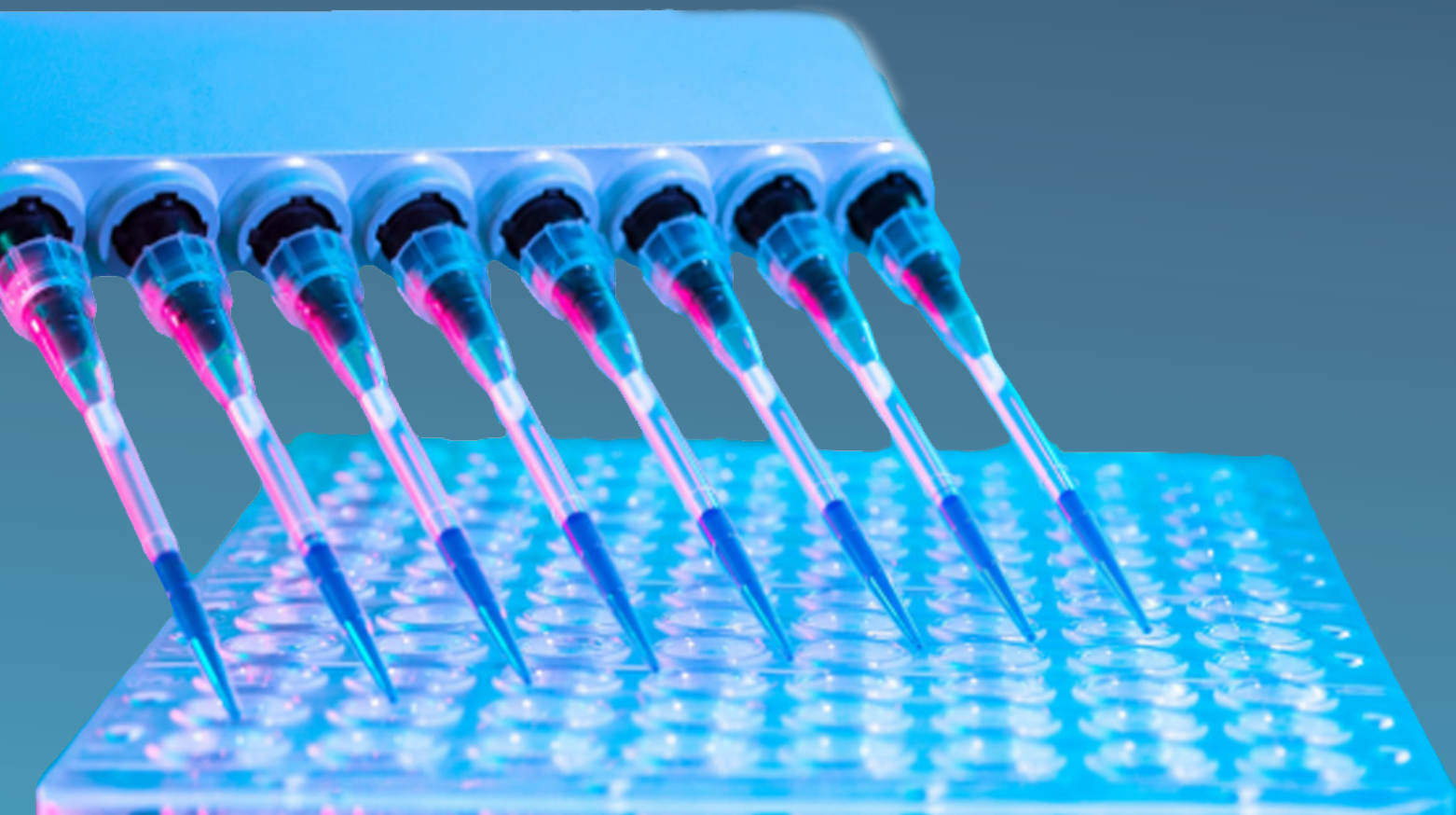




Fast. Simple. Reliable.

Comprehensive Molecular Diagnostics for Oncology and Hematology



FDA-Registered | ISO 13485 Certified | cGMP-Compliant



Who We Are

EntroGen delivers comprehensive molecular diagnostic solutions for oncology and hematology.

