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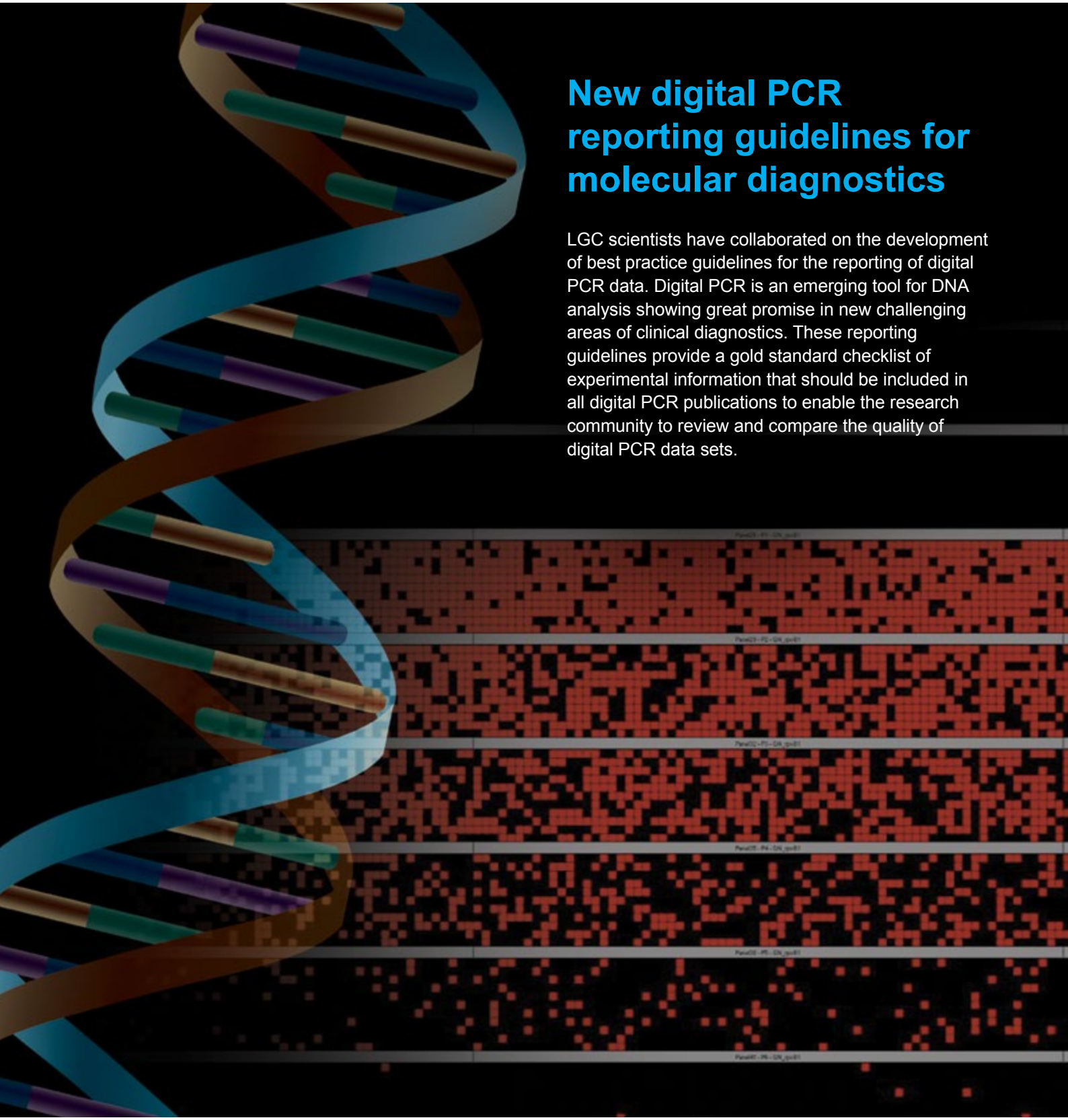

New digital PCR reporting guidelines for molecular diagnostics

LGC scientists have collaborated on the development of best practice guidelines for the reporting of digital PCR data. Digital PCR is an emerging tool for DNA analysis showing great promise in new challenging areas of clinical diagnostics. These reporting guidelines provide a gold standard checklist of experimental information that should be included in all digital PCR publications to enable the research community to review and compare the quality of digital PCR data sets.

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The Requirement

Quantitative polymerase chain reaction (qPCR) has been established as the method of choice for the analysis of DNA since its development in the late 1990s. More recently a modified version of qPCR, known as digital PCR (dPCR), has emerged as a complementary DNA analysis tool offering some advantages over conventional qPCR. dPCR performs absolute quantification of individual DNA molecules (unlike qPCR which allows only relative quantification) with improved precision and sensitivity.

PCR techniques have found many applications in the clinical sector. Recent developments in 'non-invasive' diagnostics – the concept that clinical diagnosis can be made indirectly from a patient's blood sample rather than directly from a tissue biopsy sample – require the detection of extremely low concentrations of DNA. The enhanced measurement performance of dPCR, compared to conventional qPCR, gives the potential for the technique to be used in novel clinical applications.

As these applications are pushing the boundaries of measurement capability it is imperative that they are performed with the utmost diligence and rigour. It is also vitally important that researchers clearly and comprehensively report the specific experimental details used to generate their data, so that the scientific community can compare data in a 'like for like' way and validate research findings through repeat experimentation in other laboratories.

The solution

LGC has become an internationally recognised centre of expertise in dPCR since becoming, in 2008, one of the first UK laboratories to install a microfluidic dPCR platform. Using this expertise, LGC has led an international consortium of molecular biologists to develop a set of industry guidelines for authors of dPCR studies. This defines a gold standard checklist of the information that should be included within a publication when describing data generated using dPCR. These guidelines were published in Clinical Chemistry in 2013 and have been termed the 'Minimum Information for Publication for Digital PCR Experiments (dMIQE)'.[1].

The purpose of the dMIQE guidelines is to:

1. Enable authors to design, perform and report dPCR experiments that have greater scientific integrity
2. Facilitate replication of experiments that are described in published studies in which these guidelines were followed
3. Provide critical information that allows reviewers and editors to measure the technical quality of submitted manuscripts against an established standard.

Impact

The dMIQE guidelines follow in the footsteps of similar guidelines produced for conventional qPCR in 2009 (known as the 'MIQE guidelines' [2]). A recent study co-authored by LGC (published in Nature Methods [3]) shows that the MIQE 2009 guidelines are being adopted and that papers citing use of the guidelines show more experimental detail than those that did not. As with the 2009 guidelines, the adoption of the new dMIQE checklist by the scientific community has the potential to improve the reporting of data when using dPCR. Moreover, PCR assay manufacturers are also promoting use of MIQE and dMIQE.

LGC's Dr Jim Huggett, Science Leader in Nucleic Acid Metrology and main author of the new dMIQE guidelines, adds:

> *"Confidence in the accuracy of results is paramount. We need to encourage data comparability and transparency across the scientific community, which means there needs to be a minimum level of information shared in our published findings. This will help to increase the robustness and reliability of results, as well as reducing measurement uncertainty."*

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References

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2. Bustin SA, et al, *The MIQE guidelines: minimum information for publication of quantitative real-time PCR experiments*. Clin. Chem., 2009, 55, 611-622.
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