TaqMan™ RNase P Instrument Verification Plate, 96-well

Catalog Number 4310982

Pub. No. 4314333 **Rev.** H

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from **thermofisher.com/support**.

Contents and storage

Contents	Amount	Storage
TaqMan™ RNase P Instrument Verification Plate, 96-well shipped with Optical Compression Pad	1	–25°C to –15°C Do not store in a frost-free freezer.

RNase P plate layout

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D	NTC	NTC	NTC	NTC	STND 1.25K	STND 1.25K	STND 1.25K	STND 1.25K	STND 2.5K	STND 2.5K	STND 2.5K	STND 2.5K
E	STND 5K	STND 5K	STND 5K	STND 5K	STND 10K	STND 10K	STND 10K	STND 10K	STND 20K	STND 20K	STND 20K	STND 20K
F												
G												
H												

Unknown 5K Unknown 10K

Related documentation

For detailed information on the plate set-up and analysis procedures, refer to the appropriate Sequence Detection System user guide.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale found on Life Technologies' website at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have any questions, please contact Life Technologies at **www.thermofisher.com/support**.

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thermofisher.com

1 December 2015

7500 Real-Time PCR Systems Spectral Calibration Kit I

Catalog Number 4349180

Pub. No. 4350071 **Rev.** D

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from **thermofisher.com/support**.

Contents and storage

Contents	Amount	Storage
Background Plate sealed with an optical cover	1	–25°C to –15°C
Spectral Calibration Plates sealed with optical covers	7	
Region of Interest (ROI) Calibration Plate sealed with an optical cover	1	

Related Documentation

For detailed information on instrument setup and the calibration process, refer to the *Applied Biosystems™ 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide* (Pub. no. 4347828).

Limited product warranty

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1 December 2015

ThermoFisher SCIENTIFIC

7500 Real-Time PCR Systems Spectral Calibration Kit II

Catalog Number 4351151

Pub. No. 4351155 **Rev.** B

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from **thermofisher.com/support**.

Contents and storage

Contents	Amount	Storage
Spectral Calibration Plates sealed with optical covers	3	–25°C to –15°C

Related documentation

For detailed information on instrument setup and the calibration process, refer to the *Applied Biosystems™ 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide* (Pub. no. 4347828).

Limited product warranty

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For support visit **thermofisher.com/support** or email **techsupport@lifetech.com**

1 December 2015

ThermoFisher SCIENTIFIC

Accurate and sensitive somatic mutation detection powered by castPCR™ technology

TaqMan® Mutation Detection Assays

- High specificity—mutant allele detection is based on an allele-specific primer, while wild type background is suppressed by the proprietary MGB blocker oligonucleotide
- High sensitivity—assays can detect down to 0.1% mutation in a background of wild type DNA, as demonstrated in spiking experiments
- Wide dynamic range and excellent PCR efficiency—assays demonstrate at least 4 logs of dynamic range and an average PCR efficiency of 100% ± 10%
- Fast, simple workflow—like other TaqMan® Assays, typically requires 3 hours from sample to results, with minimum hands-on time

Cancer research samples often contain rare somatic mutations within a high background of normal wild type DNA. Many mutation detection methods compatible with tumor specimens, including gene sequencing and real-time PCR, have been reported in the literature and are commercially available. However, commercially available kits have various limitations in terms of sensitivity, specificity, cost, workflow, and turnaround time. We have developed sensitive and easy-to-use TaqMan® Mutation Detection Assays to accurately assess mutation status. TaqMan® Mutation Detection Assays were designed based on the novel competitive allele-specific TaqMan® PCR (castPCR™) technology, which combines allele-specific TaqMan® qPCR with allele-specific MGB blocker oligonucleotides that effectively suppress nonspecific amplification from the off-target allele.

Currently, the assay portfolio covers key somatic mutations identified in various cancer genes including, but not limited to, *KRAS*, *BRAF*, *HRAS*, *NRAS*, *EGFR*, *PIK3CA*, *KIT*, *PTEN*, and *TP53* genes, which have been implicated in many types of cancer. These mutations were selected from the comprehensive Sanger COSMIC database for somatic mutations. The target selection was based on frequency of occurrence and input from leading cancer researchers. We will continually add more mutation assays to cover additional cancer gene mutations. For the most updated list of available assays, refer to the TaqMan® Mutation Detection Assay index file at **lifetechnologies.com/castpcr**.

life technologies

About the assays

TaqMan® Mutation Detection Assays contain mutant allele assays, which specifically detect one or more mutant alleles, and corresponding gene reference assays, which detect mutation-free regions of the genes in which the target mutations reside (Figure 1). The validated assay set additionally includes corresponding wild type allele assays (not described here; refer to the TaqMan® Mutation Detection Assay protocol for further information).

Two experiment types

Two types of experiments are required for mutation detection analysis:

1. Detection ΔC_t cutoff determination

A mutant allele assay and corresponding gene reference assay are run on three or more wild type gDNA samples that are from the same sample type as the test samples (e.g., gDNA from FFPE tissue samples, Figure 2). ΔC_t values are calculated for each sample run with a mutant allele assay/gene reference assay pair. The average ΔC_t value for all samples is then calculated and is used to derive the detection ΔC_t cutoff value for the mutant allele assay.

2. Mutation detection

A test sample is run with one or more mutant allele assays and a corresponding gene reference assay (Figure 2). The ΔC_t value for the mutant allele assay/gene reference assay pair is calculated, and this value is compared to the previously determined detection ΔC_t cutoff value to determine the sample mutation status.

Optional use of internal positive control (IPC)

You can duplex the IPC reagents with any TaqMan® Mutation Detection Assay to distinguish true target negatives from PCR failure or inhibition (Figure 3).

Figure 1. TaqMan® Mutation Detection Assay types.

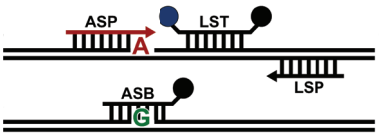
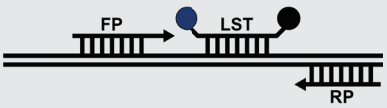
Assay type	Description	Schematic
Mutant allele assay	• Detects specific or multiple mutant alleles • An allele-specific primer detects the mutant allele • An MGB blocker oligonucleotide suppresses the wild type allele	 ASP = Allele-specific primer ASB = Allele-specific blocker (MGB) LST = Locus-specific TaqMan® probe LSP = Locus-specific primer
Gene reference assay	• Detects the gene within which the target mutations reside • A locus-specific pair of forward and reverse primers amplifies a mutation-free region of the target gene	 FP = Forward primer RP = Reverse primer LST = Locus-specific TaqMan® probe

Figure 2. Gene reference and mutant allele assays are run with a genomic DNA sample to determine the mutation status of each target mutation within the cancer gene.

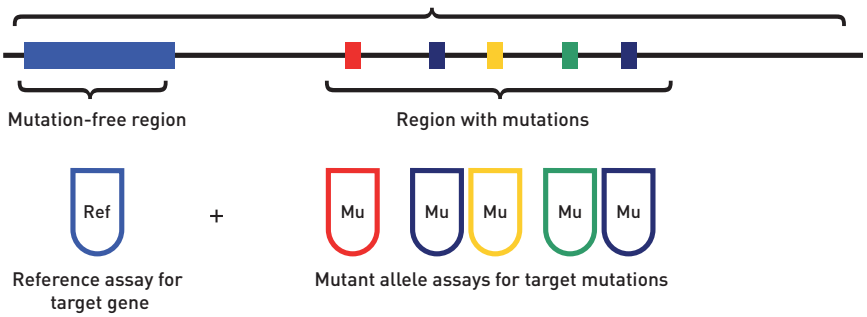
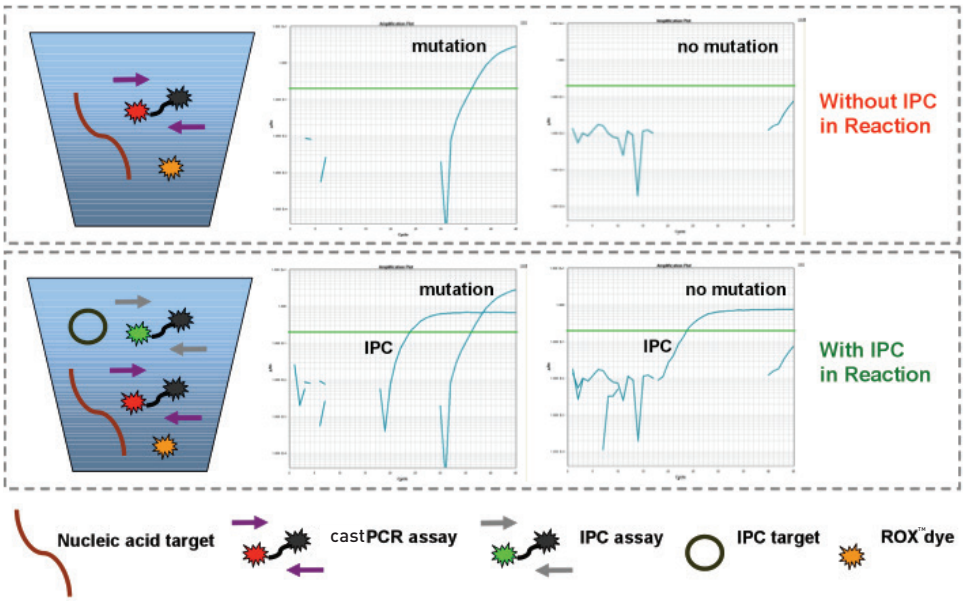


Figure 3. Internal positive controls. The TaqMan® Mutation Detection IPC Reagent Kit is a set of optional internal positive control reagents that can be duplexed with any TaqMan® Mutation Detection Assay to provide a positive PCR control result. The IPC reagents can distinguish a mutation target negative result from a PCR failure result.



