Site-Specific Biotinylated Recombinant Antigens

Autoimmune Diseases	Raw Biomaterials
Antinuclear Antibodies	▪ **dsDNA** ▪ **Histone (H1, H2a, H2b, H3, H4)** ▪ **Ro-52** ▪ **Ro-60/SSA** ▪ **La/SSB** ▪ **CENP-B** ▪ **PCNA** ▪ **M2-3E** ▪ **Ribosomal-P0** ▪ **Scl-70** ▪ **Jo-1** ▪ **PM-Scl 75**
Rheumatoid Arthritis	▪ **CCP**
Antiphospholipid Syndrome	* **aCL (developing)** * **β2-GP1 (developing)**
Others	▪ **GAD65** ▪ **TSHR**

Purified Native Antigens

Autoimmune Diseases	Raw Biomaterials
Rheumatoid Arthritis	▪ **Human IgG Fc fragment**
Antinuclear Antibodies	▪ **C1q**
Interstitial Lung Diseases	▪ **KL-6**

AID-Related Recombinant Monoclonal Antibody

Autoimmune Diseases	Raw Biomaterials
IgG Subtype Antibodies	▪ **IgG1 paired antibody** ▪ **IgG2 paired antibody** ▪ **IgG3 paired antibody** ▪ **IgG4 paired antibody**
Inflammatory Bowel Diseases	▪ **Calprotectin paired antibody**
Antinuclear Antibodies	▪ **Humanized anti-PCNA Antibody**

Biotinylated Cyclic Citrullinated Peptide

RAW MATERIALS FOR CHEMILUMINESCENCE IMMUNOASSAY

Our validated autoantigen, Catalog# ABCCP-001, N-terminal Biotinylated Synthetic Monomeric Peptide, demonstrates excellent performance.

STUDY 1: Performance comparison of AmbiGen's CCP antigen (Cat# ABCCP-001) in a reference CLIA assay vs a leading commercial kit.

Reference Kit Result	AmbiGen +	AmbiGen -	Total	Agreement
Company R +	108 (TP)	0 (FN)	108	PPA: 100.0%
Company R -	4 (FP)	56 (TN)	60	NPA: 93.3%
Total	112	56	168	OPA: 97.6%

STUDY 2: Performance comparison of AmbiGen's CCP antigen in an in-house CLIA assay vs. leading commercial kits.

Test Kit vs. Clinical	Test +	Clinical +	PPA (%)	
Company R	38	45	84.4%	
Company K	38	45	84.4%	
Company A	36	45	80.0%	
AmbiGen In-house	38	45	84.4%	

Macromolecular Conjugated Cyclic Citrullinated Peptide

✓ Innovating for Turbidimetry Immunoassay: Engineered Architecture of CCP.

Macromolecular Conjugated CCP (ABCCP-710) introduces a precisely engineered "bridge," creating an optimal 3D spatial architecture on the latex surface. This design:

- Maximizes Epitope Accessibility: Dramatically improves binding efficiency with target antibodies.
- Promotes Ideal Lattice Formation: Accelerates latex agglutination, leading to a stronger turbidity signal.

✓ Our in-house LETIA platform has confirmed the viability of this design.

In a preliminary clinical panel, the assay achieved an Overall Percent Agreement (OPA) of 80% against a leading CLIA kit, demonstrating its strong potential.

✓ An Invitation to Co-Develop:

We are now actively seeking partners to co-develop a commercial latex-enhanced turbidimetric immunoassay (LETIA) for CCP.

AMBIGEN BIOTECH CO., LTD.
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double-stranded DNA

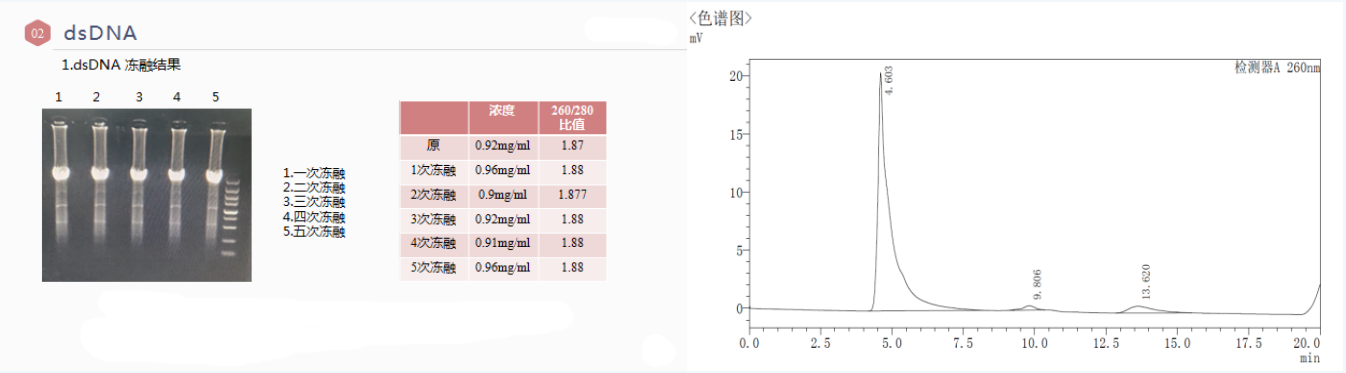
✓ Application-Specific Designs for Optimal Assay Performance
Customizable configurations, including site-specific biotinylation (5'-end, 3'-end, multi-site) for controlled conjugation strategies. A non-biotinylated, end-capped version is also available for applications requiring covalent coupling.

