

Quality Controls

## Take control of your lab

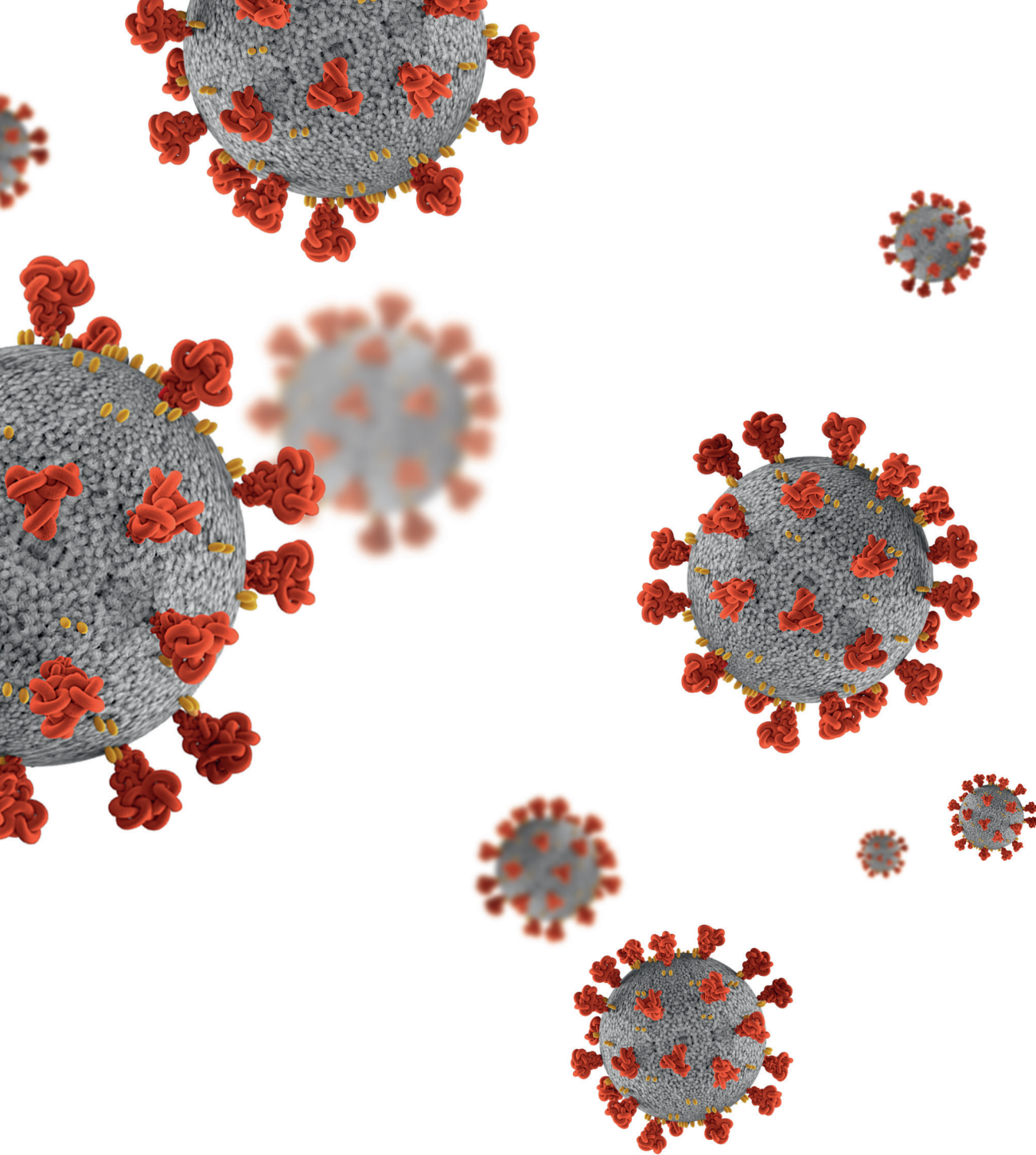
Thermo Scientific AcroMetrix molecular standards  
and quality controls

Europe, Middle East, and Africa Catalog



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# One portfolio for all your QC needs

Clinical labs, research labs, blood centers, and IVD manufacturers all over the world trust Thermo Scientific™ AcroMetrix™ molecular standards and quality controls. AcroMetrix products are designed with a single purpose in mind: ensuring the accuracy and integrity of lab test results.

