

# REAL-TIME PCR & NGS SOLUTIONS

FOR ONCOLOGY & HEMATOLOGY

# WHO WE ARE

Entrogen is a Los Angeles-based biotechnology company with a primary focus on molecular diagnostics in the areas of hematology and oncology. We have a growing commercial portfolio of real-time PCR and NGS based tests, with many of our products being used to guide and monitor targeted therapies for various malignancies.

Through ongoing research and innovation, we are gaining world-wide recognition as leaders in the area of molecular diagnostics providing accurate and reliable products that our clients can depend on. Our aim is to provide laboratory professionals with the tools and support they need to enhance their services while managing time and cost.

## HOW WE CAN SUPPORT YOU



### Internal Review

Review of current molecular diagnostic services & procedures.



### Evaluation

Identify areas to improve time, cost & efficiency.



### Implementation

Reagents are compatible with most leading qPCR/NGS instruments.



### Software

Complimentary software for automated analysis and reporting.



### Support

Prompt, knowledgeable and reliable technical support.



### Collaboration

Work with lab professionals and physicians to implement new testing procedures.

# ISOLATION KITS



## High Specificity

for cell-free DNA (cfDNA)  
vs genomic DNA (gDNA)



## Rapid

<1 hour processing  
time



## Low Input

cfDNA recovered from  
as little as 2ml of plasma

### *pureNA*<sup>TM</sup> Cell-Free DNA Isolation Kit

Technology	Magnetic Bead Based	Reactions per Kit	50
		DNA Fragment Size	100 - 500 bp

Coming  
Soon

### *pureNA*<sup>TM</sup> Genomic DNA Isolation Kit

Technology	Column Based	Reactions per Kit	50
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# QUANTITATIVE REAL-TIME PCR

Quantitative real-time polymerase chain reaction (qPCR) is a well-established, rapid and highly sensitive molecular diagnostic technique used to detect and quantify specific gene alterations in DNA and RNA.

Using specific primers and probes, EntroGen qPCR assays amplify and quantify specific targeted mutations present in a sample nucleic acid sequence. They are designed to be easily implementable in any cancer diagnostics laboratory for detection of clinically relevant SNVs, small indels and/or gene fusions.

## FEATURES

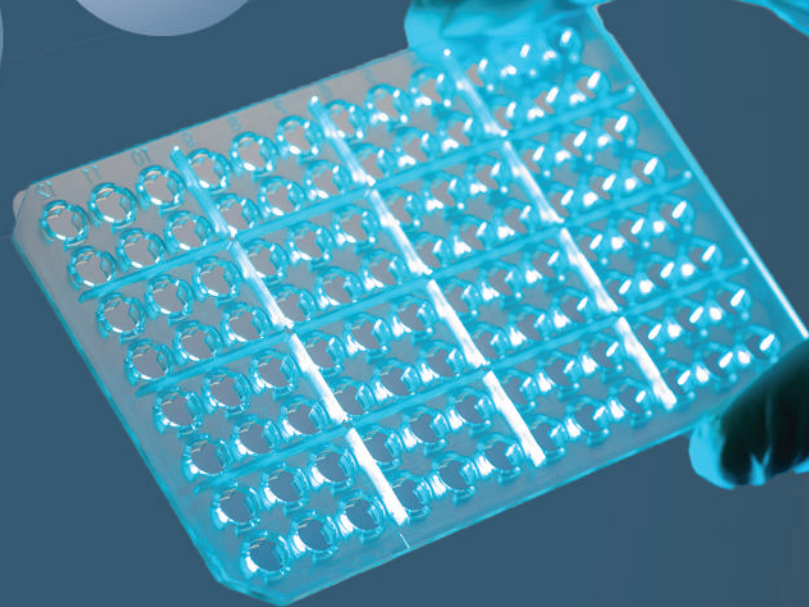
Rapid Results

Highly Multiplexed

High Sensitivity

Low DNA/  
RNA Input

Automated Analysis



## WORKFLOW

1 HOUR

.5 HOURS

1.5 HOURS



EXTRACT



SET UP



RUN



ANALYZE

# SOLID TUMOR ASSAYS

## Colorectal Cancer

### NRAS MUTATION ANALYSIS KIT

Targets	G12/13, Q61, A146T A59, K117 included in RAS Extension Kit RASX-RT50	Sensitivity	As low as .25%
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### KRAS MUTATION ANALYSIS KIT

