Chairperson, Members of the Committee,

The Academy of Clinical Science and Laboratory Medicine (the Academy) wishes to offer heartfelt sympathies to all those affected by the current cervical screening tragedy. Recent weeks have been an extremely worrying time for many Irish women and their families and has also affected the healthcare professionals providing their care in Ireland.

The Academy is the professional body, and competent authority, representing Medical Scientists in Ireland. Medical Scientists are a regulated profession. Since 1996 all Medical Scientists must hold qualifications accredited, or approved, by the Academy. We welcome the reviews called for by the Minister and we will work with the Department of Health, the Minister, the HSE, CervicalCheck and all other agencies to achieve the best outcomes for women having cervical screening in Ireland.

The Academy is part of the newly established Expert Advisory Group on Cervical Screening. The Academy will fully participate in, and make submissions to any Government or statutory enquiry, and it will use its expertise to contribute to initiatives to improve all cancer screening programmes.

In 2008, a decision was taken to tender for screening cytology (Cervical smear test analysis) which resulted in this service, previously undertaken in laboratories in hospitals in Ireland, being largely delivered by laboratories in the USA. The Academy wishes to clarify that the Irish accredited laboratories that tendered for the cervical screening service in 2007/2008, were informed that they had scored highly in all areas (quality and turn-around times) except cost. The Academy is on record as stating that the decision to outsource this screening service was short sighted. One consequence of this decision to outsource is that the Academy does not have access to information from these laboratories and is therefore not in a position to comment on the quality metrics or standards of individual laboratories at this time. Should the Scally Scoping Report identify any suboptimal performance within laboratories currently providing this service, a rigorous approach to remedying these issues will be required to bring them in to line with international standards.
Cervical screening is a screen and not a diagnostic test. Cervical screening, which involves the pathological analysis of cells from the cervix for pre-cancerous changes, still remains the most reliable and effective way of preventing and detecting early cancers. Screening that is done through a national, organised screening service, where regular smears are performed as part of a screening cycle, has helped to reduce the rate of cervical cancer in Ireland. The cervical smear is not 100% sensitive for detection of all cervical abnormalities, but when performed to a high standard as part of a screening programme, it should significantly reduce the number of women who are diagnosed with cervical cancer. In the UK there has been a 50% reduction in cervical cancer since the implementation of the screening programme in the 1960s. Medical scientists examining a smear are required to reach individual ‘pick-up’ or detection rates of 95% or greater for high-grade abnormalities, and greater than 90% for all abnormalities.

The minimum standard that the Academy recommends and would support for cervical screening in Ireland is for each smear to be examined independently by two medical scientists specialising in cervical cytology, under the governance of a clinical pathologist, in accordance with CervicalCheck ‘Guidelines for Quality Assurance in Cervical Screening’. These guidelines are based on the British Association for Cytopathology ‘Recommended Code of Practice for Cytology Laboratories.

The professional staff in cytology screening laboratories in Ireland are medical scientists and pathologists, both having specific qualifications and training. All cervical screening laboratories in Ireland practice to ISO 15189 quality standards. These professional and quality standards in cytology and other clinical laboratories ensure that the test method and verification, result interpretation and reporting are controlled, audited and inspected. This is in keeping with international best practice.

The Academy fully supports the introduction of the primary HPV test and is available to work with the National Screening Service to advise on future pathological service provision for this and other cancer screening programmes. The system chosen for HPV testing must be selected based on the sensitivity of detection, not cost.

The Academy advises and recommends that on introduction of HPV screening, the entire cervical screening service be re-established in Ireland to ensure an entirely integrated service for HPV, Cytology, Colposcopy and Histopathology for the women of Ireland in the one health system, ensuring continuity of care, and clinical governance. The Academy advises that this laboratory service be configured, led and managed by consultant medical scientists and pathologists, a service configuration that is now emerging as standard practice in the UK.

The Academy recommends and advises that the cervical screening programme that is put in place for the women of Ireland is quality assured subject to regular independent audit and review against current best practice.

The Academy’s position, in the interest of public safety, is that all the clinical laboratory services must be fully integrated with clinical services. It must be provided by qualified, registered professionals, in a properly resourced accredited system.