The AcroMetrix portfolio features controls and validation panels for initial method validation and verification and regular QC monitoring. You benefit from the same high quality, standardization, and simplification whatever you choose.



## Fully traceable

Aligned with **international reference standards**



## Mimics human specimen

Ensures reliability, accuracy, and **meaningful test results**



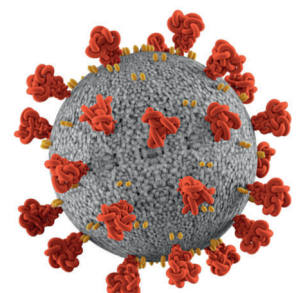
## Platform-agnostic\*

Permits **unbiased performance**



## Lot-to-lot consistency

For more **confidence** and less **waste**



\* Applies to most AcroMetrix controls

# Infectious disease testing

## Measure the full analytical range of your system

AcroMetrix products help standardize infectious disease testing in your lab, allowing you to achieve unprecedented levels of performance. For **HCV testing**, for instance, you benefit from **ultra-high-titer controls** thanks to SynTura™ technology.

### SynTura technology

- Recombinant HCV virus
- Noninfectious to humans
- Detectable in HCV assays

## Nucleic acid testing (NAT) controls

Catalog #	Product Name/Description	Vial Fill Volume	Package Size	Regulatory Designation
<b>HIV-1/HBV/HCV Multi-Analyte</b>				
967150	AcroMetrix HIV-1/HCV/HBV Low Control	50.0 mL	1 bottle	CE-IVD, IVD
967151	AcroMetrix HIV-1/HCV/HBV High Control	50.0 mL	1 bottle	CE-IVD, IVD
<b>HIV-1</b>				
942013	AcroMetrix HIV-1 Panel IU/mL (0, 1E2, 1E3, 1E4, 1E5, 1E6, 1E7 IU/mL)	1.2 mL	7 vials	RUO
950470	AcroMetrix HIV-1 Panel copies/mL (0, 1E2, 5E2, 5E3, 5E4, 5E5, 5E6 copies/mL)	1.2 mL	7 vials	RUO
964001	AcroMetrix HIV-1 Low Control	1.2 mL	5 vials	CE-IVD, IVD
964002	AcroMetrix HIV-1 Mid Control	1.2 mL	5 vials	CE-IVD, IVD
964003	AcroMetrix HIV-1 High Control	1.2 mL	5 vials	CE-IVD, IVD
951502	AcroMetrix Genotyping HIV RT/PR Mutant Control	0.5 mL	5 vials	RUO
<b>HBV</b>				
950150	AcroMetrix HBV Panel 1.2 mL (5E1, 5E2, 5E3, 5E4, 5E5, 5E6, 5E7 IU/mL)	1.2 mL	7 vials	RUO
965001	AcroMetrix HBV Low Control	1.0 mL	5 vials	CE-IVD, IVD
965002	AcroMetrix HBV Mid Control	1.0 mL	5 vials	CE-IVD, IVD
965003	AcroMetrix HBV High Control	1.0 mL	5 vials	CE-IVD, IVD
<b>HCV</b>				
950350	AcroMetrix HCV-s Panel (1E2, 5E2, 5E3, 5E4, 5E5, 5E6, 2.5E7 IU/mL)	1.2 mL	7 vials	RUO
942000	AcroMetrix HCV Genotyping Panel	0.5 mL	4 vials	RUO
963001	AcroMetrix HCV Low Control	1.2 mL	5 vials	CE-IVD, IVD
963002	AcroMetrix HCV Mid Control	1.2 mL	5 vials	CE-IVD, IVD
963003	AcroMetrix HCV High Control	1.2 mL	5 vials	CE-IVD, IVD
<b>HPV</b>				
950075	AcroMetrix HPV-16 Genotype Control	4.0 mL	5 vials	RUO
950076	AcroMetrix HPV-18 Genotype Control	4.0 mL	5 vials	RUO
950077	AcroMetrix HPV-68 Genotype Control	4.0 mL	5 vials	RUO
950078	AcroMetrix HPV Negative Control	4.0 mL	5 vials	RUO
<b>CT/NG</b>				
967146	AcroMetrix CT/NG Control	20.0 mL	1 bottle	CE-IVD, IVD
<b>SARS-COV-2</b>				
954519	AcroMetrix COVID-19 RNA Control	20 uL	2 vials	RUO
954517	AcroMetrix SARS-CoV-2 Control	1.5 ml	5 vials	RUO
954516	AcroMetrix Multi-Analyte SARS-CoV-2, Flu A/B, RSV A/B Control	1.5 ml	5 vials	RUO
<b>Assay inhibitors</b>				
956400	AcroMetrix Inhibition Panel	1.0 mL	7 vials	RUO