Procedure

Purified gDNA, extracted from a sample with an unknown mutation status, is run with one or more mutant allele assays and the corresponding gene reference assay. For each real-time PCR reaction, the gDNA is combined with:

- **A TaqMan® Mutation Detection Assay**—contains two primers and a FAM™ dye–labeled MGB probe to detect a mutant allele or reference gene target. Mutant allele assays also contain an MGB oligonucleotide blocker.
- **TaqMan® Genotyping Master Mix**—contains AmpliTaq Gold® DNA Polymerase UP (Ultra Pure), dNTPs, and buffer
- **(Optional) TaqMan® Mutation Detection IPC Reagent Kit**—contains an internal positive control (IPC) template, two primers, and a VIC® dye–labeled TAMRA™ probe. It can be used to distinguish true target negatives from PCR failure or inhibition.

Reactions are run on a real-time PCR system, using a universal mutation detection thermal cycling protocol. After the run, the real-time PCR system's analysis software determines the C_t values for each TaqMan® Mutation Detection Assay and (optional) IPC reagent reactions. Real-time results export files can be opened in the free Mutation Detector™ Software for post-PCR data analysis. The C_t difference between each mutant allele assay and reference assay is calculated. This ΔC_t value, which represents the quantity of a specific mutant allele detected in a sample, is used to determine sample mutation status by comparison to a previously determined detection ΔC_t cutoff value. You can search for, or download a list of, currently available TaqMan® Mutation Detection Assays at **lifetechnologies.com/castpcr**.

Note: All TaqMan® Mutation Detection Assays have undergone extensive testing to ensure high sensitivity and specificity. The first set of released assays, covering 14 *KRAS*, 29 *EGFR*, and the *BRAF* V600E mutations, underwent additional testing, including determination of: the inherent amplification efficiency difference between mutant allele assays and corresponding reference assays, to enable quantitative analysis of percent mutation in a sample; and assay detection ΔC_t cutoff values using spiked cell line gDNA samples.

Assay performance

Specificity

Mutant allele detection is based on an allele-specific primer, while the wild type allele background is suppressed by the proprietary MGB blocker oligonucleotide. Assays can detect down to 0.1% mutant allele in the presence of a wild type allele background (Figure 4).

High sensitivity

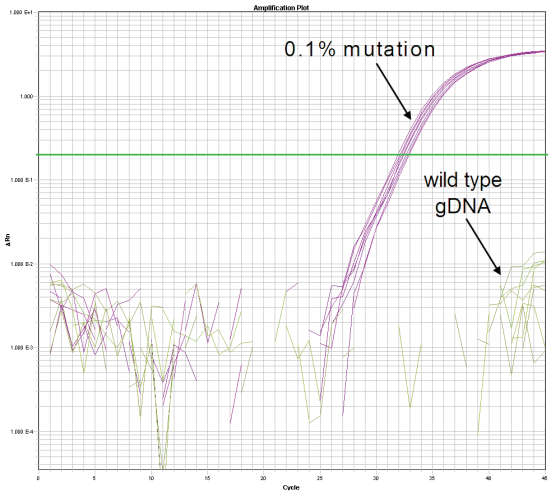
TaqMan® Mutation Detection Assays can detect as few as 1–5 mutant copies in up to one million copies of wild type background. Assay sensitivity is demonstrated using synthetic template spiking experiments (Figure 5 and 6).

Wide dynamic range and excellent PCR efficiency

Assays demonstrate up to 7 logs of dynamic range and an average PCR efficiency of 100% ± 10% (Figure 6).

Figure 4. C_t difference between 0.1% mutation samples and wild type gDNA. For each assay, 0.1% mutant allele samples were obtained by spiking 10 copies of mutant allele synthetic templates into 10,000 copies of cell line wild type gDNA. **(A)** Example of amplification plot for KRAS_522_mu assay on 0.1% mutant allele sample and wild type gDNA. **(B)** There is a significant difference in amplification C_t values between the 0.1% mutant allele sample and wild type gDNA (*P* value < 0.05 for 46 out of 48 assays in the example graph).

A



B

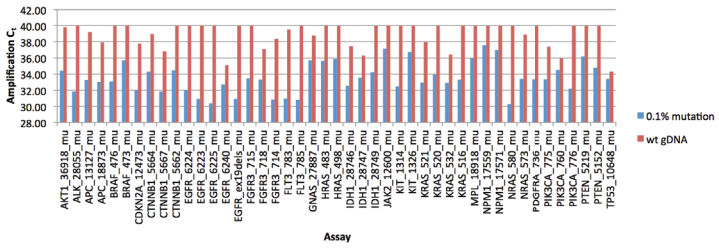


Figure 5. Assay sensitivity and selectivity. For every single assay, the sensitivity and selectivity were analyzed through synthetic template spiking experiments. 10 copies to 10^5 copies of mutant allele synthetic template were spiked into a constant background of 10^5 copies of wild type cell line genomic DNA. For a subset of the assays, 1 copy to 10^6 copies of mutant allele synthetic template were spiked into a constant background of 10^6 copies of wild type allele synthetic template. In the example shown, the BRAF_476_mu assay can detect 1 copy of mutant allele in a background of 10^6 copies of wild type allele.

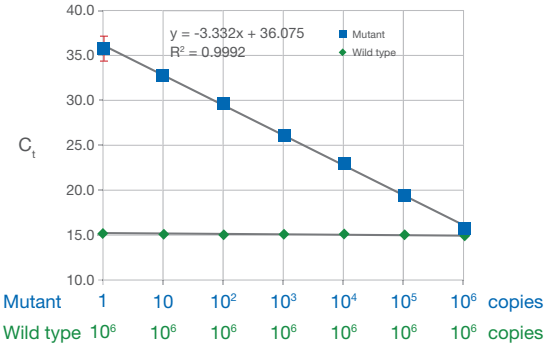
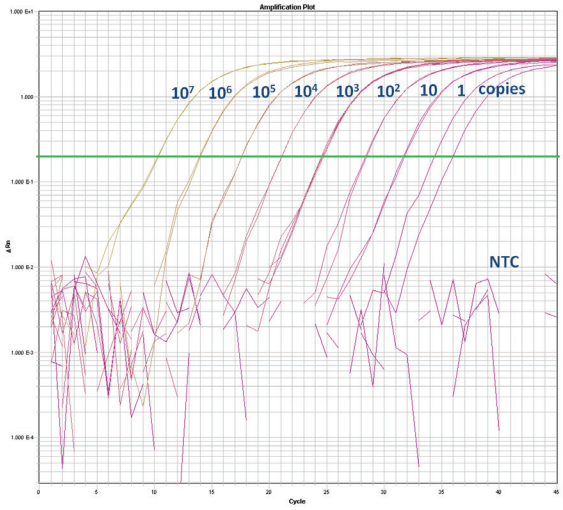


Figure 6. Assay dynamic range. Each assay was tested with 10^5 copies to 10 copies of synthetic template within a constant background of 10^5 copies of wild type genomic DNA. A subset of the assays was tested with 10^7 copies to 1 copy of synthetic template within a constant background of 10^7 copies of wild type allele synthetic template. In the example shown, the KRAS_532_mu assay has 7 logs of dynamic range, with an average PCR efficiency of 100% ± 10%.



Accuracy and reproducibility

Assays demonstrate excellent reproducibility and accurate quantification (Table 1).

Sample type compatibility

The assays can be used with gDNA samples extracted from FFPE tissues, fresh frozen tissues, and cell lines.

Data analysis software

For data analysis, Mutation Detector™ Software allows users to determine the mutation status and quantify the % mutation of their samples from TaqMan® Mutation Detection Assay data collected on the Applied Biosystems® ViiA™ 7, 7900HT, 7500, 7500 Fast, and StepOnePlus™ Real-Time PCR Systems (Table 2).

Table 1. Accuracy and reproducibility. Selected assays were tested in gDNA spiking experiments. In the example shown, G12C mutant cell line gDNA was spiked into wild type cell line gDNA at percentages ranging from 100% to 0.1%. The measured percent mutation was averaged from three experiment runs. The measured percent mutation is highly concordant with the expected percent mutation (R^2 = 0.9997). Accurate and precise quantification (CV < 20%) is obtained among the replicate runs when the target allele copy number is >30.

Copy number, target mutant allele	Expected (%)	Measured (%)	CV (%)
3,000	100.0	100.0	0.0
1,500	50.0	48.9	2.2
750	25.0	23.3	3.8
375	12.5	11.2	7.8
188	6.3	5.7	7.5
90	3.0	2.6	9.0
30	1.0	0.8	17.0
15	0.5	0.4	26.0
3	0.1	0.1	23.0

Table 2. Instrument compatibility.

