Product: rhAmp Genotyping Master Mix, 10 mL

Product number: 1076016

Batch number: 0000421650

Expiration date: 2019-APR-11

rhAmp Genotyping Master Mix is optimized for use with rhAmp Reporter Mix and rhAmp SNP Assays, or with rhAmp Reporter Mix with Reference and rhAmp SNP Assays. The formulation includes a proprietary hot start DNA Polymerase with enhanced allelic discrimination properties, hot start RNase H2 enzyme, dNTPs, and buffer components optimized for specific allelic discrimination.

Analytical testing		
Test	**Specification**	**Result**
pH at 23°C	±0.1 pH unit from target	Pass
dNTP concentration	±0.3 mM from target	Pass
DNase level	<2.0 U/µL DNase I	Pass
RNase level	<1.0 ng/mL RNase A <12.5 ng/mL RNase T1 <70.0 ng/mL RNase I	Pass
Single-stranded exonuclease level	<10% decrease in fluorescent signal	Pass
Double-stranded exonuclease level	<10% decrease in fluorescent signal	Pass

Analytical test methods:

pH is measured using a three standard calibrated pH meter and temperature probe.

dNTP concentration is measured by UV absorbance at 260 nm.

DNase level is evaluated using IDT DNaseAlert reagents via fluorescence detection after incubation at 37°C for 3 hours.

RNase level is evaluated using IDT RNaseAlert® reagents via fluorescence detection after incubation at 37°C for 3 hours.

Single-stranded exonuclease level is evaluated using a proprietary fluorescence-based assay, which monitors the degradation of a single-stranded DNA substrate after incubation at 37°C for 24 hours.

Double-stranded exonuclease level is evaluated using a proprietary fluorescence-based assay, which monitors the degradation of a double-stranded DNA substrate after incubation at 37°C for 24 hours.

Enzyme testing *Hot start RNase H2 and proprietary hot start DNA Polymerase are tested prior to addition to the rhAmp Genotyping Master Mix.*		
Test	**Specification**	**Result**
Bacterial DNA level	<10 copies of *E. coli* DNA per 1 µg of enzyme	Pass
Hot start enzyme inhibition (Polymerase)	<5% increase in fluorescent signal	Pass
Hot start enzyme inhibition (RNase H2)	<10% increase in fluorescent signal	Pass

Enzyme test methods:

Bacterial DNA level is measured using a qPCR assay targeting an *E. coli*-specific DNA sequence.

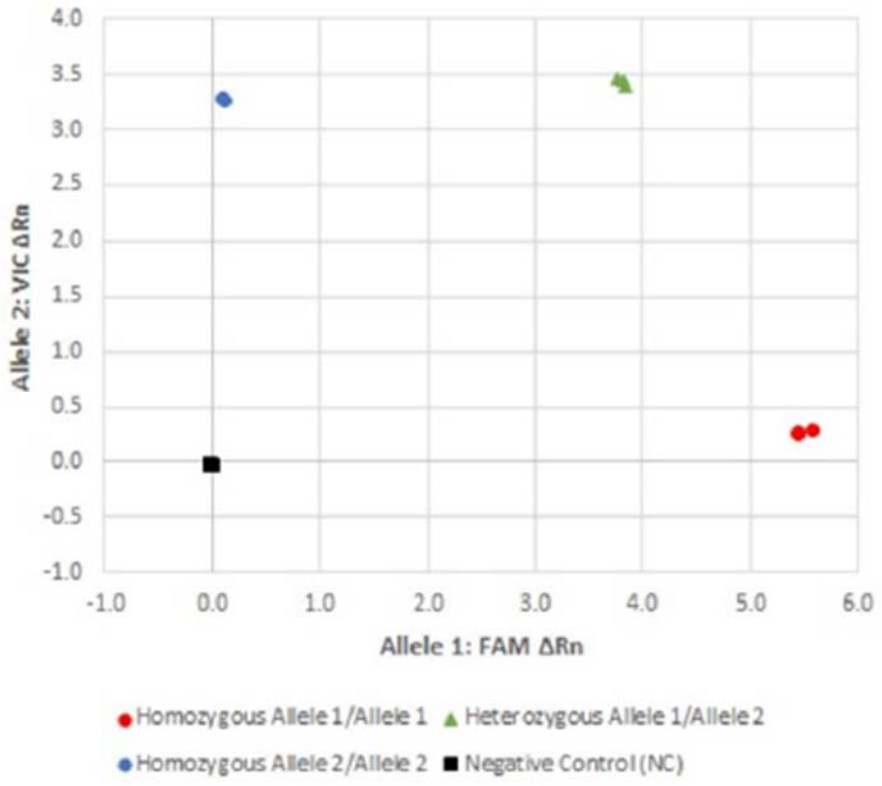
Hot start enzyme inhibition is confirmed by proprietary testing methods, which monitor enzyme activity on a fluorescently labeled substrate at an elevated temperature.

Functional testing

rhAmp Genotyping Master Mix is tested for allelic discrimination performance using rhAmp Reporter Mix with Reference and a rhAmp SNP Assay targeting 1000 copies of double-stranded gBlocks Gene Fragment template. PCR cycling and analysis is performed using the QuantStudio™ 7 Flex Real-Time PCR System (Thermo Fisher Scientific).

Test	Result
Allelic discrimination	Pass

Allelic discrimination plot



Storage: Store rhAmp Genotyping Master Mix in a sealed container at –20°C. Upon addition of rhAmp Reporter Mix, store up to 2 weeks at 2–8°C, protected from light.

Verified by: Natalie Walter

Quality release date: 2019-JAN-03

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