Custom Assay Development Process

Unravelling DNA to Enable Your Discovery

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Assay Development Process

1. Enquiry / Qualification
2. Consultation
3. Proof of Concept
4. Development
5. Validation
6. Custom Packaging / Kitting
7. Manufacturing
8. Technical Services

Full SOP; Planning, Concept, Research, Design & Development, Process Validation & Commercialization Stages (68 steps)
Assay Optimization & Validation
dUTP is an inhibitor of Taq, often influencing activity and sensitivity.
The ratio & concentrations of dNTP and Mg can influence baseline, end-point fluorescence and Ct values.
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Prioritized for further study.
Following optimization, freeze-thawing of the master mix is shown to have little impact on assay performance.
pH can influence Ct values, S-shape in amplification plots, starting and end-point fluorescence.
Improved performance as judged by curve profile and end-point fluorescence at very low target concentration.
Assay performance holds steady when the cycling protocol is reduced by 50min, enabling fast quantitation.
Salt concentration can affect the Ct, end-point fluorescence and repeatability.
Lyophilization of the optimized master mix yields comparable results.
Fluorescent dye can influence end-point fluorescence and reproducibility.
Fluorophore dye choice can influence the repeatability of fluorescent signal in different formats.
Assay Format & Stability Testing

Negligible variation in Ct value following lyophilization & storage at room temperature
Thermal Stability Testing

GAPDH / FAM

B2mg / VIC

Stability testing demonstrates lyophilized assays are stable to up 1 month at 37°C
To learn more....

http://www.bioline.com/contact-custom-development-experts