Applied Biosystems® real-time PCR system	Block module	Software version
StepOnePlus™ system	Fast 96-Well Block Module	StepOne™ Software v2.X
7500 system	Standard 96-Well Block Module	SDS v1.X and v2.X
7500 Fast system	Fast 96-Well Block Module	SDS v1.X and v2.X
7900HT Fast system	Standard 96-Well Block Module, Fast 96-Well Block Module, 384-Well Block Module	SDS v2.X
ViiA™ 7 system	Standard 96-Well Block Module, Fast 96-Well Block Module, 384-Well Block Module	ViiA™ 7 Software v1.X
QuantStudio® 12K Flex system	Standard 96-Well Block Module, Fast 96-Well Block Module, 384-Well Block Module	QuantStudio® Software v1.0

Ordering information

Product	Quantity	Cat. No.
TaqMan® Mutation Detection Assays	150 µL, 10X	4465804
TaqMan® Mutation Detection Reference Assays	150 µL, 10X	4465807
TaqMan® EGFR Exon 19 Deletions Assay	150 µL, 10X	4465805
TaqMan® Mutation Detection IPC Reagent Kit	1 kit	4467538

For more information and full terms of the TaqMan® Assays QPCR Guarantee, go to **lifetechnologies.com/taqmanguarantee**

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A Thermo Fisher Scientific Brand

TaqMan Assays for genetic variation research

Superior performance—reliable, robust solutions

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Genetic variation: decoding the blueprint for biodiversity

Research on genetic variation in animals and plants has expanded our understanding of evolution and human diseases, accelerated the pace of drug development, and helped identify and breed agricultural traits to improve the world's food and fuel supply. Researchers are looking to uncover the association between genetic makeup and phenotypes in studies focusing on single nucleotide polymorphisms (SNPs), copy number variants (CNVs), insertion/deletions (indels), and somatic mutations. A genomics revolution, fueled by advances in biotechnology tools, has significantly increased the rate at which we are able to obtain and analyze data to better understand biodiversity.

We're at the forefront of this revolution, and our reagents, Applied Biosystems™ TaqMan™ Assays, and Applied Biosystems™ platforms for genetic variation analysis, are the preeminent real-time PCR tools for variation research.

Coupled with Applied Biosystems™ capillary electrophoresis, and Ion Torrent™ DNA sequencing systems, we offer a complete solution for genetic analysis research, from discovery to confirmation.

TaqMan Assays for analyzing genetic variation

TaqMan Assays comprise preoptimized PCR primer pairs and one or two probes (depending on product family) for allelic discrimination or quantitative real-time PCR (qPCR). Each assay contains:

- An unlabeled PCR primer pair
- An Applied Biosystems™ TaqMan™ probe with a FAM™ or VIC™ dye label on the 5′ end, and a minor groove binder (MGB) and nonfluorescent quencher (NFQ) on the 3′ end

TaqMan Assays are used to amplify and detect specific variants in target genomic DNA (gDNA). Figure 1 depicts the Applied Biosystems™ TaqMan™ SNP Genotyping Assay process. Real-time PCR using TaqMan Assays is based on the 5′ nuclease activity of *Taq* DNA polymerase.

Here's how it works:

1. TaqMan probes hybridize to the target DNA between the two unlabeled PCR primers. Signal from the fluorescent dye on the 5′ end of a TaqMan probe is quenched by the NFQ on its 3′ end through fluorescence resonance energy transfer (FRET).
2. During PCR, *Taq* polymerase extends the unlabeled primers using the template strand as a guide.
3. When the polymerase reaches the TaqMan probe, it cleaves the molecule, separating the dye from the quencher. The qPCR instrument detects fluorescence from the unquenched FAM or VIC dye.

With each cycle of PCR, more dye molecules are released, resulting in an increase in fluorescence intensity proportional to the amount of amplicon synthesized.

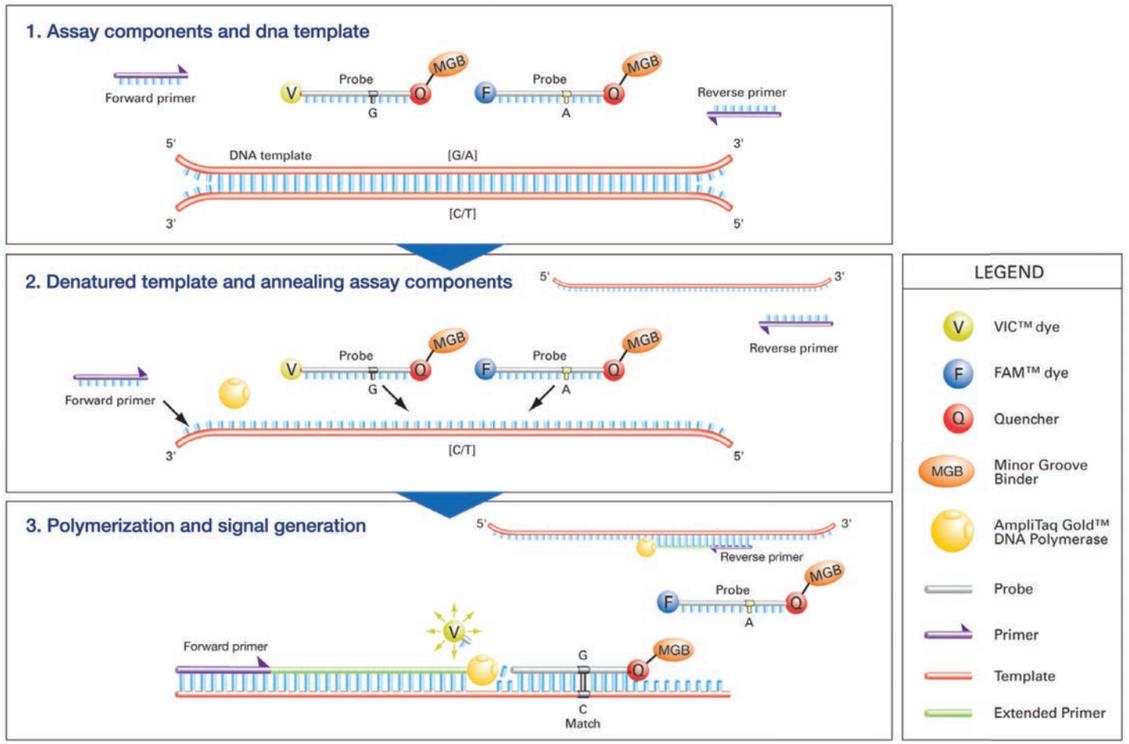


Figure 1. The TaqMan SNP Genotyping Assay. (1) The four TaqMan SNP Genotyping Assay components and the target DNA template with the SNP alleles (in brackets). **(2)** The denatured DNA target and annealing of the assay components. **(3)** Signal generation leading to specific allele detection.

TaqMan SNP Genotyping Assays

- **Better allelic discrimination**—TaqMan probes incorporate 3´ MGB technology to stabilize the probe-template complex
- **Minimize failures**—TaqMan SNP Genotyping Assays are subject to a robust design pipeline, and functional QC testing for human assays on 20 gDNA samples
- **Full-coverage assay pool**—over 7 million human SNP assays (including 160,000 validated assays tested on four ethnic populations of 45 gDNAs each) and over 10,000 mouse SNP assays
- **Simplicity**—all probes and primers are contained in a single tube: no need to optimize probe, primer, salt concentrations, or temperature; all assays use universal PCR conditions
- **Integrated run and analysis solutions**—Applied Biosystems™ instruments and associated software help you move easily from run to results

SNPs are heritable single-base pair variations that occur throughout an organism's genome. SNPs comprise the most common form of genetic variation, with some estimates of SNPs in a given human genome numbering more than 10 million. SNP genotyping plays a central role in characterizing individuals and populations, studying disease traits in humans and other organisms, and identifying genes responsible for advantageous crop traits.

TaqMan SNP Genotyping Assays provide a highly flexible technology for detection of polymorphisms within any genome. TaqMan Assays have a simple workflow and provide a quick way to generate genotyping data (Figure 2). Based on powerful TaqMan chemistry and robust probe and primer designs, and coupled to dependable Applied Biosystems instruments and software, these made-to-order assays produce high-confidence results. TaqMan Assays are ideal for genotyping applications including association studies, candidate region or gene analysis, and fine-mapping studies.

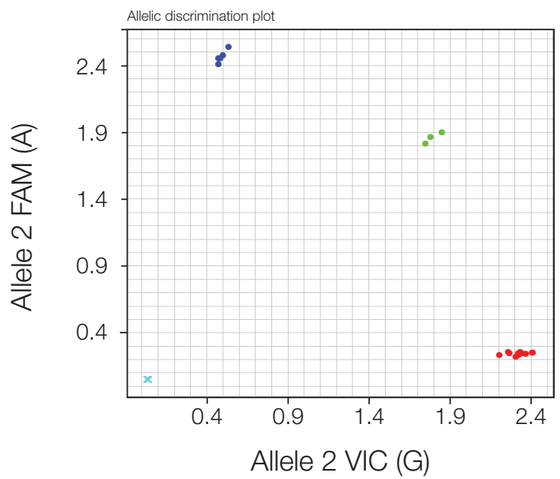


Figure 2. A three-cluster allelic discrimination plot generated with TaqMan SNP Genotyping Assay, C___1202883_20 (rs1801133) for *MTHFR* gene.

