

**Thermo Scientific AcroMetrix**  
Molecular Standards & Quality Controls

Simpler QC for your  
**Quality systems**

*simpler*QC™

**Thermo**  
SCIENTIFIC





**AcroMetrix**

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**MOLECULAR STANDARDS & QUALITY CONTROLS**

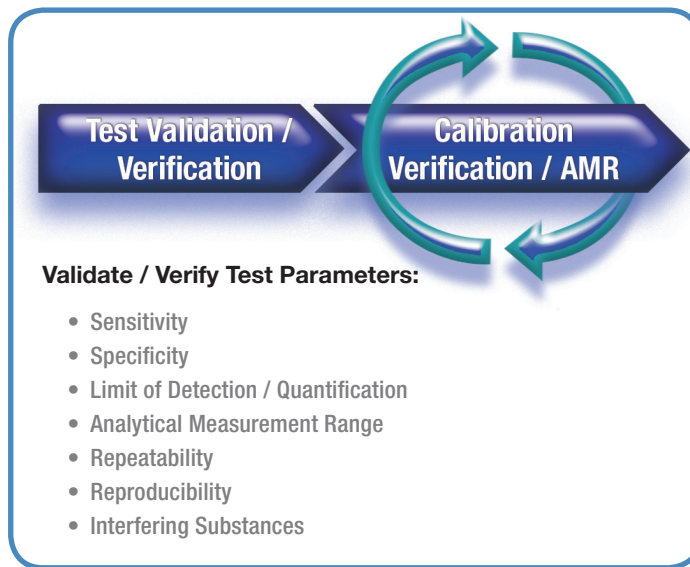
# Simplify Your Laboratory Quality System

Ensure the accuracy and integrity of laboratory test results with Thermo Scientific™ AcroMetrix™ molecular standards and quality controls, services and online tools. From initial method validation and verification to recurring regular QC monitoring and calibration verification, we support laboratories, blood screening centers, manufacturers, and proficiency survey providers engaged in molecular and serological technologies for both clinical diagnostics and research applications.

Our wide range of custom and catalog solutions are focused on the goal of standardization and simplification in molecular testing by:

1. Establishing the traceability of results and
2. Providing commutable material that ensures consistent, accurate, and meaningful test results

## Assay Validation

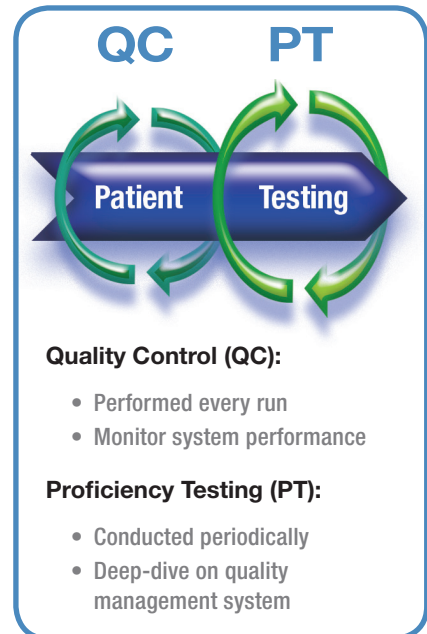


## Panels for Validation and Verification

**Routine use of ISO13485 produced quality controls can increase your laboratory quality:**

- cGMP-level documentation for your next audit
- Know what to expect with Certificate of Analysis for every lot
- Less time spent on sourcing materials and sample characterization
- Reduce variability in testing
- Minimize time spent on lot changes
- Reduce instrument downtime with easy troubleshooting

## Quality Management



## Controls for QC Monitoring

**AcroMetrix controls are designed for use with molecular and serological technologies for both clinical and research applications. Systems include:**

- Roche cobas series, LightCycler
- Abbott m2000, ARCHITECT
- Hologic TIGRIS/PANTHER
- Applied Biosystems Real-Time PCR Systems
- Cepheid GeneXpert
- Thermo Scientific Personal Genome Machine (PGM)



