ASSAYS BY AGENA

Tailored Assay Solutions

Laboratory Services for Rapid Test Deployment

For Research Use Only.
Not for use in diagnostic procedures.

Agena® BIOSCIENCE

Assays By Agena Services

Developing custom assays can be time and resource intensive. With most technologies it is not easy to balance cost, development time, and resources when creating custom panels.

The MassARRAY® System from Agena Bioscience® is an ideal platform for designing custom assays. It is a versatile technology, offering flexibility in specimen types, biomarkers, multiplexing, limit of detection, and throughput. Partner with one of our expert scientists to develop custom assays, or design assays in your laboratory with our easy-to-use assay design tools available on the Agena customer support portal.

Our Assays by Agena Services provide everything you need for designing and delivering custom content:

› DESIGN

Design SNP, insertion, deletion, translocation, copy number variant, somatic mutation, and methylation assays.

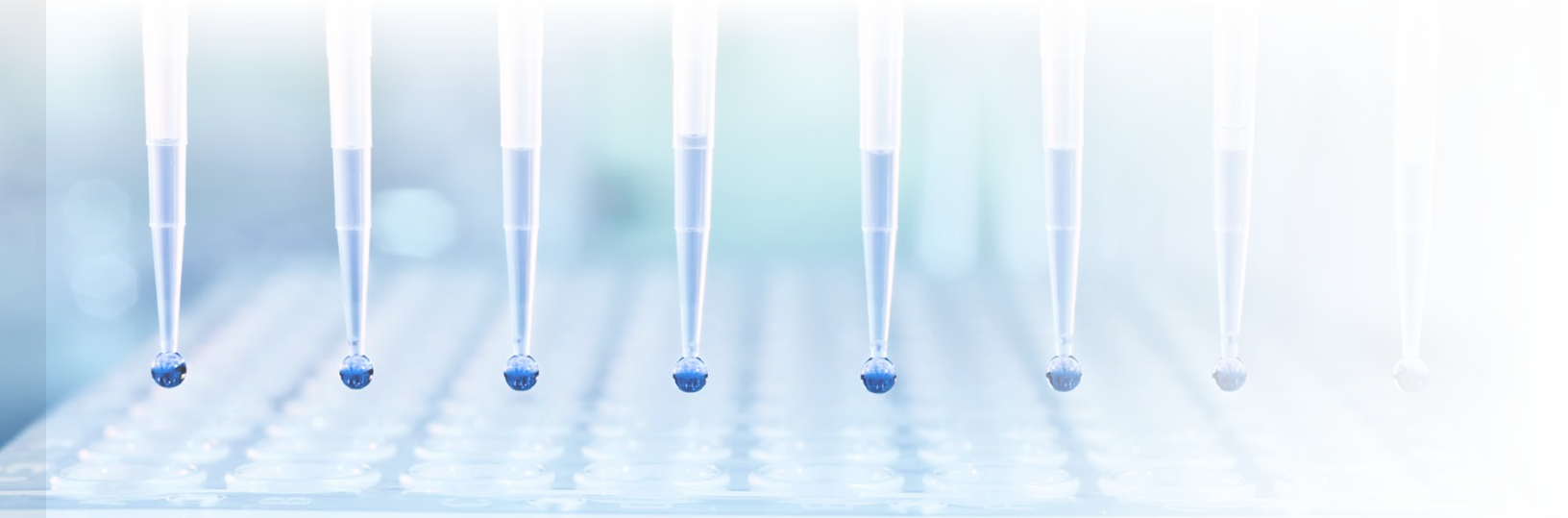
› VERIFY

Functional testing of multiplexed assays for accuracy, robustness, and performance.

› DELIVER

Delivery of ready-to-use assays and custom reports for easy implementation in the lab.

- **EXPERT** – Assays are designed and developed by Assays by Agena scientists.
- **ASSAY VERIFICATION** – Assays are functionally verified in Agena laboratories.
- **COLLABORATIVE** – Training and support provided by Agena scientists.



Partner with our expert Assays by Agena scientists

Reduce your assay development time with Assays by Agena services. Our highly skilled scientists design and verify your research use assays in the laboratory for superior performance.

