training, troubleshooting and for bi-annual AMR lab accreditation procedures. The panels are designed to span the dynamic range of quantitative infectious disease assays and evaluate instrumentation analytical sensitivity.



**FIGURE 3: EXAMPLE RESULTS OF THE ACCUSPAN™ HBV RNA LINEARITY PANEL TESTED AGAINST THE ROCHE COBAS® AMPLIPREP/COBAS® TAQMAN® HBV VERSION 2.0 TEST METHOD.**

## DISEASE STATE MATERIALS

SeraCare's portfolio of disease state specimens and high-titer viral isolates supports IVD manufacturers and clinical researchers with tools for assay development, evaluation and implementation. From small specimen aliquots to bulk-processed material and custom prospective collection services, we offer difficult-to-find, reliable materials for development, manufacturing, and validation of IVD products.

### THE BENEFITS OF SERACARE'S DISEASE STATE MATERIALS

- Streamline procurement for a wide range of disease state analytes
- Challenge your assay with characterized positive specimens with well-documented donor demographics
- Catered to your specialized requirements with custom processing options and prospective collection services

### COMPLIANCE IS IN OUR NATURE

Our Disease State Materials team includes members with more than 20 years experience working with global IVD companies, so we understand your submission requirements. We handle every aspect of collections compliance — from drafting and submitting protocols to negotiating with IRBs, if required — saving you time and reducing your regulatory risk.

### COMPREHENSIVE, CUSTOMIZED SOLUTIONS

In addition to inventoried disease state specimens, SeraCare can manage every aspect of your own custom collections program, tailored to your acquisition strategy. We have a 25-year track record of successful collections for a wide range of disease states, around the world. This, together with our materials processing expertise, enables us to deliver materials to meet your specific requirements, when you need them.

### SPECIMENS

Specimen samples are collected from individual donors worldwide. Sample types include raw plasma, serum and other biological matrices. They are extensively characterized on industry-leading IVD platforms and assays to provide detailed reactivity profiles. Positive, negative, and rare specimens are available in a variety of pre-packaged sizes to expedite order processing and shipping.

### ACCUTYPE™ VIRAL ISOLATES

SeraCare's high-titer cultured viral isolates and purified RNA are particularly helpful for HIV assays, where diverse geographical genotypes are difficult to find. We have collections from USA to Zaire and everywhere in between. SeraCare's AccuType™ collection has genotypes spanning both group M and group O; a unique portfolio of rare HIV isolates unlikely to be found anywhere else.

## OUR DISEASE STATE MATERIALS PROVIDE BIOLOGICAL MATERIALS FOR:

### INFECTIOUS DISEASE ANALYTES

SeraCare offers a wide range of analytes for a large number of infectious diseases from Chagas, Dengue and West Nile Virus, to HIV, Hepatitis and Syphilis to name just a few. Our inventory continues to expand to meet the needs of our customers.

### WOMEN'S HEALTH

SeraCare is committed to supporting efforts to develop innovative assays and therapies for women's health, targeting diseases such as CT/NG, HPV, HSV, and more. We can provide a variety of sample types, including urine, Pap specimens, swab specimens, and matched sets tailored to your specific project.

### AUTOIMMUNE DISEASE

Seracare offers characterized analytes from a wide range of autoimmune disease conditions — including Rheumatoid Arthritis, Systemic Lupus, Thyroid disorders, and Celiac disease.

### NORMAL MATERIALS

Negative disease state specimens are equally as important as positives to ensure platform/assay accuracy and reproducibility. We can also provide a variety of specimen types, such as normal human samples, synthetic cerebrospinal fluid, cord blood, whole blood, normal human plasma (EDTA, 4% sodium citrate) and serum, pooled sputum, urine and more.

## AccuSet™ Performance Panels

### HIV

| MATERIAL # | PANEL                                      | # MEMBERS | FILL SIZE (ML) |
|------------|--------------------------------------------|-----------|----------------|
| 0800-0262  | HIV-1 Group O Performance Panel            | 5         | 1.2            |
| 0800-0394  | HIV-1 Early Infection Performance Panel    | 25        | 1.0            |
| 0800-0436  | HIV-1 Mixed Titer Performance Panel        | 20        | 1.0            |
| 0800-0457  | HIV-1 Low Titer Performance Panel          | 20        | 1.0            |
| 0800-0492  | HIV Worldwide Performance Panel            | 15        | 1.0            |
| 0800-0522  | HIV-1 p24 Ag Mixed Titer Performance Panel | 15        | 1.0            |
| 0800-0538  | HIV Verification Panel 1                   | 20        | 1.5            |
| 0800-0579  | HIV Verification Panel 2                   | 20        | 1.0            |
| 0800-0580  | HIV-1/2 Mixed Titer Performance Panel      | 15        | 1.0            |

