



12 February 2019

Stephen Donnelly, TD

Email: Stephen.Donnelly@oireachtas.ie

PQ 4339/19

To ask the Minister for Health the number of repeat cervical smear tests conducted since May 2018 that are now invalid owing to delays in assessing them; and if he will make a statement on the matter.

Dear Deputy

I refer to the above parliamentary question.

CervicalCheck – The National Cervical Screening Programme processes approximately 250,000 cervical screening tests each year. In 2018, an additional 84,000 women came forward for screening, due to understandable concerns about cervical screening following the CervicalCheck crisis. Almost 350,000 screening tests were submitted during 2018 and approximately 82,000 of these are still being processed by our laboratories.

In April last year, the Minister for Health announced that any woman of screening age with concerns about her cervical screening could avail of a free consultation, and if necessary, a free repeat smear test with any GP registered with CervicalCheck. These services ceased, as scheduled, on 31st December 2018. Cervical screening is one of the most effective ways to prevent cervical cancer and the HSE recommends that all women aged 25 to 60 continue to attend their regular free cervical screening (smear) tests when invited.

In relation to the 'number of repeat smear tests conducted since May 2018 that are now invalid owing to delays in assessing them', from April to December 2018 the rate of expired cervical screening samples and vials among all samples processed by CervicalCheck was 0.25% or 550 out of 214,141 samples taken. This compares with a rate of 0.23% for the same period in 2017 and a difference of 49 expired vials or samples between 2017 and 2018.

A separate issue emerged last November, when CervicalCheck was informed by the laboratory Quest Diagnostics that a number of standard secondary HPV tests carried out on samples which reported low grade changes were done so outside the manufacturer's recommended time frame. This came to light in the context of ongoing improvement work across the screening programme, including strengthening quality assurance processes as recommended in the Scally Report.

Teach Óstaí an Rí, 200 Sráid Parnell, Baile Átha Cliath. King's Inns House, 200 Parnell Street, Dublin 1.
☎ 353 1 865 9300 ✉ info@cancerscreening.ie www.cancerscreening.ie





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On learning of this issue, action was immediately taken by CervicalCheck to validate the information supplied by the laboratory, review any clinical impact and communicate with women affected as a matter of priority. CervicalCheck's clinical management, based on clinical evidence, is assured that these HPV tests are effective outside the manufacturer's recommended timeframe. However in order to provide complete reassurance, we have asked some women to attend for a repeat smear test. CervicalCheck has written to women affected, and their healthcare professionals, to advise them of this issue and any follow-up action that might be required.

I trust this information is of assistance to you.

Yours sincerely

Frances McNamara
Interim Head of Screening
National Screening Service

Cc pquestions@hse.ie

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An tSeirbhís Náisiúnta Scagthástála
National Screening Service



BreastCheck
An Clár Náisiúnta Scagthástála Gcú.
The National Breast Screening Programme



CervicalCheck
AN CLÁR NÁISIÚNTA SCAGHTÁSTÁLA CERVICÉACAS
THE NATIONAL CERVICAL SCREENING PROGRAMME



BowelScreen
An Clár Náisiúnta Scagthástála Pulóige
The National Bowel Screening Programme



Diabetic
RetinaScreen
An Clár Náisiúnta Scagthástála Retine dá Dhuibéiligh
The National Diabetic Retinal Screening Programme