# Meeting the requirements of blood screening labs

**Effective detection** of infectious diseases at blood screening labs requires quality controls that offer exceptionally high sensitivity and accuracy. AcroMetrix products are **optimized** and **validated** to meet these specific quality assurance needs.

## Ensuring screening excellence

- Matches commonly used assays
- Reacts at appropriate levels
- Manufactured in an ISO 13485 facility

## Nucleic acid testing (NAT) controls – Blood screening

Catalog #	Product Name/Description	Vial Fill Volume	Package Size	Regulatory Designation
<b>Blood Bank Nucleic Acid Testing Controls</b>				
S2115	AcroMetrix PeliSpy NAT MM 375	1.0 mL	50 vials	RUO
964600	AcroMetrix NATBBV- (formerly NAT Negative)	1.4 mL	10 vials	CE-IVD
961240	AcroMetrix HIVRNA+ (formerly PeliSpy Pro HIV Low)	1.4 mL	10 vials	CE-IVD
961241	AcroMetrix HBVDNA+ (formerly PeliSpy Pro HBV Low)	1.4 mL	10 vials	CE-IVD
961242	AcroMetrix HCVRNA+ (formerly PeliSpy Pro HCV Low)	1.4 mL	10 vials	CE-IVD
960500	AcroMetrix WNV RNA	1.4 mL	10 vials	CE-IVD, IVD
960600	AcroMetrix BB NAT WNV Negative Control	1.4 mL	10 vials	CE-IVD, IVD
<b>Training Panels</b>				
950250	AcroMetrix WNV Training Panel	1.0 mL	6 vials	RUO
<b>Blood Screening – Nucleic Acid Testing Control Diluents</b>				
S2284	AcroMetrix EDTA Plasma Dilution Matrix 45 mL	45.0 mL	1 bottle	RUO
S2285	AcroMetrix Ultra Serum Dilution Matrix	50.0 mL	1 bottle	RUO
941050	AcroMetrix Citrate Plasma Dilution Matrix 50 mL	50.0 mL	1 bottle	RUO
941100	AcroMetrix Citrate Plasma Dilution Matrix 100 mL	100.0 mL	1 bottle	RUO

## Serology/immunoassay controls – Blood screening

Serology controls (formerly PeliSpy™ Multi-Marker)