## Superior QC: AcroMetrix Quality Controls

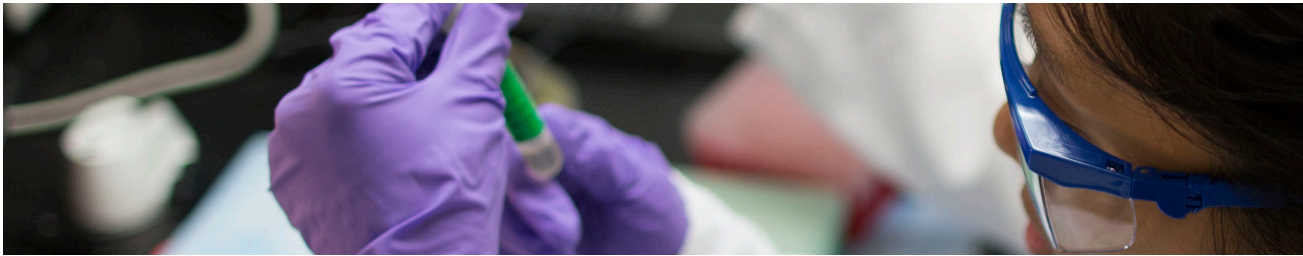
Thermo Fisher Scientific is a world class provider of high-quality molecular QC products that assist in the implementation and monitoring of assays. Our key advantages include:

- Consistent lot-to-lot performance. In accordance with World Health Organization (WHO) standards, AcroMetrix observes traceability in line with ISO 17511. Even in the absence of a WHO international standard, each lot is traceable to the very first lot manufactured.

### Example Analytes Manufactured to WHO Standards

HIV-1      HBV      HCV      CMV      EBV

- Controls that mimic human samples. AcroMetrix controls utilize whole virus and bacteria, testing both extraction and amplification workflows.
- Minimize time spent on lot changes. Materials are stable for 12–24 months, maximizing the time spent testing your assay, not your QC products.
- cGMP documentation for your next audit. A Certificate of Analysis is available with each production lot, to ease the process of passing your next laboratory audit.
- Multi-analyte controls to maximize efficiency. Monitor all the analytes in your multiplexed assays simultaneously using pooled multi-marker controls. The bulk format of the multi-analyte control allows for cost-effective QC. Also available in single-analyte configurations.



## Custom and OEM Capabilities

With a proven history of working with the world's leading diagnostic companies and EQAS/PT providers, we are ready to partner with your team to develop custom and OEM solutions unique to your customer's needs—from feasibility to product launch.

- Reliable materials for any stage of development: R&D, clinical trials, manufacturing, customer training and customer proficiency
- Varying matrices, fill volumes and product configurations
- Design control for RUO or IVD designations
- Vast array of in-house test systems
- Active or inactive viruses
- FFPE, gDNA or synthetic DNA/RNA sample types



## Infectious Disease Testing

### Ultra high-titer viruses: SynTura™ technology

As a high-titer whole virus control, AcroMetrix products made with SynTura technology allows you to reach the full analytical range of your system, beyond the viral loads grown under wild-type conditions. Key benefits include:

- Similar virus to HCV
- Grows to high titers
- Non-infectious to humans
- Detectable in HCV assays

Comparison of HCV Titer Ranges		
AcroMetrix	ZeptoMetrix®	SeraCare®
100–25,000,000 IU/mL	200–100,000 IU/mL	470–3,200,000 IU/mL



