

# Reliable performance under variable conditions

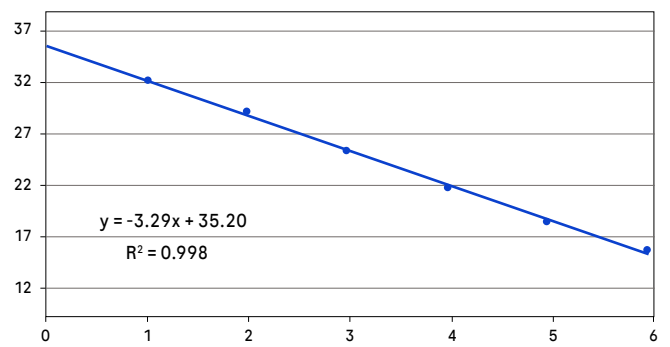
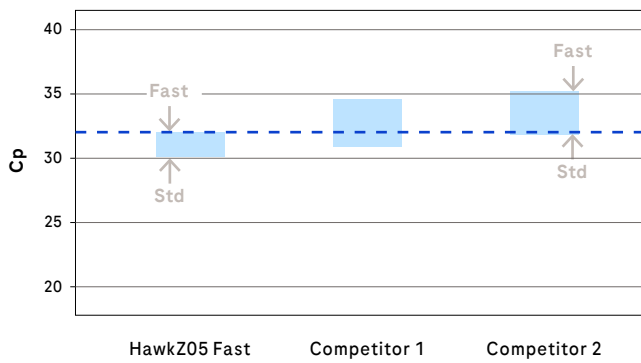
Lyo-ready reagents for molecular  
point-of-care diagnostics



# The design of reagents sets the pace for molecular point-of-care diagnostics

Rapid onsite analyses to support diagnosis and treatment decisions have become a cornerstone of medicine in our globalized society. Molecular Point-of-care testing (POCT) not only extends the reach of modern medicine to broader populations, but also underpins our understanding and management of public health.

Assays for molecular PoC must work reliably, delivering accurate results under variable handling and environmental conditions. They must also be easy to transport, store and use. Finally, they must be manufactured quickly, safely and cost-effectively. Using reagents designed for the unique conditions of PoC is key to achieving these requirements.



01

**Speed – fast reactions for short turnaround**

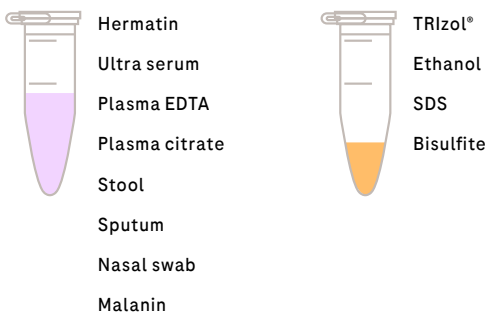
Roche CustomBiotech enzymes enable short extension times. Compared to enzymes from other providers, HawkZ05 Fast show earlier Cp values with a short reverse transcription step (5 min) and a smaller shift in Cp value between the standard and the fast PCR protocol. Data on file at Roche

02

**Sensitivity – detect targets with low copy number**

Roche CustomBiotech enzymes exhibit excellent reaction efficiency and linearity down to low target copy numbers. NxtScript 2G reverse transcriptase allows detecting from 1000 ng RNA down to 0.01 ng per reaction (a difference of 6 orders of magnitude). Data on file at Roche.

**Patient sample or sample collection tubes**

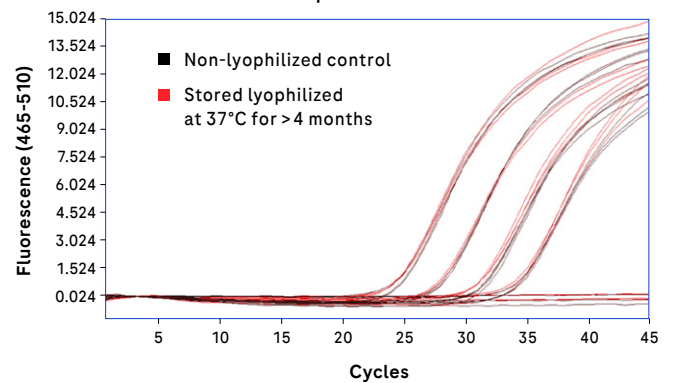


03

**Robustness – perform even in the presence of inhibitors**

Roche CustomBiotech lyo-ready enzymes have been tested with a broad range of inhibitors inherent to liquid biopsies, tissues or standard sample preparation methods. Data on file at Roche.

**Amplification curves**



04

**Direct dry down – easier production, stable performance**

Without dialyzing, Roche CustomBiotech enzymes like KAPA3G HotStart DNA polymerase can be lyophilized directly and show the same performance as non-lyophilized controls even after lengthy storage at warm temperatures. Data on file at Roche.