Easy online ordering

Predesigned TaqMan SNP Genotyping Assays
Find predesigned assays using our new TaqMan Assay search tool at **thermofisher.com/ordertaqman**

- Easy-to-use interface with a powerful, logical search engine
- Search by keyword (gene, SNP ID) or genomic location
- Filter by SNP type (e.g., missense mutation, intronic, UTR)
- View results on a genome alignment map for easy selection

Custom TaqMan SNP Genotyping Assays
Can't find your assay in our predesigned assay collection? Try designing a custom assay using our Applied Biosystems™ Custom TaqMan™ Assay Design Tool at **thermofisher.com/snpcadt**

- Manually enter your own custom target sequences or upload a file for batch design
- Enter custom primers and probes you have already designed to have us manufacture a ready-to-use assay for you

Simple workflow for quick results
TaqMan SNP Genotyping Assays constitute the simplest SNP genotyping technology available. We deliver your ready-to-use SNP genotyping assay in your choice of format: single-tube, 96- or 384-well plate (custom plating service), or Applied Biosystems™ TaqMan™ OpenArray™ plate (Figure 3). The rest is easy. Just combine the assay with Applied Biosystems™ TaqMan™ Genotyping Master Mix or TaqMan™ Universal PCR Master Mix and your purified DNA sample. There is no need to optimize probe, primer, salt concentrations, or temperature, because all assays use universal reagent concentrations and thermal cycling conditions. After generating an endpoint read using a thermal cycler or real-time PCR instrument, no transfers, washes, or additional reagents are required, and the plate remains sealed; just read the plate and analyze the genotypes. This helps reduce the chance of contamination, sample mix-ups, and sample loss. The simplicity of the chemistry allows you to easily automate the reaction for massively parallel genotyping studies, readily increasing the number of assays, number of samples, or both. Additionally, the analysis software allows you to auto-call genotypes, minimizing manual effort.

Simple data analysis
Applied Biosystems™ TaqMan™ Genotyper Software is a great resource for fast and accurate genotype calling. It is a free SNP genotyping data analysis tool for use with TaqMan SNP Genotyping Assays performed in 48-, 96-, or 384-well microtiter plates or OpenArray plates.

TaqMan Genotyper Software can be downloaded at **thermofisher.com/taqmangenotyper**

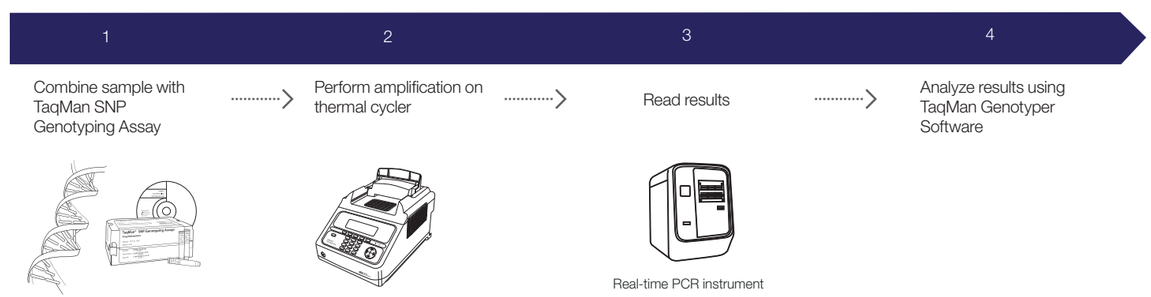


Figure 3. Workflow for TaqMan SNP Genotyping Assays.

Predesigned TaqMan SNP Genotyping Assays
Compatible Applied Biosystems™ TaqMan™ Master Mix and sample prep reagents have been developed to work in conjunction with TaqMan SNP Genotyping Assays to ensure high-quality results.

- TaqMan Genotyping Master Mix
- Applied Biosystems™ TaqMan™ Sample-to-SNP™ Kit
- Applied Biosystems™ TaqMan™ GTXpress™ Master Mix
- Applied Biosystems™ TaqMan™ Universal Master Mix II

The choice of which master mix to use depends on your sample type (tissue, blood, plant, etc.), sample preparation method (purified DNA or crude lysate), and use of fast or standard PCR cycling. For more information, go to **thermofisher.com/taqmansnp**

Ordering information

	Number of SNPs	Number of 5 µL rxns (384-well plate)	Number of 25 µL rxns (96-well plate)	Assay mix formulation	Assay type	Human assays (Cat. No.)	Nonhuman assays (Cat. No.)
Predesigned TaqMan SNP Genotyping Assays for Human and Mouse							
Small-scale	>7 million	1,500	300	40X	Made-to-order	4351379	4351384*
Medium-scale	>7 million	5,000	1,000	40X	Made-to-order	4351376	4351382*
Large-scale	>7 million	12,000	2,400	80X	Made-to-order	4351374	4351380*
Custom TaqMan SNP Genotyping Assays							
Small-scale	∞	1,500	300	40X	Made-to-order	4331349	4332077
Medium-scale	∞	5,000	1,000	40X	Made-to-order	4332072	4332075
Large-scale	∞	12,000	2,400	80X		4332073	4332076
TaqMan Drug Metabolism Genotyping Assays							
Small-scale	2,700	750	150	20X	Inventoried	4362691	N/A

***Over 10,000 mouse assays available.**

All assays are quality-control tested using a mass spectrometer to verify sequence and yield. In addition, all human (predesigned and custom) TaqMan SNP Genotyping Assays receive a genomic functional test on first synthesis. The subsequent syntheses of already-tested human assays and all nonhuman assays receive a fill volume check and mass spectrometry. All assays have a VIC dye–labeled probe, a FAM dye–labeled probe, and two target-specific primers.

Go to **thermofisher.com/taqmansnp** to order.

TaqMan Drug Metabolism Genotyping Assays

- **Excellent ADME panel coverage**—target polymorphisms in 221 genes encoding drug metabolism enzymes and associated transport proteins
- **Simple protocol**—all assays in the collection are run under the same PCR conditions, and specific allele detection is achieved with the Applied Biosystems™ TaqMan™ 5´ nuclease chemistry
- **Detects multiple polymorphisms**—detect SNPs, insertion/deletions (indels), and multinucleotide polymorphisms (MNPs)
- **Rapid receipt of order**—performance-tested assays are already in inventory, ready to ship to you.
- **Assays match databases**—assays are aligned with allele nomenclature from public allele nomenclature sites

Pharmacogenetics is the study of how a person's genetic makeup affects how he or she responds to drugs. This research offers the promise of providing information that will not only allow current drugs to be dosed and delivered more effectively but also allow the development of drugs that are specifically tailored to treat an individual.

We offer 2,700 unique Applied Biosystems™ TaqMan™ Drug Metabolism Genotyping Assays for detecting polymorphisms in 221 genes that code for various drug metabolism enzymes (DMEs) and associated transport proteins. Polymorphisms associated with these genes may influence the rate of drug metabolism within individuals, potentially affecting drug efficacy and the occurrence of side effects (Figure 4). The complex nature of these genes have had limited research conducted because few technologies and products could effectively characterize these polymorphisms. All of the assays in this collection target potentially causative polymorphisms, including those within regulatory elements, coding regions, and associated splice junctions.

TaqMan SNP Genotyping Assay technology delivers superior specificity
Each TaqMan Drug Metabolism Genotyping Assay contains two allele-specific probes and a primer pair to detect the specific SNP target. Both the probes and primers uniquely align within the genome, enabling the TaqMan genotyping technology to provide superior specificity. It is this specificity that allows these assays to detect targets residing in highly homologous gene families that may include pseudogenes.

TaqMan Drug Metabolism Genotyping Assays were developed using a high level of bioinformatics and wet-lab stringency. The assays were designed with information from several public SNP databases, including recognized public allele nomenclature sites. All assays have passed performance tests involving 180 unique DNA samples from four different populations.

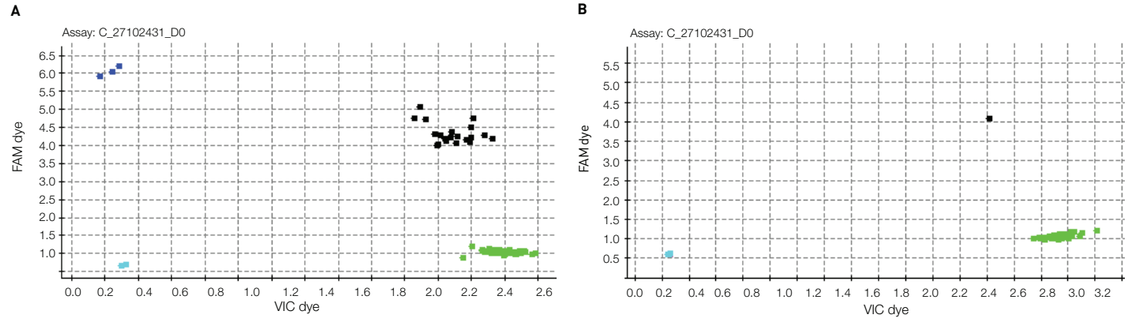


Figure 4. Allelic discrimination plots for the C__27102431_D0 assay run on (A) 45 each African-American and Caucasian, and (B) 45 each Chinese and Japanese gDNA samples. C__27102431_D0 targets the CYP2D6*4,g.1846G>A polymorphism, which encodes an mRNA splicing defect that results in a nonfunctional CYP2D6 protein. If an individual carries two nonfunctional CYP2D6 alleles, they will have the poor metabolizer (PM) phenotype and the metabolism of numerous drugs will be impacted.