## HEPATITIS (HAV, HBV, HCV)

| MATERIAL # | PANEL                                               | # MEMBERS | FILL SIZE (ML) |
|------------|-----------------------------------------------------|-----------|----------------|
| 0805-0216  | Anti-HBc IgM Mixed Titer Performance Panel Modified | 22        | 1.0            |
| 0805-0341  | Anti-HBc/HBs Performance Panel                      | 20        | 1.5            |
| 0805-0417  | HBsAg Low Titer Performance Panel                   | 20        | 1.0            |
| 0805-0438  | HBsAg Mixed Titer Performance Panel                 | 25        | 1.0            |
| 0810-0230  | HCV Worldwide Performance Panel                     | 22        | 1.0            |
| 0810-0256  | HCV Low Titer Performance Panel                     | 20        | 1.0            |
| 0810-0304  | HCV Verification Panel 2                            | 20        | 1.0            |
| 0810-0325  | HCV Verification Panel 1                            | 20        | 1.5            |
| 0810-0346  | HCV Mixed Titer Performance Panel                   | 25        | 1.0            |
| 0820-0443  | HAV Mixed Titer Performance Panel                   | 21        | 1.0            |
| 0820-0503  | HEV Performance Panel                               | 10        | 1.0            |

## TORCH

| MATERIAL # | PANEL                                 | # MEMBERS | FILL SIZE (ML) |
|------------|---------------------------------------|-----------|----------------|
| 0815-0003  | HSV-1/2 Mixed Titer Performance Panel | 21        | 1.2            |
| 0820-0321  | Toxoplasmosis Performance Panel       | 24        | 1.0            |
| 0820-0347  | Rubella Performance Panel             | 20        | 1.0            |
| 0820-0389  | CMV Performance Panel                 | 20        | 1.0            |

## VECTOR-BORNE DISEASES

| MATERIAL # | PANEL                                | # MEMBERS | FILL SIZE (ML) |
|------------|--------------------------------------|-----------|----------------|
| 0845-0142  | Zika IgM Performance Panel           | 10        | 1.0            |
| 0845-0169  | Lyme Performance Panel               | 15        | 1.0            |
| 0845-0185  | Babesia Performance Panel            | 15        | 1.0            |
| 0845-0222  | Chagas (T. cruzi) Performance Panel  | 20        | 1.0            |
| 0845-0243  | Dengue Mixed Titer Performance Panel | 15        | 1.0            |

## OTHER DISEASES

| MATERIAL # | PANEL                                   | # MEMBERS | FILL SIZE (ML) |
|------------|-----------------------------------------|-----------|----------------|
| 0820-0410  | SARS-CoV-2 Performance Panel            | 11        | 1.0            |
| 0820-0481  | HTLV-I/II Mixed Titer Performance Panel | 21        | 1.2            |
| 0820-0514  | Syphilis Mixed Titer Performance Panel  | 20        | 1.0            |
| 0850-0025  | Anti-EBV Mixed Titer Performance Panel  | 21        | 1.2            |