Our products are designed with simplicity in mind and are built to be accurate, cost-effective, and easily scalable.

We offer a broad portfolio of disease-specific and pan-cancer real-time PCR and NGS assays, along with tools for sample preparation, nucleic acid isolation, and quality assessment—supporting every step of the molecular testing workflow.

Our end-to-end solutions include:

- **Automation**
- **Reagents**
- **Software**



Speed and Simplicity

EntroGen real-time PCR technology enables rapid turnaround times that support timely clinical decisions.

Our simplified workflows minimize hands-on time and reduce the need for specialized training, making it easy for labs of all sizes to implement.

With ready-to-use reagents, straightforward protocols, and flexible throughput options, EntroGen tests streamline molecular diagnostics without compromising accuracy.

Whether for oncology or hematology applications, our solutions help labs operate efficiently, improve productivity, and accelerate patient care—all while maintaining the high standards required in modern clinical testing.



Culture of Innovation

Since our founding in 2007, EntroGen has been at the forefront of innovation in molecular oncology.

Built by a passionate and diverse team of scientists, we've consistently developed cutting-edge diagnostic solutions that support the growth of targeted cancer therapies.

From some of the earliest real-time PCR kits for oncology to scalable NGS panels and automation-ready workflows, innovation is embedded in everything we do.



Committed to Quality

As an FDA-registered manufacturing facility operating under current Good Manufacturing Practices (cGMP) and certified to ISO 13485 standards, we uphold the highest levels of quality and consistency.

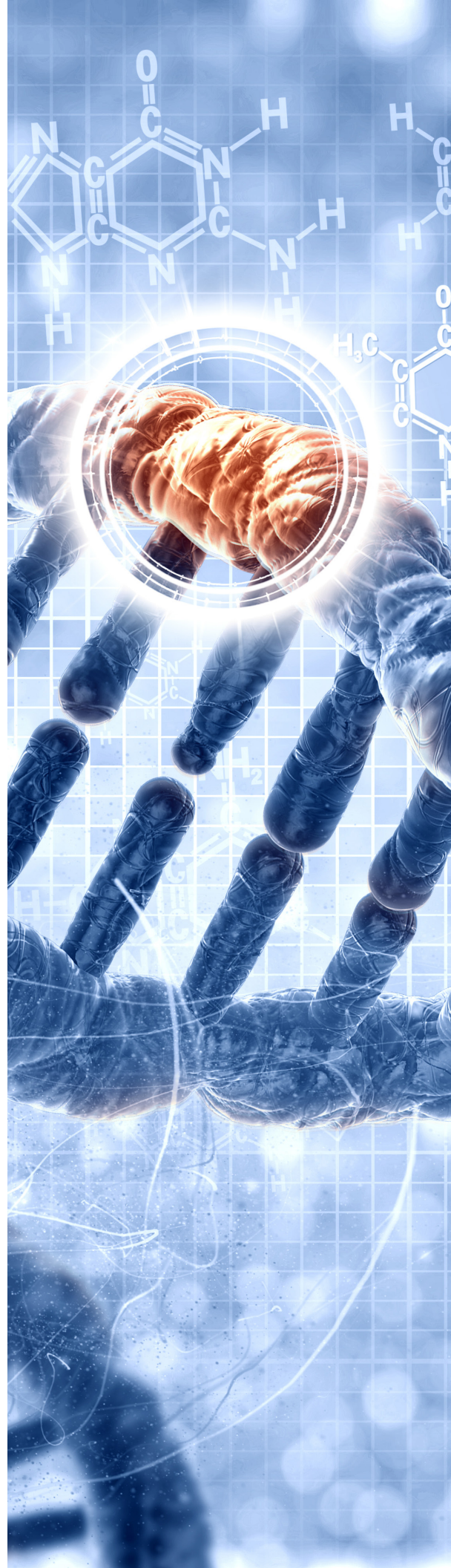
Through continuous improvement of our quality systems and business processes, we enhance operational excellence and deliver greater value to our customers worldwide.

Precision Starts Here

Companion diagnostics are essential to precision medicine, helping identify patients who are most likely to benefit from specific targeted therapies. These tests guide more effective, personalized treatment decisions and improve clinical outcomes.