Markers relevant for drug metabolism

The Applied Biosystems™ TaqMan™ DME Assay PharmaADME Core Marker Set contains a predefined group of TaqMan Drug Metabolism Genotyping and Applied Biosystems™ TaqMan™ Copy Number Assays, providing over 95% coverage of core markers in 33 ADME genes identified by the PharmaADME consortium.

This assay set greatly simplifies the study of these key putative functional genetic ADME variants and consists of:

- 164 DME assays for SNP and indel polymorphisms
- 14 copy number assays for copy number and hybrid gene variants

Assay sets are delivered in individual tubes, providing the flexibility to select a subset of assays or the entire PharmaADME Core Marker Set.

DME Assay Index

A DME Assay Index is also available with all drug metabolism assays. This file lists each assay along with context sequence, location on the NCBI assembly, the refSNP number (from dbSNP), and the common allele nomenclature from a public allele nomenclature site, when available.

Quick delivery, convenient format

For fast delivery, all assays in this collection have been manufactured and placed into inventory and are ready to ship at ambient temperature. Like other TaqMan SNP Genotyping Assays, these single-tube products consist of two allele-specific TaqMan MGB probes (labeled with either VIC or FAM dye) and two locus-specific primers. TaqMan Drug Metabolism Genotyping Assays are supplied as single tubes and in 96- and 384-well plates (custom plating service). Additionally, all products are formulated for the small-scale reaction size: a 20X single-tube assay, supporting 750 reactions at a 5 µL reaction size.

Optimized supporting reagents

Compatible TaqMan Master Mix and sample preparation reagents have been developed to work in conjunction with TaqMan Drug Metabolism Genotyping Assays to ensure high-quality results:

- TaqMan Genotyping Master Mix
- TaqMan Universal Master Mix II

Additional information about TaqMan Drug Metabolism Genotyping Assays, including links to the PharmaADME Core Marker Set and the DME Assay Index, can be found at **thermofisher.com/taqmandme**

TaqMan Copy Number Assays

- **Gold standard technology**—extraordinary accuracy and reliability; performance guaranteed for all predesigned assays**
- **Results in hours**—simplest method available to study CNV
- **Scalable solution**—automated workflow offers optimum platform for high-throughput validation of copy number changes
- **Comprehensive assay collection**—predesigned assays for human, mouse, and common vector marker/reporter genes
- **Option for custom assays**—Custom Plus and Custom TaqMan Assays for user-defined targets of interest

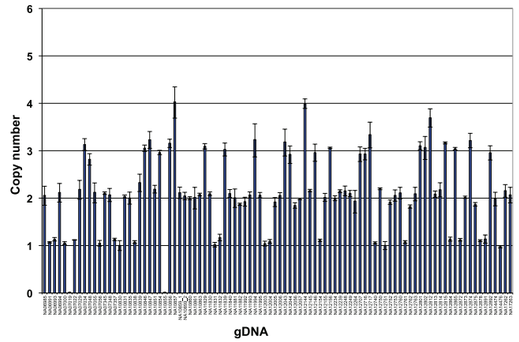
CNV, initially defined as variation in copy number of segments of DNA ≥1 kb in size, between individuals, is found in all humans as well as other animals and plants.

CNV affects a significant portion of the genome (approximately 12% of the human genome) and includes deletions, duplications, and other complex genotyping patterns. These CNVs can influence gene expression and be associated with specific phenotypes and diseases, as observed in microdeletion and microduplication syndromes.

Superior chemistry and streamlined methods offer reliable results

TaqMan Copy Number Assays combine Applied Biosystems™ TaqMan™ Assay chemistry with Applied Biosystems™ real-time PCR instruments to form a method for obtaining specific, reproducible, and easy-to-interpret copy number results (Figure 5). TaqMan Copy Number Assays are an ideal validation tool for microarray or next-generation sequencing follow-up studies and can be used to find specific targets. The workflow can be automated so that several hundred to thousands of samples can be processed in a single day.

A



B

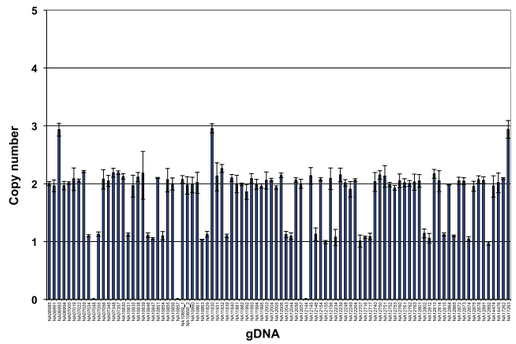


Figure 5. High specificity of TaqMan Copy Number Assays. C4A and C4B represent two isoforms of the C4 gene family. The sequences for these two genes differ in only 5 bases, but the encoded C4A and C4B proteins are functionally different. Differential detection of **(A)** C4A and **(B)** C4B is very challenging. Shown are TaqMan Copy Number Assays for C4A and C4B with the HAPMAP CEU sample set. Distinct copy number changes are observed. (JPT/CHB and YRI data not shown.)

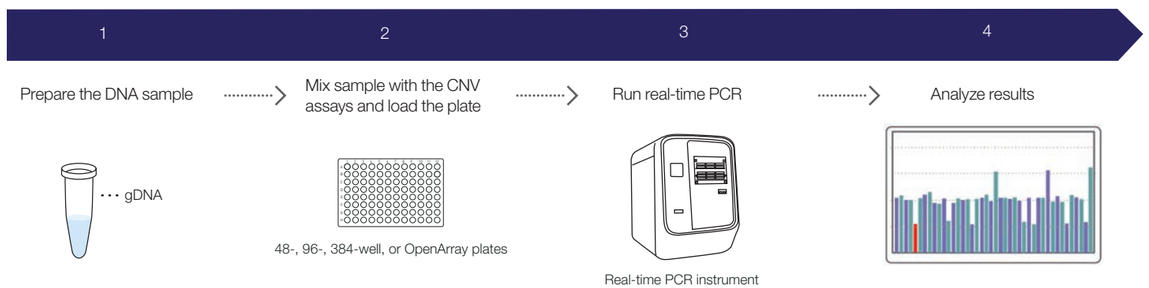


Figure 6. Workflow for TaqMan Copy Number Assays.

TaqMan Copy Number Assays

TaqMan Copy Number Assays include predesigned collections for both human and mouse genomes. The human collection includes more than 1.6 million assays for genome-wide coverage. The mouse predesigned collection includes more than 180,000 assays targeting gene exons. Predesigned assays to common vector marker and reporter genes are also available for transgenic studies.

Find predesigned assays using our online TaqMan Assay search tool at **thermofisher.com/cnv**

Applied Biosystems™ Custom Plus TaqMan™ Copy Number Assays are an optimal solution for studying variation in human and mouse genomic regions of interest for which a predesigned assay is not available. Custom Plus assays use the same bioinformatics pipeline used to manufacture predesigned TaqMan Copy Number Assays (which includes premasking of SNPs and repetitive sequences and assay genome uniqueness checks) and can be generated for high-quality genomic targets of interest using the online Applied Biosystems™ GeneAssist™ Copy Number Assay Tool. Standard Custom TaqMan Copy Number Assays are an option for additional targets of interest. Unlike Custom Plus assays, standard Custom assay designs do not go through premasking or genome quality checks, but can be compared with the human or mouse reference assays for compatibility in duplex reactions.

Two Applied Biosystems™ TaqMan™ Copy Number Reference Assays are available for copy number analysis in both human and mouse species. Note that the reference assays are species-specific.

Feature	Predesigned TaqMan Copy Number Assay	Custom Plus TaqMan Copy Number Assay	Custom TaqMan Copy Number Assay
Designed using copy number–specific algorithm optimized for performance	✓	✓	✓
Availability limited to human and mouse assays	✓	✓	
Contains TaqMan FAM dye–labeled MGB probes and two unlabeled PCR primers	✓	✓	✓
Targets undergo SNP and repetitive sequence masking	✓	✓	
Genome specificity check	✓	✓	
Reference assay compatibility check	✓	✓ (optional)	✓
Assay sequences provided			✓
Assay context sequences and genome location provided	✓	✓	

A simple CNV analysis workflow

TaqMan Copy Number Assays have one of the simplest workflows of all currently available CNV analysis methods (Figure 6). The test assay (FAM dye–labeled), the reference assay (VIC dye–labeled), your sample DNA, and TaqMan Master Mix (TaqMan Genotyping Master Mix is recommended, with TaqMan Universal Master Mix II and Applied Biosystems™ TaqMan™ Gene Expression Master Mix also being compatible) are combined and then run on an Applied Biosystems real-time PCR system using standard TaqMan Assay PCR conditions. On average, setup to primary analysis takes only 3–4 hours (including a ~2 hour PCR run).

Analysis tools and methods

TaqMan Copy Number Assays are supplied in single tubes, or the assays can be custom-plated in 96- and 384-well plates. The assay reactions are run on a real-time PCR instrument, and the data are analyzed using Applied Biosystems™ CopyCaller™ Software.

