IMMULITE 2000/2000 XPi Immunoassay System

Making allergy testing routine

Consolidate allergy testing with one of the industry's most reliable solutions

siemens-healthineers.com

SIEMENS Healthineers

Scale your allergy testing capabilities without disrupting regular day-to-day operations

Providing multiple tests on a single, easy-to-use analyzer

The IMMULITE® 2000/2000 XPi Immunoassay System allows you to customize the configuration of each allergen wedge with up to six allergen vials of your choice. As many as 23 wedges, plus a Universal Reagent Wedge, fit on each carousel, for a capacity of up to 138 allergens onboard at any time, enabling easier consolidation, improved workflow efficiency, and reduced downtime.

- Automated daily maintenance with **AutoStart*** provides high reliability with minimal operator intervention.
- **Ready-state** functionality* allows operations to resume according to your defined workflow.
- The system provides **continuous monitoring** of reagents and bulk supplies with software alerts.*
- No-pause sample loading **enhances turnaround time.***
- Automated rerun, dilution, and reflex capabilities **minimize hands-on time** for technologists.

Increase allergen-specific IgE efficiencies

- High throughput: 100–200 tests/hour.†
- 90-day onboard reagent stability minimizes waste.
- 50 µL minimum dead volume enables use of very small samples.
- ~500 allergens, panels, and allergen components increase testing capability.
- 138 allergens onboard enable a more-extensive test menu.
- 5520-test capacity.‡

Transform care delivery at every stage of the diagnostic process:

Enhance patient care with reliable assay performance from a simple blood test, delivered by a system that offers enhanced sensitivity and specificity.

Boost operational efficiency by centralizing allergy testing onto an easy-to-use platform that offers full automation connectivity, simple assay adjustments, bar-coded specific allergens, and an AutoStart* feature.

Improve the patient experience by offering quantifiable results that can lead to more-informed care decisions, derived from a less-invasive test that doesn't require cessation of medication or carry the risk of potential reactions.

**Available on IMMULITE 2000 XPi Immunoassay System only.*
†Depending on tests performed.
‡Allergy testing.

IMMULITE® 2000/2000 XPi 3gAllergy™: a unique combination of technologies

Liquid-allergen technology

The IMMULITE 2000/2000 XPi Specific IgE assay is based on a patented liquid-allergen technology. This technology couples individual allergen molecules to a soluble carbohydrate backbone, preserving their three-dimensional structure and increasing accessibility of a large variety of epitopes to serum IgE antibodies. Siemens Healthineers takes great care in the preparation and testing of its liquid allergens, from raw materials to final product, to ensure maximum allergen activity.

Allergen qualification

Before use in allergen-specific IgE assays, extracts are thoroughly evaluated using our in-house quality control testing panel to ensure the very highest quality in terms of both potency and the allergenic composition required for uncompromised assay performance.

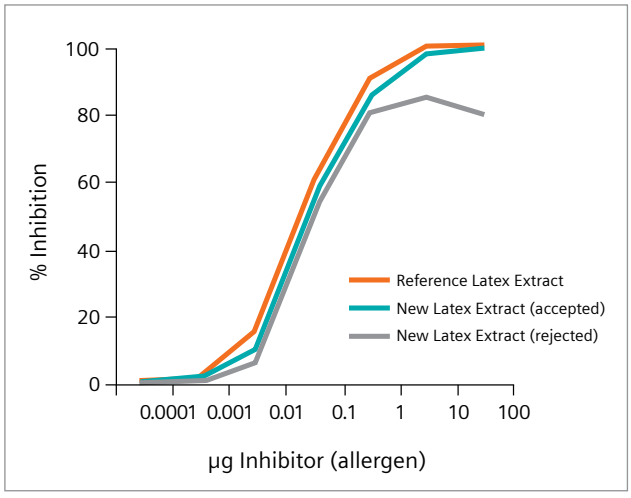


Figure 1. Competitive inhibition. The allergenic reactivity of raw material extracts is compared to that of well-characterized reference material. In an inhibition assay, allergenic molecules in the extract and in the reference material compete for binding to allergen-specific IgE molecules in patient sera. Complete inhibition occurs only if the extract contains all the competitive counterparts for every component of the reference material.

