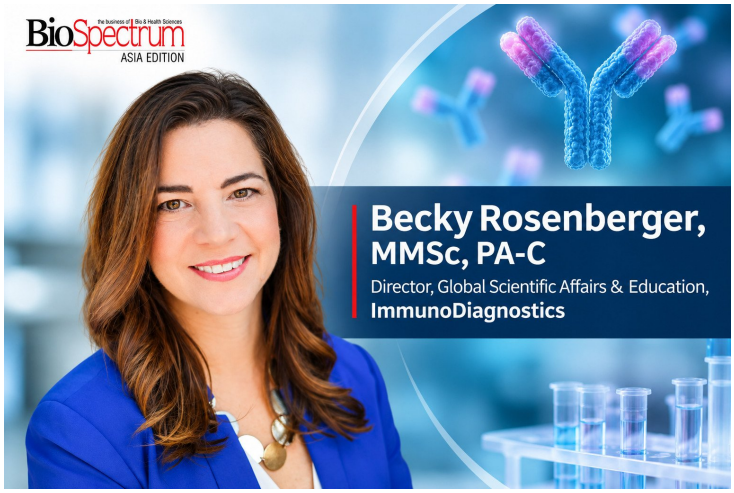
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Smarter Testing and AI Are Redefining the Future of Autoimmune and Allergy Diagnostics

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Becky Rosenberger explains why diagnostic precision, connected laboratory data and intelligent automation will be critical to delivering faster, more reliable and personalised patient care.



As autoimmune and allergic diseases present increasingly complex diagnostic challenges, laboratories face growing pressure to deliver faster, more accurate and clinically meaningful results. In an interview with *BioSpectrum Asia*, **Becky Rosenberger, MMSc, PA-C, Director, Global Scientific Affairs & Education, ImmunoDiagnostics**, discusses the evolving role of laboratory standardisation, specific IgE testing, digital connectivity and artificial intelligence. She highlights why the future of diagnostics lies not simply in performing more tests, but in translating reliable laboratory data into actionable clinical insights while preserving the importance of professional judgement.

Autoimmune and allergy conditions often present with overlapping symptoms. From a laboratory perspective, what are the biggest diagnostic complexities today, and how are they evolving?

Autoimmune and allergic conditions are immunologically distinct, but both can be diagnostically challenging because many of their clinical manifestations are nonspecific and may overlap with other inflammatory, infectious, dermatologic, respiratory or gastrointestinal conditions. Allergic diseases have increased significantly over time and now affect an estimated 10% to 30% of the global population, while the frequency of autoimmune disorders varies markedly, with conditions such as autoimmune thyroid disease and rheumatoid arthritis driving most of the burden. Environmental exposures and sensitization patterns can also differ considerably between populations – and for both categories, arriving at an accurate diagnosis is rarely a single-step process.

That difficulty is especially pronounced on the autoimmune side. Many patients may experience a prolonged diagnostic journey because these conditions do not present with a single, definitive symptom or laboratory marker. Fatigue is a common and often debilitating symptom among people with autoimmune disease. One review estimated that nearly 98% of individuals with autoimmune disease report experiencing fatigue, compared with an estimated 7–45% of the general population experiencing persistent fatigue. From a laboratory perspective, the challenge is therefore less about confirming

one suspected diagnosis and more about interpreting multiple, often nonspecific findings within the broader clinical picture.

Polyautoimmunity adds another layer of complexity. A systematic review and meta-analysis estimated overt polyautoimmunity in approximately 13% of patients with autoimmune thyroid disease, illustrating that more than one autoimmune process may coexist in the same individual. Clinically, this means that new symptoms should not automatically be attributed to an established diagnosis and they may warrant reassessment for another autoimmune disease or an unrelated process.