EntroGen's companion diagnostic assays deliver rapid, actionable insights that support timely therapeutic choices. With simplified workflows and quick turnaround times, our solutions are designed for seamless integration into routine clinical labs.

Backed by strong performance data and regulatory compliance, our assays empower oncologists and laboratories to match patients with the right treatment—bringing the full promise of precision oncology to everyday care.



Automation



Benchbot® 4800 Liquid Handling System

The Benchbot® 4800 Liquid Handling System is an automated platform designed for high-throughput nucleic acid extraction and PCR setup. It streamlines complex workflows while minimizing hands-on time and user variability. With intuitive software and customizable protocols, the Benchbot 4800 enhances consistency, scalability, and throughput in molecular diagnostic laboratories.

- Simple, rapid, efficient workflow
- High throughput
- Reduces hands-on time
- Intuitive, user-friendly interface
- Reduced risk of contamination
- Minimizes risk of human error
- Consistent reproducible results
- Easily integrated into any lab

Reagents

Glioblastoma

Product	Targets	Specimen	Catalog Num	Registration	Reactions
IDH1/2 Mutation Detection Kit	IDH1 R100, R132; IDH2 R140, R172	FFPE, Fresh/frozen samples	IDH-RT38	RUO, CE-IVD	38
MGMT Methylation Detection Kit w/ Bisulfite Conversion Kit	MGMT promoter methylation	FFPE, Fresh/frozen samples	MGMTX-RT44	RUO, CE-IVD	60

Lung Cancer

Product	Targets	Specimen	Catalog Num	Registration	Reactions
EGFR Mutation Analysis Kit	T790M, Ex19Del, L858R, L861Q, S768I, G719X, Ex20ins	FFPE, Fresh/frozen samples	EGFR-RT52	RUO, CE-IVD	52
EGFRX Mutation Analysis Extension Kit	L858M, L861R E709 A/D/G	FFPE, Fresh/frozen samples	EGFRX-RT52	RUO, CE-IVD	52
ctDNA EGFR Mutation Detection Kit	T790M, Ex19Del, L858R, C797S, L861Q, S768I, G719X, Ex20Ins	Plasma	CTEGFR-48	RUO, CE-IVD	48
Lung Cancer RNA Panel	ALK, ROS1, RET fusions MET exon 14 skipping mutation	FFPE, Fresh/frozen samples	LUNG-RT48	RUO, CE-IVD	48
NTRK RNA Fusion Panel	NTRK 1, 2, 3	FFPE, Fresh/frozen samples	NTRK-RT48	RUO, CE-IVD	48

Thyroid Cancer

Product	Targets	Specimen	Catalog Num	Registration	Reactions
Thyroid Cancer Mutation Detection Kit	BRAF V600E, KRAS G12/13, NRAS Q61, HRAS G12/13, Q61R	FFPE, Fresh/frozen & FNA samples	THDNA-RT64	RUO, CE-IVD	64
Thyroid Cancer Fusion Gene Detection Kit	RET/PTC1, RET/PTC6 PAX8/PPARγ	FFPE, Fresh/frozen & FNA samples	THRNA-RT32	RUO, CE-IVD	32



CRCdx®

The CRCdx® RAS Mutation Detection Kit is a qPCR-based in vitro diagnostic test that detects 35 KRAS and NRAS somatic mutations in colorectal cancer (CRC) tissue samples, helping identify patients who may benefit from anti-EGFR treatment.

Simple Workflow: 90 minutes from PCR setup to results

Highly sensitive and specific: More sensitive than NGS

Reimbursement: Covered by Medicare and insurance

Automated interpretation: Analysis software included

CRCdx® is the most comprehensive real-time PCR companion diagnostic for RAS Mutation Testing.

