

Recently, 120 European clinical laboratories were surveyed to discover exactly what they are looking for in an immunoassay system. Here, the findings from France, Germany, Italy and Spain are reported.

Ease-of-use, traceability and result security – the top priorities for European laboratories

The survey, conducted by leading market research group TNS Sofres, found that laboratories had a significant number of expectations regarding immunoassay (IA) systems, with priority being given to three main criteria: ease-of-use, traceability and security of results.

The survey was conducted with 120 laboratory directors in four European countries – France, Germany, Italy and Spain. Thirty clinical laboratories in each country were interviewed by telephone between November and December 2003. An equal proportion of private (50%) and public (50%) laboratories were surveyed; however, the survey profile was confined to laboratories processing between 100–400 IA tests per day (Fig 1).

The purpose of the survey was to identify the key criteria and expectations of laboratory decision-makers when considering the choice of an immunoassay system. The survey covered four main topics: essential technical features of an IA system; ease-of-use; traceability; and choice of supplier. Also explored were issues such as maintenance times, test menu size, customisation and type of data archived.

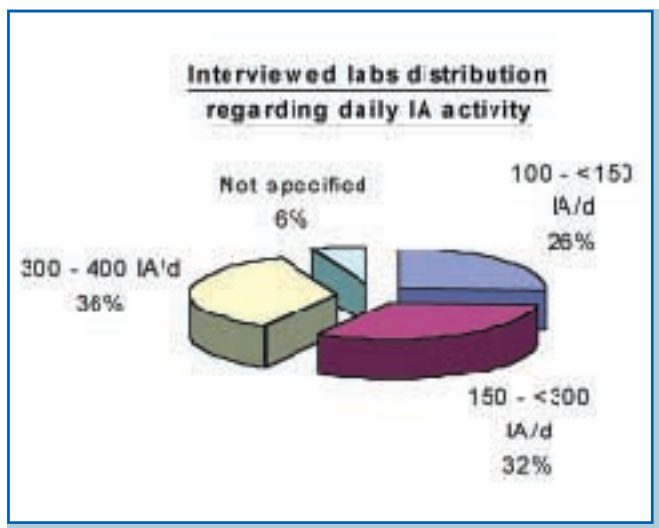
Essential technical features

The survey found that laboratories have very clear expectations of technical performance. When questioned on a list of technical features relating to IA systems, the number of features considered to be 'very important' was unusually high, according to TNS Sofres. However,

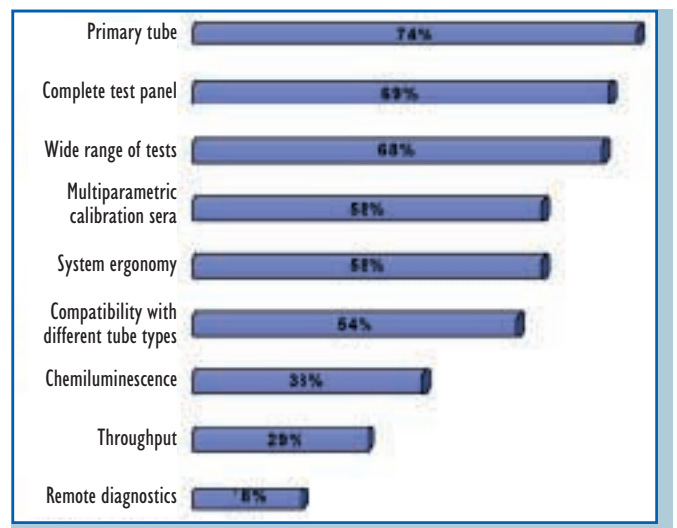
this can be explained by the fact that the features listed were highly specific to the clinical laboratory environment.

For example, the use of a primary tube came top of the list of 'very important' features (74% of laboratories overall). This figure rose to 83% and 87% in France and Italy, respectively. In second position came the availability of complete panels (69%) and a wide test range in both immunochemistry and infectious diseases (68%). Multiparametric calibration sera and system ergonomics came in joint third place with 58%.

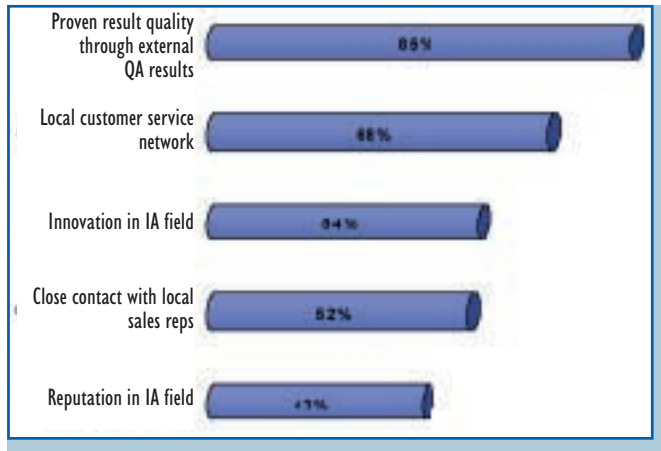
Figure 2 shows full details of technical features. When questioned about reagent menu size, surveyed laboratories specified the average number of parameters expected on an IA system to be 20.