Catalog #	Product Name/Description	Vial Fill Volume	Package Size	Regulatory Designation
S2407	AcroMetrix PeliSpy Sero Control Type 17 HBsAg, anti-HCV, anti-HIV, anti-HTLV	5.0 mL	10 vials	RUO
S2408	AcroMetrix PeliSpy Sero Control Type 36 HBsAg, anti-HCV, anti-HIV, anti-HTLV, anti-HBc	5.0 mL	10 vials	RUO
S2409	AcroMetrix PeliSpy Sero Control Negative	5.0 mL	10 vials	RUO
969032	AcroMetrix Blue 5pk (formerly PSMM Type 38) HBsAg, anti-HCV, anti-HIV-1	5.0 mL	5 vials	CE-IVD

# Transplant disease testing

## It's like working with patient samples

With **full-process controls**, you can ensure optimal performance for transplant disease testing in your lab. AcroMetrix products are quality controls made from whole, unaltered virus in either EDTA-based plasma or in a synthetic matrix similar to cerebrospinal fluid.

### True full-process controls

- Mimics patient samples
- Permits extraction, amplification, and detection
- Controls can be traced to WHO standards

## Nucleic acid testing (NAT) controls

Catalog #	Product Name/Description	Vial Fill Volume	Package Size	Regulatory Designation
<b>Transplant Multi-Analyte</b>				
957041	Multi-Analyte Control – Transplant (Low/High) BKV, CMV, EBV, HHV-6B, HSV-1, HSV-2, VZV	50.0 mL	2 bottles	RUO
<b>BK Virus</b>				
950360	AcroMetrix BKV Panel (3E2, 3E3, 3E4, 3E5, 3E6 IU/mL)	0.5 mL	5 vials	RUO
960050	AcroMetrix BKV Low Control	0.5 mL	5 vials	CE-IVD, IVD
960051	AcroMetrix BKV High Control	0.5 mL	5 vials	CE-IVD, IVD
<b>CMV</b>				
942016	AcroMetrix CMVtc Panel (3E2, 3E3, 3E4, 3E5, 3E6 IU/mL)	0.8 mL	5 vials	RUO
951700	AcroMetrix CMV Negative Control	0.8 mL	5 vials	RUO
951701	AcroMetrix CMV Low Control	0.8 mL	5 vials	RUO
951702	AcroMetrix CMV High Control	0.8 mL	5 vials	RUO
<b>EBV</b>				
942017A	AcroMetrix EBV Plasma Panel (1E2, 1E3, 1E4, 1E5, 1E6 IU/mL)	0.5 mL	5 vials	RUO
961230	AcroMetrix EBV Low Plasma Control	0.5 mL	5 vials	CE-IVD, IVD
961231	AcroMetrix EBV High Plasma Control	0.5 mL	5 vials	CE-IVD, IVD
<b>HSV-1</b>				
954520	AcroMetrix HSV-1 Plasma Panel (1E2, 1E3, 1E4, 1E5, 1E6 copies/mL)	0.5 mL	5 vials	RUO
951301	AcroMetrix HSV-1 Low CSF Control	0.5 mL	5 vials	RUO
954501	AcroMetrix HSV-1 High CSF Control	0.5 mL	5 vials	RUO
<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
<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

## Nucleic acid testing (NAT) controls (continued)

Catalog #	Product Name/ Description	Vial Fill Volume	Package Size	Regulatory Designation
<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
<b>Enterovirus</b>				
960499	AcroMetrix EV Negative Control	0.3 mL	5 vials	CE-IVD, IVD
960501	AcroMetrix EV Low Control	0.3 mL	5 vials	CE-IVD, IVD
<b>Negative Control</b>				
962000A	AcroMetrix Negative Control	1.0 mL	5 vials	IVD
951300	AcroMetrix HHV Negative Control	0.5 mL	5 vials	RUO

CE-IVD CE marking according to the Requirements of European Directive 98/79/EC | IVD In Vitro Diagnostics | RUO Research Use Only



# Oncology testing

## Ready to assess NGS performance?

The AcroMetrix Oncology Hotspot Control lets you monitor the performance of various **next-generation sequencing (NGS) platforms**, including custom library preparation panels. The highly multiplexed quality control is manufactured using MegaMix™ technology and is **suitable for assays that detect somatic mutations**. To ensure the highest levels of accuracy, over 500 SNPs, insertions, and deletions of varying lengths and complexities are added against a highly characterized genomic background. You can use the AcroMetrix Oncology Hotspot Control to track multiple variant types of varying nucleotide lengths.