Colorectal Cancer

Product	Targets	Specimen	Catalog Num	Registration	Reactions
CRCdx® RAS Mutation Detection Kit	KRAS/NRAS G12/13, Q61, A59, K117, A146	FFPE	CRCDX-RAS	IVD	40
RAS Mutation Analysis Kit	KRAS/NRAS G12/13, Q61, A59, K117, A146	FFPE, Fresh/frozen samples	RAS-RT50	RUO, CE-IVD	50
KRAS Mutation Analysis Kit	G12/13, Q61, K117, A146	FFPE, Fresh/frozen samples	KRAS-RT50	RUO, CE-IVD	50
NRAS Mutation Analysis Kit	G12/13, Q61, A146T	FFPE, Fresh/frozen samples	NRAS-RT50	RUO, CE-IVD	50
Colorectal Cancer Mutation Detection Panel	KRAS/NRAS G12/13, Q61, A59, K117, A146, PIK3CA E542/545, H1047, AKT1 E17K, BRAF V600	FFPE, Fresh/frozen samples	CRC-RT48	RUO, CE-IVD	48
PIK3CA Mutation Analysis Kit	C420, E542, E545, Q546, H1047	FFPE, Fresh/frozen samples	PI3K-RT48	RUO, CE-IVD	48
KRAS/BRAF Mutation Analysis Kit	KRAS/NRAS G12/13, Q61, K117, A146	FFPE, Fresh/frozen samples	KRBR-RT50	RUO, CE-IVD	50
ctDNA RAS Mutation Detection Kit	KRAS G12, G13, NRAS G12, G13, Q61	Fresh/frozen plasma	CTRAS-RT40	RUO, CE-IVD	40
RAS c.59/117 Mutation Detection Kit	Add-on kit for KRAS and NRAS Mutation Analysis - KRAS A59 T/E/G, NRAS A59 T/D, K17R	FFPE	RASX-RT50	RUO, CE-IVD	50
MLH1 Methylation Detection Kit	Methylation detection of MLH1 promoter regions C and D	FFPE, Fresh/frozen samples	MLH1-RT24	RUO, CE-IVD	24
Microsatellite Instability Detection Kit	KIT, MSH2, SLC7A8, BIRC3, MAP4K3	FFPE	MSI-RT34	RUO	34

A woman with blonde hair tied back, wearing safety glasses and a white lab coat, is shown in profile, looking towards the left. The background is a blurred laboratory setting with various pieces of equipment.

Streamlined MRD

EntroGen's leukemia assays are built for simplicity without sacrificing performance. Every assay is capable of detecting Minimal Residual Disease (MRD), offering the sensitivity needed for precise molecular monitoring.

Our one-step format combines cDNA synthesis and real-time PCR quantification in a single reaction—reducing complexity, hands-on time, and potential for error.

Designed for ease of use in any lab environment, these assays offer reliable performance with minimal workflow disruption. No extra reagents, no separate reverse transcription step—just efficient, accurate results.

With EntroGen, MRD detection is streamlined, reproducible, and ready to run.

