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Al clinical study demonstrates major benefits of machine learning for infection detection

In a large prospective <u>clinical trial</u>, diagnostics.ai demonstrated greater accuracy than specialists for routine interpretation of clinical tests for a wide range of pathogens – improving test reliability, reducing costs and freeing up staff for other work including patient care as well as enabling laboratories without access to skilled data analysts to run molecular diagnostic tests.

A study by scientists at NHS Glasgow & Clyde hospital involving some 22,200 tests compares current specialist manual methods for routine DNA/RNA-based infection test interpretation with a new Al system trained to detect a wide range of respiratory viruses and noroviruses. The study finds the Al to be a highly accurate time-saving tool that reduces the complexity of test analysis. The authors conclude that PCR.ai could be taught to detect other viruses, getting results out more quickly, with lower costs and less risk of errors while reducing the need for specialists and hands-on time. The research will be published in the November 2019 issue of the *Journal of Clinical Virology*.

qPCR is globally the most popular method used by diagnostic laboratories for detecting diseases by R/DNA, with hundreds of millions to billions of such tests run each year for patient diagnostics testing. At present, most tests are in-house developed and maintained, and final test interpretation is complex, requiring expertise and rigorous oversight. Over a month, PCR.ai was compared with this manual analysis for 22,200 tests. In no cases was the PCR.ai analysis incorrect, however in a small number of tests the manual result was wrong and was corrected by the AI.

Leading clinical scientists at the WoSSVC (West of Scotland Specialist Virology Centre) at NHS G&C (Glasgow & Clyde Hospital) used two qualitative qPCR tests, one for the detection of a wide range of respiratory pathogens and the other for norovirus. They are both commonly used tests run on commonly used platforms and produced 22,200 test results in one month for comparison purposes.

PCR.ai is a tool developed by diagnostics.ai that can interpret qPCR results after being trained on samples of a chosen virus. The AI uses machine learning for calibration to determine positive, negative and indeterminate samples by analysing a series of tests done previously. Once trained it uses inferencing and so can be used as often as required for chosen tests to provide automated analyses in seconds.

Rory Gunson, co-author and director of WoSSVC: "We believed that automating tests for pathogens could save time and costs in our laboratory and elsewhere but we were surprised at how effective and efficient PCR.ai was. If laboratories were to apply PCR.ai to these and other tests it could help achieve greater standardisation and accuracy, as well as significant savings and turn out results more quickly, ultimately improving patient care."

Aron Cohen, CEO of diagnostics.ai: "We are delighted that this large study was able to demonstrate the capabilities of pcr.ai to deliver consistent high-quality test results with no errors, fatigue or limitations on availability. We believe this is a first demonstration of an AI system not just meeting but rather exceeding specialist capabilities for routine clinical testing. The provision of such a large and wideranging clinical validation dataset was invaluable for verifying accuracy and efficiency of the pcr.ai service, and the results speak for themselves."

There are an estimated 685 million norovirus cases every year, with 200,000 deaths. Though there is no treatment, however if cases can be confirmed rapidly, measures can be taken to reduce transmission and vulnerable patients can be kept hydrated. Respiratory infections can be caused by a number of viruses and if detected quickly appropriate treatment (or discharge) can occur as rapidly as possible, avoiding incorrect prescriptions and resulting in better patient safety and more effective use of scarce hospital resources. These viruses circulate far more widely in the winter months and laboratories can be inundated with tests as it is difficult to retain flexible capacity for seasonal pressures given need to keep costs down.

PCR.ai was found to be straightforward to learn and easy to use. It could standardise the interpretation of in-house qPCR tests and free up experts to focus on other work. It can additionally be used to enable qPCR testing by laboratories without particular expertise in complex manual data-analysis processes. For each run of 60 tests, there was a hands-on time saving of 45 minutes for respiratory virus and 32 minutes for norovirus. This reflects the more complex nature of the respiratory pathogen tests where more than one virus is being screened for.

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WoSSVC (NHS G&C): The WoSSVC (West of Scotland Specialist Virology Centre) delivers routine patient testing services for a large region in Scotland, providing pathology services for thousands of patients every month. Based at NHS Glasgow and Clyde hospital, it is one of the UK's five specialist reference laboratories providing advice on regional and even national issues. Laboratory director and study coauthor Rory Gunson is a globally recognised leader in clinical virology.

diagnostics.ai: the diagnostics.ai team are dedicated to using AI to save lives by transforming the \$170bn clinical testing market - enabling tests to be provided at in a more accurate and timely manner, close to the point of need and at accessible costs without the need for hard-to-find specialists.

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