FROM MARKERS OF INTEREST TO WORKING ASSAYS

START	2 – 3 days	4 – 6 weeks	1 week
Customer provides markers of interest	**Agena performs in silico assay design**	**Assay performance testing**	**Assays ready for laboratory evaluation**
○ RS numbers ○ FASTA sequences ○ CpG regions ○ COSMIC IDs	Highly multiplexed assays designed to ensure efficiency and robustness	Functional testing performed with HapMap DNA	Verified oligos are mixed and packaged for shipment

* The timeline is based on developing germline genotyping assays and may differ for other chemistries/applications.

Our scientists functionally test all assays using cell lines and deliver ready-to-use oligonucleotide mixes for easy validation and implementation in your laboratory. Software services to simplify data analysis with custom reports are also available.

A Versatile Platform

The MassARRAY® System is a flexible platform that allows you to perform a variety of DNA analyses with different chemistries tailored to your biomarkers of interest. With general purpose reagents and standard, non-labeled oligonucleotides, generating custom assays is simple, fast, and cost-effective.

Biomarkers that can be tested on the MassARRAY® System

	iPLEX® Pro	iPLEX® HS / ClearSEEK™	UltraSEEK®	MassCLEAVE™
Ideal For	Genotyping germline variants	Detecting somatic and low-frequency variants	Detecting very low-frequency and rare variants	Quantifying methylation changes
Biomarkers	• SNPs • Insertions • Deletions • Translocations • Copy Number Variants	• SNPs • Insertions • Deletions	• SNPs • Insertions • Deletions	• CpG Methylation
Limit of Detection	5% - 10%	≥ 1%	≥ 0.1%	≥ 5%
Quantitative Range	5% - 100%	1% - 20%	0.1% - 10%	5% - 100%
Markers per Reaction	≤ 40	≤ 15	≤ 10	150 bp – 550 bp CpG-rich region
Sample Types	• Blood • Buccal cells • Hair follicles • Ear punches • WGA DNA • FTA cards	• Formalin-fixed, paraffin-embedded tissue (FFPE) • Fine needle aspirates (FNA) • Cytology blocks • Core needle biopsy • Seed mixtures	• Plasma • Circulating cell-free DNA (ccfDNA) • Circulating tumor DNA (ctDNA) • Circulating tumor cells (CTCs)	• Blood • FFPE
Application Areas	• Pharmacogenetics • Inherited disease • Biomarker validation • Livestock testing • Crop strain validation	• Somatic mutations • Low-frequency variants • NGS discovery validation • GMO screening	• Oncogenic resistance and progression monitoring	• Epigenetic studies • Environmental factors studies • Biomarker validation • Disease prognostic markers

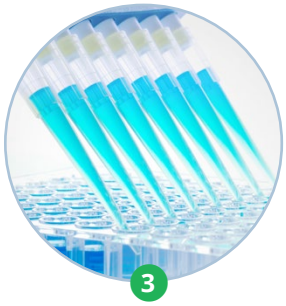
Rapid Results

All chemistries utilize a simple workflow with convenient, universal reaction conditions and general use reagents, generating results in as quickly as a day.

SAMPLE-TO-RESULTS WORKFLOW

Design and develop custom assays using Assays by Agena services

Sample collection



DNA/RNA isolation

Sample processing with general use reagents and assay-specific primers from Assays by Agena

Transfer of analytes to the SpectroCHIP Array and data acquisition with the MassARRAY Analyzer