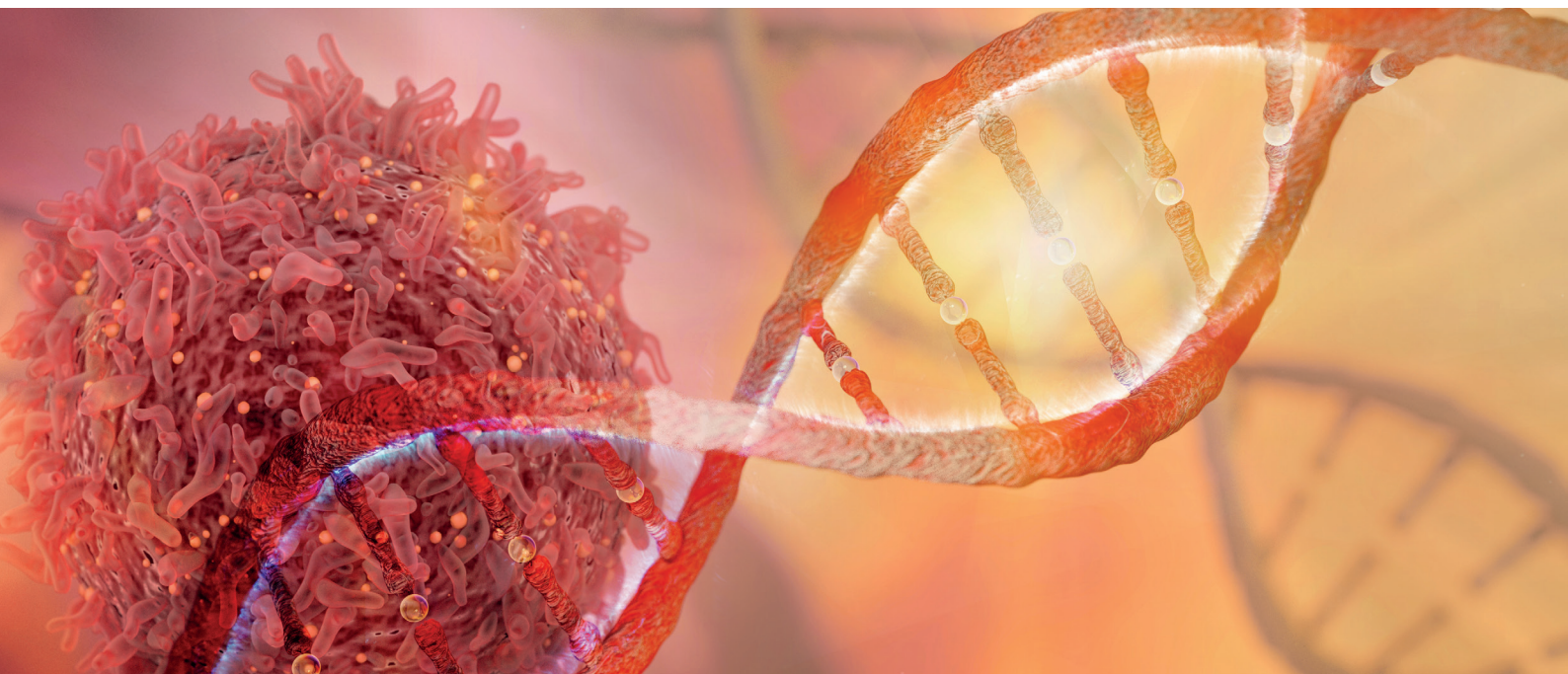
### MegaMix technology

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

## Oncology quality controls


Catalog #	Product Name/Description	Vial Fill Volume	Package Size	Regulatory Designation
<b>Multiplex Controls</b>				
969056	AcroMetrix Oncology Hotspot Control	25 µL	3 vials	CE-IVD, IVD
957563	AcroMetrix Multi-Analyte ctDNA Plasma Control A	2 ml	1 vial	RUO
957564	AcroMetrix Multi-Analyte ctDNA Plasma Control B	2 ml	1 vial	RUO
957565	AcroMetrix Multi-Analyte ctDNA Plasma Control C	2 ml	1 vial	RUO
957566	AcroMetrix Multi-Analyte ctDNA Plasma Control D	2 ml	1 vial	RUO
957567	AcroMetrix Multi-Analyte ctDNA Plasma Control E	2 ml	1 vial	RUO
10026229	AcroMetrix Hotspot Frequency Ladder	30 µL	7 vials	RUO
10024431	AcroMetrix Core Hotspot-CNV DNA Control	8 µL	8 vials	RUO
10024432	AcroMetrix Core Fusion RNA Control	8 µL	8 vials	RUO
<b>BCR-ABL</b>				
956980	AcroMetrix BCR-ABL Panel	1 x 10 <sup>6</sup> cells	5 vials	RUO

CE-IVD CE marking according to the Requirements of European Directive 98/79/EC | IVD In Vitro Diagnostics | RUO Research Use Only