Targets	G12/13, Q61, K117, A146 A59 included in RAS Extension Kit RASX-RT50	Sensitivity	As low as .25%
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### PIK3CA MUTATION DETECTION KIT

Targets	E542/545, H1047	Sensitivity	As low as 1.2%
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### KRAS/BRAF MUTATION ANALYSIS KIT

Targets	KRAS G12/13, Q61, K117, A146, BRAF V600E	Sensitivity	As low as .25%
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### RAS MUTATION SCREENING PANEL

Targets	KRAS/NRAS G12/13, Q61, A59, K117, A146	Sensitivity	As low as .32%
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### COLORECTAL CANCER MUTATION DETECTION PANEL

Targets	KRAS/NRAS G12/13, Q61, A59, K117, A146, PIK3CA 542/545, 1047 AKT1 E17K & BRAF V600	Sensitivity	As low as .5%
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## Lung Cancer

### EGFR MUTATION ANALYSIS KIT

Targets	T790M, Ex19Del, L858R, L861Q, S768I, G719X, Ex20ins	Sensitivity	As low as 1%
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### LUNG CANCER FUSION GENE PANEL

Targets	ALK, ROS1, RET fusions MET exon 14 skipping mutation	Sensitivity	As low as 10 copies
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## Glioblastoma

### MGMT METHYLATION DETECTION KIT

Targets	MGMT promoter methylation	Sensitivity	6.25% Methylation
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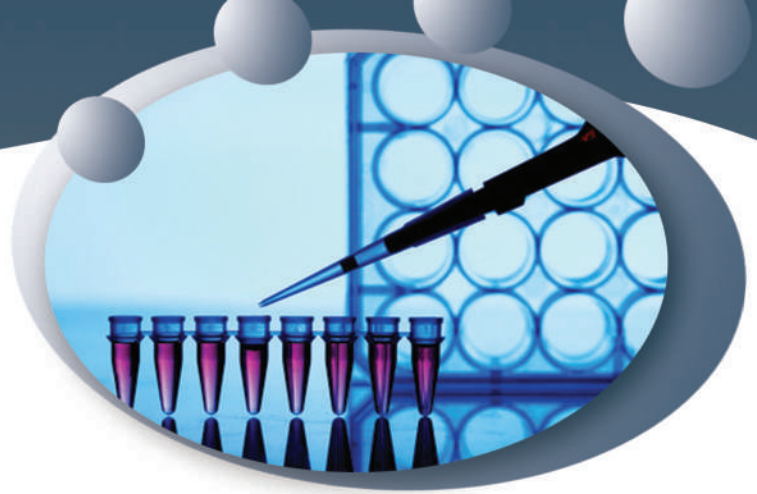
### IDH1/2 MUTATION DETECTION KIT

Targets	IDH1 R100, R132 IDH2 R140, R172	Sensitivity	As low as 1%
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Coming Soon

### EGFR V3 DETECTION KIT

Targets	EGFR vIII transcript
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## Melanoma

### BRAF MUTATION ANALYSIS KIT II

Targets	BRAF V600 (E, E2, K, R, D, M, G)	Sensitivity	As low as 0.5%
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### c-KIT MUTATION DETECTION KIT

Targets	Exons 9, 11, 13, 17	Sensitivity	As low as 1%
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## Thyroid Cancer

### THYROID CANCER MUTATION DETECTION KIT

Targets	BRAF V600E KRAS G12/13 NRAS Q61, HRAS G12/13, Q61R	Sensitivity	0.25% - 10%
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### THYROID CANCER FUSION GENE DETECTION KIT