# AccuVert™ Seroconversion Panels

## HIV

| MATERIAL # | PANEL                         | # MEMBERS | FILL SIZE (ML) | HIV-1 RNA | HIV-1 P24 AG | HIV-1 AB |
|------------|-------------------------------|-----------|----------------|-----------|--------------|----------|
| 0600-0227  | HIV-1 Seroconversion Panel AV | 4         | 1.0            | ▲         | ▲            | ○        |
| 0600-0237  | HIV-1 Seroconversion Panel    | 4         | 1.0            | ●         | ▲            | ▲        |
| 0600-0243  | HIV-1 Seroconversion Panel    | 9         | 1.0            | ▲         | ▲            | ○        |
| 0600-0245  | HIV-1 Seroconversion Panel    | 7         | 1.0            | ▲         | ▲            | ◻        |
| 0600-0246  | HIV-1 Seroconversion Panel    | 6         | 1.0            | ▲         | ▲            | ○        |
| 0600-0248  | HIV-1 Seroconversion Panel    | 10        | 1.0            | ▲         | ▲            | ▲        |
| 0600-0252  | HIV-1 Seroconversion Panel    | 4         | 1.0            | ●         | ●            | ▲        |
| 0600-0253  | HIV-1 Seroconversion Panel    | 4         | 1.0            | ●         | ▲            | ▲        |
| 0600-0256  | HIV-1 Seroconversion Panel    | 4         | 1.2            | ●         | ▲            | ▲        |
| 0600-0258  | HIV-1 Seroconversion Panel    | 4         | 1.2            | ▲         | ▲            | ◻        |
| 0600-0260  | HIV-1 Seroconversion Panel    | 5         | 1.2            | ▲         | ▲            | ○        |
| 0600-0261  | HIV-1 Seroconversion Panel    | 4         | 1.2            | ●         | ▲            | ○        |
| 0600-0262  | HIV-1 Seroconversion Panel    | 4         | 1.2            | ●         | ▲            | ▲        |
| 0600-0265  | HIV-1 Seroconversion Panel    | 9         | 1.0            | ▲         | ▲            | ○        |
| 0600-0270  | HIV-1 Seroconversion Panel    | 4         | 1.0            | ▲         | ○            | ▲        |
| 0600-0271  | HIV-1 Seroconversion Panel    | 8         | 1.0            | ●         | ◈            | ◈        |
| 0600-0272  | HIV-1 Seroconversion Panel    | 6         | 1.0            | ▲         | ◈            | ▲        |
| 0600-0291  | HIV-1 Seroconversion Panel    | 5         | 1.0            | ▲         | ▲            | ○        |
| 0600-0297  | HIV-1 Seroconversion Panel    | 8         | 1.0            | ▲         | ▲            | ▲        |

### LEGEND

- ▲ converts negative to positive
- all members positive
- ▽ converts positive to negative
- ◻ members negative or indeterminate
- ◈ variable conversion
- NT not tested
- all members negative

## HBV

| MATERIAL # | PANEL                    | # MEMBERS | FILL SIZE (ML) | HBV DNA | HBSAG | HBEAG | HBC IGM AB | HBC TOTAL AB | HBE AB | HBS AB |
|------------|--------------------------|-----------|----------------|---------|-------|-------|------------|--------------|--------|--------|
| 0605-0038  | HBV Seroconversion Panel | 8         | 1.5            | ●       | ●     | ▲     | ○          | ○            | NT     | NT     |
| 0605-0039  | HBV Seroconversion Panel | 5         | 1.5            | ●       | ▲     | ○     | ○          | ○            | ○      | ○      |
| 0605-0041  | HBV Seroconversion Panel | 5         | 1.5            | ●       | ▲     | ▲     | ○          | ○            | ○      | ○      |
| 0605-0059  | HBV Seroconversion Panel | 8         | 1.5            | ●       | ▲     | ○     | ○          | ○            | ○      | ○      |
| 0605-0062  | HBV Seroconversion Panel | 6         | 1.5            | ●       | ▲     | ▲     | ▲          | ▲            | ○      | ○      |

## HCV

| MATERIAL # | PANEL                    | # MEMBERS | FILL SIZE (ML) | HCV RNA | HCV AB (EIA) | HCV AB RIBA |
|------------|--------------------------|-----------|----------------|---------|--------------|-------------|
| 0610-0217  | HCV Seroconversion Panel | 7         | 1.0            | ▲       | ▲            | ▲           |
| 0610-0221  | HCV Seroconversion Panel | 6         | 1.2            | ●       | ▲            | ◻           |
| 0610-0223  | HCV Seroconversion Panel | 6         | 1.2            | ●       | ▲            | ▲           |
| 0610-0224  | HCV Seroconversion Panel | 5         | 1.2            | ●       | ▲            | ▲           |
| 0610-0225  | HCV Seroconversion Panel | 5         | 1.2            | ●       | ▲            | ◻           |
| 0610-0293  | HCV Seroconversion Panel | 5         | 1.2            | ▲       | ○            | ○           |
| 0610-0294  | HCV Seroconversion Panel | 9         | 1.2            | ▲       | ○            | ○           |
| 0610-0295  | HCV Seroconversion Panel | 6         | 1.2            | ▲       | ○            | ○           |

## OTHER DISEASES

| MATERIAL # | PANEL                                      | # MEMBERS | FILL SIZE (ML) |
|------------|--------------------------------------------|-----------|----------------|
| 0615-0026  | HAV Seroconversion Panel                   | 8         | 1.2            |
| 0615-0038  | Chagas (T. cruzi) Seroconversion Panel     | 10        | 1.2            |
| 0615-0039  | CMV Seroconversion Panel                   | 4         | 1.2            |
| 0615-0044  | Syphilis Seroconversion Panel              | 7         | 1.2            |
| 0820-0187  | West Nile Virus (WNV) Seroconversion Panel | 5         | 1.5            |
| 0820-0465  | SARS-CoV-2 Seroconversion Panel            | 14        | 1.0            |

