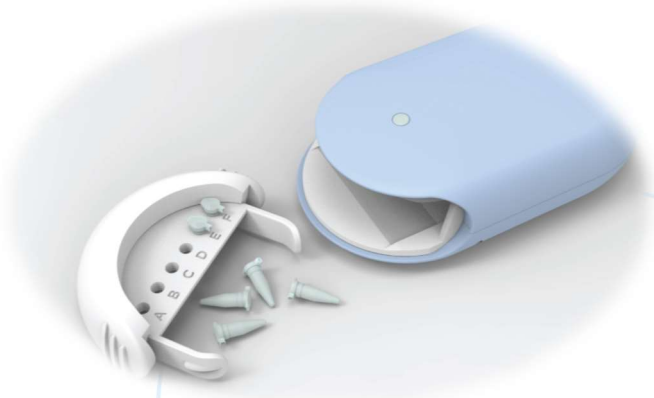
PEBBLE

real-time laboratory diagnostics in the palm of your hand

BIOPIX-T

What is the PEBBLE device?

PEBBLE is a compact, portable, biomedical, **colorimetric LAMP (qcLAMP*) Platform**[3] for real-time molecular diagnostics. It combines the accuracy of **lab-based molecular diagnosis** with the simplicity of **point-of-care** testing.



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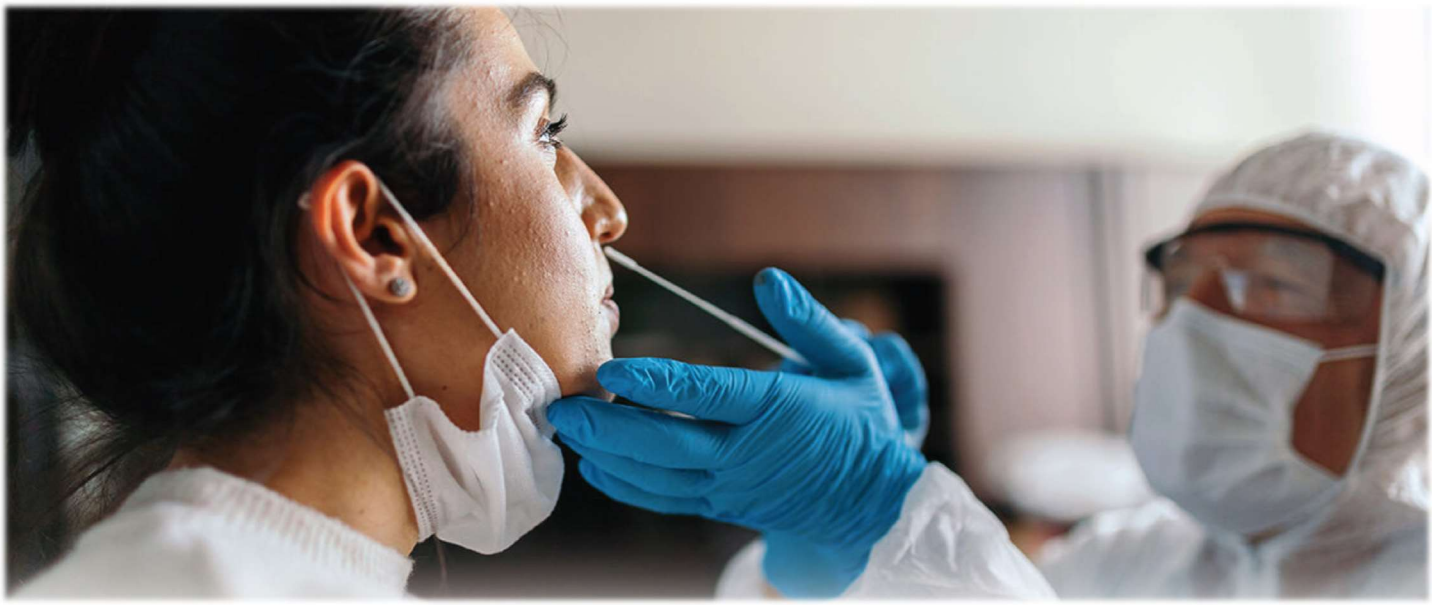
Effective infection prevention, control and treatment requires rapid and extensive diagnosis of infectious diseases and accurate identification of the underlying pathogens. Molecular detection of these infectious pathogens is believed to require expensive equipment and well-trained aboratory technicians in a centralized facility.

In many settings globally, the ideal molecular detection test should be able to detect a minimum viral load, provide a rapid and simple result and be minimally invasive.[1,2]

The PEBBLE system answers this need.



The PEBBLE qcLAMP (isothermal PCR) assays show **comparable sensitivity and specificity to traditional PCR methods**.[4] Tests are performed on the PEBBLE qcLAMP Platform, which controls the reaction temperature, timing and facilitates the real-time digital colorimetric analysis of the amplification reactions.