### Infectious disease testing nucleic acid controls

Infectious Disease Nucleic Acid Testing Controls				
Catalog #	Product Name/Description	Fill Volume	Package Size	Regulatory Designation
<b>HIV-1</b>				
<b>942013</b>	AcroMetrix HIV-1 Panel IU/mL (0, 1E2, 1E3, 1E4, 1E5, 1E6, 1E7 IU/mL)	1.2 mL	7 vials	RUO
<b>950470</b>	AcroMetrix HIV-1 Panel copies/mL (0, 1E2, 5E2, 5E3, 5E4, 5E5, 5E6 copies/mL)	1.2 mL	7 vials	RUO
<b>964001</b>	AcroMetrix HIV-1 Low Control	1.2 mL	5 vials	IVD
<b>964002</b>	AcroMetrix HIV-1 Mid Control	1.2 mL	5 vials	IVD
<b>964003</b>	AcroMetrix HIV-1 High Control	1.2 mL	5 vials	IVD
<b>951502</b>	AcroMetrix Genotyping HIV RT/PR Mutant Control	0.5 mL	5 vials	RUO
<b>HBV</b>				
<b>950150</b>	AcroMetrix HBV Panel 1.2 mL (5E1, 5E2, 5E3, 5E4, 5E5, 5E6, 5E7 IU/mL)	1.2 mL	7 vials	RUO
<b>965001</b>	AcroMetrix HBV Low Control	1.0 mL	5 vials	IVD
<b>965002</b>	AcroMetrix HBV Mid Control	1.0 mL	5 vials	IVD
<b>965003</b>	AcroMetrix HBV High Control	1.0 mL	5 vials	IVD
<b>HCV</b>				
<b>950350</b>	AcroMetrix HCV-s Panel (1E2, 5E2, 5E3, 5E4, 5E5, 5E6, 2.5E7 IU/mL)	1.2 mL	7 vials	RUO
<b>942000</b>	AcroMetrix HCV Genotyping Panel	0.5 mL	4 vials	RUO
<b>963001</b>	AcroMetrix HCV Low Control	1.2 mL	5 vials	IVD
<b>963002</b>	AcroMetrix HCV Mid Control	1.2 mL	5 vials	IVD
<b>963003</b>	AcroMetrix HCV High Control	1.2 mL	5 vials	IVD
<b>HPV</b>				
<b>950075</b>	AcroMetrix HPV-16 Genotype Control	4.0 mL	5 vials	RUO
<b>950076</b>	AcroMetrix HPV-18 Genotype Control	4.0 mL	5 vials	RUO
<b>950077</b>	AcroMetrix HPV-68 Genotype Control	4.0 mL	5 vials	RUO
<b>950078</b>	AcroMetrix HPV Negative Control	4.0 mL	5 vials	RUO
<b>MRSA/MSSA</b>				
<b>960025</b>	AcroMetrix MSSA Positive Control	0.2 mL	5 vials	IVD
<b>960091</b>	AcroMetrix MRSA Positive Control	0.2 mL	5 vials	IVD

GPR = General Purpose Reagent IVD = In Vitro Diagnostics RUO = Research Use Only



## Transplant disease testing nucleic acid controls

AcroMetrix materials are the only quality control materials made from whole, unaltered virus in either EDTA based plasma or in a synthetic matrix similar to cerebrospinal fluid. This means you get a true full-process control—from extraction through amplification and detection—that effectively mimics a patient sample. Calibrated against an in-house standard in accordance with ISO 17511, AcroMetrix control materials and panels display excellent reproducibility and consistency from lot to lot.

Transplant Disease Nucleic Acid Testing Controls				
Catalog #	Product Name/Description	Fill Volume	Package Size	Regulatory Designation
<b>BK Virus</b>				
<b>950360</b>	AcroMetrix BKV Panel (5E2, 5E3, 5E4, 5E5, 5E6 copies/mL)	0.5 mL	5 vials	RUO
<b>960050</b>	AcroMetrix BKV Low Control	0.5 mL	5 vials	IVD
<b>960051</b>	AcroMetrix BKV High Control	0.5 mL	5 vials	IVD
<b>CMV</b>				
<b>942016</b>	AcroMetrix CMVtc Panel (3E2, 3E3, 3E4, 3E5, 3E6 IU/mL)	0.8 mL	5 vials	RUO
<b>951700</b>	AcroMetrix CMV Negative Control	0.8 mL	5 vials	RUO
<b>951701</b>	AcroMetrix CMV Low Control	0.8 mL	5 vials	RUO
<b>951702</b>	AcroMetrix CMV High Control	0.8 mL	5 vials	RUO
<b>EBV</b>				
<b>942015</b>	AcroMetrix EBV CSF Panel (0, 1E2, 1E3, 1E4, 1E5 IU/mL)	0.5 mL	5 vials	RUO
<b>942017A</b>	AcroMetrix EBV Plasma Panel (1E2, 1E3, 1E4, 1E5, 1E6 IU/mL)	0.5 mL	5 vials	RUO
<b>951304</b>	AcroMetrix EBV Low CSF Control	0.5 mL	5 vials	RUO
<b>961230</b>	AcroMetrix EBV Low Plasma Control	0.5 mL	5 vials	IVD
<b>951307A</b>	AcroMetrix EBV High CSF Control	0.5 mL	5 vials	RUO
<b>961231</b>	AcroMetrix EBV High Plasma Control	0.5 mL	5 vials	IVD
<b>HSV-1</b>				
<b>954520</b>	AcroMetrix HSV-1 Plasma Panel (1E2, 1E3, 1E4, 1E5, 1E6 copies/mL)	0.5 mL	5 vials	RUO
<b>951301</b>	AcroMetrix HSV-1 Low CSF Control	0.5 mL	5 vials	RUO
<b>954501</b>	AcroMetrix HSV-1 High CSF Control	0.5 mL	5 vials	RUO
<b>951300</b>	AcroMetrix HHV Negative Control	0.5 mL	5 vials	RUO