### LEGEND

- ▲ converts negative to positive
- all members positive
- ▽ converts positive to negative
- ◻ members negative or indeterminate
- ◆ variable conversion
- NT not tested
- all members negative

## AccuSpan™ Linearity Panels

| MATERIAL # | PANEL                               | # MEMBERS | FILL SIZE (ML) |
|------------|-------------------------------------|-----------|----------------|
| 2410-0161  | HBsAg Sensitivity Panel             | 15        | 1.5            |
| 2410-0162  | HBV DNA Linearity Panel             | 9         | 1.2            |
| 2410-0166  | HCV RNA Linearity Panel (Plasma)    | 8         | 1.2            |
| 2410-0174  | CMV DNA Linearity Panel             | 9         | 2.0            |
| 2410-0221  | HIV-1 RNA Linearity Panel           | 10        | 1.2            |
| 2410-0327  | HCV RNA Linearity Panel (AccuPlex™) | 8         | 1.2            |
| 2410-0344  | BKV Linearity Panel                 | 7         | 1.4            |
| 2410-0345  | EBV Linearity Panel                 | 8         | 1.4            |

## AccuTrak™ Qualification Panels

| MATERIAL # | PANEL                                         | # MEMBERS | FILL SIZE (ML) |
|------------|-----------------------------------------------|-----------|----------------|
| 2400-0140  | HIV-1 RNA/HCV RNA/HBV DNA Qualification Panel | 5         | 4.0            |
| 2400-0141  | HBsAg Qualification Panel                     | 6         | 2.0            |
| 2400-0145  | Anti-HBc Qualification Panel                  | 6         | 2.0            |
| 2400-0148  | Anti-HCV Qualification Panel                  | 6         | 1.0            |
| 2400-0158  | HIV-1/2/O/p24 Qualification Panel             | 6         | 3.5            |
| 2400-0160  | Anti-HIV-1/2 Qualification Panel              | 6         | 1.0            |
| 2400-0161  | HPV Genotype Qualification Panel              | 25        | 4.0            |
| 2400-0163  | Syphilis Qualification Panel                  | 6         | 2.0            |
| 2400-0164  | Anti-CMV Qualification Panel                  | 6         | 3.0            |
| 2400-0181  | Anti-HTLV-I/II Qualification Panel            | 6         | 1.5            |
| 2400-0182  | HCV RNA Genotype Qualification Panel          | 9         | 1.2            |
| 2400-0225  | HBV DNA Genotype Qualification Panel          | 9         | 1.2            |
| 2400-0245  | CT/NG Verification Panel                      | 9         | 1.2            |
| 2400-0246  | TV/MG Verification Panel                      | 9         | 1.2            |

# Disease State Material

## NORMAL/HEALTHY OR SYNTHETIC MATRICES

| MATERIAL # | PRODUCT NAME                    |
|------------|---------------------------------|
| 0175-0007  | Synthetic Cerebral Spinal Fluid |
| 0300-0005  | Normal Human Serum              |
| 0300-0008  | Normal Human K2 EDTA Plasma     |
| 0375-0002  | Normal Human Pooled Sputum      |
| 0375-0003  | Cord Serum                      |
| 0300-0002  | Normal Human Plasma             |

## HIV

| MATERIAL # | PRODUCT NAME                                                      |
|------------|-------------------------------------------------------------------|
| 0315-0020  | HIV-1/2 Antibody Positive Plasma                                  |
| 0315-0024  | HIV-1 Antibody Confirmed Positive Plasma                          |
| 0315-0028  | HIV-2 Antibody Confirmed Positive Plasma                          |
| 0315-0031  | HIV-2 Antibody Confirmed Positive, HIV-1 Antibody Negative Plasma |
| 0315-0034  | HIV-1 Antigen Positive Plasma                                     |
| 0315-0037  | HIV-1 RNA Positive Plasma                                         |
| 0315-0040  | HIV-1 RNA Positive, HIV-1/2 Antibody Positive Plasma              |
| 0315-0043  | HIV-1 RNA Positive, HIV-1/2 Antibody Negative Plasma              |
| 0315-0046  | HIV-1 Subtype A Positive Plasma                                   |
| 0315-0049  | HIV-1 Subtype B Positive Plasma                                   |
| 0315-0052  | HIV-1 Subtype C Positive Plasma                                   |
| 0315-0055  | HIV-1 Subtype D Positive Plasma                                   |
| 0315-0058  | HIV-1 Subtype F Positive Plasma                                   |
| 0315-0064  | HIV-1 Subtype CRF01_AE Positive Plasma                            |
| 0315-0067  | HIV-1 Subtype CRF02_AG Positive Plasma                            |
| 0315-0070  | HIV-1 Subtype CRF03_AB Positive Plasma                            |
| 0315-0073  | HIV-1 Other Subtype Positive Plasma                               |
| 0315-0076  | HIV-1 Group O Positive Plasma                                     |
| 0315-0079  | HIV-1 RNA EDTA Positive Plasma                                    |