Additional information on TaqMan Copy Number Assays, as well as links to CopyCaller Software and the GeneAssist Copy Number Assay Tool, can be found at **thermofisher.com/cnv**

	Number of 10 µL rxns (384-well plate)	Number of 20 µL rxns (96-well plate)	Assay mix formulation	Assay type	Cat. No.
Predesigned TaqMan Copy Number Assays					
Small-scale	720	360	20X	Made-to-order	4400291
Medium-scale	1,500	750	20X	Made-to-order	4400292
Large-scale	5,800	2,900	60X	Made-to-order	4400293
Custom Plus TaqMan Copy Number Assays					
Small-scale	720	360	20X	Made-to-order	4442487
Medium-scale	1,500	750	20X	Made-to-order	4442520
Large-scale	5,800	2,900	60X	Made-to-order	4442488
Custom TaqMan Copy Number Assays					
Small-scale	720	360	20X	Made-to-order	4400294
Medium-scale	1,500	750	20X	Made-to-order	4400295
Large-scale	5,800	2,900	60X	Made-to-order	4400296
TaqMan Copy Number Reference Assays (Human)					
RNase P	1,500	750	20X (1 tube)	Inventoried	4403326
RNase P	6,000	3,000	20X (4 tubes)	Inventoried	4403328
TERT	1,500	750	20X (1 tube)	Inventoried	4403316
TERT	6,000	3,000	20X (4 tubes)	Inventoried	4403315
TaqMan Copy Number Reference Assays (Mouse)					
Tfrc	1,500	750	20X (1 tube)	Inventoried	4458366
Tfrc	6,000	3,000	20X (4 tubes)	Inventoried	4458367
Tert	1,500	750	20X (1 tube)	Inventoried	4458368
Tert	6,000	3,000	20X (4 tubes)	Inventoried	4458369

Looking for a different formulation, scale, or label? The TaqMan Custom Assay and Oligo Service can accommodate special requests. To learn more, email specialoligos@thermofisher.com or contact your local sales representative.

Go to **thermofisher.com/cnv** to order.

TaqMan Mutation Detection Assays for somatic mutation detection

- **High specificity**—mutant allele detection is based on an allele-specific primer, while wild type background is suppressed by the proprietary MGB blocker oligonucleotide
- **High sensitivity**—assays can detect down to 0.1% mutant molecules in a background of wild type DNA, as demonstrated in spiking experiments (Figure 8)
- **Detect multiple types of mutations**—detect single- and multiple-nucleotide mutations and insertion/deletions (indels)
- **Wide dynamic range and excellent PCR efficiency**—assays demonstrate at least 4 logs of dynamic range and an average efficiency of 100% ± 10%
- **Fast, simple workflow**—like other TaqMan Assays, typically require 3 hours from sample to results, with minimum hands-on time

Somatic mutations can be present at low levels against a high background of wild type sequences, and methods used to detect and characterize these mutations in tumor specimens need to be highly sensitive and accurate. Methods that are commonly used include gene sequencing (including pyrosequencing and traditional Sanger sequencing) and real-time PCR.

Applied Biosystems™ TaqMan™ Mutation Detection Assays were designed based on a novel competitive allele-specific Applied Biosystems™ TaqMan™ (castPCR™) technology (Figure 7), which combines allele-specific TaqMan qPCR with an allele-specific MGB blocker oligonucleotide to effectively suppress nonspecific amplification of the off-target allele. These assays target mutations in 45 genes implicated in a number of cancer models:

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

TaqMan Mutation Detection Assays

TaqMan Mutation Detection Assays contain mutant allele assays, which specifically detect one or more mutant alleles, and corresponding gene reference assays, which detect mutation-free regions of the genes in which the target mutations reside.

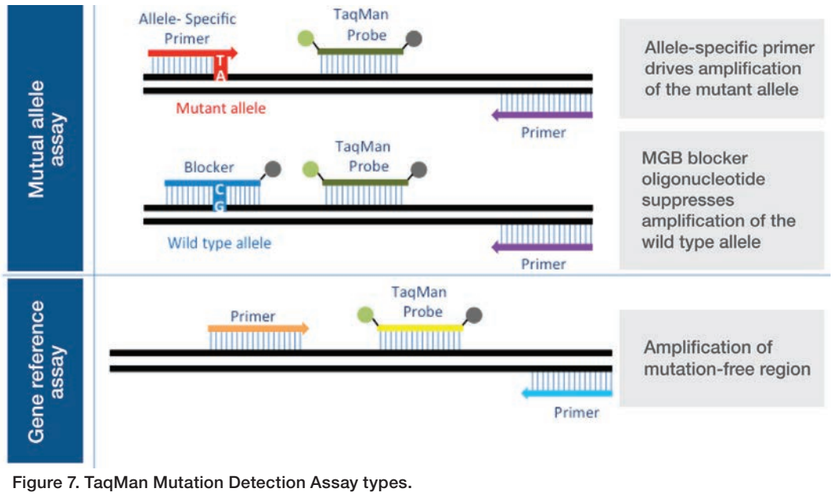


Figure 7. TaqMan Mutation Detection Assay types.

Two experiment types

Mutation detection analysis requires two types of experiments:

Detection ΔC_t cutoff determination

A mutant allele assay and corresponding gene reference assay are run on three or more wild type gDNA samples that are from the same sample type as the test samples (e.g., gDNA from FFPE tissue samples). The ΔC_t value is calculated for the mutant allele assay/gene reference assay pair, for each sample. The average ΔC_t for all samples is then calculated and is used to derive the detection ΔC_t cutoff value for the mutant allele assay.

Mutation detection

A test sample is run with one or more mutant allele assays and a corresponding gene reference assay. The ΔC_t for the mutant allele assay/gene reference assay pair is calculated, and this value is compared to the previously determined detection ΔC_t cutoff value to determine the sample's mutation status.

Simple workflow

Purified gDNA, extracted from a sample of unknown mutation status, is run with one or more mutant allele assays and corresponding gene reference assays. For each real-time PCR, the gDNA is combined with:

- A TaqMan Mutation Detection Assay
- TaqMan Genotyping Master Mix
- (Optional) Applied Biosystems™ TaqMan Mutation Detection IPC Reagent Kit—to distinguish true target negatives from PCR failure or inhibition

Reactions are run on a real-time PCR system using a universal thermal cycling protocol for mutation detection. After the run, the real-time PCR system analysis software determines the C_t for each TaqMan Mutation Detection Assay and (optional) IPC reagent reactions. Real-time results can be exported as files that can be opened in free Applied Biosystems™ Mutation Detector™ Software.

Ordering information

Product	Size	Assay type	Cat. No.
TaqMan Mutation Detection Assays	150 µL, 10X	Inventoried	4465804
TaqMan Mutation Detection Reference Assays	150 µL, 10X	Inventoried	4465807
TaqMan EGFR Exon 19 Deletions Assay	150 µL, 10X	Inventoried	4465805
TaqMan Mutation Detection IPC Reagent Kit	1 kit	Inventoried	4467538

New assays for other cancer gene mutation targets will continually be released.

Go to **thermofisher.com/castpcr** for the most current list.

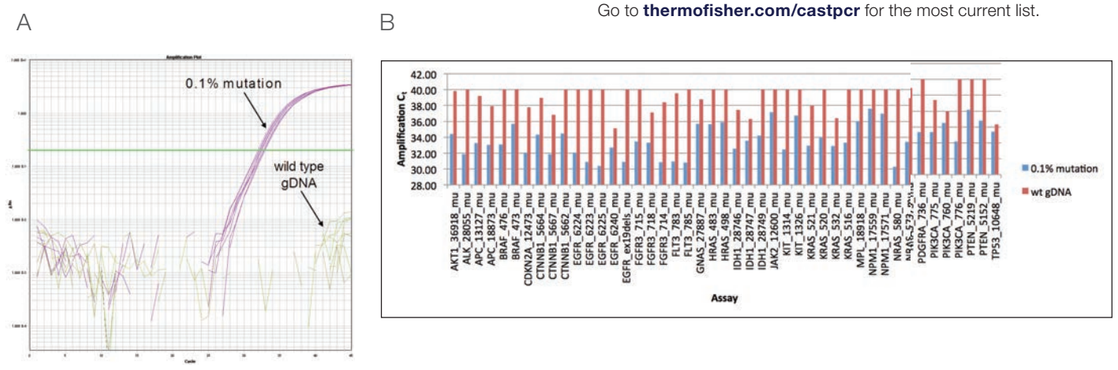


Figure 8. C_t differences between 0.1% mutation samples and wild type gDNA in TaqMan Mutation Detection Assays. For each mutant allele assay, 0.1% mutant allele samples were obtained by spiking cell line wild type gDNA (30 ng, ~10,000 copies) with 10 copies of mutant allele synthetic templates. **(A)** Example of amplification plot for KRAS_522_mu assay run on a 0.1% mutation sample and a wild type gDNA sample (30 ng gDNA). **(B)** For a majority of the assays, there is a significant difference in amplification C_t values between the 0.1% mutant allele sample and wild type gDNA (*P* value < 0.05).