# Cutting-edge technology for NGS QC needs



**500+**  
Mutations



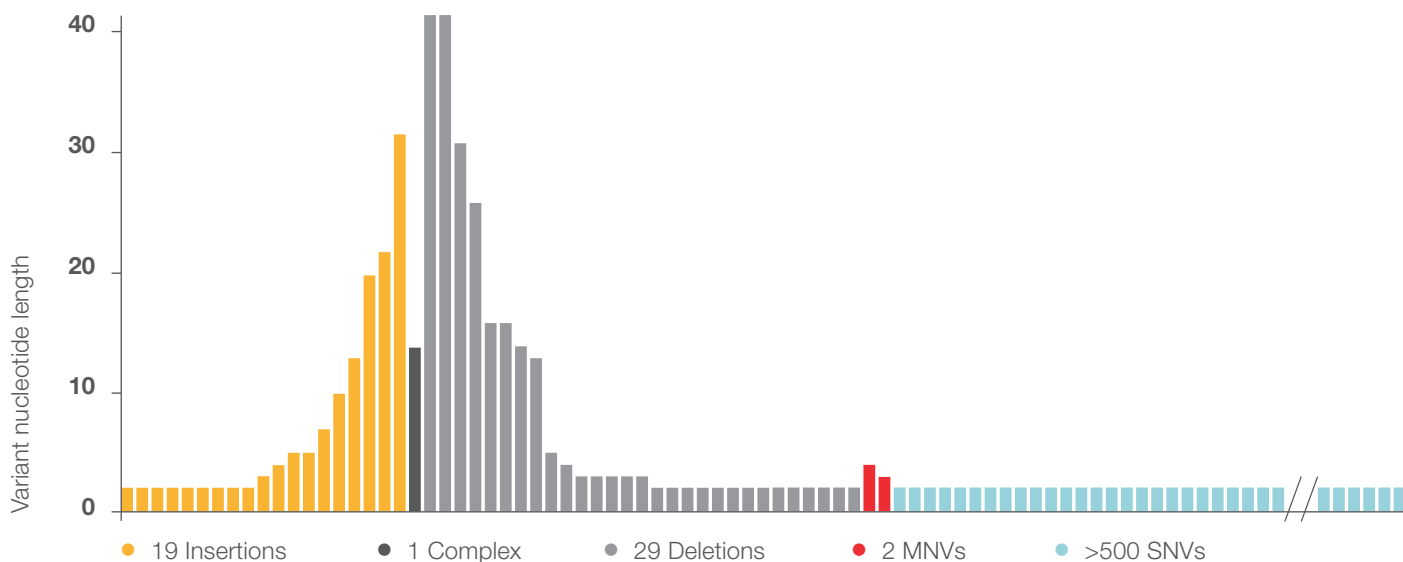
**53**  
Genes



**5**  
Variant types

500+ gene mutations available thanks to MegaMix technology

Track multiple variant types of varying nucleotide lengths



53 genes 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	

# Custom and OEM capabilities

## A partnership that takes you places

Thermo Fisher Scientific has a proven history of working with the world's leading diagnostic companies and EQAS/PT providers to meet a broad range of QC needs. You will benefit from an experienced partner that can create custom solutions based on existing catalog products or new analytes with respect to concentration, matrices, and fill volumes. We also specialize in developing OEM (RUO/IVD) solutions to help meet your unique needs for in-kit controls and other training/assay QC release control needs.

### Mix and match your QC needs



#### Broad range of matrices

- Normal human plasma
- Serum
- Synthetic plasma
- Viral transport medium
- CSF



#### Several sample types

- Inactivated or attenuated whole virus
- Recombinant virus
- FFPE
- ctDNA
- ctRNA
- Genomic DNA
- cRNA
- Plasmids
- In-vitro transcripts



#### Flexible packaging

- Fill volume
- Number of vials
- Concentration

### Supporting your entire assay life cycle with controls that fit your needs



# Customer service

## Order placement

**Phone** 1-800-232-3342 – press 1 for Customer Service, then 3 for quality controls

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

**Email** [mgc-masorders@thermofisher.com](mailto:mgc-masorders@thermofisher.com)

**For orders via email 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 two-day air freight.

## Sales support

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