Leukemia

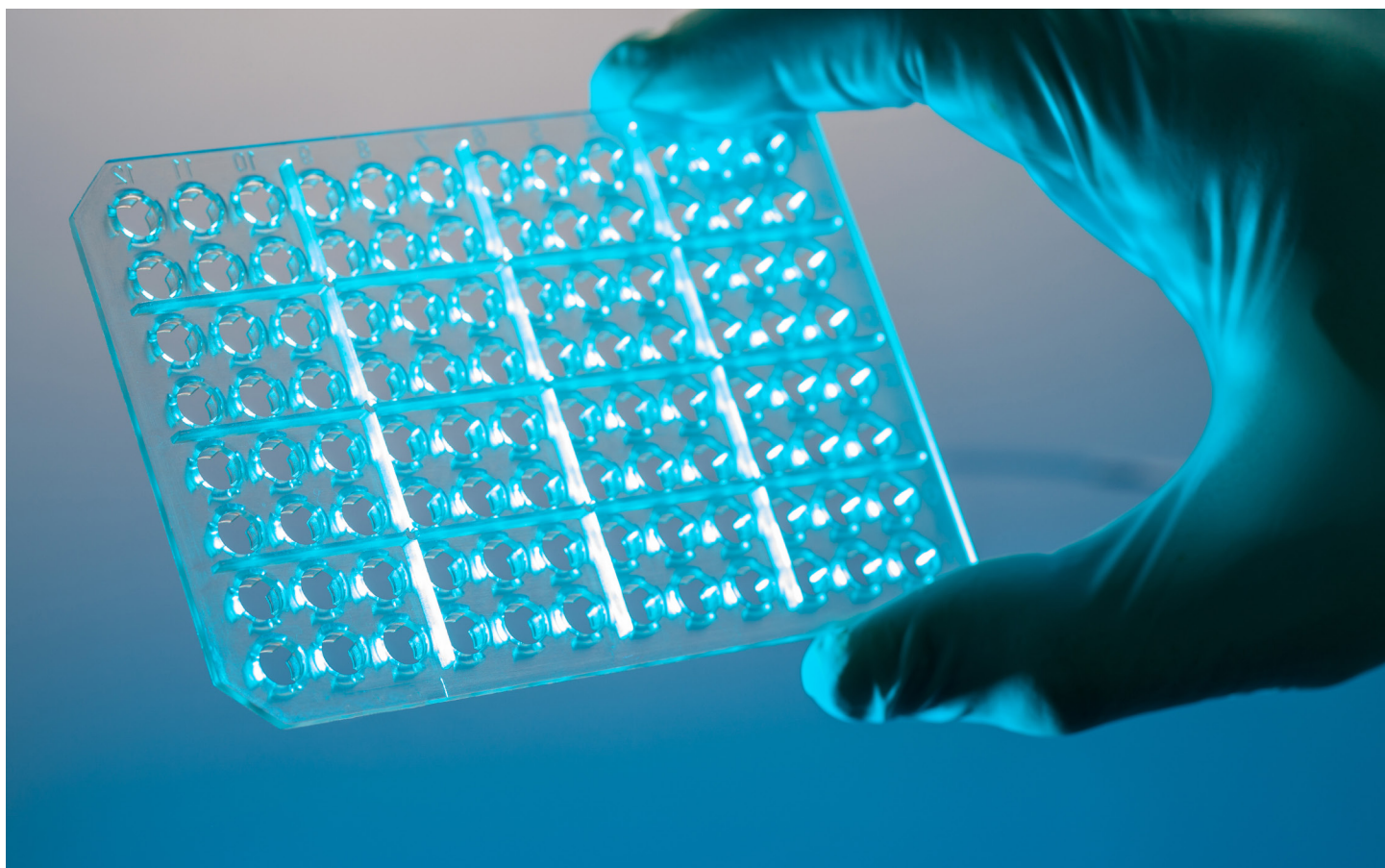
Product	Targets	Specimen	Catalog Num	Registration	Reactions
NPM1 One-Step MRD Kit	Types A, B, and D	Peripheral blood, Bone marrow	NPM1-QRT32	RUO	24
BCR-ABL P210 (Mbc) One Step Detection Kit	b2a2, b3a2	Peripheral blood, Bone marrow	BCR210-QRT46	RUO, CE-IVD	46
BCR-ABL P190 (Mbc) One Step Detection Kit	e1a2 fusion transcript	Peripheral blood, Bone marrow	BCR190-QRT46	RUO, CE-IVD	46
IDH1/2 Mutation Detection Kit	IDH1 R100, R132; IDH2 R140, R172	FFPE, Fresh/frozen samples	IDH-RT38	RUO, CE-IVD	38
AML1-ETO One-Step Detection Kit	AML-ETO	Peripheral blood, Bone marrow	LEUK1-QRT24	RUO, CE-IVD	24
E2A-PBX1 One-Step Detection Kit	E2A-PBX1	Peripheral blood, Bone marrow	LEUK2-QRT24	RUO, CE-IVD	24
MLL-AF4 One-Step Detection Kit	MLL-AF4	Peripheral blood, Bone marrow	LEUK3-QRT24	RUO, CE-IVD	24
PML-RARA bcr1, 2, 3 One-Step Detection Kit	PML-RARA	Peripheral blood, Bone marrow	LEUK4-QRT24	RUO, CE-IVD	24
TEL-AML1 One-Step Detection Kit	TEL-AML1	Peripheral blood, Bone marrow	LEUK5-QRT24	RUO, CE-IVD	24
CBFb-MYH11 One-Step Detection Kit	CBFb-MYH11	Peripheral blood, Bone marrow	LEUK6-QRT24	RUO, CE-IVD	24
Leukemia Translocation Panel V2	AML1-ETO, CBFb-MYH11, MLL-AF4, TEL-AML1, E2A-PBX1, PML-RARA	Peripheral blood, Bone marrow	LEUKMP-RT24	RUO, CE-IVD	24
JAK2 V617F Mutation Analysis Kit	JAK2 V617F	Peripheral blood, Bone marrow	MUT-RT50	RUO	50