Data analysis with easy-to-use application software and reports

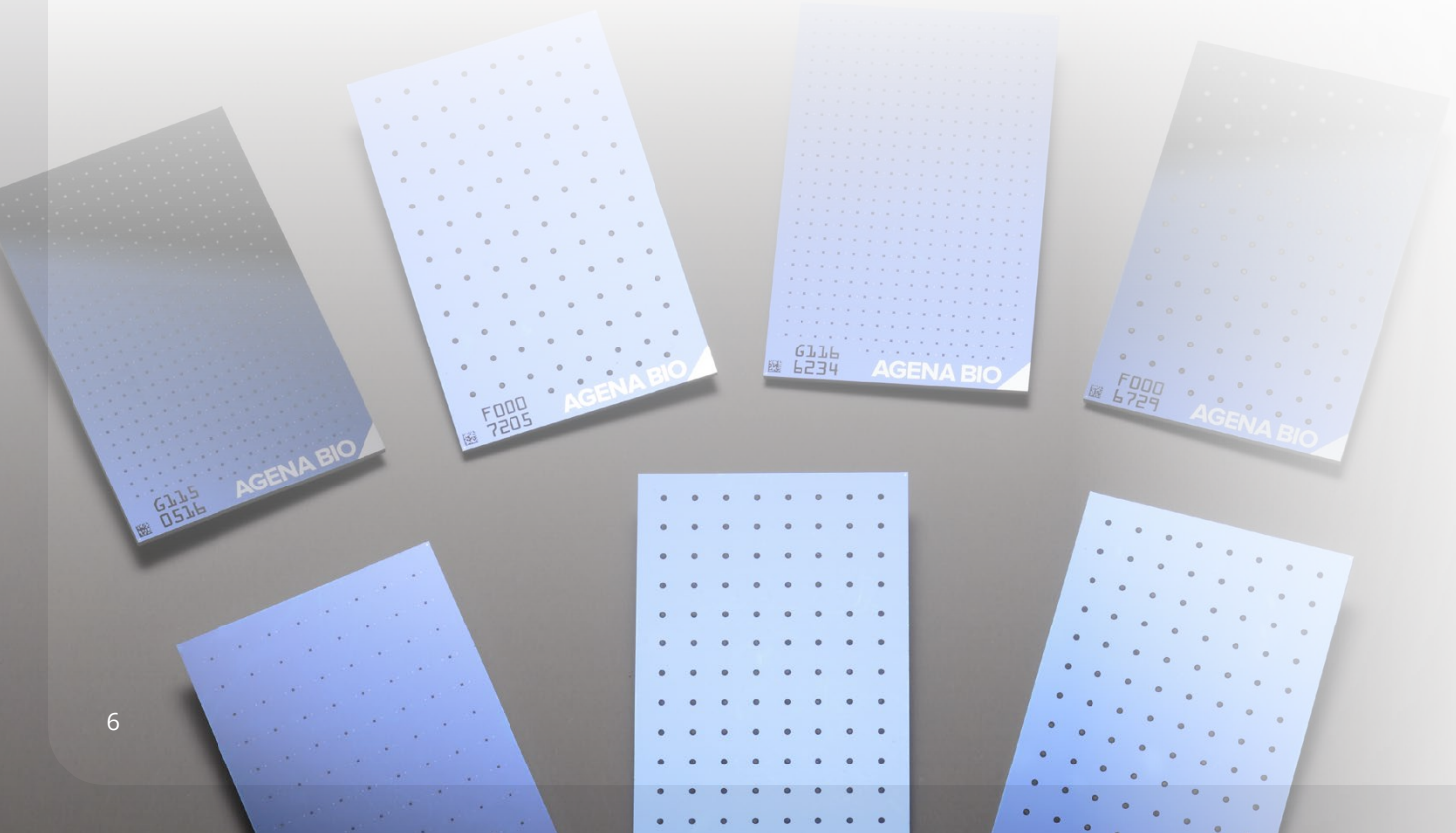
Flexible Throughput

The MassARRAY System is a truly open platform providing flexibility in both sample and assay numbers. Use the power of multiplexing to assay tens to hundreds of genotyping and somatic mutation targets efficiently, with minimal input DNA. The open access format of the SpectroCHIP® Arrays allows you to test any combination of assays and samples, eliminating the need to batch samples. The SpectroCHIP Arrays are available in 96 and 384 configurations, and anywhere from one to ten SpectroCHIP Arrays can be processed on an instrument in a single day, accommodating varying sample throughputs.

