An tSeirbhís Náisiúnta Scagthástála
National Screening Service

17 October 2019

Our ref: GM/Communications

Brid Smith, TD
Email: brid.smith@oireachtas.ie

PQ 40777/19
To ask the Minister for Health the laboratories from which the 221 cases in relation to Cervical Check of misdiagnosed smears came by laboratory, by year in tabular form

Dear Deputy

I refer to the above parliamentary question.

Firstly, I would like to provide clarification on the word 'misdiagnosed' used in your question. A cervical screening test is a way of detecting abnormal cells in the cervix. It looks to see if a woman might be at greater risk of developing cervical cancer in the future. It is not a diagnostic test, i.e. a test that is offered to people who have symptoms or to those identified to be at risk of a disease.

In the case of the 221 women impacted by the original CervicalCheck audit, a review of their cytology slides gave a different interpretation to the original result. While those interpretations may have resulted in a different referral pathway for women, it is not accurate to describe them as 'misdiagnoses' because screening, as stated above, is not a diagnostic test.

I attach for your reference the *221 Patient Group Laboratory Audit Results Profile* report. It provides information as to which laboratories reviewed cervical screening slides for the 221 women impacted by the original CervicalCheck audit. In particular, I would like to draw your attention to Table 4 on page 8, which contains the specific information that you have requested.

This report was commissioned by the HSE CervicalCheck Steering Group in conjunction with the 221+ Support Group. As well as outlining the laboratories that reviewed slides for the 221 group, it highlights the impacting factors that need to be considered when referencing the data.

The information in this report represents a very small subset of overall data for CervicalCheck, which has completed in excess of 3 million screening tests since 2008. The 221 patient group is a self-selecting patient population based on an adverse outcome. Implicit in sub-set analysis is the concept of statistical anomaly. As such, while this data is accurate as to which laboratories were used for women within the 221 group, it would not be statistically sound to use it as a means of assessing the performance of any particular laboratory.

The performance of laboratories used by CervicalCheck has been analysed by Dr Scally and has been found to be within the required standards. Our ongoing performance of laboratories is a key part of quality assurance for the programme; no single metric is used to measure it, rather a range of measures which are carried out at regular intervals. Quality assurance measures taken by CervicalCheck include regular monitoring of key performance indicators, including at individual screener level, and increased quality assurance visits to laboratories.

I trust this information is of assistance to you but should you have any further queries please contact me.

Yours sincerely

Celine Fitzgerald
Interim CEO
National Screening Service