

ALLERGY DIAGNOSTICS RAW MATERIALS

Innovation from Molecular Design to Immunoassay Application

Allergen Extracts -- Mixed proteins

✓ Application-Specific Functional Validation

In addition to component analysis via methods like SDS-PAGE, each production lot of our natural allergen extracts is evaluated on an in-house chemiluminescence (CLIA) platform. This functional testing is performed to confirm that the material's immunoreactivity is consistent and meets established performance specifications for diagnostic applications.

✓ Scalable Production and Supply Management

Key food and pollen allergens are produced at a gram-scale per batch. This large-batch manufacturing capability, combined with a managed supply chain, is designed to provide a stable, long-term supply, thereby reducing the need for frequent lot requalification by the end-user.

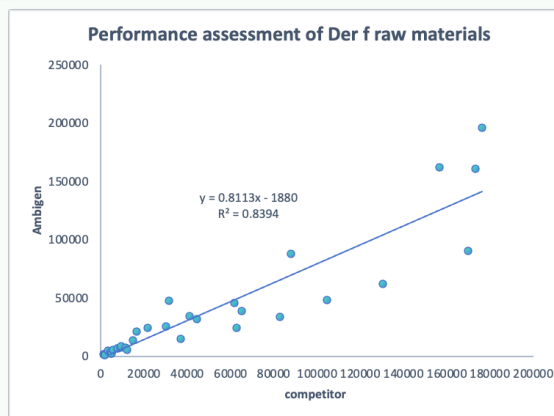
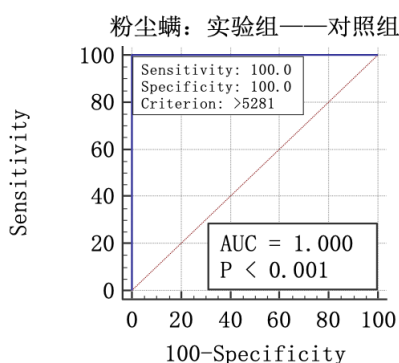
✓ Ready-to-Use Liquid Formulation

Our allergen extracts are supplied in a liquid format. This formulation is intended for direct use in coating solid-phase carriers after thawing, which can streamline the end-user's manufacturing process by removing certain raw material processing steps.

1. Case Study: Dust Mite (*Dermatophagoides farinae*)

Ambigen partners with a leading acarology research institute to establish a standardized mite breeding system.

We are expanding our mite portfolio with upcoming products for *Tyrophagus putrescentiae* and *Acarus siro*.



Performance Data

✓ Testing AmbiGen's raw material and a market leader's Der f **raw materials** on the same CLIA platform shows a strong correlation in reactivity ($R^2=0.8394$, $n=38$)

✓ Our in-house CLIA assay system, built with AmbiGen's raw material, demonstrates exceptional concordance with a market-leading kit.

ROC analysis shows an AUC of 1.000 , $n=38$

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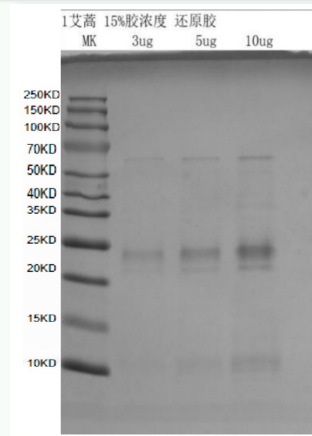
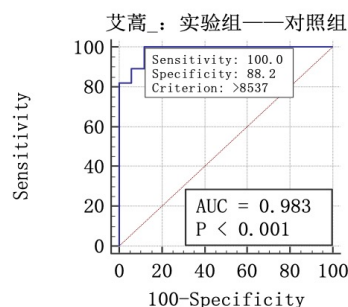
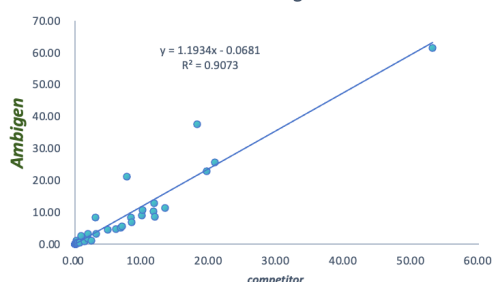
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2. Case Study: Mugwort (*Artemisia*)

We have established long-term collection bases in core northern China regions to ensure a stable, pure, and traceable supply of pollen. Our substantial production capacity meets multi-year demand, fundamentally mitigating the risks of batch variation inherent in seasonal harvesting.