Total duration of the test in the PEBBLE qcLAMP platform is 30 minutes to conclude a negative result.[5] Time-to-positive can range between **10 and 27 minutes** depending on the initial target concentration.[5]

The PEBBLE device uses **smartphone-based** colour analyses, enabling **simple, rapid, and reliable nucleic acid detection** without the need for expensive fluorescence equipment.[3]

Compared to real-time quantitative polymerase chain reaction (RT-qPCR)-based methods, the PEBBLE RT-qcLAMP assays require incubation at a constant temperature (provided by the compact unit), thus **eliminating the need for sophisticated instrumentation**.[3]

*** Quantitative colorimetric Loop-mediated isothermal amplification**

References:

1. Mautner, L et al. Rapid point-of-care detection of SARS-CoV-2 using reverse transcription loop-mediated isothermal amplification (RT-LAMP). Virol J (2020)17:160.
2. Diaz, LM, Johnson, BE, Jenkins, DM. Real-time optical analysis of a colorimetric LAMP assay for SARS CoV-2 in saliva with a handheld instrument improves accuracy compared to endpoint assessment. MedRxiv. https://doi.org/10.1101/2021.01.13.21249412. Posted 15 January 2021.3.
3. Papadakis, G et al. Portable real-time colorimetric LAMP-device for rapid quantitative detection of nucleic acids in crude samples. May 27, 2021. bioRxiv preprint doi: https://doi.org/10.1101/2020.07.22.215251.
4. Notomi, T et al. Loop-mediated isothermal amplification of DNA. Nucleic Acids Research, 2000, Vol. 28, No.12.
5. COV19 qcLAMP kit. Information for Use. Biopix DNA Technology P.C. Ref. 000055. V1.0 16/07/2021.

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What makes PEBBLE unique?

- **Point-of-Care Testing (PoCT)** - PEBBLE offers a near-to-patient solution. The clinical benefits of PoCT vary with the particular test but these can include:
  - Quicker diagnosis or exclusion of diagnosis
  - More appropriate treatment
  - Improved treatment outcomes based on the two points above.

The device is constructed using miniaturized electronic components' cases and holders produced by three-dimensional (3D) additive manufacturing and operates via an in-house developed smartphone application. For monitoring the colour change during DNA amplification, a **novel way of heating** was introduced allowing efficient amplification with **parallel visualization** of the reaction by a **mini digital camera** controlled by a microcontroller[6]. The above, when combined with an application for **digital image analysis**, can **rapidly extract quantitative information** at a **wide dynamic range** of the genetic target[3].

PEBBLE qcLAMP Platform

- Compact **colorimetric LAMP**
- Offers **accurate molecular detection** of low viral loads in rapid time
- **Portable** - allows for truly decentralized diagnostic testing
- **Cost-effective**, affordable
- Requires **minimal training**
- **Smartphone-based** application

Main advantages of the PEBBLE[3]

- ☑ Rapid analysis time (<30min). Time-to-positive can range between **10 and 27 minutes** depending on the initial target concentration.
- ☑ Quantification over a large dynamic range (9 log units).
- ☑ Crude samples: ability to test crude samples in a single test.
- ☑ Extraction samples: ability to use extracted **RNA or DNA** for increased sensitivity.
- ☑ Smartphone-operation - the device connects via **Bluetooth** to a smartphone or tablet and operates through an in-house developed **Android** application.*

* Cloud storage of results.

6. Raspberry Pi is a series of small, inexpensive single-board computers developed in the United Kingdom by the Raspberry Pi Foundation in association with Broadcom. A low-cost Linux and ARM-based computer on a small circuit board sponsored by the charitable Raspberry Pi Foundation in the UK. "Raspberry Pi Foundation - About Us". https://www.raspberrypi.org/about/. Raspberry Pi. (Accessed 12/08/21).

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Where can PEBBLE be deployed?*

- Pharmacy Clinics
- Doctor's Surgeries
- Patient Bedsides
- Old Age Home Clinics
- Airport Screening Centres
- Cruise Liner Testing Centres and Clinics
- Drive-through Test Centres, etc.

P · E · B · B · L · E

Portable

Ease-of use

Budget-friendly (cost effective device and test kits)

Blue-tooth enabled for smartphone application

Localised testing (truly decentralized near to patient point-of-care diagnostics)

Evidence-based (scientific support for efficacy and accuracy)

* For use by, or under the supervision of, a trained healthcare professional.

BIOPIX-T is certified as per ISO 13485:2016 and ISO/IEC 27001:2013. Their ISO/IEC 27001:2013 certification confirms that BIOPIX-T has designed a system that can ensure the security and integrity of all the information that is handled by the company, be that of clients, suppliers or its own R&D and assets. Moreover its ISO 13485:2016 certification and its commitment to quality ensures the successful implementation of its mission which is to offer safe portable In-vitro diagnostic medical devices (instruments and kits) to every potential end-user, regardless of financial status, geographical location, and training.

CE IVD

Information Security ISO/IEC 27001

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

BIOPIX-T

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