Melanoma

Product	Targets	Specimen	Catalog Num	Registration	Reactions
BRAF Codon 600 Mutation Analysis Kit II	BRAF V600 (E, E2, K, R, D, M, G)	FFPE, Fresh/ frozen samples, FNA & plasma	BRAF-X-RT64	RUO, CE-IVD	64
C-KIT Mutation Detection Kit	Exons 9, 11, 13, 17	FFPE, Fresh/ frozen & FNA samples	CKIT-RT44	RUO, CE-IVD	44

Gastrointestinal Stromal Tumors (GIST)

Product	Targets	Specimen	Catalog Num	Registration	Reactions
GIST Mutation Detection Kit	cKIT exons 9, 11, 13, 17; PDGFRA exon 18	FFPE, Fresh/frozen samples	GIST-RT44	RUO, CE-IVD	44



NGS Assays

EntroGen's NGS assays are designed to detect clinically relevant, actionable mutations with accuracy and efficiency. Using a tiled amplicon approach and high-fidelity polymerase for target enrichment, our assays minimize allele dropout and reduce off-target reads. Each kit includes all necessary reagents for library preparation and clean-up, streamlining the workflow from start to finish. For data analysis, our intuitive software performs local analysis and queries two independent clinical databases—delivering confident results without the need for cloud-based tools.

Product	Targets	Specimen	Catalog Num	Registration	Reactions
BRCA Complete™ Expanded Panel For Illumina® Platforms	BRCA1, BRCA2, CHEK2, PALB2, RAD51C, TP53, POLE exons 9-14 upon request	FFPE, Fresh/frozen samples, blood	BRCAX-NGS	RUO, CE-IVD	40
NGS Targeted Hotspot Panel For Illumina® Platforms	BRAF - Exons 11 & 15, EGFR - Exons 3, 7, 12, 15, 18-21 ERBB2 - Exons 8, 14, 17-21, 24, 26 HRAS - Exons 2, 3 C-KIT - Exons 2, 8-11, 13-15, 17, 18 IDH1 - Exon 2 IDH2 - Exon 4 JAK2 - Exon 12, 14 KRAS - Exons 2-4 MET - Exons 2, 11, 14, 16, 18-20 NRAS - Exons 2-4 PDGFRA - Exons 12, 14, 15, 18 PIK3CA - Exons 1, 4, 6, 7, 9, 13, 18, 20 RET - Exons 10, 11, 13, 15, 16 TERT - Promoter TP53 - Entire Exome PTEN - Exons 1-9 upon request	FFPE, Fresh/frozen samples, blood	THSP-ILNGS	RUO, CE-IVD	40
RNA Fusion Gene Panel For Illumina® Platforms	ABL1 - 1 detected fusion ALK - 61 detected fusions AKT3 - 1 detected fusion AXL - 1 detected fusion BRAF - 15 detected fusions EGFR - 2 detected fusions ERBB2 - 1 detected fusion ERG - 16 detected fusions ETV1 - 4 detected fusions ETV4 - 1 detected fusion ETV5 - 3 detected fusions FGFR1 - 4 detected fusions FGFR2 - 10 detected fusions FGFR3 - 25 detected fusions MET - 10 detected fusions NTRK1 - 34 detected fusions NTRK2 - 18 detected fusions NTRK3 - 16 detected fusions PDGFRA - 1 detected fusion PPARG - 4 detected fusions RAF1 - 2 detected fusions RET - 41 detected fusions ROS1 - 34 detected fusions	FFPE, Fresh/frozen samples, blood	RFGP-NGS	RUO, CE-IVD	40

