



Our Ref: GM/Communications

9 February 2022

Deputy David Cullinane TD david.cullinane@oireachtas.ie

PQ3715/22: To ask the Minister for Health the number of CervicalCheck samples sent abroad in 2021; the laboratories to which these were sent; the way these services were procured; if these laboratories were inspected by a State body or otherwise certified for quality; and if he will make a statement on the matter.

Dear Deputy,

I refer to the query above.

Laboratories: CervicalCheck uses two quality-assured laboratory providers to process its cervical screening samples. These are Quest Diagnostics in the USA, and the Coombe Women and Infants University Hospital (CWIUH) in Dublin. The laboratories perform HPV primary testing and reflex cytology testing. The quality assurance requirements and standards for the cervical screening programme are based on European guidance, as set out in the European guidelines for quality assurance in cervical cancer screening, and our Standards for Quality Assurance in Cervical Screening.

We use a laboratory provider in the US because there are not enough quality-assured labs available in Ireland to meet our needs, and to ensure resilience in our system. We are this year progressing with the development of the National Cervical Screening Laboratory, in collaboration with the CWIUH. We expect this new laboratory to be operational later this year.

Procurement: The procurement for the private laboratory services was through the EU tendering process. A Memorandum of Understanding in place with the CWIUH, as it is a public body.

Samples sent abroad for processing: CervicalCheck sent 326,490 samples abroad for testing in 2021. Samples were sent to Quest Diagnostics' laboratory facilities in Teterboro and Clifton (both in New Jersey in the US).

Quality certification of US laboratory provider: Quest laboratory facilities are accredited by the College of American Pathologists. They were subject to CervicalCheck Quality Assurance audits in April and November 2019, and in June and November 2021.

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

Yours sincerely,

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Fiona Murphy Chief Executive, National Screening Service