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Transplant Disease Nucleic Acid Testing Controls (continued)				
Catalog #	Product Name/Description	Fill Volume	Package Size	Regulatory Designation
<b>HSV-2</b>				
954525	AcroMetrix HSV-2 Plasma Panel (1E2, 1E3, 1E4, 1E5, 1E6 copies/mL)	0.5 mL	5 vials	RUO
951302	AcroMetrix HSV-2 Low CSF Control	0.5 mL	5 vials	RUO
954502	AcroMetrix HSV-2 High CSF Control	0.5 mL	5 vials	RUO
951300	AcroMetrix HHV Negative Control	0.5 mL	5 vials	RUO
<b>VZV</b>				
954530	AcroMetrix VZV Plasma Panel (1E2, 1E3, 1E4, 1E5, 1E6 copies/mL)	0.5 mL	5 vials	RUO
954511	AcroMetrix VZV Low CSF Control	0.5 mL	5 vials	RUO
954512	AcroMetrix VZV High CSF Control	0.5 mL	5 vials	RUO
954514	AcroMetrix VZV High Plasma Control	0.5 mL	5 vials	RUO
<b>Adenovirus</b>				
954535	AcroMetrix Adenovirus Plasma Panel (1E3, 1E4, 1E5, 1E6, 1E7 copies/mL)	0.5 mL	5 vials	RUO
954505	AcroMetrix Adenovirus Low Plasma Control	0.5 mL	5 vials	RUO
954506	AcroMetrix Adenovirus High Plasma Control	0.5 mL	5 vials	RUO
954504	AcroMetrix Adenovirus High CSF Control	0.5 mL	5 vials	RUO
<b>Enterovirus</b>				
950499	AcroMetrix EV Negative Control	0.3 mL	5 vials	RUO
950500	AcroMetrix EV Low Control	0.3 mL	5 vials	RUO
<b>GBS</b>				
960041	AcroMetrix GBS Positive Control	0.2 mL	5 vials	IVD
<b>Assay Inhibitors</b>				
956400	AcroMetrix Inhibition Panel	1.0 mL	7 vials	RUO
<b>Nucleic Acid Testing - Control Diluents</b>				
S2284	AcroMetrix EDTA Plasma Dilution Matrix	45 mL	1 bottle	RUO
941050	AcroMetrix Citrate Plasma Dilution Matrix	50.0 mL	1 bottle	GPR
941100		100.0 mL	1 bottle	GPR
962000A	AcroMetrix Negative Control	1.0 mL	5 vials	IVD

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## Multi-analyte controls

Infectious Disease Testing - Multi-Analyte Controls				
Catalog #	Product Name/Description	Fill Volume	Package Size	Regulatory Designation
<b>HIV-1/HBV/HCV Multi-Analyte</b>				
<b>967150</b>	AcroMetrix HIV-1/HCV/HBV Low Control	50.0 mL	1 bottle	IVD
<b>967151</b>	AcroMetrix HIV-1/HCV/HBV High Control	50.0 mL	1 bottle	IVD
<b>CT/NG</b>				
<b>967146</b>	AcroMetrix CT/NG Control	20.0 mL	1 bottle	IVD
<b>Transplant Multi-Analyte</b>				
<b>957041</b>	Multi-Analyte Control - Transplant BKV, CMV, EBV, HHV-6B, HSV-1, HSV-2, VZV	50.0 mL	2 bottles	RUO

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HIV-1/HCV/HBV Low and High Controls are the first and only bulk, multi-analyte, third-party quality controls designed for assessing the performance of molecular assays that detect HIV-1 RNA, HCV RNA, and HBV DNA in patient samples. Additionally, these controls enable routine monitoring of day-to-day test variation, lot-to-lot performance of test kits, and operator variation.