**Email** [sales.diagnostics.fmt@thermofisher.com](mailto: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

### Emails for non-urgent inquiries

**MAS** [mas.controls@thermofisher.com](mailto: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.

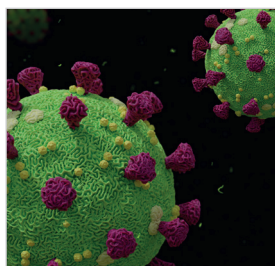
**Shipment** Shipping terms are Free on Board (FOB) shipping point. Customer is responsible for transportation costs from our facility to customer facility; freight is prepaid, then billed on invoice. Transfer of ownership occurs when the shipment leaves our facility.

**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 and may be subject to a restocking fee. Call Thermo Fisher Scientific prior to returning any material.

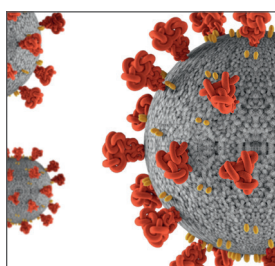
## COVID-19 QC for every use case



### Thermo Scientific AcroMetrix SARS-CoV-2 Control

- Mimics human specimen
- For fully automated lab setups

Visit [thermofisher.com/sars-cov-2-control](https://thermofisher.com/sars-cov-2-control)

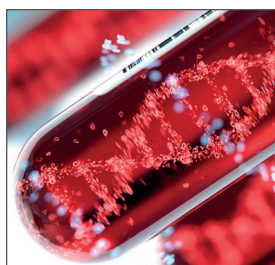


### Thermo Scientific AcroMetrix COVID-19 RNA Control

- Full-length genomic RNA
- Low-positive and ultra-low-positive concentrations

Visit [thermofisher.com/covid-19-rna-control](https://thermofisher.com/covid-19-rna-control)

## Liquid biopsy research just got even stronger



### Thermo Scientific AcroMetrix Multi-Analyte ctDNA Plasma Control

- Unique third-party control for monitoring liquid biopsy assays
- Normal human plasma matrix

Visit [thermofisher.com/957563](https://thermofisher.com/957563)

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