

# Palm PCR™ COVID-19 Fast Real-time RT-PCR Kit

## ❖ The State of the Art **COVID-19** Diagnosis

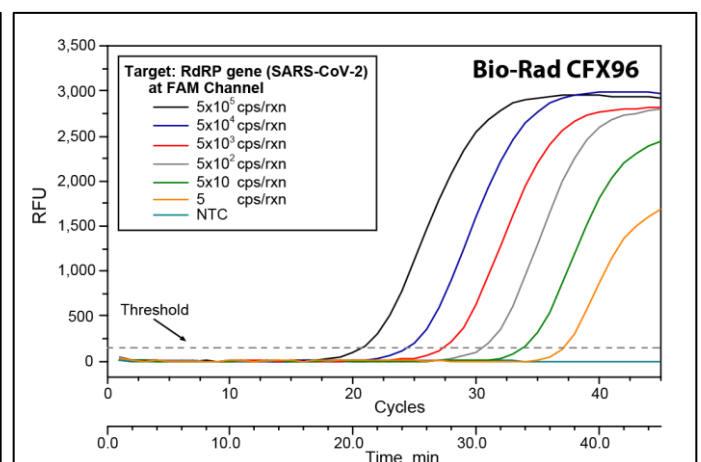
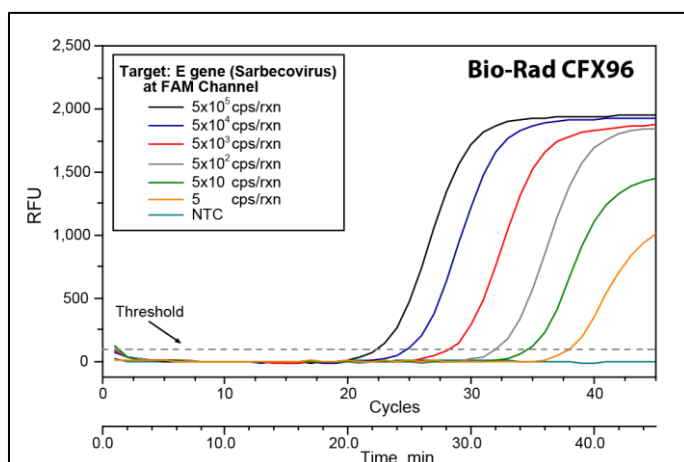
Part No. DX5010

- **Ultra-fast RT-PCR Assays:** **Within 50 min** on conventional real-time PCR instruments
- **Two Target Test:** **E gene** and **RdRP gene** (one target per tube)
- **High Sensitivity & Specificity:** 100% PPA and 100% NPA
- **High Throughput:** Over **368 patients** (768 assays) per 8 hours
- **More than 200% Enhancement** of RT-PCR Throughput



## ❖ Ultra-Fast RT-PCR Assays with Extreme Sensitivity

- **The Shortest RT-PCR Time:** **≤ 50 min** on Bio-Rad CFX96 and ABI QuantStudio 5, and **58 min** on ABI 7500 Fast (3 min for reverse transcription, 1 min for hot start, and 1 min per cycle)
- **Ultimate High Sensitivity:** Can detect **down to 5 copies/reaction** of SARS-CoV-2 with at least 95% hit rate (LoD: 8.2 copies/reaction for E gene and 5.3 copies/reaction for RdRP gene)



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## ❖ Assay Format and Product Components

- **Two Assay Format: Assay 1** using **Premix 1** for detecting **E gene** that is common to Sarbecovirus; and **Assay 2** using **Premix 2** for detecting **RdRP gene** that is specific to SARS-CoV-2
- Each assay contains an internal control (IC) to exclude the possibility of false-negative results due to inefficient or false RNA extraction.

### Product Components

Component	Quantity	Cap color
Premix 1 for E gene (lyophilized)	50 tests x 2	Green
Premix 2 for RdRP gene (lyophilized)	50 tests x 2	Green
Reconstitution buffer	850 µL x 4	Yellow
Positive Control	100 µL	Red
Negative Control	500 µL	Blue

## ❖ Lyophilized Premix Format - Robust and Simple to Use

- **Each Assay** is provided in a **lyophilized Premix** that contains all core components for the RT-PCR assay, including fast enzymes, primers, probes and dNTP, in a temperature-resistant lyophilized form.
- **Multiples of Advantages** for simplifying the RT-PCR diagnosis and securing the high sensitivity and specificity from the shipment to use:
  - ✓ **Longer shelf life** - 12 months from the date of production
  - ✓ **Cheaper shipping cost** - Ice pack shipment (the dry ice not required)
  - ✓ **Easy to use** - Just add Premix + Sample (no multi-component preparation)
  - ✓ **Sensitivity and Accuracy** - guaranteed

## ❖ Medical Device Certifications

- **KFDA Approved:** Product License No. IVD-20-569
- **Mexico INDRE Approved:** Oficio No. DGE-DDYR-11170-2020
- **US FDA EUA under Review:** Submission No. PEUA201671
- **Health Canada EUA under Review:** Submission No. 313758