TaqMan genotyping reagents for optimal performances

TaqMan Sample-to-SNP Kit
The TaqMan Sample-to-SNP Kit takes you from biological sample to results typically in less than an hour, without isolating DNA. The kit consists of two parts: the Applied Biosystems™ DNA Extract All Reagents and the TaqMan GTXpress Master Mix. The DNA All Lysis Reagents reduce prolonged procedures for the release of real-time PCR–ready DNA to a 5-minute protocol. They are compatible with a wide variety of samples ranging from blood to buccal swabs to animal and plant tissues. DNA extracted with DNA Extract All Reagents can be used with TaqMan SNP Genotyping Assays (not recommended for other TaqMan Assays).

TaqMan master mixes
TaqMan master mixes contain buffer, dNTPs, passive reference dye, thermostable hot-start DNA polymerase, and other components, and are provided in a convenient single-vial format. They are formulated to provide optimal results for TaqMan Assays.

- **TaqMan Genotyping Master Mix**—the TaqMan Genotyping Master Mix is optimized for end-point fluorescence detection in SNP genotyping applications in standard mode; the TaqMan Genotyping Master Mix provides excellent pre- and post-PCR stability for high-throughput setup and analysis
- **TaqMan GTXpress Master Mix**—the TaqMan GTXpress Master Mix is designed to deliver accurate genotyping results with robust performance in less than 50 minutes; the TaqMan GTXpress Master Mix is also available as part of the TaqMan Sample-to-SNP Kit

Ordering information and assay compatibility

	TaqMan Genotyping Master Mix	TaqMan GTXpress Master Mix
Cat. No. (size)	4371355 (10 mL)†	4401892 (10 mL)
TaqMan SNP Genotyping Assays	††	††
TaqMan Drug Metabolism Genotyping Assays	††	+
TaqMan Copy Number Assays	††	–
TaqMan Mutation Detection Assays for somatic mutation detection	††	–

†Other pack sizes are available.

††Thermo Fisher Scientific validated: We have performed extensive testing and optimization.
+Thermo Fisher Scientific demonstrated: Limited testing has been performed. We cannot guarantee optimal performance for all TaqMan Assays.
–Not recommended.

Quality service and support at every step of your workflow

From manufacturing to follow-up—consistent reliability

TaqMan Assays are designed, manufactured, packaged, tested, and shipped using the highest-quality materials and methods. Furthermore, they are backed by our worldwide technical support teams.

Quality manufacturing and stringent quality control
TaqMan Assays are manufactured in-house at our ISO 13485–certified manufacturing facilities and are never outsourced.

Comprehensive worldwide support
Whether you need help finding a TaqMan Assay for your target, deciding which format best suits your needs, placing your order through our online ordering system, or setting up your reactions, our sales and technical support staff are here to help.

Sales support
Your sales representative can help you find Web and print resources to help you choose the right TaqMan Assay products for your genetic variation research. For more demanding projects, she or he can also involve our technical sales specialists, who have more in-depth knowledge of TaqMan Assay technology and our relevant supporting reagents and instruments.

Technical support
If you have questions about how to use TaqMan Assays or how to analyze results, go to **thermofisher.com/support** to contact our technical support specialists. These agents are skilled in experimental planning and design, are expert troubleshooters, and are familiar with a wide variety of applications that use TaqMan Assays.

Rapid delivery
We continually strive to minimize delivery time on TaqMan Assay products. To that end, we have implemented streamlined order processing systems that interface with our new manufacturing facilities to help reduce delivery times.

TaqMan Assay type	Estimated delivery time (business days/weeks)
Inventoried (in stock)	1–4 days
Made-to-order/Custom TaqMan Assays (manufactured when order is placed)	5–12 days
TaqMan Custom Plating Service (configure 96- or 384-well plates with any TaqMan assays)	2–5 weeks

**The TaqMan Assays QPCR Guarantee
We stand behind every predesigned TaqMan Assay you buy. We're committed to helping you achieve your research goals and believe our predesigned TaqMan Assays establish the benchmark for high-quality and easy-to-use real-time PCR products. If you are not satisfied with the performance of a predesigned TaqMan Assay, we'll replace it at no cost or credit your account. For more information, and full terms and conditions of the guarantee, go to **thermofisher.com/taqmanguarantee**

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Find out more at **thermofisher.com/taqman**

ThermoFisher SCIENTIFIC

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Gilson Pipette Tips**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	

CE

Suzhou, 201.05.26

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data	Name und Funktion / Name and function / Nom et fonction / Nome e funzione

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-08-07
Certificate Registration No.:	SX 60138020 0001
An audit was performed. Report No.:	15092074 004
This Certificate is valid until:	2022-02-27

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-08-07

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail.cert-validity@de.tuv.com http://www.tuv.com/safety

ELITech Clinical Systems
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

ELITechGroup
EMPOWERING IVD

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages) , conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2023).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 12 Mai 2021

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

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61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250/M830	53597
ALBUMIN ENVOY	ALBU-0850	
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP	CRSL-M490	53250
CREATININE PAP SL	CRSL-0630/0250	
DIRECT BILIRUBIN	BIDI-M430	53233
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPSL-0850	53301
GLUCOSE HK	GHSL-M490	
GLUCOSE HK SL	GHSL-0600/0250	
GLUCOSE PAP	GPSL-M690	
GLUCOSE PAP SL	GPSL-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230/M430	59123
PHOSPHORUS ENVOY	PHOS-0850	
TOTAL BILIRUBIN	BITO-M430	53229
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN	PROB-M830	53985
TOTAL PROTEIN ENVOY	PROB-0850	
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA	URSL-M830	53587
UREA ENVOY	URSL-0850	
UREA UV SL	URSL-0427/0420/0500/0507/0250/0455	
URIC ACID	AUML-M830	53583
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	
URIC ACID SL	AUSL-0250	
URINE PROTEIN	PRTU-M230	53481
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	52928
ALP ENVOY	PIVD-0850	
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	52923
ALT/GPT	ALSL-M490	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	
AMYLASE	AMSL-M430	52940
AMYLASE ENVOY	AMSL-0850	
AMYLASE SL	AMSL-0390/0400/0230	
AST/GOT	ASSL-M490	52954
AST ENVOY	ASVD-0850	
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL / CKMB	CMSL-0410/0430/0230	
CK NAC	CKSL-M230	53003
CK NAC SL	CKSL-0410/0430/0230	
GAMMA-GT	GISL-M230	53027
GAMMA-GT PLUS SL	GISL-0400/0420/0250	
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	53072
LDH IFCC	LLSL-M230	
LDH-L SL	LLSL-0400/0420/0230	
LIPASE	LPSL-0250	53108
LIPASE ENVOY	LPSL-0850	
LIPASE SL	LPSL-0230	
Electrolytes / Oligo-élements / Electrolytes / Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250/M430	45789
CALCIUM ENVOY	CALA-0850	
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600/M230	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600/M430	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL	CHSL-M690	53359
CHOLESTEROL ENVOY	CHSL-0850	
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	53359
HDL CHOLESTEROL	CHDL-0250/0600/M330	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	
LDL CHOLESTEROL	CLDL-0250/M330	53395
LDL CHOLESTEROL ENVOY	LDLL-0850	
TRIGLYCERIDES	TGML-M690	53460
TRIGLYCERIDES ENVOY	TGML-0850	
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	

Vla

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400/M230	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
µALBUMIN IP	IMAL-0400	53475
µALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
µALBUMIN IP CONTROL I	IMAL-0046	53478
µALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
WASH SOLUTION A	SOLA-M163	59058
WASH SOLUTION B	WASH SOLUTION B	59058
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

Current issue date: 22 June 2021
Expiry date: 21 June 2024
Certificate identity number: 10361225

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register

Certificate identity number: 10361225

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

UKAS MANAGEMENT SYSTEMS
001

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

and

2) European authorized representative: **CEpartner4U BV,**

Address**: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS Tel.: +31 (0)6 516 536 26;
or as: CEpartner4U, 3951DB; 13. NL tel: +31 (0)6 – 516.536.26)

3) Product(s) *(name, type or model/batch number, etc.)*:

Immunoassay products; **ELISA**, **CLIA**, **Control,** **Instruments** (see appendix)

4) The product(s) described above is in conformity with:

Document No.	Title	Edition / Date of issue
L 331; 98/79/EC	In-Vitro-Diagnostic Directive	1998-10-27

5) Additional information *(conformity procedure, Notified Body, CE certificate, etc.)*:

Conformity assessment procedure for CE marking: IVD Directive, Annex III

Lake Forest, USA;2011-09-27 ---------- A Shatola ----------

Tony Shatola; QA Director, Monobind Inc.