✓ High Purity and Structural Integrity
Manufactured under gentle reaction conditions to preserve the native double-stranded conformation, which is critical for the detection of conformation-dependent epitopes. This process minimizes DNA damage, ensuring high purity and effectively mitigating interference from ssDNA contaminants.

✓ Batch-to-Batch Consistency
Our validated manufacturing process ensures a highly controlled lot-to-lot coefficient of variation. The process has demonstrated scalability, with a cumulative production of over 1000 mg across multiple batches, ensuring a reliable supply for large-scale manufacturing.

✓ Assessed Stability for Enhanced Robustness
The stability of the double-stranded structure and the biotinylated design has been evaluated to support robust and consistent results. This contributes to better inter-laboratory reproducibility under standardized conditions.
(Note: End-user validation for the specific application is recommended).

Stability & Identity: 5× Freeze–Thaw, SEC/RP-HPLC Characterization

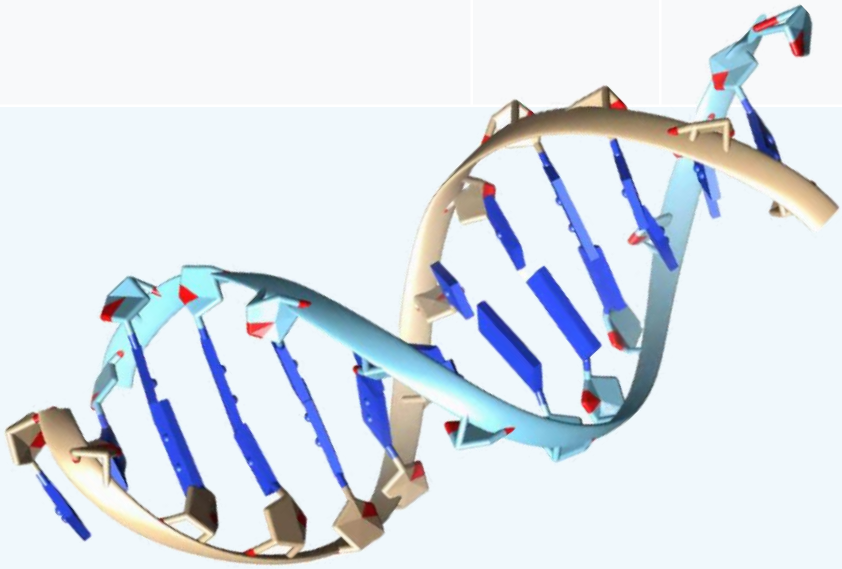


Pediatric Specificity Assessment — False-Positive Reduction Study

Sample Type	Positive	Negative	Total
Clinical SLE positive Samples	49 (98%)	1 (2%)	50
Clinical Healthy Donors (children)	0(0%)	10 (100%)	10

double-stranded DNA

Product Code	Key Features	Molecular Weight	Validation Status
ABDSDNA-C110	• Site-specific biotinylated at 5'-end; • Preserves native double-strand structure; • Excellent lot-to-lot consistency with high purity; • The initial Validated dsDNA	~5000 bp	✅ Commercially Validated
ABDSDNA-D10	• Biotin labels at both 5'-end and 3'-end • Engineered for signal amplification on a specific CLIA platform.	~5000 bp	✅ Commercially Validated
ABDSDNA-W110B	• Optimized for application requiring smaller DNA • Maintains structural integrity and purity of C110	~2000 bp	NEW Samples Available
ABDSDNA-C252	• Based on C110 with tandem dual-biotin design • May improve detection sensitivity and thermal stability	~5000 bp	NEW Samples Available
ABDSDNA-C351	• Based on C110 with tandem triple-biotin design • Maximum streptavidin binding capacity • Potential for highest sensitivity and stability	~5000 bp	NEW Samples Available
ABDSDNA-F111E	• Based on C110 with end-capping modification • Biotin-free design • End-capping inhibits heat- or enzyme-induced denaturation • Suitable for applications of covalent coupling via dehydration reactions	~5000 bp	NEW Samples Available



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