

NOTICE OF PRIVACY PRACTICES

Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Effective Date: January 1, 2024

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN ACCESS THIS INFORMATION.

PLEASE REVIEW IT CAREFULLY.

About Us – Advanta Genetics, LLC

In this Notice, terms such as "we," "us," or "our" refer to Advanta Genetics, LLC ("Advanta"). Advanta Genetics, LLC is a high-complexity clinical and research laboratory certified under CLIA, registered with the Drug Enforcement Administration, and compliant with Current Good Manufacturing Practices (cGMP). Advanta holds prestigious ISO 15189:2022 accreditation granted by the ANSI National Accreditation Board (ANAB), distinguishing Advanta for its scientific excellence, rigorous quality assurance, and advanced technical competence in medical and clinical laboratory testing. ISO 15189 is internationally recognized as the gold standard for quality management systems in medical laboratories. In addition, Advanta maintains certifications in ISO 13485:2016 and ISO 9001:2015 and is accredited by the College of American Pathologists (CAP). The laboratory also ensures compliance with the Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS), enabling trusted partnerships with the U.S. federal government and the Department of Defense. Our laboratorians include experts in pharmacology, biochemistry, toxicology, microbiology, cytogenetics, and molecular genetics.

Scope of This Notice

This Notice applies to all staff and facilities of Advanta Genetics, including our clinical laboratory scientists, laboratory directors, genetic counselors, toxicologists, and administrative personnel. It also applies to the protected health information (PHI) we create, maintain, or receive in the course of delivering laboratory services.

Our laboratory locations are listed on our website at: www.advanta.com

Phone: 903.707.2197

ADVANTA ANALYTICAL LABORATORIES 10935 CR 159, Tyler, TX 75703

www.aalabs.com

PHONE: 903.805.9955

advanta@aalabs.com

FAX: 903.839.2494



We use your Protected Health Information (PHI) to:

- Perform clinical testing services as requested by your treating provider
- Seek payment from your insurer or responsible party
- Support internal operations such as quality control, billing, compliance, and audit readiness

We do not release your test results to any third party other than your ordering healthcare provider or authorized healthcare professional, except as required or permitted by law.

What Is "Protected Health Information" (PHI)?

Protected Health Information (PHI) refers to any information—oral, written, or electronic—that identifies you and relates to:

- Your past, present, or future physical or mental health condition
- The provision of healthcare services to you
- Payment for your healthcare, including insurance and billing details

PHI includes, but is not limited to:

- Your name, date of birth, and contact information
- Medical record numbers, lab order identifiers, and insurance data
- Laboratory test results, including genetic and genomic information
- Information shared with or received from your treating physician or healthcare team

PHI does not include information that has been "de-identified"—meaning all identifying elements have been removed and there is no reasonable basis to believe it can be used to identify you.

Under the Health Information Technology for Economic and Clinical Health (HITECH) Act and the 21st Century Cures Act, your genetic data and certain electronic health information (EHI) are also protected under expanded privacy provisions.

We collect, maintain, and disclose your PHI as necessary to perform our core functions:

- 1. Treatment: Coordinating and providing your laboratory testing services
- 2. Payment: Billing you or your insurance for laboratory services
- 3. Healthcare Operations: Activities such as quality assurance, auditing, compliance, training, and accreditation

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Our Legal Obligations

We are legally required to:

- Maintain the privacy and security of your PHI using reasonable and appropriate safeguards
- Provide you with this Notice, which outlines our privacy practices and legal responsibilities
- Abide by the terms of this Notice
- Notify you promptly if a breach of your unsecured PHI occurs that compromises the privacy or security of your information

California Breach Notification Requirement

In accordance with California Health & Safety Code § 1280.15(b)(2), if a breach of medical information occurs involving a California resident, Advanta Genetics must:

- Notify the affected individual(s) within five (5) business days of discovering the breach
- Include in the notice:
 - o A general description of the incident
 - o The type of information involved
 - The date and time of the breach (if known)
 - Contact information for major credit reporting agencies

If the breach affects more than 500 California residents, Advanta is also required to notify the California Attorney General electronically.

Note: Under California law, individuals have the right to bring a legal action against Advanta or any individual responsible for the breach. However, proof of actual monetary harm is required for recovery of damages.

How We Protect Your PHI

At Advanta Genetics, we take the privacy and security of your health information seriously. We implement and maintain a comprehensive data protection framework to ensure your Protected Health Information (PHI) is safeguarded against unauthorized access, use, or disclosure.