Timing is also important. Autoimmune and allergic diseases can fluctuate between periods of activity and remission, and laboratory findings may change accordingly. A single measurement may therefore provide only a snapshot of a disease process that is inherently dynamic. As a result, the role of laboratory testing is increasingly moving toward longitudinal assessment, which needs to be disease and marker specific. Certain laboratory measurements can contribute to monitoring select autoimmune diseases, while other tests generally should not be repeated simply to monitor established disease. The evolving emphasis is on diagnostic stewardship rather than simply generating more data: selecting the appropriate test for the clinical question and understanding whether its validated role is in diagnosis, risk assessment or longitudinal monitoring.

With rising test volumes, how are laboratories balancing the need for speed with the requirement for high clinical accuracy and reproducibility?

The goal is not to achieve faster turnaround time at the expense of quality, but to reduce unnecessary variability throughout the total testing process. Pre-analytical errors account for roughly 46% to 68% of all laboratory errors, and they occur before a sample ever reaches the analyzer, including issues such as mislabeling, incorrect tube selection, inadequate collection and hemolysis. Studies also demonstrate that workload, specimen handling and identification processes can materially affect laboratory quality.

That is where laboratories can make a meaningful difference, and it illustrates why speed and accuracy do not necessarily have to compete. Closing that error gap through standardized collection and handling procedures, barcode-based identification, appropriate automation and well-designed laboratory information systems can reduce manual steps and improve traceability.

Laboratory environments can range from highly centralized reference laboratories to geographically dispersed health systems with very different workforce, infrastructure and connectivity needs. Ultimately, reproducibility helps ensure that results are delivered quickly enough to support clinical decisions and reliably enough to act on with confidence. A rapid result that requires repeat testing is not truly a faster result. It simply moves the delay to a later stage of the diagnostic process.

How are standardized workflows and structured testing pathways helping laboratories reduce variability and improve diagnostic confidence?

The greatest value does not necessarily come from performing more tests. It often comes from selecting, sequencing and reporting tests more deliberately. When a patient presents with overlapping or ambiguous symptoms, the instinct may be to broaden the testing panel in the hope that an additional result will provide clarity. Structured pathways instead take a more defined approach by establishing which markers are clinically relevant for a given presentation, the sequence in which they should be evaluated and which result patterns warrant additional testing or specialist evaluation.

That structure can meaningfully reduce variability. When a pathway is established in advance, technologists and clinicians are working from the same validated framework rather than relying on individual interpretation for each case. This can help ensure that comparable samples are evaluated consistently, regardless of who is reviewing the case or when the testing is performed. For clinicians, that consistency provides greater confidence that a result reflects the patient's underlying biology rather than differences in how the testing process was applied.

Standardized reporting is equally important, but standardization does not always mean applying identical numerical cutoffs across every assay or laboratory. Different analytical methods may have different performance characteristics. Harmonized terminology, validated method specific reference intervals, transparent reporting of methodology, likelihood ratios and clinically relevant interpretive comments can make results easier to interpret across laboratories and care settings. This is particularly important in autoimmune and allergic disease, where a single marker rarely provides a complete answer and laboratory findings must be considered alongside the patient's broader clinical picture.

At a system level, well-designed pathways can also help laboratories manage increasing test volumes more consistently. A laboratory operating from validated, well-documented pathways can accommodate additional volume without every case becoming an ad hoc decision.

Standardization is not about removing clinical judgment from the process. It is about applying that judgment where it adds the most value, while allowing routine, well-characterized cases to move efficiently through an established pathway.

In allergy diagnostics, specific IgE testing remains central to identifying sensitization to food and environmental allergens. How is this area evolving, and what role do automation and digital connectivity play in enhancing its clinical value?

The most important principle remains that a positive serum specific IgE result provides evidence of sensitization, but sensitization alone does not establish clinical allergy. The field is therefore moving toward a more contextual approach, in which specific IgE testing algorithms and results are considered alongside a patient's symptoms, clinical history and prior reactions rather than interpreted in isolation. Advances in automation and assay technology can support that evolution by improving consistency and reproducibility across testing. One area of continued development is the use of allergen components to further characterize IgE sensitization in selected clinical scenarios. Component resolved diagnostics (CRD) can help distinguish primary sensitization from cross-reactivity and, for certain allergens, provide clinically relevant information beyond whole-allergen extracts.