## HEPATITIS

| MATERIAL # | PRODUCT NAME                                       |
|------------|----------------------------------------------------|
| 0301-0006  | HAV IgM Antibody Positive Plasma >4 S/CO           |
| 0301-0010  | HAV IgG/Total Antibody Positive Plasma >2 S/CO     |
| 0301-0014  | HAV RNA Positive Plasma                            |
| 0301-0020  | HAV IgM Antibody Positive Plasma                   |
| 0305-0018  | HBc IgM Antibody Positive Plasma >4 S/CO           |
| 0305-0022  | HBc IgM Antibody Positive Plasma >2 S/CO           |
| 0305-0026  | HBc Total Antibody Positive, HBsAg Positive Plasma |
| 0305-0030  | HBc Total Antibody Positive, HBsAg Negative Plasma |
| 0305-0034  | HBe Antibody Positive Plasma                       |
| 0305-0038  | HBs Antibody Positive Plasma >2 S/CO               |
| 0305-0042  | HBs Antibody Positive Plasma >20 mIU/mL            |
| 0305-0046  | HBs Antibody Positive Plasma >200 mIU/mL           |
| 0305-0050  | HBs Antibody Positive Plasma >1000 mIU/mL          |
| 0305-0054  | HBeAg Positive Plasma >2 S/CO                      |
| 0305-0058  | HBsAg Positive Plasma                              |
| 0305-0061  | HBsAg Quantitative Positive Plasma                 |
| 0305-0066  | HBsAg Subtype AY Positive Plasma                   |
| 0305-0070  | HBsAg Subtype AD Positive Plasma                   |
| 0305-0074  | HBV DNA Positive Plasma                            |
| 0305-0078  | HBV Genotype A Positive Plasma                     |
| 0305-0081  | HBV Genotype B Positive Plasma                     |
| 0305-0084  | HBV Genotype C Positive Plasma                     |
| 0305-0087  | HBV Genotype D Positive Plasma                     |
| 0305-0090  | HBV Genotype E Positive Plasma                     |
| 0305-0093  | HBV Genotype F Positive Plasma                     |
| 0305-0099  | HBV Genotype H Positive Plasma                     |
| 0310-0020  | HCV Antibody Positive Plasma                       |
| 0310-0024  | HCV Antibody Confirmed Positive Plasma             |
| 0310-0028  | HCV Antigen Positive Plasma                        |
| 0310-0031  | HCV RNA Positive Plasma                            |
| 0310-0034  | HCV RNA Positive, HCV Antibody Positive Plasma     |
| 0310-0037  | HCV RNA Positive, HCV Antibody Negative Plasma     |
| 0310-0040  | HCV RNA Genotype 1 Positive Plasma                 |
| 0310-0043  | HCV RNA Genotype 1a Positive Plasma                |
| 0310-0046  | HCV RNA Genotype 1b Positive Plasma                |

|           |                                          |
|-----------|------------------------------------------|
| 0310-0049 | HCV RNA Genotype 2 Positive Plasma       |
| 0310-0052 | HCV RNA Genotype 2a Positive Plasma      |
| 0310-0055 | HCV RNA Genotype 2b Positive Plasma      |
| 0310-0058 | HCV RNA Genotype 3 Positive Plasma       |
| 0310-0061 | HCV RNA Genotype 4 Positive Plasma       |
| 0310-0064 | HCV RNA Genotype 5 Positive Plasma       |
| 0310-0067 | HCV RNA Genotype 6 Positive Plasma       |
| 0310-0070 | HCV RNA EDTA Positive Plasma             |
| 0311-0005 | HEV IgM Antibody Positive Plasma >4 S/CO |
| 0311-0010 | HEV IgG Antibody Positive Plasma >2 S/CO |
| 0311-0014 | HEV IgG Antibody Positive Plasma >4 S/CO |
| 0311-0018 | HEV RNA Positive Plasma                  |

