

Bringing the next generation of food allergy diagnostics into the clinic

A clinical commentary review of three novel food allergy tests currently transitioning into clinical practice

Santos AF, et al. J Allergy Clin Immunol Pract. 2022;10:1–9.

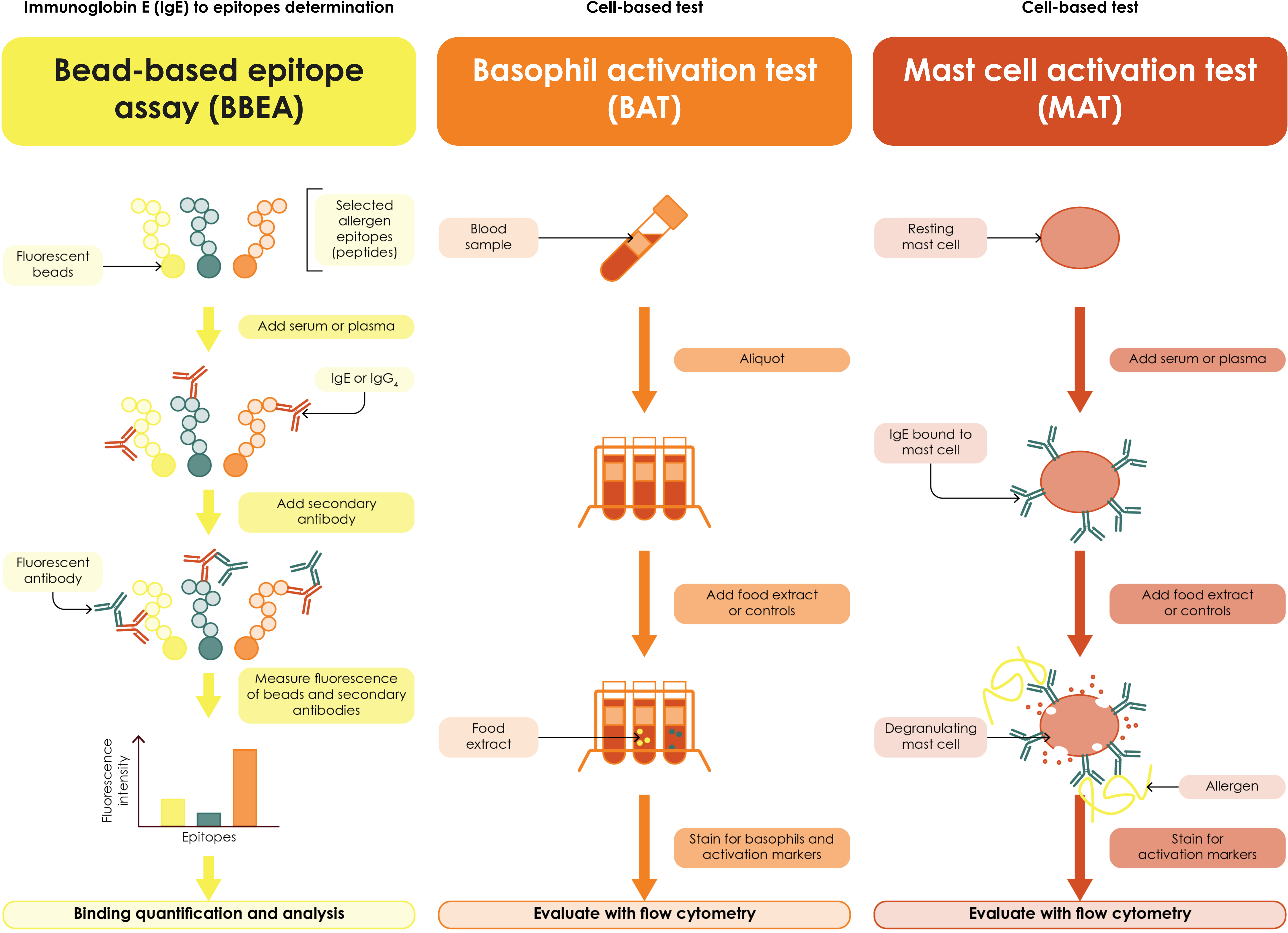
Background

Oral food challenge is the standard method to diagnose food allergy but **has limitations**, **requires intensive resources** and can itself **cause an allergic response**

There is **a need for simpler tests** that provide more **accurate diagnosis**

Primary aim of new tests To reduce the need for oral food challenge in establishing a diagnosis of food allergy