Examples showing flexibility in sample and assay numbers

Panel	# and Type of Variants	# of Reactions per Sample	# of Samples per 96 SpectroCHIP Array	# of Samples per 384 SpectroCHIP Array
Exome QC	21 exonic SNPs, 3 gender assays & 25 QC assays	1	96	384
CFTR	74 germline variants	3	32	128
iPLEX HS Colon	86 somatic variants	8	12	48
UltraSEEK Lung	74 rare somatic variants	12	8	32
MGMT Methylation	CpG's across 100 bp region	1	96	384

Note: Two SpectroCHIP Arrays can be processed by the MassARRAY System in a single run.



Oncology

Utilize targeted assays to profile only the clinically relevant variants across oncogenes, tumor suppressors, and resistance markers. Agena Bioscience provides different chemistries to meet the limit of detection (LOD) requirements for somatic variant testing.

- **iPLEX® Pro –** With a LOD of 5% - 10% variant allele frequency (VAF), iPLEX Pro enables detection of translocations and germline variants.
- **iPLEX® HS/ClearSEEK™ –** Best suited to detect variants as low as 1% VAF from FFPE tissue, core needle biopsies, FNA and cytology smears. Low DNA input enables testing samples with less than 20% tumor content.
- **UltraSEEK® –** Specialized for the detection of rare and low abundance somatic variants as low as 0.1% VAF, enabling resistance and disease progression monitoring from ctDNA, CTC and ccfDNA from plasma.

Examples of Oncology Assays Developed on the MassARRAY System

Area of Focus	Sample Type	Limit of Detection	# of Genes	# of Targets
Colon cancer disease monitoring	Plasma	≥ 0.1%	5	107
NSCLC disease monitoring	Plasma	≥ 0.1%	5	74
Melanoma disease monitoring	Plasma	≥ 0.1%	13	>55
EGFR resistance monitoring	Plasma	≥ 0.1%	1	6
Melanoma, colon & lung cancers	Tissue	5% - 10%	5	230
Colon cancer tumor profiling	Tissue	≥ 1%	5	86
NSCLC tumor profiling	Tissue	≥ 1%	5	70
Melanoma tumor profiling	Tissue	≥ 1%	11	>90
Myeloproliferative disorders, Gliomas & glioblastomas	Blood	5% - 10%	6	22
Gene translocations in NSCLC	Tissue	5% - 10%	3	3

METHYLATION PROFILING

Quantitatively assess methylation changes in CpG-rich-regions ranging from 150bp – 550bp in length using MassCLEAVE™ chemistry. Easily validate findings from genome-wide methylation screening studies and cost-effectively test hundreds to thousands of samples.

Examples of Methylation Assays Developed on the MassARRAY System

Area of Focus	Sample Type	Limit of Detection	# of Genes	Targets
Lynch syndrome	Tissue	5%	1	MLH1 Promoter
Gliomas & glioblastomas	Tissue	5%	1	MGMT Promoter

Pharmacogenetics

Target the most important haplotypes related to drug absorption, distribution, metabolism, excretion, and toxicity (ADME-T) with robust assays. Investigate copy number variants and hybrid alleles along with SNPs, insertions, and deletions in the same workflow, increasing lab efficiency. Use PGx report modules to generate haplotypes and star alleles from genotypes. Enhance drug development and clinical trial research with assays to:

- Identify individuals susceptible to adverse drug reactions.
- Distinguish between poor, intermediate, extensive, and ultra-extensive metabolizers.
- Target variants prevalent in specific ethnicities or populations for improved drug efficacy.

Examples of Pharmacogenetics Assays Developed on the MassARRAY System

Area of Focus	# of Genes	# of Targets	Biomarkers
Veridose Core Panel	20	68 + 5 CNV	SNPs and indels across CYP2D6, CYP2C9, CYP2C19, VKORC1, etc.
ABA CYP2C9 Panel	4	51	SNPs and indels across CYP2C9, VKORC1
Chemotherapeutic drugs	6	15	TPMT and DPYD
Adverse drug reactions	1	4	TA repeats across UGT1A1
HLA-A and HLA-B subtypes associated with drug response	2	6	SNPs across HLA-A and HLA-B

Carrier Screening & Inherited Disease

Develop assays to screen for variants associated with inherited disease across one or more populations. Germline genotyping on the MassARRAY System is cost-effective, enabling labs to test 10s to 100s of variants through high multiplexing efficiency.