Sample Quality Assessment

Product	Targets	Specimen	Catalog Num	Registration	Reactions
Internal Quality Control Assay	Predicts optimal DNA input for maximal and reliable data output when using EntroGen's qPCR assays.	FFPE, Cell-free DNA	IQCA-RT50	RUO, CE-IVD	50
DNA Fragmentation Quantification Assay	Assesses sample quality by measuring the fragmentation ratio and quantifies the amount of amplifiable DNA for downstream for NGS assays.	FFPE, Fresh/frozen samples	FQA-RT40	RUO, CE-IVD	40
Library Quantification for Illumina®	Qualifies and quantifies library molecules that can be sequenced in downstream Illumina® assays.	Library	LIBQ-NGS	RUO, CE-IVD	75

Manual Isolation

Product	Targets	Specimen	Catalog Num	Registration	Reactions
pureNA® Cell-Free DNA Isolation Kit	Enables efficient, high-purity DNA extraction from plasma samples for downstream applications like qPCR. 100-500 bp DNA Fragment Size.	Plasma	CFDNA-50	RUO, CE-IVD	50
pureNA® Genomic DNA Isolation Kit	Optimized for the removal of paraffin, partial reversal of formalin cross-linking and release of DNA from fixed tissue.	FFPE	GDNA-50	RUO, CE-IVD	50

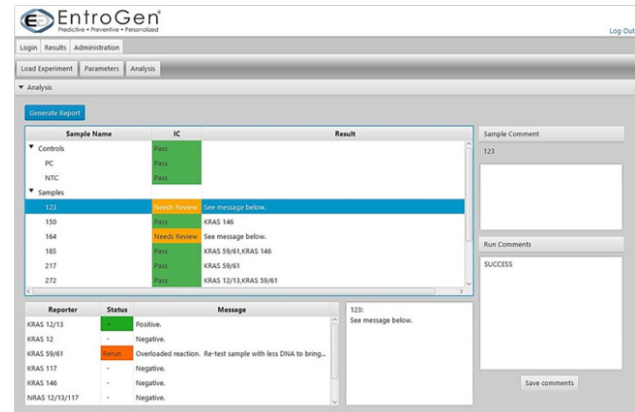
Reference Controls

Product	Catalog Num	Registration
5% MGMT Methylation Reference Control	MGMT-LPC	RUO
Low Positive Control for LEUKMP-RT24	LEUKMP-LPC	RUO
Low Positive Control for LEUK4-RT24	LEUK4-LPC	RUO
Low Positive Control for BCR190-QRT46	BCR190-LPC	RUO
Low Positive Control for BCR210-QRT46	BCR210-LPC	RUO
BCR-ABL P210 Quantitative Control Standards	BCR210-AQSTD	RUO

Software

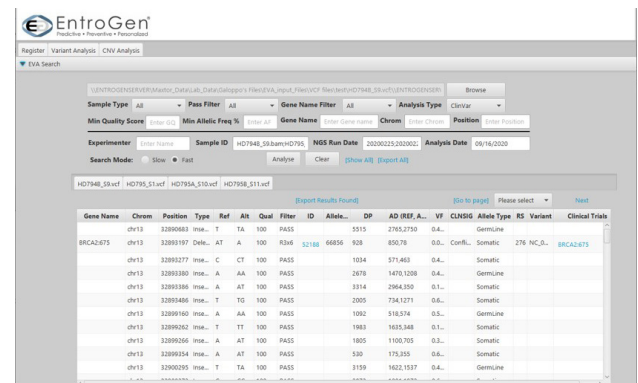
EPAS - EntroGen PCR Analysis Software

- Streamlines reporting and simplifies data interpretation
- Raw data files undergo QC check and mutation status call
- Simple point-and-click parameter setup and report generation
- Easy to interpret reports provide results that can be exported for integration with laboratory information management systems (LIS/LIM)
- Locally installed and available with select assays



EVA - EntroGen Variant Analysis Software

- Simplifies data interpretation
- Quickly determines variant calls, clinical reference, and current clinical trials
- Queries two independent databases for the most current genome annotations
- Locally installed and available with all NGS assays



EntroGen develops real-time PCR, NGS-based diagnostic assays and automation and software to support oncology and hematology.

Ready to streamline your lab?
Contact us today.



www.entrogen.com