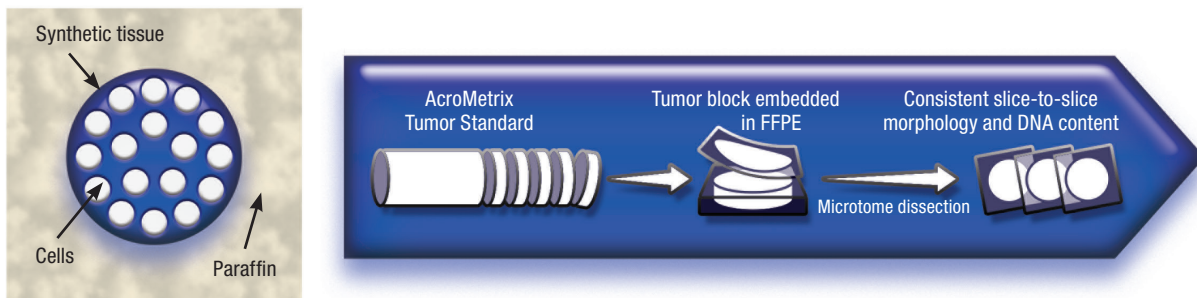
- Achieve greater flexibility and cost efficiency due to the 50 mL bulk format
- Accurately monitor assay performance over time due to our lot-to-lot consistency achieved by meeting ISO 17511 manufacturing guidelines
- Whole virus controls enable workflow monitoring from extraction through detection

# Oncology Testing

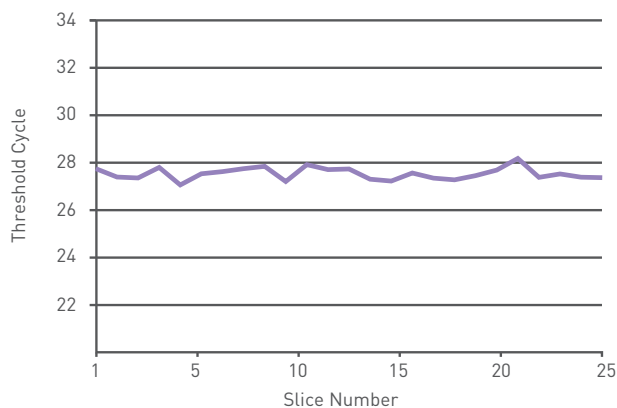
## FFPE full process controls for assessing entire oncology testing workflow

AcroMetrix commercially available synthetic formalin-fixed and paraffin-embedded (FFPE) controls using a proprietary process that optimizes reproducibility of the sections within a single production lot. By embedding synthetic tissue in a homogeneous block, the tumor content in each section can be controlled and quantified.

FFPE controls make ideal full process controls for the testing of tumor samples because they can be used in all steps of processing a solid tumor sample.



Consistency of DNA Content from Serial Slices of AcroMetrix FFPE



Reference: Dijkstra, Jeroen R. et al. "Implementation of Formalin-Fixed, Paraffin-Embedded Cell Line Pellets as High-Quality Process Controls in Quality Assessment Programs for KRAS Mutation Analysis." *The Journal of Molecular Diagnostics* 14.3 (2012):187-191.