Access to PHI is strictly limited to authorized personnel who need the information to perform specific job functions in support of laboratory testing, quality control, billing, or compliance operations.

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Our Safeguards Include:

• Administrative Controls:

- Role-based access controls and workforce HIPAA training
- Confidentiality agreements and mandatory compliance certifications
- Security awareness programs and incident response protocols

• Technical Safeguards:

- o Data encryption at rest and in transit (e.g., HTTPS, VPN, secure SFTP)
- o Multi-factor authentication (MFA) for all remote access
- o Firewalls, endpoint protection, and continuous monitoring tools
- o Access logs and audit trails for all PHI systems

• Physical Security:

- o Controlled facility access (badge entry, video surveillance)
- Secure workstation configuration and device controls
- o Restricted laboratory zones with authorized personnel-only entry

Ongoing Monitoring and Evaluation

We conduct regular:

- Risk assessments and HIPAA security audits
- Vulnerability scans and penetration tests
- Business continuity and disaster recovery reviews

These proactive measures ensure compliance with the HIPAA Security Rule (45 CFR §§ 164.302–318) and other applicable regulations governing healthcare data privacy.

If you have questions or concerns about how we protect your information, you may contact our Privacy Officer at privacy@advanta.com or 903-805-9955.

advanta@aalabs.com

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Types of Use and Disclosure of PHI We May Make Without Your Authorization

Under federal law, Advanta Genetics may use or disclose your Protected Health Information (PHI) without your written authorization for specific purposes permitted or required by HIPAA. These include uses for treatment, payment, and healthcare operations, as well as certain other circumstances described below.

1. Treatment, Payment, and Health Care Operations

We may use and disclose your PHI to:

- Perform laboratory testing services ordered by your healthcare provider
- Communicate results to the ordering provider or their designee
- Bill and collect payment from your insurance provider, health plan, or other payer
- Conduct internal quality assessments, audits, and accreditation reviews
- Engage business associates (e.g., secure IT vendors, billing services) who are contractually required to safeguard your information in accordance with HIPAA

Note: Genetic test results are disclosed only to your ordering provider or another healthcare professional authorized by law to receive them.

2. Other Uses and Disclosures Permitted by Law (Without Authorization)

We may disclose your PHI without your consent in the following situations:

- 1. As required by law When disclosure is mandated by federal, state, or local law
- 2. For public health activities Including disease reporting, registries, and clinical outcomes tracking
- 3. For reporting abuse, neglect, or domestic violence
- 4. To health oversight agencies For audits, inspections, and investigations (e.g., CMS, HHS OIG)
- 5. In connection with judicial or administrative proceedings If ordered by a court or authorized subpoena
- 6. To law enforcement When required for legal processes, locating a suspect, or reporting a crime
- 7. To medical examiners, coroners, or funeral directors For identification or lawful duties
- 8. For organ or tissue donation purposes
- 9. For approved research purposes When reviewed by an Institutional Review Board (IRB) or Privacy Board

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- 10. To avert a serious threat to health or safety When disclosure may prevent harm to an individual or the public
- 11. For specialized government functions Such as military operations, national security, or custodial law enforcement duties
- 12. To comply with workers' compensation laws and programs

Important: When disclosing PHI without authorization, we follow the minimum necessary standard—meaning only the essential information needed to accomplish the intended purpose is shared.

Uses and Disclosures Requiring You to Have the Opportunity to Agree or Object

In certain limited circumstances, Advanta Genetics may use or disclose your Protected Health Information (PHI) without a written authorization only after providing you the opportunity to agree or object.

These situations typically involve the disclosure of information to individuals who are involved in your care or the payment for your care.

Examples Where You May Agree or Object

We may disclose your PHI to:

- A family member, close friend, or other person involved in your medical care or payment, but only if you agree or do not object when given the opportunity
- Someone who may act on your behalf during a medical emergency or while you are incapacitated, if, in our professional judgment, the disclosure is in your best interest

If you are present and able to communicate your preferences, we will provide you the opportunity to:

• Agree, object, or request restrictions on how much information is shared and with whom

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If You Are Unable to Respond

If you are unconscious, disoriented, or otherwise unable to respond, we may use our professional judgment to determine whether disclosing limited PHI is necessary for:

- Coordinating your care or
- Informing someone involved in your healthcare or emergency response

We will always act in good faith to protect your privacy while ensuring appropriate and compassionate care.

You may revoke or restrict these permissions at any time by submitting a written request to our Compliance Department.