Since no single test can provide all the necessary information for determining extract quality, Siemens Healthineers uses the following panel of tests:

- Total protein and carbohydrate analysis
- A competitive inhibition assay performed against well-characterized reference material (Figure 1)
- Western blots performed using individual patient sera and/or serum pools as probes to ensure that all the desired allergenic components are present in the extract (Figure 2)

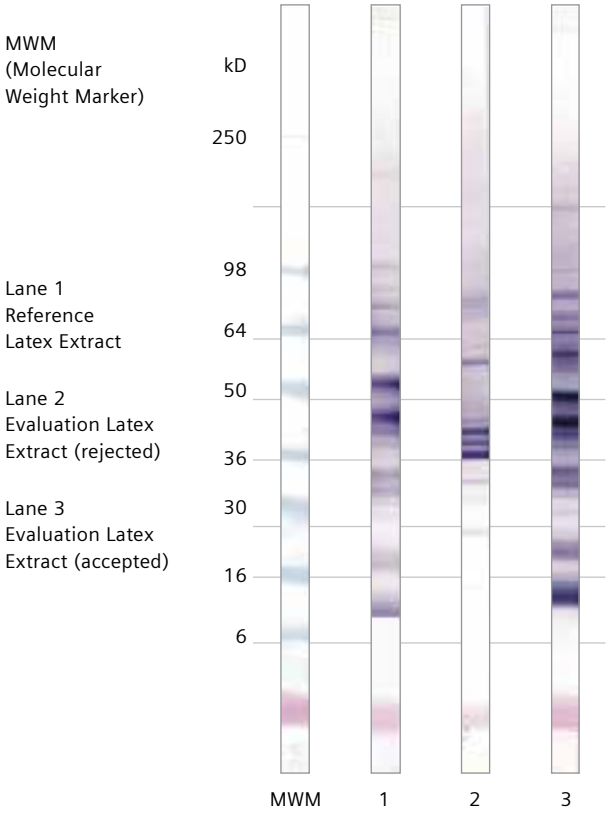


Figure 2. Immunoblot for several latex extract evaluations. The latex extract in Lane 3 contains all the allergenic components present in the reference extract. Binding of patient IgE by allergenic components is depicted by colored bands. The potency or reactivity of these allergenic components with patient IgE is indicated by the intensity of the bands.

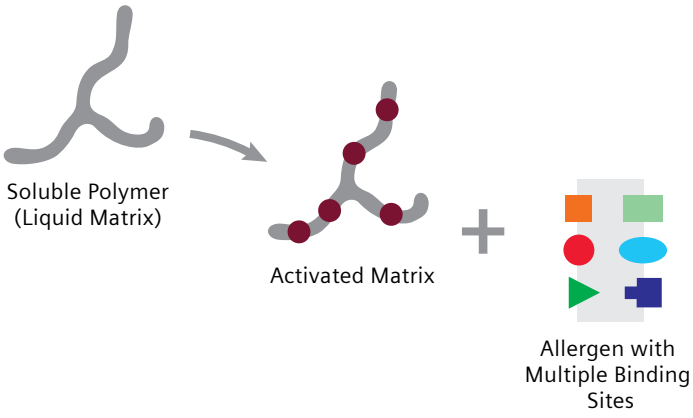
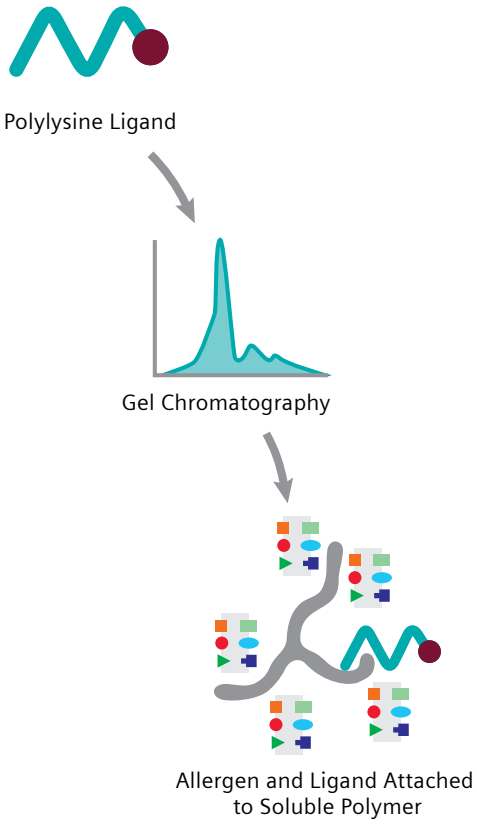