Standardized automated processes can reduce technique-dependent variation while allowing laboratories to manage increasing test volumes efficiently. A staged approach can begin with testing to the clinically relevant whole allergen, followed by reflex testing to appropriate allergen components when predefined criteria are met. When integrated through laboratory information systems or middleware, these pathways can support more consistent testing workflows, reduce manual steps and maintain connectivity between initial sensitization results and subsequent allergen component findings. This is particularly important when laboratory results may inform decisions such as allergen avoidance or consideration of immunotherapy.

Digital connectivity adds another dimension by making those results easier to incorporate into the broader clinical record. A specific IgE result viewed in isolation is one data point. When that result is readily accessible alongside a patient's previous testing, clinical history and other relevant information, it becomes more useful for clinical interpretation and longitudinal assessment.

The opportunity is therefore not simply to test for sensitization to more allergens or generate results more quickly. It is to make specific IgE testing more consistent, connected and clinically interpretable, so that laboratory results can contribute more effectively to the overall assessment of allergic disease.

As laboratories scale their diagnostic capabilities, what operational or infrastructure shifts are most critical to maintain quality and turnaround times?

Scaling successfully requires looking at the testing process as an interconnected system rather than focusing only on analytical capacity. When testing volumes increase, the first instinct may be to add instruments or expand physical capacity. Before doing so, laboratories should examine whether existing workflows and infrastructure are creating unnecessary complexity. Allergy and autoimmune laboratories can accumulate multiple platforms over time, with each system bringing its own maintenance requirements, training needs and workflow considerations. Consolidating methods where appropriate can reduce that complexity while freeing staff time and physical space.

Physical workflow is another important consideration. Instrument placement, reagent storage and the number of systems a technologist must monitor can all affect efficiency. These factors may seem operational rather than diagnostic, but they directly influence how smoothly samples move through the laboratory.

Data flow is equally important. Greater analytical capacity will have limited impact on end-to-end turnaround time if orders, sample identification, result verification or reporting still depend on disconnected or manual processes. The objective should therefore be to increase capacity while maintaining traceability, quality and operational resilience throughout the complete testing pathway.

Looking ahead, how do you see integration of data, automation and AI shaping the future of autoimmune and allergy diagnostics, particularly in delivering more personalized and actionable insights?

In the near term, some of the most practical opportunities for AI in laboratory medicine are likely to involve areas such as workflow optimization, quality management, result verification, pattern recognition and clinical decision support. There is also potential to integrate longitudinal laboratory information with other clinical data to identify patterns that may be difficult to recognize from individual results alone.

This longitudinal perspective is particularly relevant to autoimmune disease. A laboratory result obtained during a period of low disease activity may look very different from one obtained during a flare. Viewing either result in isolation can therefore provide an incomplete picture. Connecting results over time can help clinicians identify patterns that may not be apparent from a single measurement.

AI has the potential to support this process by identifying patterns across large and complex datasets that would be difficult to assess manually. For example, combining laboratory trends with longitudinal clinical information could help identify changes that warrant further evaluation. However, the evidence base for many AI applications remains in development, and high technical performance in a research dataset does not necessarily translate into clinical benefit in routine practice.

The foundation remains high-quality laboratory data. AI cannot compensate for poorly characterized analytical variation or fragmented information. Recent international laboratory-medicine guidance therefore emphasizes local verification and professional oversight when AI systems are implemented in clinical laboratories. Laboratories that establish standardized workflows, connected systems and high-quality longitudinal data today will be better positioned to use advanced analytics and AI. The long-term opportunity is not simply to make laboratories more automated. It is to use standardized, clinically meaningful data more effectively while preserving the professional judgment required to translate laboratory information into appropriate patient care.