Oncology Testing Quality Controls				
Catalog #	Product Name/Description	Fill Volume	Package Size	Regulatory Designation
<b>KRAS FFPE</b>				
950450	AcroMetrix KRAS FFPE Process Controls (G12A, G12C, G12D, G12R, G12S, G12V, G13D, WT)	>200ng DNA	8 vials	RUO
950451	AcroMetrix Wild-Type KRAS FFPE Controls	>200ng DNA	5 vials	RUO
<b>MultiMix FFPE</b>				
957184	AcroMetrix MultiMixA FFPE Control	>200ng DNA	5 vials	RUO
957185	AcroMetrix MultiMixB FFPE Control	>200ng DNA	5 vials	RUO
957186	AcroMetrix MultiMixC FFPE Control	>200ng DNA	5 vials	RUO
957187	AcroMetrix MultiMixD FFPE Control	>200ng DNA	5 vials	RUO
957188	AcroMetrix MultiMixE FFPE Control	>200ng DNA	5 vials	RUO
957189	AcroMetrix MultiMixF FFPE Control	>200ng DNA	5 vials	RUO
957190	AcroMetrix MultiMixG FFPE Control	>200ng DNA	5 vials	RUO
957191	AcroMetrix MultiMixH FFPE Control	>200ng DNA	5 vials	RUO

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## Oncology hotspot control for somatic mutation detection by NGS

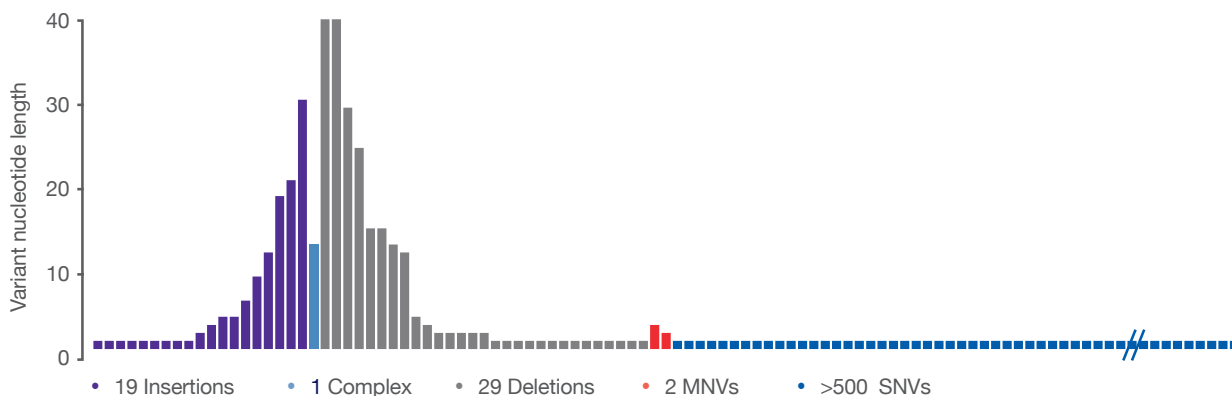
The AcroMetrix Oncology Hotspot Control is a highly multiplexed quality control used to assess the performance of next-generation sequencing (NGS) assays that detect somatic mutations. Against a highly characterized genomic background, we added over 500 SNPs, insertions, and deletions of varying lengths and complexities. The different mutation types would allow a lab to use this control with various next-generation sequencing platforms, including their custom library preparation panels.

Hotspot controls are manufactured using MegaMix technology, a proprietary, high-multiplex variant blend process containing:

- Synthetic + genomic DNA blend
- Variants confirmed by Sanger sequencing
- GM24385 genomic background characterized by Genome in a Bottle

### +500 gene mutations available through MegaMix Technology.

#### Track multiple variant types of varying nucleotide lengths



#### Fifty-three genes are represented

ABL1	CTNNB1	FLT3	JAK2	NOTCH1	SMARCB1
AKT1	EGFR	FOXL2	JAK3	NRAS	SMO
ALK	ERBB2	GNA11	KDR	PDGFRA	SRC
APC	ERBB4	GNAQ	KIT	PIK3CA	STK11
ATM	EZH2	GNAS	KRAS	PTEN	TP53
BRAF	FBXW7	HNF1A	MET	PTPN11	VHL
CDH1	FGFR1	HRAS	MLH1	RB1	MAP2K1
CDKN2A	FGFR2	IDH1	MPL	RET	NPM1
CSF1R	FGFR3	IDH2	MSH6	SMAD4	

Oncology Quality Controls				
Catalog #	Product Name/Description	Fill Volume	Package Size	Regulatory Designation
969056	AcroMetrix Oncology Hotspot Control	25.0 uL	3 vials	IVD

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# Blood Screening and Serology Testing

## Controls for nucleic acid testing (NAT) and serological testing

Optimized and validated to meet the quality assurance needs of blood screening labs, Thermo Scientific offers a wide range of quality controls that deliver the high sensitivity and accuracy required to ensure the effective detection of infectious diseases.

