



National Screening Service
King's Inns House
Parnell Street
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24 January 2019

Dear Colleague

We are writing to inform you of an issue which has arisen in relation to a number of human papillomavirus (HPV) tests carried out on smear test samples by one of our laboratories between 2015 and 2018.

It is important to state that patients who are awaiting their smear test results are not affected by this issue. This issue concerns HPV tests carried out on a number of smear tests, following cytology, during the period 2015 to 2018 and where results were issued.

Quest Laboratories, one of CervicalCheck's three contracted laboratories, has advised us of an issue in relation to a number of standard HPV tests that were carried out outside of the manufacturer's recommended timeframe of 30 days.

These HPV tests were carried out on smear test samples which reported low-grade abnormalities, which is standard practice in the screening programme since 2015.

Our expert clinical team has reviewed the potential for any clinical impact. Evidence shows that these HPV tests are likely to remain effective outside the manufacturer's recommended timeframe. We are therefore assured that this issue poses little risk to women's health. However as a precaution and to ensure women's management recommendations remain appropriate, we will be writing to some women to ask them to attend their GP for a repeat smear test.

Based on our current assessment of the information provided by Quest Laboratories, we expect that up to 6,000 women will likely be called for a repeat smear test. These tests will be processed by the laboratory as a priority. We have been working to validate the details of patients affected, so that we can communicate with patients and their GPs. We expect these letters to be issued by the end of next week.

We appreciate that you may have initially become aware of this issue in the media and we apologise for this. We would like to state that this was not our intention and formal communication to patients and their GPs was planned to be issued in advance of other public communication.

We understand that patients may have queries or concerns and we appreciate your assistance during this time to provide support and reassurance to any concerned patients. We will be keeping information on this issue, and all aspects of cervical screening, updated on our website – www.hse.ie/cervicalcheck.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Peter McKenna'.

Dr Peter McKenna
Clinical Director
CervicalCheck – The National Cervical Screening Programme