Laboratory Diagnostics, Point of Care Testing and Pathology Managed Services Framework Agreement Objective Conditions

Condition		Definition
Innovation and Development		This justification relates to (a) research and development contracts, where the production or supply concerns a specific prototype, or "novel" goods and services which the contracting authority has commissioned for development. The goods or services concerned must have been produced for one or more of three specified purposes; namely, testing their suitability, researching whether their production at scale would be viable, and any other research, experiment, study, or development (b) the act of creating new financial models, products or processes
Additional or repeat goods, services or works by existing suppliers	**Extension**	where the supply of goods, services, or works by an existing supplier is required as an extension to or partial replacement of those already in place. This is permitted where the sourcing of alternative goods, services, or works would result in an incompatibility with the existing goods, services, or works. If the original contract is outside of NHS Supply Chain framework agreements, the extension must utilise the NHS Supply Chain framework Call-off Terms and Conditions.
	Similar Goods/Services	This justification can be used if: (a) the original contract was awarded within the period of five years ending with the day of publication of the transparency notice (see our first article on Notices); (b) the intention to rely on this direct award justification to procure those similar goods, services or works was made clear in the authority's tender notice or tender documents for the original contract
Urgency		This applies where a situation of "extreme and unavoidable urgency" exists, such that there is no time to run a competitive tender. Note: this justification does not apply where the urgency stems from any act or omission of the authority, or arises from a situation that should have been foreseen by that authority.
Switching to direct award where no suitable tenders have been received		Provided a supplier is not an excluded supplier, a contracting authority can award it a public contract directly if it has run a competitive tendering process but has received no suitable tenders or requests to participate.

		What is “not suitable”? Under Section 42(2), a tender or request to participate is not suitable if: (a) it would be disregarded on the grounds set out under Section 18(3) (e.g. because it does not satisfy the conditions of participation or materially breaches a procedural requirement in the tender notice or tender documents); (b) it does not satisfy the award criteria when assessed by reference to the assessment methodology and the relative importance of the criteria; (c) the price is abnormally low; or (d) there is evidence of corruption or collusion between suppliers or between suppliers and contracting authorities.
The standardisation of equipment, goods and services.		This justification can be used where: (a) A customer has goods or services and requires an Original Equipment Manufacturer (OEM) to provide a mix of its own and third-party equipment, consumables, reagents and services (b) A customer requires a Vendor Neural supplier to provide provision for the management of multiple third party equipment, consumables, reagents and services
Clinical Justification	**Semi/Fully Automated**	Measurement of diagnostically relevant characteristics of biological samples in a short time period with minimal human or manual intervention
	Capacity	The maximum number/volume of samples that can be loaded and analysed on an analyser, instrument or device during a defined period of time
	Connectivity and Interoperability	The ability of analyser, equipment, instrument or device to interface with IT systems (e.g. Laboratory Information Management Systems, middleware) in order to track and manage patient samples or devices to work in conjunction to exchange and utilise test or sample information between them; and between laboratory and clinical settings and systems
	Detection Method	The primary biological detection process employed on an analyser, instrument or device to measure and detect a certain diagnostically relevant analyte from a biological sample. For example, PCR-ELISA or FISH in Molecular Testing

	Image Quality	The accuracy of imaging systems – e.g. microscopes – to capture, process, store, transmit or display the signals from an image
	Position (upright v inverted)	In microscopy, the orientation by which the image is viewed in terms of the position of objectives relative to the stage; in an upright microscope, the objective is placed above the stage (ideal for fixed/coverslip samples) whereas an inverted microscope will have objectives placed below the stage
	Resolution	In microscopy, resolution refers to ability to distinguish detail, defined as the minimum distance at which two point on a specimen can be distinguished as separate entities by the user or the microscope camera
	Sensitivity	Also known as the true positive rate, sensitivity is a measure of the proportion of actual positives correctly identified from the test i.e. the ability of the test to correctly identify patients who do have a particular disease or condition
	Specificity	Also known as the true negative rate, specificity refers to the proportion of actual negatives correctly identified from the test; e.g. the ability of the test to correctly identified patients who do not have a particular disease or condition
	Standardisation	The ability to streamline testing methodologies or analyser capability to carry out a test in a more simplified or faster way without comprising accuracy and quality of results
	Temperature Range	The difference between the minimum and maximum temperature reached on an analyser, instrument or device during the testing process
	Throughput	For analysers, instruments or devices, the maximum number of tests that can be performed in a defined time period
	Internal Controls	A measure of precision designed to detect and reduce errors in analytical process or sample testing process to improve the quality of the results issued

	Training Requirements	The extent to which users must undergo training in order to effectively use an analyser, equipment, instrument or device in order to generate accurate and reliable results
	Turnaround Times	The time from when a test is ordered to when the result is reported; definitions may vary according to the test type or laboratory
	Installation	The process (or constraints) by which an analyser, equipment, instrument or device is fitted or put into place in the correct environment, such as a medical laboratory or ward
	Internal Components	The sub-parts required to assemble an analyser, equipment, instrument or device correctly; or to enable the end to end testing of biological sample; or to ensure the maintenance of conditions within the laboratory e.g. temperature control monitors
Other		The Participating Authority may add a Heading to cover a specific requirement which is not covered above