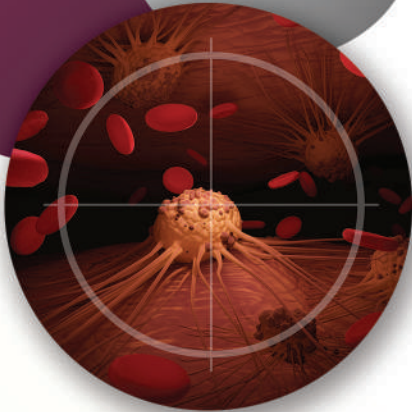
Targets	ERET/PTC1, RET/PTC3, PAX8/PPAR $\gamma$	Sensitivity	As low as 0.78% - 1.56%
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## Gastrointestinal Stromal Tumors (GIST)

### GIST MUTATION SCREENING PANEL

Targets	cKIT exons 9, 11, 13, 17 PDGFRA D842V	Sensitivity	As low as 1%
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# Liquid Biopsy Assays



The utility of cell-free tumor DNA (ctDNA) from plasma has been demonstrated as an alternative source of genomic material for detection of specific mutations in certain types of cancers. EntroGen offers three ctDNA Mutation Detection Kits that allow non-invasive, ultra-sensitive testing to accurately detect the presence of mutations in ctDNA extracted from plasma.

## ctDNA EGFR MUTATION DETECTION KIT

Targets	T790M, Ex19Del, L858R	Sensitivity	As low as 0.4% (10 copies in 5ng)
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Low input requirements

## ctDNA RAS MUTATION DETECTION KIT

Targets	KRAS 12/13 NRAS 12/13, Q61	Sensitivity	25 copies in 1.6ng or 5%
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Simple set-up and interpretation

## ctDNA BRAF V600 MUTATION DETECTION KIT

Targets	BRAF V600E/E2, D, K	Sensitivity	As low as .25%
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Compatible with most leading real-time PCR instruments



# Leukemias

Many hematologic malignancies carry characteristic chromosomal translocations believed to play an important role in leukemia pathogenesis. Detecting and identifying fusion gene transcripts in patient blood or bone marrow samples enables accurate diagnosis, prognosis, and treatment stratification for ALL, AML, CML and APL.

EntroGen's leukemia assays are all one-step RT-qPCR tests that offer results in under 2 hours with minimal hands-on time. Our assay portfolio includes a multiplexed translocation panel for initial diagnosis as well as separate kits targeting individual fusion gene transcripts for molecular monitoring during treatment.

ALIGNED WITH THE  
INTERNATIONAL  
SCALE

## BCR-ABL P190 (mbcr) ONE-STEP DETECTION KIT

Targets	e1a2	Sensitivity	10 <sup>-4</sup> / 0.01%
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## BCR-ABL P210 (Mbc) ONE-STEP DETECTION KIT

Targets	b2a2, b3a2	Sensitivity	10 <sup>-4.5</sup> / 0.0032%
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## LEUKEMIA TRANSLOCATION PANEL

Targets	AML1-ETO, CBFB-MYH11, MLL-AF4, TEL-AML1, E2A-PBX1, PML-RARA	Sensitivity	10 <sup>-3</sup> / 0.1%
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## IDH1/2 MUTATION DETECTION KIT

Targets	IDH1 R100, R132 IDH2 R140, R172	Sensitivity	As low as 1%
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# NEXT GENERATION SEQUENCING

Next Generation Sequencing (NGS) is revolutionizing molecular diagnostics by advancing the capabilities of DNA sequencing far beyond traditional technologies. The speed, ultra-high throughput and multiplexing capabilities of NGS makes it possible to batch multiple samples, and interrogate hundreds of variants, all on a single run.

## FEATURES

High Throughput

High Sensitivity

Low DNA Input

Quality Assessment Assays Included

Automated Analysis



## WORKFLOW



# NGS ASSAYS

EntroGen NGS assays focus on identifying clinically relevant and actionable targets. A tiled amplicon PCR approach coupled with a high fidelity polymerase for target enrichment are used to reduce allele dropouts and off target reads. Reagents for library preparation and clean-up are included, as well as user-friendly software that queries two independent databases for local data analysis.