- Matches assays commonly used for infectious disease testing
- Reacts at appropriate level within the analytical range of specific assays
- Manufactured in an ISO 13485 facility and, where applicable, standardized against WHO standards for traceability in accordance with ISO 17511
- Supported by QConnect, a partnership with blood screening experts from the NRL



Blood Screening - Nucleic Acid Testing Controls				
Catalog #	Product Name/Description	Fill Volume	Package Size	Regulatory Designation
<b>Blood Bank Nucleic Acid Testing Controls (BB NAT - formerly VeriSure Pro)</b>				
<b>963600</b>	AcroMetrix BB NAT Negative Control	1.4 mL	10 vials	IVD
<b>963601</b>	AcroMetrix BB NAT HCV Positive Control	1.4 mL	10 vials	IVD
<b>963602</b>	AcroMetrix BB NAT HIV-1 Positive Control	1.4 mL	10 vials	IVD
<b>963603</b>	AcroMetrix BB NAT HBV Positive Control	1.4 mL	10 vials	IVD
<b>960500</b>	QConnect WNV RNA (formerly BB NAT WNV Positive Control)	1.4 mL	10 vials	IVD
<b>960600</b>	AcroMetrix BB NAT WNV Negative Control	1.4 mL	10 vials	IVD
<b>Training Panels</b>				
<b>950250</b>	AcroMetrix WNV Training Panel	1.0 mL	6 vials	RUO
<b>S2340</b>	AcroMetrix HIV, HBV, HCV Training Panel	1.0 mL	10 vials	RUO
<b>Blood Screening - Nucleic Acid Testing Control Diluents</b>				
<b>S2284</b>	AcroMetrix EDTA Plasma Dilution Matrix	45.0 mL	1 bottle	RUO
<b>S2285</b>	AcroMetrix Ultra Serum Dilution Matrix	50.0 mL	1 bottle	RUO
<b>941050</b>	AcroMetrix Citrate Plasma Dilution Matrix	50.0 mL	1 bottle	GPR
<b>941100</b>		100.0 mL	1 bottle	GPR

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QC is made easier with QConnect, an integrated and simplified solution that incorporates customized QC samples, results management and reporting, control limits, Uncertainty of Measurement (MU) reports, troubleshooting, and the ability to liaise with other users and experts.

Developed by NRL of Melbourne, Australia, QConnect promotes the quality of tests and testing for infectious disease globally. Member labs include Australia, Hong Kong, Italy, The Netherlands, Portugal, Poland, South Africa, U.S., and others.



Blood Screening - Serology/Immunoassay Controls				
Catalog #	Product Name/Description	Fill Volume	Package Size	Regulatory Designation
<b>QConnect Serology Controls (formerly PeliSpy™ Multi-Marker)</b>				
<b>950050</b>	QConnect Anti-HBs	1.0 mL	5 vials	RUO
<b>969035</b>	QConnect Syphilis	1.0 mL	5 vials	IVD
<b>960378</b>	QConnect Chagas	3.5 mL	5 vials	IVD
<b>960811</b>	QConnect TriScreen	1.0 mL	10 vials	IVD
<b>PeliSpy™ Serology Controls (formerly PeliSpy™ Multi-Marker)</b>				
<b>S2409</b>	AcroMetrix® PeliSpy™ Sero Control Negative	5.0mL	10 vials	RUO
<b>S2407</b>	AcroMetrix PeliSpy Sero Control Type 17 (Abbott AxSym, Ortho Vitros ECI) HBsAg, anti-HCV, anti-HIV, anti-HTLV	5.0 mL	10 vials	RUO
<b>S2408</b>	AcroMetrix PeliSpy Sero Control Type 36 (Abbott Prism) HBsAg, anti-HCV, anti-HIV, anti-HTLV, anti-HBc	5.0 mL	10 vials	RUO
<b>Blood Screening - Serology/Immunoassay Control Diluents</b>				
<b>S2284</b>	AcroMetrix EDTA Plasma Dilution Matrix	45.0 mL	1 bottle	RUO
<b>S2285</b>	AcroMetrix Ultra Serum Dilution Matrix	50.0 mL	1 bottle	RUO

