



Reliable performance under variable conditions

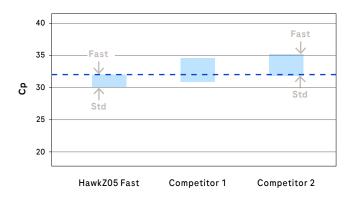
Lyo-ready reagents for point-of-care diagnostics

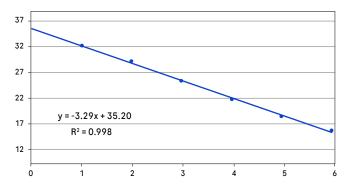


The design of reagents sets the pace for point-of-care diagnostics

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

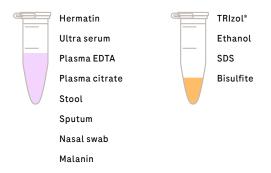
Roche CustomBiotech enzymes enable short extension times. Compared to enzymes from other providers, HawkZ05 Fast show earlier Cp values with a short reverse transcription step (5 min) and a smaller shift in Cp value between the standard and the fast PCR protocol. Data on file at Roche

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



Amplification curves 15.024 13.524 ■ Non-lyophilized control 12.024 Fluorescence (465-510) Stored lyophilized 10.524 at 37° C for > 4 months 9.024 7.524 6.024 4.524 3.024 1.524 0.024 10 15 20 25 30 35 40

Cycles

03

${\bf Robustness-perform\ even\ in\ the\ presence\ of\ inhibitors}$

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.

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.

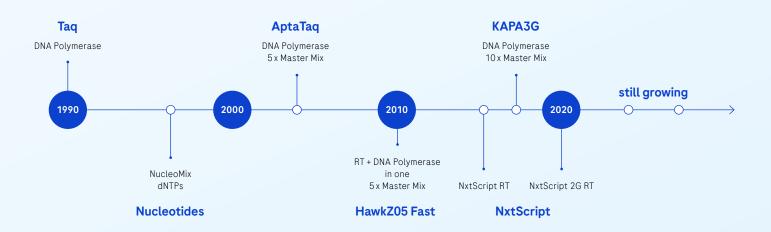
Roche CustomBiotech lyo-ready enzymes: a quick overview

Product	DNA	RNA	Master mix	HotStart	Concen- tration (U/µL)	% glycerol (v/v)	Comments
Taq DNA Polymerase	Yes	-	_	-	50	≤0.1	-
KAPA3G HotStart DNA Polymerase	Yes	-	10x	Antibody- mediated	30	≤0.1	Designed for speed and inhibitor tolerance; suitable for probe-based PCR
AptaTaq DNA Polymerase	Yes	-	5x	Aptamer- mediated	50	≤0.1	2 additional formulations: LDx is proven free of contaminating DNA; delta exo is N-terminal trun- cated and suitable for mismatch detection in allele-specfic PCR, SNP analysis, genotyping
NxtScript 2G Reverse Transcriptase	-	yes	-	-	500	≤0.1	Highly concentrated and inhibitor-tolerant; enables RT steps at up to 70°C
HawkZ05 Fast DNA Polymerase	Yes	yes	5x	Aptamer- mediated	500	≤0.1 master mix: 0.5	Reversible hot start DNA polymerase for fast one-step RT-PCR

Your partner above and beyond enzymes

The CustomBiotech offering for PoC is not just components – it's expertise, advice and a secure global supply of materials 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-theart facilities under strict quality control, so when you use CustomBiotech materials, you build quality and compliance into your assay.



Regulatory Disclaimer

For further processing only.

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.

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