Dedication to the IVD industry?

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The future of engineered polymerases? Zeroing the step of quantitative reverse transcription PCR (RT-qPCR)

Dr. Kevin Eboigbodin, PhD, MBA

Senior Director, Molecular Diagnostic Reagents

Medix Biochemica Group

Medix Biochemica

Weston, FL, USA

- Independent, international, and industry-leading critical raw materials partner to the IVD industry
- Founded in 1985
 - Headquarters in Espoo, Finland
 - Growing global branches
- Developing and manufacturing essential high cites add text
 raw materials for diagnostic applications
 - Antibodies, antigens, clinical chemistry enzymes, lipoproteins, DNA and RNA polymerases, biospecimens
- Over 250 employees, with 1 in 5 employees dedicated to R&D
- Trusted by leading names in the IVD industry
 - We work with 23 out of the 25 biggest global IVD companies
 - Products used in over 70 countries

Shanghai, China

Espoo, Finland

Kostanz, Germai

Besançon, France

MedixMDx - Innovative portfolio of best-in-class MDx reagents

- High-quality, robust polymerases and mastermix for applications used by both IVD and research customers
- Custom, novel DNA/RNA polymerase development services



Genotyping



Isothermal Amplification



Direct PCRs



RNA / RT-PCR



Freeze-Dried Products



PCR & qPCR

 CE-IVD/FDA approved raw materials used in broad range of diagnostic tests globally



Mutant DNA Polymerases







Services



Zero-step of quantitative reverse transcription qPCR (RT-qPCR)?



Zero-step RT-PCR: Uses an Engineered highly thermostable Taq DNA polymerase with reverse transcriptase activity reading both RNA and DNA template

0-step RT-PCR





Reverse transcription (cDNA generation) and DNA amplification happens at the same time.

Faster! Unique!

| No conventional |
|------------------------------|
| Reverse Transcription |
| (RT) incubation step |
| needed (0-step) thus |
| enabling faster |
| detection time to result |

Typical protocol

| | Step | Тетр | Time | Cycles |
|----------|------|------|--------|--------|
| Protocol | 1. | 95°C | 1 min | 1 x |
| | 2. | 95°C | 10 sec | — 45 x |
| | 3. | 60°C | 1 min | |



The time to result can be further shorten: By reducing the number of cycles and/or reducing the annealing/extension time (instrument dependent)

Zero-step RT-qPCR has been validated using a number of RNA targets

Human mRNA

18 20

Cycle

Volcano3G® RT-PCR Probe 2x Master Mix

---- Human mRNA, 10^4 copies

0 2 4 6 8 10 12 14 16



Influenza



| | Step | Temp | Time | Cycles |
|----------|------|------|--------|--------|
| Protocol | 1. | 95°C | 2 min | 1 x |
| | 2. | 95°C | 10 sec | 4E y |
| | 3. | 60°C | 45 sec | — 45 X |

The time to result can be further shorten: By reducing the number of cycles and/or reducing the annealing/extension time (instrument dependent)

Medix Biochemica

4000

3500-

3000

2500

1500

1000 '

500

륜 2000

Multiplex SARS-CoV-2 RT-qPCR assay using Volcano3G mix



The time to result can be further shorten : By reducing the number of cycles and/or reducing the annealing/extension time (instrument dependent)

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High thermostability enabling better flexibility in assay development



structure and minimize sample derived inhibition!

Suitable for pre-treating clinical samples and RNA template for secondary structures.

competitors lose their activity at 60°C and 70°C.

Rapid RT-qPCR detection within 15 mins!



 The engineered Volcano3G RT-PCR mix enabled the quantitative SARS-COV-2 detection result in under 15 mins

 Ultra fast, Highly sensitive and specific test with similar speed as a point-of-care immunoassay test.

https://www.imm.fraunhofer.de/en/press-publications/qpcr-15min.html

Summary: Engineered polymerases for molecular diagnostic application



• Expert DNA/RNA polymerase engineering

- \checkmark The core component in PCR/RT-PCR and core competence
- ✓ Ensure robustness of MDx test
- \checkmark Customization and flexibility in assay development

• High thermal stability

- ✓ Simplify sample preparation workflow
- ✓ Reduce sample derived inhibition

• Zero-step

- ✓ Shorter time-to-result
- \checkmark Save time and money

Medix MDx Unparallel partnership offering – Reducing your time to market



- MedixMDx specializes in supporting you from concept to commercialization.
- A single point of contact for a comprehensive portfolio of best-inclass raw materials and service for molecular diagnostics.
- Best in class team and capabilities in MDx reagents development
- We shorten your time to market by combining
 - Highest scientific expertise in MDx
 - Consistent quality
 - Strong global presence and customer support
 - Consolidated supply chain management
- By reducing complexity, we enable you to bring commercially viable products to market sooner

Tech support and general inquires:

Contact:

mdx@medixbiochemica.com

Medix Biochemica and myPOLS Biotec Molecular Reagents web shop





Thank you for your time