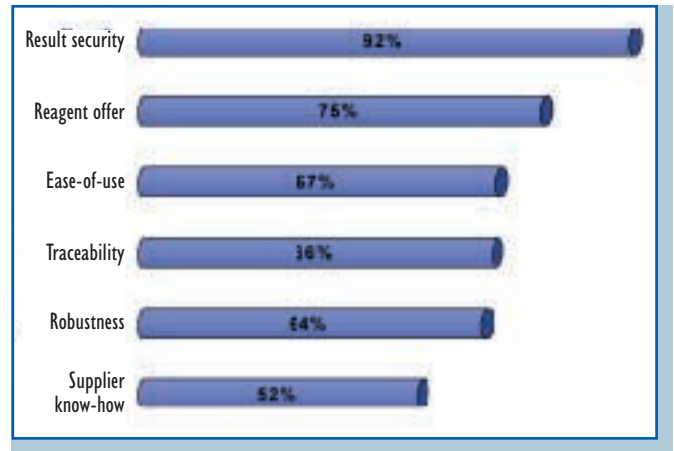
▲ Fig 1. Laboratory profile of daily IA activity.



▲ Fig 2. Technical features rated very important.



▲ **Fig 3.** Supplier criteria rated very important.



▲ **Fig 4.** Top IA system criteria rated very important.

Ease-of-use for efficient workload processing

In a busy laboratory environment, ease-of-use is essential for efficient workload processing. The survey revealed several aspects of ease-of-use to be classed as 'very important': user-friendly interface (65%); easy maintenance (63%); automatic data entry (63%), short operator training of less than three days (63%); and operator time spent on maintenance (47%). When questioned further on the subject of maintenance, 93% of laboratories declared that a daily maintenance time of less than 15 minutes would be an advantage.

Laboratories also considered alarm customisation to be an important 'ease-of-use' feature. Customised alarms were expected for reagent/consumable levels (59%), specific alarms for validation assistance (48%) and the frequency of controls (38%).

Traceability contributes to laboratory management

Traceability is an issue that is taking on increasing importance in today's immunoassay laboratories. Although imposed by local regulatory authorities according to 89% of laboratories surveyed (rising to 100% of laboratories in France), traceability is nevertheless seen to contribute positively to laboratory management and security.

In the survey, laboratories were asked to imagine an automated analyser that could offer automatic storage and traceability of the relevant information required to validate a test result (ie date, lot number and shelf-life, reagent, operator), as well as the calibration and controls performed. The large majority of survey participants (95%) considered it important for their laboratory to be able to have fully automated traceability of each result, both from the test itself and from the calibration and controls. In addition, they reported that this type

What are laboratories looking for in an IA system?

- 87% considered that full traceability improved incident management
- 85% prioritised high-quality results proven by external QA in choice of supplier
- 65% classed user-friendly interface as top ease-of-use criterion

of full traceability (ie result, calibration, control) would be useful in the event of medicolegal issues (95%), and in improving laboratory incident management (87%).

Result quality determines choice of supplier

Running parallel to the technical choices of an IA system is the choice of the system supplier. Significantly, proven result quality through external quality assessment (Q&A) results clearly topped the list of supplier choice criteria, with 85% of the laboratories interviewed classing it as a 'very important' criterion. This indicates that there is now generalised acceptance of the importance of external control validations among laboratories.

The comparison of objective results on the performance of commercialised immunoassay systems obtained by official national and international organisations can be a useful element in helping laboratories to orient their choice in terms of both the instrument and the supplier.

Other 'very important' factors entering into the choice of a supplier are shown in Figure 3.

Top expectations for IA systems

Result security figured, not surprisingly, at the top of the list of 'very important' IA system expectations for 92% of laboratories surveyed. Providing reliable results is, of course, critical to the reputation of a clinical laboratory, and

external quality assessment results – also cited in the survey as the most important criterion for choosing an IA system supplier – can be used to identify the most secure systems available.

In second position came the reagent offer on the system (75%), which was particularly important for German laboratories. Ease-of-use (67%), traceability (66%) and robustness (64%) all held almost the same level of importance. Manufacturer's know-how was also found to be a criterion entering into the choice of an IA system (52%).

Although the survey results should be interpreted on a European rather than on a country level, certain trends can nevertheless be outlined. For example, in Italy, ease-of-use and traceability are the most important system features, with innovation and reputation being the top criterion for choosing a supplier. In Spain, however, a polyvalent system (large reagent menu) and close relations with a well-known supplier are most demanded. In France, the criteria of choice focus on traceability and polyvalence for the system, and a strong local customer service network for the supplier. In Germany, a large reagent offer is the top requirement. [PIP](#)

TNS Sofres draws attention to the fact that the results of this survey are based on an unweighted average of the countries included. Although the survey population was relatively limited, it was highly homogeneous in profile (clinical laboratory directors), which increases the value of the results as representative of the targeted population.

Further details are available from Mrs Karine Bondarenko, Healthcare Department, 138 avenue Marx Dormoy, 92129 Montrouge, France (tel + 33 [0]1 40 92 47 60) www.tns-sofres.com

