Review of allergen analytical testing methodologies: Estimation of costs

An estimation of costs associated with setting up a testing service for the main technologies identified for current allergen testing techniques (ELISA, PCR and LC- MS with multiple reaction monitoring) in an established laboratory that already offers testing services and with personnel already trained in the relevant technology is set out in Appendix 3.

This estimate assumes that the laboratory already has access to common laboratory equipment including centrifuge, vortex, incubator, fridge freezer, pipettes. Equipment servicing and calibration are not included in this cost estimate. Average prices have been taken for consumables (included testing kits, RMs). Costs of method-specific items (plate reader, real-time PCR instrument, LC-MS instrument) have been averaged from recent quotes received. In terms of analyst time, 1 day equates to 7.5 hours.

Costs to gain UKAS-accreditation have not been included as these will, to some extent, depend on the size of the organisation, the policies and procedures already in place, the number of test services offered and the current UKAS status. There will be costs linked provision of general policies and procedures, record keeping, quality management such as non-conformance investigations, complaints procedure, equipment performance checks, training, laboratory information management system, equipment maintenance, calibration and servicing. There will also be costs linked to ISO 9001 certification and audit.

Regarding the costs of the different techniques, ELISA is a relatively low-cost laboratory technique with the instrumentation involved costing around £16K and each test kit costing around £250 to accommodate the analysis of approximately 14 samples in duplicate along with QCs and standards. PCR is more expensive, with the associated hardware costing around £61.5K and test kit costs are approximately in line with ELISA kits. Both techniques are often offered by a wide range of laboratories and are used for a wide range of food (and other) testing requirements in addition to allergen testing. Mass spectrometry methods tend to be offered by a smaller number of testing laboratories, requiring a hardware investment of upwards of approximately £416K.

Regarding costs to businesses for submitting samples for allergen testing, depending on the allergen required, analysis can be completed by testing labs, charging from approximately £55 to £141 per sample for UKAS-accredited testing with a standard turnaround of five working days.