Figure 3. Liquid allergen synthesis. An activated soluble polymer is combined with the allergen extract and polylysine ligand. The large peak shown by gel chromatography identifies the liquid allergen complex.



Allergen synthesis

After the extract has been qualified, a unique, patented manufacturing method combines an activated soluble polymer with the allergen extract and a polylysine "capture" ligand. The resulting mixture undergoes gel chromatography to isolate the liquid allergen complex, which is identified by a large molecular size peak (Figure 3).

After coupling with the soluble matrix, each bound allergen component is free to rotate in three dimensions. The immunoreactivity of the allergens is maintained, and all epitopes of each allergen are available to react with allergen-specific IgE antibodies. Figure 4 depicts the total availability of allergen epitopes when coupled with the soluble matrix. This technology offers increased assay sensitivity due to the broad range of allergen epitopes displayed.

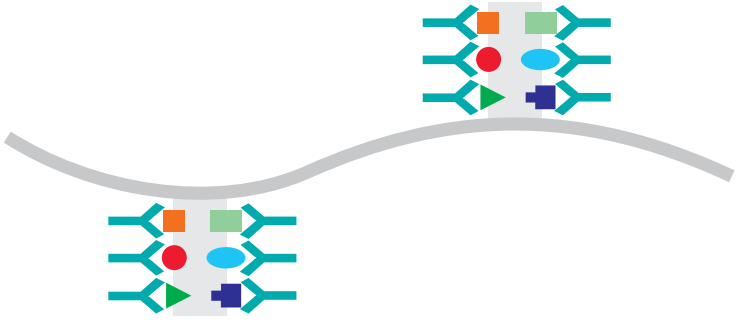


Figure 4. Binding sites. The binding sites of Siemens Healthineers liquid allergens are accessible from all sides, as is the case with allergens in vivo.

Titration

After the allergen is synthesized, allergen concentration is optimized to produce maximal IgE binding. Titration is performed with a pool of atopic serum. The optimal titer of synthesized allergen is determined by testing various dilutions of synthesized allergen complex with a serum pool containing specific-IgE antibodies (Figure 5).

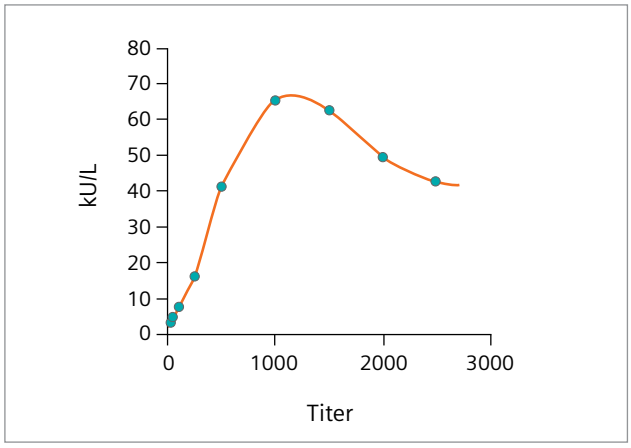


Figure 5. Titering of allergens. Dilutions of synthesized allergen are evaluated to identify the optimal allergen titer for producing maximal IgE binding. In this example, the optimal titer is slightly over 1000.

Final evaluation

A multiple serum evaluation is then performed to confirm the optimal titer and ensure all epitopes are present in the allergen. This is achieved by running 20 patient sera (15 positive and 5 negative) and comparing values to the reference lot, as shown in Figure 6. Comparable performance ensures lot-to-lot consistency of the synthesized allergen.

