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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Health Protection (Notification) Regulations 2010 (“the Principal Regulations”) and require diagnostic laboratories that process tests, and persons who carry out point of care tests, for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or influenza virus to notify Public Health England of the results of those tests.

Regulation 3 amends regulation 4 of the Principal Regulations to require diagnostic laboratories to notify Public Health England of the results of the SARS-CoV-2 or influenza virus detection tests which they process.

Regulation 4 inserts a new regulation 4A into the Principal Regulations. This regulation sets out the information that must be provided to Public Health England by those who carry out point of care tests for the detection of SARS-CoV-2 or influenza virus. Point of care tests are diagnostic tests which are carried out otherwise than in a diagnostic laboratory. It provides that someone who fails without reasonable excuse to comply with this regulation commits an offence for which, on summary conviction, that person would be liable for a fine.

Regulation 5 amends regulation 7 of the Principal Regulations to ensure that the notification made under regulation 4A may be made electronically where there is consent.

The net costs imposed on business, the voluntary sector and the public sector by these Regulations have been assessed as being less than £5m in any year and therefore a full impact assessment has not been prepared.