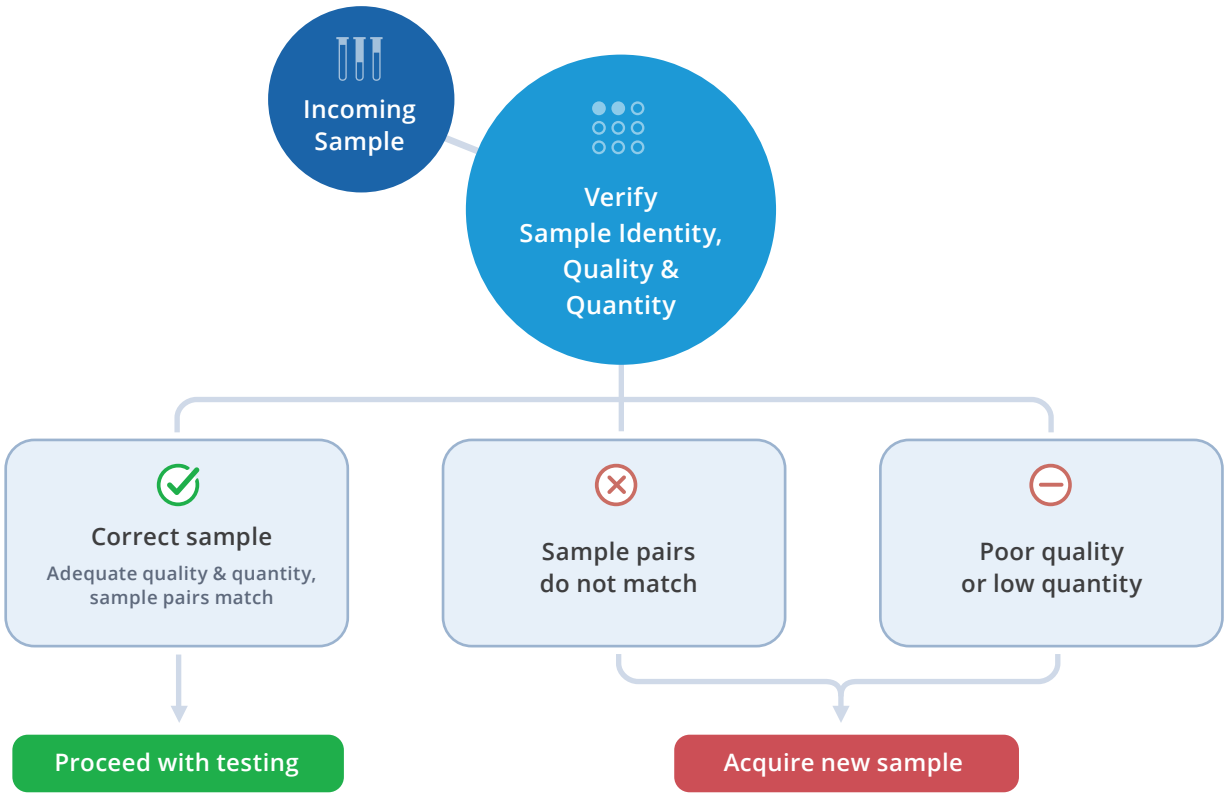
Examples of Inherited Disease Assays Developed on the MassARRAY System

Area of Focus	# of Genes	# of Targets	Biomarkers
Cystic fibrosis	1	5 – 150	SNPs and indels across CFTR
Beta thalassemia	2	20	SNPs across HBB and HBG1
Hearing impairment	4	28	SNPs and indels
Ashkenazi Jewish diseases	39	123	SNPs
Inherited cancer risk	99	276	SNPs

Sample Identification & Qualification

Develop custom solutions to track samples through your laboratory's workflow using a SNP-based barcode. Prevent costly sample failures due to insufficient quality and quantity by simultaneously assessing DNA degradation and the number of available amplifiable copies. Utilize pre-designed assays to assess DNA quality across a broad dynamic range of 100 – 100,000 (0.3 ng – 300 ng) amplifiable template copies and 100bp – 500bp amplicons. Apply powerful algorithms to match sample pairs such as tumor and normal tissue, as well as multiple samples acquired from the same individual at different times.