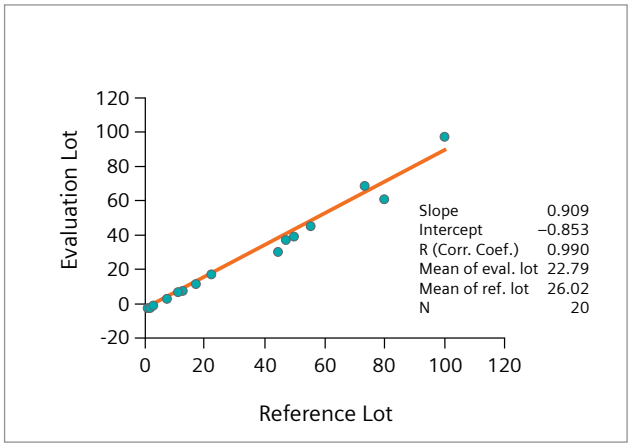


Figure 6. Reference test: multiserum evaluation. 3gAllergy test results obtained by testing the titered synthesized allergen (using several patient sera) are compared to results obtained with the reference synthesized allergen to ensure lot-to-lot consistency.

Wash technique and chemiluminescence

The IMMULITE 2000/2000 XPi system's exclusive wash technique enhances assay specificity by facilitating the thorough removal of excess reagent, which consistently results in extremely low nonspecific binding (Figure 7).

After incubation, the assay tubes are shuttled out of the incubation carousel to the spin-wash station, where the tubes are rapidly spun at high speed. Excess reagent and sample are immediately expelled by centrifugation. The wash procedure is repeated three times, ensuring excellent separation of bound from unbound material. Upon completion of the wash step, the tubes are shuttled back to the incubation carousel.

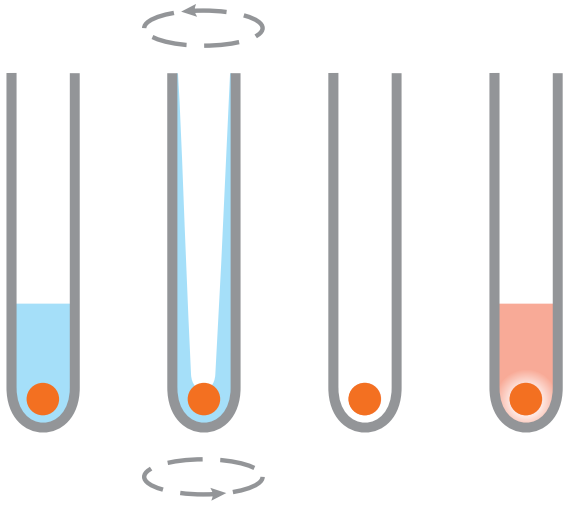


Figure 7. The proprietary high-speed centrifugal wash technique of the IMMULITE 2000/2000 XPi system ensures excellent separation of bound from unbound material. The sustained chemiluminescent signal allows multiple readings for more-precise measurements.

The IMMULITE 2000/2000 XPi system's enzyme-enhanced chemiluminescence translates to lower detection limits compared to conventional "flash" chemiluminescence (Table 1). Rather than one or two photons per immunobinding event, thousands of photons are emitted per binding event with the IMMULITE 2000/2000 XPi system reaction. The sustained signal produced by the enzyme-enhanced chemistry allows multiple readings to be taken for more-precise measurements.

Table 1. The IMMULITE 2000/2000 XPi system's enzyme-enhanced chemiluminescence translates to lower detection limits compared to other commonly used methods. (Adapted from Kricka LJ. Principles of immunochemical techniques. In: Burtis CA, Ashwood ER, editors. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: WB Saunders; 1999. p. 218.)

Method	Detection Limit (zmol)§
Enzyme Immunoassay Photometry	50,000
125I Radioimmunoassay	1000
Fluorescence	1000
Direct Chemiluminescence	800
Enzyme-enhanced Chemiluminescence	1

§zeptomole = 10^-21 moles

Mechanism of assay

3gAllergy assay is an enzyme-labeled sequential immunoassay that runs through two incubation cycles. The initial step requires a 30-minute incubation of serum, liquid allergen, and an anti-ligand-coated polystyrene bead (Figure 8). The ligand-labeled allergens bind to serum IgE antibodies and to the anti-ligand-coated bead.