(Place & date of issue (yyyy-mm-dd)) *(name, function and signature of manufacturer)*

Maarn, NL; 2011-09-27 ----------

Olga Teirlinck; Consultant, CEpartner4U BV

(Place & date of issue (yyyy-mm-dd)) *(name; function and signature of authorized representative)*

Appendix

Date: 2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE-marking
Thyroid								
T3 – Triidothyronine	125-300	175-300			12.04.01.05.00	Low		2005-11-11
fT3 – Free Triidothyronine	1325-300	1375-300			12.04.01.01.00	Low		2005-11-11
T4 – Thyroxine	225-300	275-300			12.04.01.07.00	Low		2005-11-11
fT4 – Free Thyroxine	1225-300	1275-300			12.04.01.02.00	Low		2005-11-11
TSH – Thyrotropin	325-300	375-300			12.04.01.11.00	Low		2005-11-11
Rapid TSH – Rapid Thyrotropin	6025-300	6075-300			12.04.01.11.00	Low		2010-06-29
T3U – Triidothyronine Uptake	525-300	575-300			12.04.01.06.00	Low		2005-11-11
TBG – Thyroxine-Binding Globulin	3525-300	3575-300			12.04.01.09.00	Low		2005-11-11
Tg – Thyroglobulin	2225-300	2275-300			12.04.01.08.00	Low		2005-11-11
T3, T4 & TSH – Triidothyronine, Thyroxine & Thyrotropin Combo (VAST)	8025-300	8075-300			12.04.01.01.00	Low		2005-11-11
T3 – Triidothyronine (SBS)	8125-300	8175-300			12.04.01.01.00	Low		2010-06-29
T4- Thyroxine (SBS)	8225-300	8275-300			12.04.01.01.00	Low		2010-06-29
fT3, fT4 & TSH – Free Triidothyronine, Free Thyroxine & Thyrotropin Combo (VAST)	7025-300	7075-300			12.04.01.01.00	Low		2010-06-29
Neonatal Thyroid & Genetics								
NTSH – Neonatal Thyrotropin	3425-300	3475-300			12.04.01.90.00	Low		2005-11-11
NT4 – Neonatal Thyroxine	2625-300	2675-300			12.04.01.12.00	Low		2005-11-11
N 17OHP – Neonatal 17 OH Progesterone	5525-300				12.05.01.07	Low		2008-02-01
Biotinidase	8825-300				12 07 02 90 00	Low		2011-09-26
AutoImmune Thyroid								
Anti-Tg – Anti-Thyroglobulin Antigen	1025-300	1075-300			12.10.03.04.00	Low		2005-11-11
Anti-TPO – Anti-Thyroperoxidase Antigen	1125-300	1175-300			12.10.03.01.00	Low		2005-11-11
Fertility & Prenatal								
LH – Lutropin	625-300	675-300			12.05.01.05.00	Low		2005-11-11
FSH – Follitropin	425-300	475-300			12.05.01.04.00	Low		2005-11-11
PRL – Prolactin	725-300	775-300			12.05.01.08.00	Low		2005-11-11
PRL – Prolactin Sequential	6025-300	6075-300			12.05.01.08.00	Low		2005-11-11
hCG – Human Chorionic Gonadotropin	825-300	875-300			12.05.02.05.00	Low		2005-11-11
Rapid hCG – Rapid Human Chorionic Gonadotropin	3325-300				12.05.02.05.00	Low		2005-11-11
FSH, LH, hCG, sPRL Combo (VAST)	8325-300	8375-300			12.05.01.90.00	Low		2006-08-24
AFP, hCG, uE3 Combo (VAST)	8525-300	8575-300			12.05.01.90.00	Low		2010-06-29
Steroid								
Cortisol	3625-300	3675-300			12.06.02.04.00	Low		2005-11-11
DHEA-S – Dehydroepiandrosterone sulfate	5125-300	5175-300			12.05.01.02.00	Low		2010-06-29
DHEA - Dehydroepiandrosterone	7425-300	7475-300			12.05.01.02.00	Low		2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE-marking
E2 – Estradiol	4925-300	4975-300			12.05.01.03.00	Low		2010-06-29
uE3 – Estriol, Unconjugated	5025-300	5075-300			12.05.02.02.00	Low		2010-06-29
Progesterone	4825-300	4875-300			12.05.01.06.00	Low		2010-06-29
Testosterone	3725-300	3775-300			12.05.01.10.00	Low		2007-11-01
Free Testosterone	5325-300	5375-300			12.05.01.10.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone	5225-300	5275-300			12.05.01.07.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone Ext. Range	9925-300	9975-300			12.05.01.07.00	Low		2010-10-18
Vitamin D3 – 25-Hydroxyvitamin D3	7725-300	7775-300			12.06.03.10.00	Low		2011-09-26
Growth & Bone Metabolism								
hGH - Human Growth Hormone	1725-300	1775-300			12.06.04.02.00	Low		2005-11-11
PTH - Parathyroid Hormone	7825-300	7875-300			12.06.03.13.00	Low		2011-09-26
Diabetes								
Insulin	2425-300	2475-300			12.06.01.03.00	Low		2005-11-11
Insulin Rapid	5825-300				12.06.01.03.00	Low		2010-06-29
C-peptide	2725-300	2775-300			12.06.01.01.00	Low		2005-11-11
Insulin & C-peptide Combo (VAST)	7325-300	7375-300			12.06.01.03.00	Low		2005-11-11
Cardiac Markers								
CKMB – Circulating Creatine Kinase (MB)	2925-300	2975-300			12.13.01.02.00	Low		2005-11-11
CTnI – Troponin I	3825-300	3875-300			12.13.01.07.00	Low		2005-11-11
DIG – Digoxin	925-300	975-300			12.08.01.01.00	Low		2005-11-11
HS-CRP – High Sensitivity C-Reactive Protein	3125-300	3175-300			12.13.01.90.00	Low		2005-11-11
Myoglobin	3225-300	3275-300			12.13.01.05.00	Low		2005-11-11
Infectious Diseases								
IgG – Anti/H. Pylori	1425-300	1475-300			15.01.04.03.00	Low		2005-11-11
IgM – Anti/H. Pylori	1525-300	1575-300			15.01.04.03.00	Low		2005-11-11
IgA – Anti/H. Pylori	1625-300	1675-300			15.01.04.03.00	Low		2005-11-11
Cancer Markers								
AFP – Alpha-Fetoprotein	1925-300	1975-300			12.03.90.01.00	Low		2005-11-11
CA 125 Ovarian Cancer Antigen	3025-300	3075-300			12.03.01.06.00	Low		2005-11-11
CA 15-3 Breast Cancer Antigen	5625-300	5675-300			12.03.01.02.00	Low		2010-06-29
CA 19-9 - Pancreatic Cancer Antigen	3925-300	3975-300			12.03.01.03.00	Low		2005-11-11
CEA – Carcinoembryonic Antigen	1825-300	1875-300			12.03.01.31.00	Low		2005-11-11
CEA - Carcinoembryonic Antigen Next Generation	4625-300	4675-300			12.03.01.31.00	Low		2010-06-29
fβhCG – Free Beta Human Chorionic Gonadotropin	2025-300	2075-300			12.03.01.90.00	Low		2005-11-11
Allergy & Anemia								
Ferritin	2825-300	2875-300			12.07.01.02.00	Low		2005-11-11
Folate	7525-300	7575-300			12.07.01.03.00	Low		2010-06-29
IgE – Immunoglobulin E	2525-300	2575-300			12.02.01.02.00	Low		2005-11-11
sTfR - Transferrin Soluble Receptor	8625-300	8675-300			12.07.01.06.00	Low		2010-06-29
Vitamin B12	7625-300	7675-300			12.07.02.04.00	Low		2011-09-26

Miscellaneous Controls								
Anti-Tg & Anti-TPO – Positive & Negative - Anti-Thyroglobulin, Anti-Thyroperoxidase			AIT-101		12.50.01.16.00	Low		2010-06-29
High Level Fertility Control – Single Level – Progesterone, Estradiol, Human Chorionic Gonadotropin			FC-300		12.50.01.16.00	Low		2010-06-29
Maternal Control – Tri Level - Human Chorionic Gonadotropin, Free Beta Human Chorionic Gonadotropin Subunit, Alpha Feta Protein, Estriol			MC-300		12.50.01.16.00	Low		2010-06-29
Thyroglobulin Control – Tri Level			TG-300		12.50.01.16.00	Low		2010-06-29
H. Pylori IgG Control – Positive & Negative			HPy-IgG-300		12.50.01.16.00	Low		2010-06-29
Miscellaneous Instruments								
IC hardware + dedicated accessories + software – Autoplex ELISA Analyzer & CLIA Processor				IN006	21.02.10.01	Low		2010-06-29
IC hardware + dedicated accessories + software – Lumax Chemiluminescence Strip Reader				IN001	21.02.10.01	Low		2006-08-24
IC hardware + dedicated accessories + software – Neo-Lumax Chemiluminescence Strip Reader				IN010	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Impulse 2 Chemiluminescence Strip Reader				IN005	21.02.10.01	Low		2006-08-24
IC hardware + dedicated accessories + software – Impulse 3 Chemiluminescence Strip Reader				IN007	21.02.10.01	Low		2010-06-29
IC hardware + dedicated accessories + software – Lumax96 Chemiluminescence Plate Reader				IN004	21.02.10.01	Low		2007-03-01
IC hardware + dedicated accessories + software – LuMatic Chemiluminescence Plate Reader				IN008	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Eldex 3.8 ELISA Strip Reader				IN003	21.02.10.01	Low		2007-09-10
IC hardware + dedicated accessories + software – Neo-Eldex ELISA Strip Reader				IN009	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Mircoplate Washer				IN002	21.02.10.01	Low		2010-06-29

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: MD19.4585
Certification Granted: May 18, 2010
Effective Date: September 25, 2019
Expiry Date: September 24, 2022

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

Annex to Certificate Number: MD19.4585

Scope of Registration:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.

Activity	Location
Headquarters, Administration, Design, Manufacturing, Distribution	Monobind Inc. 100 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585
Manufacturing, Distribution	Monobind Inc. 103 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585/A

Verified by:
Operations Manager