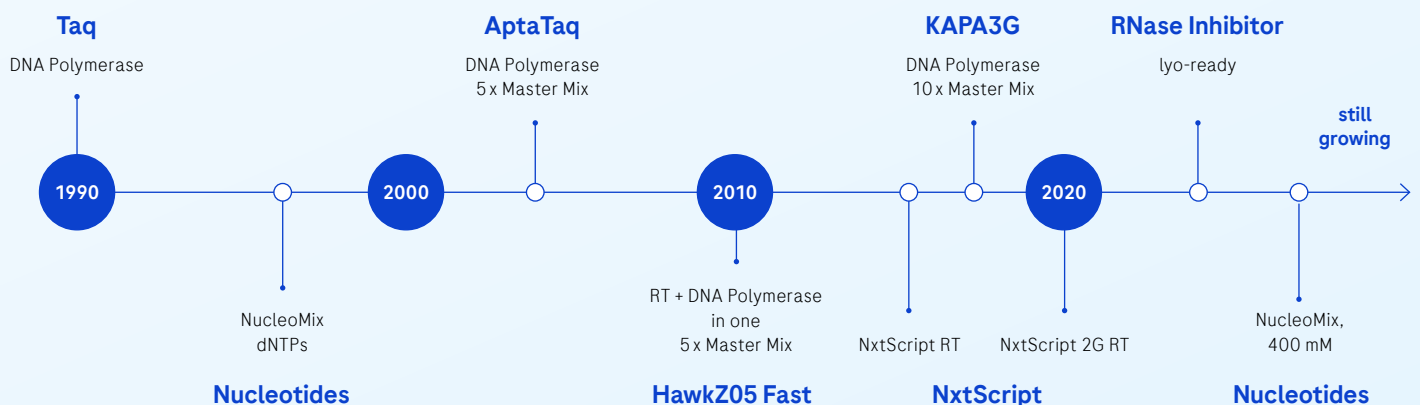
# Roche CustomBiotech lyo-ready reagents: a quick overview

Product	DNA	RNA	Master mix	HotStart	Concentration (U/ $\mu$ L)	% glycerol (v/v)	Comments
Taq DNA Polymerase <sup>2</sup>	Yes	-	-	-	50	$\leq 0.1$	-
KAPA3G HotStart DNA Polymerase <sup>1</sup>	Yes	-	10x	Antibody-mediated	30	$\leq 0.1$	Designed for speed and inhibitor tolerance; suitable for probe-based PCR
AptaTaq DNA Polymerase <sup>2</sup>	Yes	-	5x	Aptamer-mediated	50	$\leq 0.1$	2 additional formulations: LDx is proven free of contaminating DNA; delta exo is N-terminal truncated and suitable for mismatch detection in allele-specific PCR, SNP analysis, genotyping
NxtScript 2G Reverse Transcriptase <sup>1</sup>	-	yes	-	-	500	$\leq 0.1$	Highly concentrated and inhibitor-tolerant; enables RT steps at up to 70°C
HawkZ05 Fast DNA Polymerase <sup>1</sup>	Yes	yes	5x	Aptamer-mediated	500	$\leq 0.1$ master mix: 0.5	Reversible hot start DNA polymerase for fast one-step RT-PCR
RNase Inhibitor <sup>1</sup>	-	yes	-	-	400	$\leq 0.5\%$	Highly concentrated to protect against RNase degradation in molecular assays
NucleoMix, 400 mM <sup>3</sup>	-	-	-	-	100 mM of each nucleotide	-	Highly concentrated nucleotide mix (dATP, dCTP, dGTP, dTTP)

## Your partner above and beyond enzymes

The CustomBiotech offering for PoC is not just components – it's expertise, advice and and core lab molecular diagnostics to keep your business going. We offer premium reagents that you can use to design fast and simple assay protocols. We create solutions around real samples, both difficult targets and complex matrices.

Finally, our reagents are manufactured in state-of-the-art facilities under strict quality control, so when you use CustomBiotech materials, you build quality and compliance into your assay.



05

We foster innovation in the industry by continuously launching new glycerol-free and high concentration reagents

For regulatory disclaimers please refer to product table on previous page.

#### **Regulatory Disclaimer**

<sup>1</sup> For further processing only.

<sup>2</sup> Taq DNA Polymerase and AptaTaq; For customers in the European Economic Area: Contains SVHC: octyl/nonylphenol ethoxylates. For further processing on its own or in a mixture as part of an IVD method and under controlled conditions only – acc. to Art. 56 (3) and 3 no. 23 REACH Regulation.

<sup>3</sup> For further processing into IVD products and medical devices only.

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