## TORCH (TOXOPLASMA, RUBELLA, CYTOMEGALOVIRUS, AND HERPES)

| MATERIAL # | PRODUCT NAME                            |
|------------|-----------------------------------------|
| 0320-0004  | Toxoplasma IgG Antibody Positive Plasma |
| 0320-0008  | Toxoplasma IgM Antibody Positive Plasma |
| 0320-0012  | ToRCH Negative Plasma                   |
| 0320-0016  | Cytomegalovirus IgG Antibody Plasma     |
| 0320-0020  | Cytomegalovirus IgM Antibody Plasma     |
| 0320-0024  | Rubella IgG Antibody Positive Plasma    |
| 0320-0028  | Rubella IgM Antibody Positive Plasma    |
| 0320-0032  | HSV-1 IgG Antibody Positive Plasma      |
| 0320-0040  | HSV-2 IgG Antibody Positive Plasma      |

## VECTOR-BORNE

| MATERIAL # | PRODUCT NAME                                 |
|------------|----------------------------------------------|
| 0325-0014  | Dengue IgG Antibody Positive Plasma          |
| 0325-0018  | Dengue IgM Antibody Positive Plasma          |
| 0325-0041  | Chagas Antibody Positive Plasma              |
| 0325-0045  | Lyme Disease IgG Antibody Positive Plasma    |
| 0325-0049  | Lyme Disease IgM Antibody Positive Plasma    |
| 0325-0053  | Lyme Disease Total Antibody Positive Plasma  |
| 0325-0058  | West Nile Virus IgM Antibody Positive Plasma |
| 0325-0062  | West Nile Virus IgG Antibody Positive Plasma |
| 0325-0073  | Zika IgG Antibody Positive Plasma            |
| 0325-0079  | Zika IgM Antibody Positive Plasma            |

|           |                                  |
|-----------|----------------------------------|
| 0325-0083 | Malaria Positive Plasma          |
| 0325-0091 | Babesia Antibody Positive Plasma |

## AUTOIMMUNE

| MATERIAL # | PRODUCT NAME                                                    |
|------------|-----------------------------------------------------------------|
| 0340-0002  | Anti-Mitochondrial Antibody (AMA) Positive Plasma               |
| 0340-0006  | Antinuclear Antibody (ANA) Centromere Positive Plasma           |
| 0340-0010  | Antinuclear Antibody (ANA) Homogeneous Positive Plasma          |
| 0340-0014  | Antinuclear Antibody (ANA) Nucleolar Positive Plasma            |
| 0340-0018  | Antinuclear Antibody (ANA) Speckled Positive Plasma             |
| 0340-0022  | Antinuclear Antibody (ANA) Other Pattern Positive Plasma        |
| 0340-0030  | Double Stranded DNA (dsDNA) Antibody Positive Plasma            |
| 0340-0034  | Gliadin IgA Antibody Positive Plasma                            |
| 0340-0038  | Gliadin IgG Antibody Positive Plasma                            |
| 0340-0042  | Jo-1 Antibody Positive Plasma                                   |
| 0340-0046  | Rheumatoid Factor (RF) Antibody Positive Plasma <1000 IU/mL     |
| 0340-0054  | Rheumatoid Factor (RF) Antibody Positive Plasma 1001-2000 IU/mL |
| 0340-0058  | Rheumatoid Factor (RF) Antibody Positive Plasma 2001-4000 IU/mL |
| 0340-0066  | Ribonucleoprotein (RNP) Antibody Positive Plasma                |
| 0340-0070  | Smith/Ribonucleoprotein (SM/RNP) Antibody Positive Plasma       |
| 0340-0074  | SCL-70 Antibody Positive Plasma                                 |
| 0340-0082  | SSA Antibody Positive Plasma                                    |
| 0340-0090  | Thyroglobulin (TG) Antibody Positive Plasma                     |
| 0340-0094  | Thyroid Peroxidase Antibody (TPO) Positive Plasma               |
| 0340-0098  | Ribosomal P Antibody Positive Plasma                            |