Performance assessment of mugwort raw materials



Performance Data

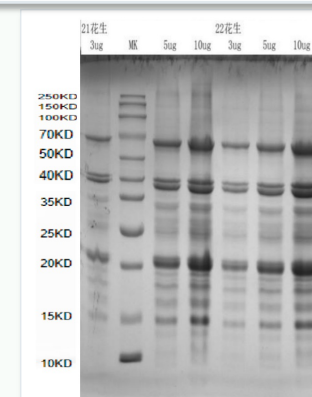
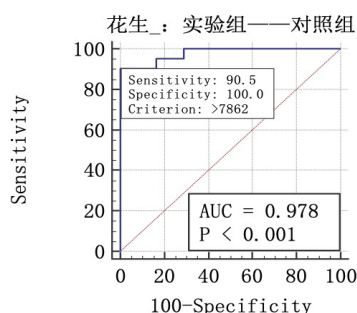
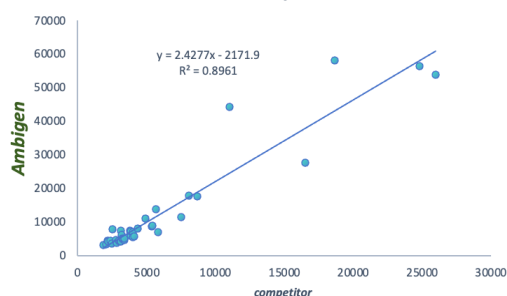
✓ **Raw materials:** AmbiGen's and a market leader's mugwort raw materials on the same CLIA platform show a strong correlation in reactivity ($R^2=0.9073$).

✓ **Kit:** Our in-house CLIA assay system, built with AmbiGen's raw material, demonstrates high concordance with a market-leading kit. ROC analysis shows an AUC of 0.983.

3. Case Study: Peanut (*Arachis hypogaea*)

Peanut is a leading cause of severe anaphylaxis. Its complex and stable protein profile (incl. Ara h 1, h 2, h 3, h 6) poses a significant challenge for extraction processes, which must preserve the integrity and consistency of these critical components.

Performance assessment of peanut raw materials



Performance Data

✓ **Raw materials:** Testing AmbiGen's and a market leader's peanut raw materials on the same CLIA platform shows a strong correlation in reactivity ($R^2=0.8961$)

✓ **Kit:** Our in-house CLIA assay system, built with AmbiGen's raw material, demonstrates high concordance with a market-leading kit. ROC analysis shows an AUC of 0.978.

✓ **Component:** Key allergenic proteins are confirmed: Ara h 1 (7S vicilin), Ara h 2 (2S albumin/conglutin), Ara h 3 (11S legumin/glycinin), and Ara h 6 (2S albumin).

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Foods

ABALM-A142	Almond	
ABAPL-A147	Apple	
ABBEF-A158	Beef	👍
ABBRZ-A143	Brazil Nut	
ABCCN-A152	Coconut	
ABCLM-A166	Northern Quahog Clam	
ABCOD-A168	Codfish	👍
ABCRB-A164	Blue Crab	👍
ABCSH-A144	Cashew Nut	
ABEGG-A174	Egg, Chicken	👍
ABEGW-A160	Egg White, Chicken	👍
ABEGY-A161	Egg Yolk, Chicken	
ABHOP-A172	Hops (Humulus lupulus)	
ABHZL-A141	Hazelnut (Filbert)	
ABLMB-A159	Lamb	👍
ABLOB-A163	Lobster (Maine)	👍
ABMLK-A157	Milk (Bovine)	👍

Foods

ABOYS-A167	Atlantic/Eastern Oyster	
ABPCN-A145	Pecan	
ABPNP-A148	Pineapple	
ABPNT-A140	Peanut	👍
ABPRC-A169	Ocean Perch	👍
ABPST-A146	Pistachio Nut	
ABRCE-A156	Rice	
ABSCL-A165	Scallops	
ABSES-A139	Sesame Seed	👍
ABSHR-A162	Brown Shrimp	👍
ABSLM-A170	Salmon	👍
ABSOY-A153	Soybean	👍
ABSTB-A149	Strawberry	
ABTOM-A150	Tomato	
ABWHT-A154	Whole Wheat	
ABMNG-A151	Mango	👍
ABOAT-A155	Oat	

* 👍: This product has been implemented in the production of commercial IVD kits.



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Pollens

ABBER-A129	Bermuda Grass	
ABBOM-A175	Bombax Ceiba	
ABBRC-A122	Birch (European white)	
ABCBR-A130	Cocklebur	
ABCTW-A121	Cottonwood (Eastern)	
ABDAN-A127	Dandelion	
ABDSY-A133	Daisy, Ox-Eye	
ABLMQ-A131	Lamb's Quarter	
ABMUG-A126	Mugwort (Common)	👍
ABPIN-A123	Pine (White/Eastern)	
ABPLT-A128	Plantain (English)	
ABRAG-A125	Ragweed, short	👍
ABSYC-A120	Planetree Sycamore	👍
ABTIM-A132	Timothy	👍
ABWIL-A119	Black Willow	

Mites & Insects

ABDM-A110	Dermatophagoides farinae	👍
ABHDM-A111	Dermatophagoides pteronyssinus	👍
ABSM1-A113	Tyrophagus putrescentiae	
ABSM2-A114	Acarus siro	
ABTM-A112	Blomia tropicalis	👍
ABCOC-A173	Cockroach	

Fungi

ABALT-A137	Alternaria alternata	
ABASP-A134x	Aspergillus	👍
ABCAN-A138	Candida albicans	
ABCLA-A136	Cladosporium herbarum	
ABPEN-A135	Penicillium Chrysogenum	

Animal Proteins

ABCAT-A115	Cat Epithelia	
ABCTL-A117	Cattle Epithelia	
ABDOG-A116	Dog Epithelia, Mixed-Breed	
ABHRS-A118	Horse Dander	

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