Tests



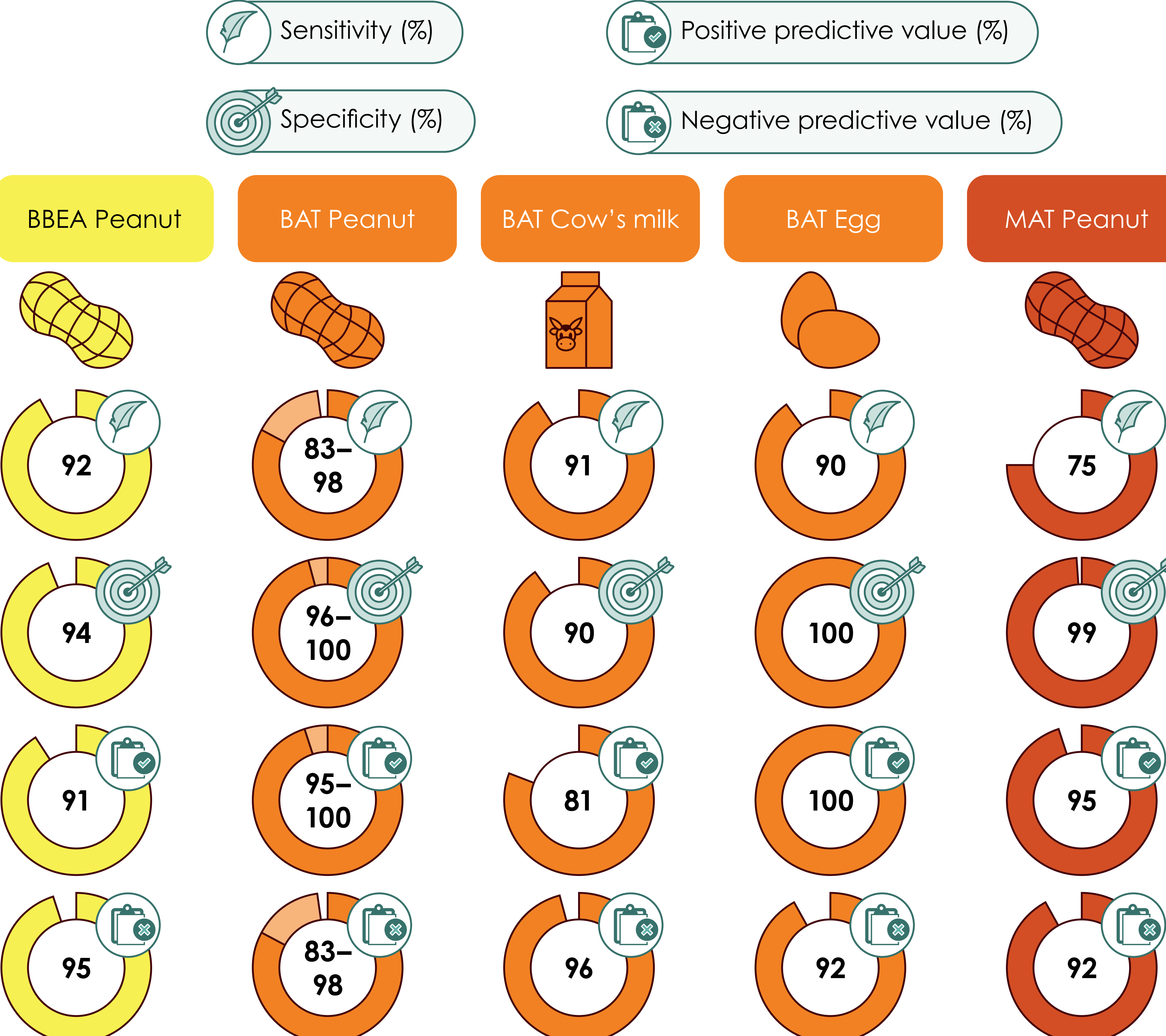
Advantages include:

- High-throughput
- High reproducibility
- Only microlitre quantities of serum or plasma required
- High accuracy
- Easy to perform
- Accounts for quantity and quality of allergen-specific IgE
- High sensitivity and specificity
- Accounts for quantity and quality of allergen-specific IgE
- High specificity

Challenges include:

- Requires knowing the amino acid sequence of allergenic epitopes
- Requires sophisticated diagnostic/prediction algorithms
- Test validation requires large, well-characterised cohorts
- Requires flow cytometry
- Should be performed soon after blood sample collection
- Requires flow cytometry
- Requires maintaining cultured cell line
- Lower sensitivity than BAT

Diagnostic performance



Potential applications

- Diagnosis/Defining prognosis
- Risk assessment/Predicting clinical sensitivity
- Predicting treatment response

Steps toward clinical practice

- Standardisation
- Validation (technical, clinical, and external)
- Overcoming technical and logistical hurdles (e.g., sample storage and transportation)
- Regulatory approval

It may take **several more years** before the new tests become part of clinical practice.

So far, **one BBEA test (peanut)** has been granted laboratory development test status in the USA.

Conclusions

BBEA, **BAT**, and **MAT** have the potential to reduce the need for oral food challenge and allow for a more exact diagnosis. **Further validation and standardisation are needed** to obtain regulatory approval for these tests and incorporate them into clinical practice.