BRCA COMPLETE® V2			
Targets	BRCA1/2, CHEK2, PALB2, RAD51C, TP53	Sensitivity	5%

BRCA Complete® v1 is available - detects BRCA 1 and BRCA 2 only

Combinatorial

NGS TARGETED HOTSPOT PANEL					
Targets				Sensitivity	5%
BRAF	EXONS 11 & 15	KRAS	EXONS 2, 3, 4		
EGFR	EXONS 3, 7, 12, 15, 18-21	MET	EXONS 2, 11, 14, 16, 8-20		
ERBB2	EXONS 8, 14, 17-21, 24, 26	NRAS	EXONS 2, 3, 4		
HRAS	EXONS 2, 3	PDGFRA	EXONS 12, 14, 15, 18		
c-KIT	EXONS 2, 8-11, 13-15, 17, 18	PIK3CA	EXONS 1, 4, 6, 7, 9, 13, 18, 20		
IDH1	EXON 2	RET	EXON 10, 11, 13, 15, 16		
IDH2	EXON 4	TERT	PROMOTER		
JAK2	EXON 12,14	TP53	ENTIRE EXOM		

# SAMPLE QUALITY ASSESSMENT

DNA fragmentation, presence of PCR inhibitors, and chemical modifications due to formalin-fixed paraffin embedding (FFPE) affect sample integrity and compromise the sensitivity and reliability of downstream real-time qPCR and NGS assays. In order to utilize patient samples effectively and control the quality of qPCR and NGS data, EntroGen offers sample integrity assays to guide loading optimal DNA input for downstream qPCR and NGS testing.

## INTERNAL QUALITY CONTROL ASSAY

Predicts optimal DNA input for maximal and reliable data output when using EntroGen's qPCR assays.



Simple set-up and interpretation

## DNA FRAGMENTATION QUANTIFICATION ASSAY

Quantifies the amount of amplifiable DNA for downstream qPCR and NGS assays.



Automated analysis available

## LIBRARY QUANTIFICATION KIT FOR ILLUMINA®

Qualifies and quantifies library molecules that can be sequenced in downstream Illumina® assays.



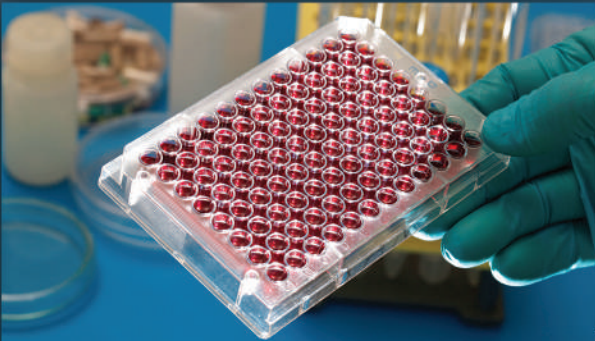
Saves samples, reagents, and time by eliminating the need for reruns

# SAMPLE SCREENING SERVICES

EntroGen provides a wide offering of somatic mutation screening, genotyping and expression analysis services for basic, translational and clinical research (RUO). The facility has all the expertise and equipment for tissue processing, DNA/RNA isolation, and genetic analysis. Using a variety of real-time PCR instruments as well as an NGS platform, EntroGen's genomic services offer unmatched quality and turnaround time.

## Services include:

- » DNA/RNA isolation
- » Somatic mutation screening: substitutions, insertions, deletions, translocations
- » Single nucleotide polymorphism (SNP) screening
- » Gene expression analysis
- » Customizable report