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## Customer Service

**Phone:** 1-800-232-3342 - Press 1 for Customer Service, then 3 for Quality Controls

**Fax:** 1-800-829-8115

**e-mail:** mgc-masorders@thermofisher.com

### For orders via e-mail or Fax

Please indicate the following required information on your purchase order:

- Customer Account Number
- Purchase Order Number
- Shipping Address with Contact
- Product Catalog Number
- Quantity Desired
- Contact Person and Phone Number

### Mail

Thermo Fisher Scientific  
46500 Kato Road  
Fremont, CA 94538-7310  
USA  
ATTN: Customer Service

### Hours

7 a.m. - 4 p.m. Monday - Friday, pacific time

### Delivery

Domestic orders are shipped next-day air freight.

**Minimum Orders:** We have a minimum order requirement of \$100.

### Sales Support

**Phone:** 1-800-232-3342

**e-mail:** sales.diagnostics.fmt@thermofisher.com

### Technical Service and Support

In most cases, technical assistance is available, 24 hours a day, 7 days a week.

**Phone:** 1-800-232-3342- option 2, then 2 for quality controls

### For non-urgent inquiries:

**e-mail:** mas.controls@thermofisher.com

### Terms

**Payment:** Payment terms are NET 30 days. Payment is expected within 30 days from the date of the invoice. Thermo Fisher Scientific reserves the right to require payment in advance, C.O.D., credit card or otherwise modify credit terms.

### Prices

Prices are subject to change without notice.

### Shipment

Shipping terms are Free on Board (FOB) shipping point. Customer is responsible for transportation costs from our facility to customer facility; freight is prepaid, then billed on invoice. Transfer of ownership occurs when the shipment leaves our facility.

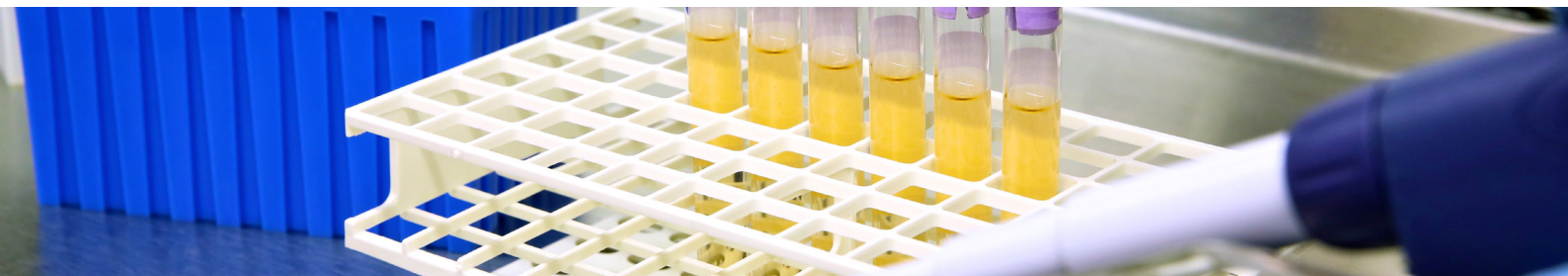
### Damaged Goods

Be sure to inspect your shipment immediately upon arrival. Please notify the Thermo Fisher Scientific Customer Service Department of any product discrepancy or damage within 10 working days of shipment receipt.

### Product Claims

Failure to use the product as set forth in the product labeling and application sheets can affect performance.

**NOTE:** Sales are subject to the other terms and conditions on Thermo Fisher Scientific invoice. All sales are final. Returned products require a Return Materials Authorization





**AcroMetrix**





# AcroMetrix

## Simplifying validation and QC

[thermoscientific.com/QC](http://thermoscientific.com/QC)

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