An tSeirbhís Náisiúnta Scagthástála
National Screening Service

15 December 2020

Deputy Kathleen Funchion
kathleen.funchion@oireachtas.ie

Our Ref: HM/Communications

PQ39825/20: To ask the Minister for Health the number of women that have had to have a repeat cervical check due to the fact their samples were out of date by the time they were presented at labs in the USA for testing, by county in tabular form.

Dear Deputy Funchion,

I refer to the above Parliamentary Question.

Firstly, I would like to explain how samples can be categorised as out of date. Out-of-date samples are a factor in all cervical screening programmes worldwide, and can occur in one of two ways, as follows:

Expired vial: Each sample vial has a manufacturer's expiry date recorded. These vials are distributed to sampletaking premises with a minimum shelf life of 18 months at delivery. As per manufacturer's instructions, samples cannot be analysed if the vial is not in-date on receipt at the screening laboratory. Practices that submit samples in out-of-date vials are recorded and contacted by CervicalCheck.

Expired sample: Each sample is viable for 42 days once taken. Since the implementation of HPV cervical screening on March 2020, the sample must be received on or before day 35. This is to allow time for HPV testing and any reflex cytology testing required before day 42 - as per manufacturer storage requirements. Practices that do not submit samples in a timely fashion are recorded and contacted by CervicalCheck.

If a person's result is in an expired vial or the sample has expired, they must have a repeat screen taken in three months' time. We continue to emphasise to sampletakers the importance of checking vial dates and timely submission of samples.

Number of repeat tests
Unfortunately we do not record the data on repeat tests on a per-county basis. However, the below table illustrates the number of samples where a repeat test was requested due to an expired sample or expired vial received by the laboratory, in 2019 and 2020. The numbers given up to March 2020 relate to samples taken for cytology testing. Please note, unique samples do not always equate to unique participants, as some people may have multiple samples taken in the time period.

Test date	01/01/2019 to 29/03/2020 (source CS/OPR/A-8)	06/07/2020-01/12/2020 (source- TIQ log Quest)	Total
No. of samples where repeat test was requested due to expired sample received by the laboratory	622	54	676

No. of samples where repeat test was requested due to expired vial received by the laboratory	518	419	937

On March 30, 2020 CervicalCheck introduced the HPV test as the primary screening method for the detection of abnormal cervical cells which could develop into cervical cancer. This policy change was recommended in a report by HIQA in 2017 and was made after approval by the Department of Health. It brings the Irish cervical screening programme in line with international best practice in cervical screening. Numbers given subsequent to March 30 relate to samples taken for HPV cervical screening.

Between programme restart on 06 July until 01 December, c89,000 sample notifications have been received. Of these, 0.06% were expired samples and 0.5% were expired vials.

Since HPV cervical screening began in March 2020, all samples have been analysed in Quest Diagnostics Inc in the US. Samples are received in Dublin, where they are identified as being in out-of-date vials or too old to process. All other samples are shipped overnight for analysis in the US screening laboratory. Samples received in out-of-date vials or when too old to process are not included in the shipment to the US.

For other queries please call the Freephone information line on 1800 45 45 55, email info@cervicalcheck.ie or contact your clinic directly.

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

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Fiona Murphy
Chief Executive
National Screening Service