# REAL-TIME PCR ASSAYS

	PRODUCT NAME	CATALOG NUMBER	REGISTRATION	RXN/ KIT	VALIDATED INSTRUMENTS
COLORECTAL CANCER	KRAS MUTATION ANALYSIS KIT	KRAS-RT50	RUO, CE-IVD	50	ABI Prism®-7000, 7300, 7500/Fast, 7900HT, StepOne, StepOne Plus, LightCycler®480, Cobas® 4800, Cobas® z480, Bio-Rad CFX96
	NRAS MUTATION ANALYSIS KIT	NRAS-RT50	RUO, CE-IVD	50	ABI Prism®-7300, 7500, 7900HT, StepOne, StepOne Plus, LightCycler® 480, Cobas® 4800, Cobas® z480
	PIK3CA MUTATION DETECTION KIT	PI3K-RT48	RUO, CE-IVD	48	ABI Prism®-7500/7500 Fast, StepOne, StepOne Plus, Qiagen Rotor-Gene® Q, LightCycler® 480, Cobas® 4800, Cobas® z480, Bio-Rad CFX96
	KRAS/BRAF MUTATION ANALYSIS KIT	KRBR-RT50	RUO, CE-IVD	50	ABI Prism®-7000, 7300, 7500/Fast, 7900HT, StepOne, StepOne Plus, LightCycler®480, Cobas® 4800, Cobas® z480, Bio-Rad CFX96
	RAS MUTATION SCREENING PANEL	RAS-RT50	RUO, CE-IVD	50	ABI Prism®-7000, 7300, 7500/Fast, 7900HT, StepOne, StepOne Plus, Qiagen Rotor-Gene®Q, 3000, 6000, LightCycler® 480, Cobas® 4800, Cobas® z480, Bio-Rad CFX96
	COLORECTAL CANCER MUTATION DETECTION PANEL	CRC-RT48	RUO, CE-IVD	48	ABI Prism®-7500/Fast, LightCycler® 480
	CELL-FREE RAS MUTATION DETECTION KIT	CTRAS-48	RUO, CE-IVD	40	ABI Prism®-7500/Fast
GIST GASTROINTESTINAL STROMAL TUMORS	GIST MUTATION SCREENING PANEL	GIST-RT44	RUO, CE-IVD	41	ABI Prism®-7500/Fast, LightCycler® 480
GLIOBLASTOMA	MGMT METHYLATION DETECTION KIT	MGMT-RT44	RUO, CE-IVD	60	ABI Prism®-7500, LightCycler® 480
	IDH1/2 MUTATION DETECTION KIT	IDH-RT38	RUO, CE-IVD PENDING	38	BioRad CFX96, ABI QuantStudio 5TM
	EGFR V3 DETECTION KIT	EGFRV3-RT42	PENDING	36	Pending
LUNG CANCER	EGFR MUTATION ANALYSIS KIT	EGFR-RT52	RUO, CE-IVD	52	ABI Prism®-7500/7500 Fast, StepOne, StepOne Plus, QuantStudio, LightCycler® 480, Rotor-Gene® Q, Bio-Rad CFX96, Cobas® 4800, Cobas®z480
	LUNG CANCER FUSION GENE PANEL	LUNG-RT48	RUO, CE-IVD	48	ABI 7500/Fast
	CELL-FREE EGFR MUTATION DETECTION KIT	CTEGFR-48	RUO, CE-IVD	48	ABI Prism®-7500/Fast, Roche® LightCycler 480. Bio-Rad CFX96
MELANOMA	BRAF MUTATION ANALYSIS KIT II	BRAF-RT64	RUO, CE-IVD	48	ABI Prism®-7300, 7500, 7900HT, StepOne, StepOne Plus, ABI QuantStudio 5TM, Rotor-Gene® Q, 3000, 6000, LightCycler® 480, Cobas® 4800, Cobas®z480
	C-KIT MUTATION DETECTION KIT	CKIT-RT44	RUO, CE-IVD	41	ABI Prism®-7500/Fast
	CELL-FREE BRAF MUTATION DETECTION KIT	CTBRAF-48	RUO, CE-IVD	48	ABI Prism®-7500, StepOne, StepOne Plus, Rotor-Gene®Q, LightCycler® 480, Bio-Rad CFX96