## OTHER INFECTIOUS

| MATERIAL # | PRODUCT NAME                                               |
|------------|------------------------------------------------------------|
| 0325-0029  | HTLV-I Confirmed Antibody Positive Plasma                  |
| 0325-0033  | HTLV-II Confirmed Antibody Positive Plasma                 |
| 0325-0037  | HTLV-I/II Antibody Positive Plasma                         |
| 0345-0004  | Epstein-Barr Virus (EBV) VCA IgM Positive Plasma           |
| 0345-0008  | Epstein-Barr Virus (EBV) VCA IgG Positive Plasma           |
| 0345-0012  | Epstein-Barr Virus (EBV) Negative Plasma                   |
| 0345-0020  | Epstein-Barr Virus (EBV) EBNA IgG Antibody Positive Plasma |
| 0350-0003  | Varicella Zoster Virus (VZV) IgM Antibody Positive Plasma  |

|           |                                                           |
|-----------|-----------------------------------------------------------|
| 0350-0007 | Varicella Zoster Virus (VZV) IgG Antibody Positive Plasma |
| 0350-0011 | Parvovirus IgM Antibody Positive Plasma                   |
| 0350-0015 | Parvovirus IgG Antibody Positive Plasma                   |
| 0350-0019 | Parvovirus DNA Positive Plasma                            |
| 0350-0023 | Mycoplasma IgM Antibody Positive Plasma                   |
| 0350-0027 | Mycoplasma IgG Antibody Positive Plasma                   |
| 0350-0035 | Chlamydia IgG Antibody Positive Plasma                    |
| 0350-0039 | Chlamydia IgA Antibody Positive Plasma                    |
| 0365-0003 | Syphilis (T. pallidum) IgG Antibody Positive Plasma       |
| 0365-0007 | Rapid Plasma Reagin (RPR) Positive Plasma                 |
| 0365-0010 | Syphilis (T. pallidum) IgM Antibody Positive Plasma       |
| 0325-0087 | SARS-CoV-2 Antibody Positive Plasma                       |

## AccuType™ Viral Isolates and Purified RNA

### HIV VIRAL ISOLATES

| MATERIAL # | PRODUCT NAME            | COUNTRY OF ORIGIN | ISOLATE ID |
|------------|-------------------------|-------------------|------------|
| 0400-0001  | HIV-1 Genotype CRF02-AG | Djibouti          | DJ258      |
| 0400-0002  | HIV-1 Genotype A        | Uganda            | UG273      |
| 0400-0003  | HIV-1 Genotype CRF02-AG | Djibouti          | DJ263      |
| 0400-0004  | HIV-1 Genotype A        | Uganda            | UG275      |
| 0400-0005  | HIV-1 Genotype CRF02-AG | Liberia           | POC44951   |
| 0400-0006  | HIV-1 Genotype AG       | Ghana             | I-2496     |
| 0400-0007  | HIV-1 Genotype B        | Thailand          | BK132      |
| 0400-0008  | HIV-1 Genotype B        | USA               | US2        |
| 0400-0009  | HIV-1 Genotype B        | Brazil            | BZ167      |
| 0400-0010  | HIV-1 Genotype B        | USA               | US4        |
| 0400-0011  | HIV-1 Genotype B        | USA               | 93US144    |
| 0400-0012  | HIV-1 Genotype B        | Thailand          | CM237      |
| 0400-0013  | HIV-1 Genotype B        | USA               | US1        |
| 0400-0014  | HIV-1 Genotype B        | USA               | 93US143    |
| 0400-0015  | HIV-1 Genotype B        | USA               | 93US141    |
| 0400-0016  | HIV-1 Genotype B        | USA               | US3        |
| 0400-0017  | HIV-1 Genotype C        | Ethiopia          | ETH2220    |
| 0400-0018  | HIV-1 Genotype C        | Senegal           | SE364      |
| 0400-0019  | HIV-1 Genotype C        | Somalia           | SM145      |
| 0400-0020  | HIV-1 Genotype C        | Djibouti          | DJ259      |