Applications for Sample ID and QC



Examples of Sample Integrity Assays Developed on the MassARRAY System

Area of Focus	ID Markers	Sex Markers	QC Markers
Sample identification using exonic SNPs and DNA quality assessment across various amplicon lengths	21	3	25
Sample identification from urine	22	3	0
Transplant monitoring, genetic or sample mixtures	92	0	0

Blood Group Genotyping

Develop DNA-based extended antigen typing of erythrocytes, neutrophils, and platelets. Utilize Agena's expertise in typing over 100 antigens in 16 blood group systems, including 23 platelet and neutrophil antigens (HPA/HNA). Resolve complex *RH* genotypes and identify *RHD* zygosity and *RHD-RHCE* hybrid alleles.

Examples of Blood Group Genotyping Assays Developed on the MassARRAY System

Blood Group	Predicted Phenotypes Assayed
Kell	K/k, Kmod, Kpa/Kpb, Jsa/Jsb, KEL11/KEL17, Knull or K0
Kidd	Jka/Jkb, Jk(a–b–) or Jk0
Duffy	Fya/Fyb, Fy(a–b–) or Fy0 (GATA), Fy(b+w) or Fyx+
MNS	M/N, S/s, Mta Vw, Hut, IVS5 or P2
RHD	RHD weak type, RHD categories, partial RHD, deletions
RHD-RHCE	Identify over 30 RHDCE hybrid alleles
HNA	HNA-1a/b/ab/ac/bc /c, HNA-3a/b, HNA-4a/bw, HNA-5a/bw
HPA	HPA-1a/b, HPA-2a/b, HPA-3a/b, HPA-4a/b, HPA-5a/b, HPA-6a/bw, HPA-15a/b
Donor Quick Screen	Quickly screen donors for rare antigens across Rhesus, KKD, MNS, Lutheran, Dombrock, Landsteiner-Wiener, Diego, Colton, Scianna, and Cartwright blood group systems

Infectious Disease

Employ multiplexed assays to rapidly identify *Staphylococcus aureus, Pseudomonas aeruginosa, M. tuberculosis* Complex (MTBC), or gram negative bacteria, and screen for resistance to antibiotics.

Examples of Infectious Disease Panels Developed on the MassARRAY System

Area of focus	# of Targets
Detection and discrimination of SARS-CoV-2 variants	36 mutations
Detection and discrimination of SARS-CoV-2, Flu A/B, and RSV	5
Head and neck, gynecological, and dermatological cancer research	24 HPV subtypes

Agricultural Genetics

Create custom assays for any species, including complex polyploids, to validate sequencing discoveries and test large numbers of samples cost-effectively, with a low cost per genotype. The MassARRAY is a high-throughput system enabling you to generate >150,000 genotypes per day with the help of a single technician.

Sampling of plants and animals genotyped with the MassARRAY System

- Alpaca
- Arabidopsis
- Barley
- Canola
- Cattle
- Corn
- Cotton
- Deer
- Elk
- Goat
- Hardwood Tree
- Horse
- Maize
- Oak Tree
- Palm Oil Tree
- Pig
- Pine Tree
- Prawn
- Salmon
- Sheep
- Soybean
- Sugarcane
- Tomato
- Watermelon
- Wheat

Examples of Bovine Parentage and Trait selection panels on the MassARRAY System

Species	Targets
Bos taurus	>115 markers including international society for animal genetics (ISAG) recommended core markers
Bos indicus	100 ISAG recommended core markers

PLANT GENOTYPING

Create custom panels to perform crop strain validation, marker assisted breeding, bulk segregant analysis (BSA), genetic mapping, quantitative trait locus (QTL) analysis, and distinguish genetically modified organisms (GMO) on a variety of plant species such as corn, barley, wheat, and soybean.

INTERESTED IN DEVELOPING YOUR OWN ASSAY?

Agena Bioscience has laboratories located globally to provide custom assay services worldwide. Contact your local sales representative to learn more about Assays by Agena services and to get started with your project.

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