## REAL-TIME PCR ASSAYS

	PRODUCT NAME	CATALOG NUMBER	REGISTRATION	RXN/ KIT	VALIDATED INSTRUMENTS
THYROID CANCER	THYROID CANCER MUTATION DETECTION KIT	THDNA-RT64	RUO, CE-IVD	64	ABI Prism®-7500/7500Fast, StepOne, StepOne Plus, Rotor-Gene®Q, LightCycler®480, Bio-Rad CFX96
	THYROID CANCER FUSION GENE DETECTION KIT	THRNA-RT32	RUO, CE-IVD	32	ABI Prism®-7500, 7900HT, StepOne, StepOne Plus
LEUKEMIA	BCR-ABL P190 (Mbc) ONE-STEP DETECTION KIT	BCR190-QRT46	RUO, CE-IVD	48	ABI Prism®-7500, 7900HT, StepOne, StepOne Plus, Qiagen Rotor-Gene® 3000, 6000, Q, LightCycler® 480, Cobas® 4800, Cobas® z480
	BCR-ABL P210 (Mbc) ONE-STEP DETECTION KIT	BCR210-QRT46	RUO, CE-IVD	48	ABI Prism®-7500, StepOne/ StepOne Plus, Qiagen Rotor-Gene® Q, LightCycler® 480, QuantStudio™5
	LEUKEMIA TRANSLOCATION PANEL	LEUKMP-RT24	RUO, CE-IVD	24	ABI Prism®-7500, StepOne, Qiagen Rotor-Gene®Q, LightCycler® 480
	AML1-ETO ONE-STEP DETECTION KIT	LEUK1-QRT24	RUO, CE-IVD	24	ABI Prism®-7500, StepOne, Qiagen Rotor-Gene®Q, LightCycler® 480
	E2A-PBX1 ONE-STEP DETECTION KIT	LEUK2-QRT24	RUO, CE-IVD	24	ABI Prism®-7500, StepOne, Qiagen Rotor-Gene®Q, LightCycler® 480
	MLL-AF4 ONE-STEP DETECTION KIT	LEUK3-QRT24	RUO, CE-IVD	24	ABI Prism®-7500, StepOne, Qiagen Rotor-Gene®Q, LightCycler® 480
	PML-RARA ONE-STEP DETECTION KIT	LEUK4-QRT24	RUO, CE-IVD	24	ABI Prism®-7500, StepOne, Qiagen Rotor-Gene®Q, LightCycler® 480
	TEL-AML1 ONE-STEP DETECTION KIT	LEUK5-QRT24	RUO, CE-IVD	24	ABI Prism®-7500, StepOne, Qiagen Rotor-Gene®Q, LightCycler® 480
CBFb-MYH11 ONE-STEP DETECTION KIT	LEUK6-QRT24	RUO, CE-IVD	24	ABI Prism®-7500, StepOne, Qiagen Rotor-Gene®Q, LightCycler® 480	

## NGS ASSAYS

BREAST CANCER	BRCA COMPLETE v2	BRCA-NGS	PENDING	40	Illumina®MiniSeq Compatible with MiSeq and NextSeq
SOLID TUMOR	NGS TARGETED HOTSPOT PANEL	THSP-ILNGS	RUO, CE-IVE PENDING	40	Illumina®MiniSeq Compatible with MiSeq and NextSeq

## ISOLATION KITS & SAMPLE QUALITY ASSESSMENT

<i>pureNA</i> ™ CELL-FREE DNA ISOLATION KIT	CFDNA-50	RUO, CE-IVD PENDING	50	Not Applicable
<i>pureNA</i> ™ GENOMIC DNA ISOLATION KIT	GDNA-50	RUO, CE-IVD PENDING	50	Not Applicable
INTERNAL QUALITY CONTROL ASSAY	IQCA-RT50	RUO, CE-IVD	50	ABI Prism®-7300, 7500, 7900HT, StepOne, StepOne Plus, Rotor-Gene® Q, 3000, 6000, LightCycler®480
DNA FRAGMENTATION QUANTIFICATION ASSAY	FQA-RT40	RUO, CE-IVD	40	Bio-Rad CFX96, LightCycler® 480
LIBRARY QUANTIFICATION KIT FOR ILLUMINA®	LIBQ-NGS	RUO, CE-IVD	75	ABI Prism®-7500Fast