|           |                         |            |            |
|-----------|-------------------------|------------|------------|
| 0400-0021 | HIV-1 Genotype C        | Uganda     | UG268      |
| 0400-0022 | HIV-1 Genotype C        | Zambia     | ZAM18      |
| 0400-0023 | HIV-1 Genotype C        | Unknown    | I-2516     |
| 0400-0024 | HIV-1 Genotype D        | Senegal    | SE365      |
| 0400-0025 | HIV-1 Genotype D        | Uganda     | UG274      |
| 0400-0026 | HIV-1 Genotype D        | Uganda     | UG270      |
| 0400-0027 | HIV-1 Genotype CRF01-AE | Thailand   | CM240      |
| 0400-0028 | HIV-1 Genotype CRF01-AE | Indonesia  | ID12       |
| 0400-0029 | HIV-1 Genotype CRF01-AE | Thailand   | CM235      |
| 0400-0030 | HIV-1 Genotype CRF01-AE | Indonesia  | ID17       |
| 0400-0031 | HIV-1 Genotype CRF01-AE | Thailand   | NP1465     |
| 0400-0032 | HIV-1 Genotype CRF01-AE | Thailand   | CM243D     |
| 0400-0033 | HIV-1 Genotype CRF01-AE | Thailand   | 42368      |
| 0400-0034 | HIV-1 Genotype CRF01-AE | Thailand   | POC30506   |
| 0400-0035 | HIV-1 Genotype CRF01-AE | Thailand   | NP03       |
| 0400-0036 | HIV-1 Genotype CRF01-AE | Thailand   | CM238      |
| 0400-0037 | HIV-1 Genotype F        | Brazil     | BZ163      |
| 0400-0038 | HIV-1 Genotype F        | Brazil     | BZ126      |
| 0400-0039 | HIV-1 Genotype F        | Brazil     | BZ162      |
| 0400-0040 | HIV-1 Genotype F        | Romania    | BCI-R07    |
| 0400-0041 | HIV-1 Genotype F        | Romania    | BCI-R08    |
| 0400-0042 | HIV-1 Genotype CRF06    | Zaire      | BCF-DIOUM  |
| 0400-0043 | HIV-1 Genotype G        | Kenya      | HH8793     |
| 0400-0044 | HIV-1 Genotype G        | Zaire      | BCF-KITA   |
| 0400-0045 | HIV-1 Group O           | Cameroon   | BCF06      |
| 0400-0046 | HIV-1 Group O           | Cameroon   | BCF11      |
| 0400-0047 | HIV-1 Group O           | USA        | I-2478B    |
| 0400-0048 | HIV-1 Group O           | Spain      | I-2481     |
| 0400-0051 | HIV-1 Genotype A        | Kyrgyzstan | 9250622-01 |
| 0400-0094 | HIV-2 Subtype A         | Africa     | NIH-Z      |
| 0400-0095 | HIV-2 Subtype B         | USA        | Seattle    |

## HIV-1 PURIFIED RNAS

| MATERIAL # | PRODUCT NAME                         | COUNTRY OF ORIGIN | ISOLATE ID |
|------------|--------------------------------------|-------------------|------------|
| 0400-0075  | HIV-1 Purified RNA Genotype AG       | Ghana             | I-2496     |
| 0400-0076  | HIV-1 Purified RNA Genotype CRF02-AG | Liberia           | POC44951   |
| 0400-0077  | HIV-1 Purified RNA Genotype B        | Thailand          | BK132      |
| 0400-0078  | HIV-1 Purified RNA Genotype B        | USA               | US1        |
| 0400-0079  | HIV-1 Purified RNA Genotype C        | Djibouti          | DJ259      |
| 0400-0080  | HIV-1 Purified RNA Genotype C        | Unknown           | I-2516     |
| 0400-0081  | HIV-1 Purified RNA Genotype D        | Uganda            | UG274      |
| 0400-0082  | HIV-1 Purified RNA Genotype D        | Senegal           | SE365      |
| 0400-0083  | HIV-1 Purified RNA Genotype CRF01-AE | Thailand          | 42368      |
| 0400-0084  | HIV-1 Purified RNA Genotype CRF01-AE | Thailand          | POC30506   |
| 0400-0085  | HIV-1 Purified RNA Genotype F        | Brazil            | BZ126      |
| 0400-0086  | HIV-1 Purified RNA Genotype F        | Brazil            | BZ162      |
| 0400-0087  | HIV-1 Purified RNA Genotype CRF06    | Zaire             | BCF-DIOUM  |
| 0400-0088  | HIV-1 Purified RNA Genotype G        | Kenya             | HH8793     |
| 0400-0089  | HIV-1 Purified RNA Genotype G        | Zaire             | BCF-KITA   |
| 0400-0090  | HIV-1 Purified RNA Genotype O        | Cameroon          | BCF06      |
| 0400-0091  | HIV-1 Purified RNA Genotype O        | Cameroon          | BCF11      |
| 0400-0092  | HIV-1 Purified RNA Genotype O        | USA               | I-2478B    |
| 0400-0093  | HIV-1 Purified RNA Genotype O        | Spain             | I-2481     |

## OTHER VIRUSES

| MATERIAL # | PRODUCT NAME   | ISOLATE ID |
|------------|----------------|------------|
| 0410-0002  | WNV Lineage I  | 2001-6263  |
| 0410-0003  | WNV Lineage II | 956-99     |
| 0410-0004  | EBV            | B95-8      |
| 0410-0014  | HSV-1          | VR539      |
| 0410-0015  | HSV-2          | VR540      |

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