During the second cycle, alkaline phosphatase-conjugated monoclonal anti-IgE is added and binds to captured serum IgE. A chemiluminescent substrate is added, and the degree of light produced during the reaction correlates with a quantitative IgE value.

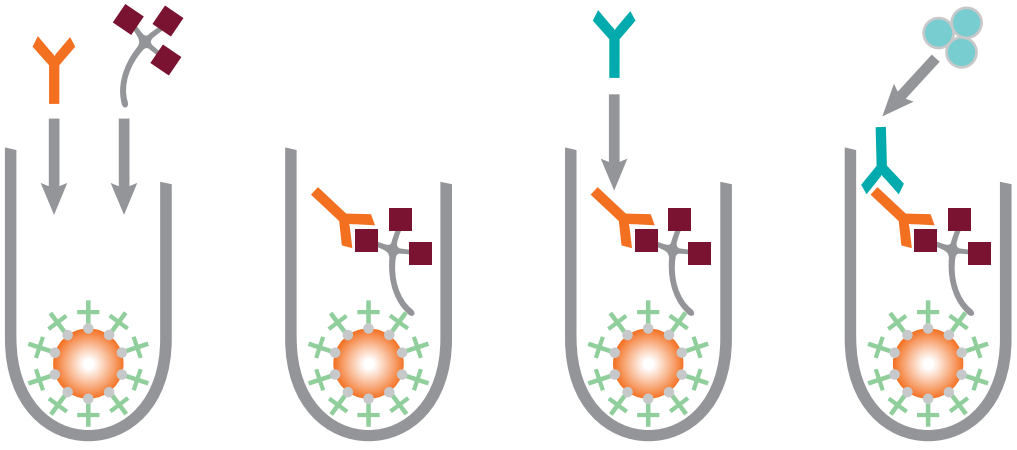


Figure 8. 3gAllergy assay sequence.

Serum and allergens incubate with anti-ligand-coated bead.

Ligand-labeled liquid allergens bind to serum antibodies and to the anti-ligand-coated bead.

Antibody conjugate binds to serum IgE.

Substrate initiates chemiluminescent reaction.

Workstation consolidation

One platform for allergy tests and all other immunoassays offers:

- **Full automation** for less technician hands-on time, resulting in reduced errors and labor costs
- **Easy operation** and proven system reliability
- **Fast turnaround** time of 65 minutes

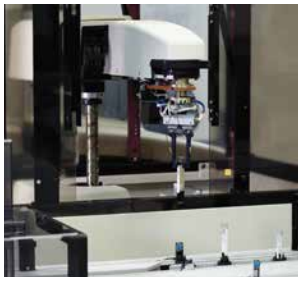
Broad test menu

Accommodate an extensive panel of allergy tests. The IMMULITE allergy test menu includes:

- **IMMULITE 2000 XPi 3gAllergy Specific IgE**
- **AlaTOP® Allergy Screen**
- **Specific allergens and panels**
  - **Universal Kit:** The basic component of the module-based, specific-allergen testing procedure. With the Universal Kit, one master curve applies for all specific allergens and panels.
  - **Allergens and panels:** These determine the specific allergens or panels to which an allergenic patient reacts. Shipped as individual bar-coded vials. Available as 20-test and, in some cases, 40-test kit sizes. Each vial has a 2-year shelf life. Specific allergens and panels require the Universal Kit.

One tube, one point of entry.

Seamless connectivity with VersaCell® X3 Solution.



Connection to Aptio® Automation.

Automation connectivity for a multidisciplinary, total lab solution

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. By constantly bringing breakthrough innovations to market, we enable healthcare professionals to deliver high-quality care, leading to the best possible outcome for patients.

Our portfolio, spanning from in-vitro and in-vivo diagnostics to image-guided therapy and innovative cancer care, is crucial for clinical decision-making and treatment pathways. With our strengths in patient twinning, precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the biggest challenges in healthcare. We will continue to build on these strengths to help fight the world's most threatening diseases, improving the quality of outcomes, and enabling access to care.

We are a team of 66,000 highly dedicated employees across more than 70 countries passionately pushing the boundaries of what's possible in healthcare to help improve people's lives around the world.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

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Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000

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