Use and Disclosure of "De-Identified" PHI

Under HIPAA, information that has been "de-identified" is no longer considered Protected Health Information (PHI) and is not subject to HIPAA privacy protections.

De-identified information is data that has been stripped of all identifiable elements, such that there is no reasonable basis to believe the information could identify you, directly or indirectly.

How We De-Identify PHI

Advanta Genetics may de-identify health information by following one of two HIPAA-approved methods:

1. Expert Determination Method:

A qualified expert applies accepted statistical or scientific principles and determines that the risk of identification is very small.

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2. Safe Harbor Method:

We remove 18 specific identifiers, including:

- o Name
- Date of birth
- Contact information
- o Social Security numbers
- o Medical record numbers
- o Any other unique identifying information

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<mark>ialabs.com</mark> advanta@aalabs.com



Once PHI has been properly de-identified, it may be used or disclosed for purposes such as:

- Internal quality assurance and analytics
- Scientific research
- Public health reporting
- Data modeling and laboratory performance optimization

Important: De-identified data cannot be used to re-identify you or to contact you, and we never sell or disclose it in a way that would compromise your privacy.

Special Rules for Parental Access to PHI of Minor Children

As a general rule, parents, legal guardians, or other authorized representatives may access the Protected Health Information (PHI) of their minor child. However, both federal and state laws recognize circumstances in which a minor may control access to their own health information, and in such cases, Advanta Genetics must comply with these legal restrictions.

When Parental Access Is Permitted

Parents or guardians typically have the right to:

- Request copies of their child's laboratory test results
- Authorize or restrict disclosure of their child's PHI
- Receive updates related to billing or healthcare operations

When Parental Access May Be Limited or Denied

Access to a minor's PHI may be limited or denied in the following situations:

- The minor has the legal right to consent to their own care under state law (e.g., reproductive health services, mental health treatment, substance use care)
- The minor has requested that their information remain confidential and is legally permitted to do
- A court order or state law explicitly limits parental access
- The treating provider determines, consistent with law, that disclosure may pose a risk to the minor's health or safety

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Advanta Genetics will always follow the applicable federal and state regulations when determining whether parental access to a minor's PHI is allowed. If we must deny access, we will provide a written explanation and outline any available appeal options.

Uses and Disclosures Requiring Your Authorization

In general, Advanta Genetics may not use or disclose your Protected Health Information (PHI) for purposes beyond treatment, payment, healthcare operations, or those permitted by law without your written authorization.

We will obtain your specific, written permission before using or disclosing your PHI in the following situations:

1. Marketing

We will obtain your written authorization before using your PHI to send you:

- Marketing materials promoting third-party products or services
- Paid promotional communications (e.g., sponsored advertisements or outreach)

Exceptions: We may contact you without written authorization if the communication:

- Occurs face-to-face, or
- Involves a nominal value promotional gift (e.g., educational pamphlet)

2. Sale of PHI

We will never sell your PHI. However, should such a scenario arise in the future, we are required to obtain your written authorization before disclosing your PHI in exchange for direct or indirect financial compensation.

3. Other Non-Routine Disclosures

Any other use or disclosure of your PHI not specifically described in this Notice requires your written authorization. This includes:

- Sharing PHI with third parties for research without de-identification or waiver
- Use of PHI in media, testimonials, or publications

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Revoking Your Authorization

You may revoke a prior authorization at any time by submitting a written request to:

Advanta Genetics – Compliance Department 10935 CR 159 Tyler, TX 75703 privacy@advanta.com

Your Rights Regarding Your Protected Health Information (PHI)

As a patient of Advanta Genetics, you have several important rights related to your Protected Health Information (PHI). These rights ensure transparency, control, and access to your personal health data, in accordance with federal and state law.

1. Right to Access Your PHI

You have the right to:

- Inspect or request a copy of your PHI maintained by Advanta, including laboratory reports and billing records
- Receive PHI in paper or electronic format (including via secure portal or encrypted email)
- Access your information within 5 business days of submitting a written request, unless otherwise permitted by law

Requests can be submitted in writing to: Advanta Genetics – Compliance Department 10935 CR 159, Tyler, TX 75703 privacy@advanta.com

A reasonable fee may apply for producing hard copies, as allowed by law. Identification verification is required.

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2. Right to Amend Your PHI

If you believe any part of your PHI is inaccurate or incomplete, you may submit a written request to amend it. Your request should include:

- The correction or clarification being requested
- Your reason for the amendment

We will respond in writing to your request, typically within 60 days. If we deny your request, we will explain why and offer you the opportunity to submit a written statement of disagreement, which will be added to your medical record.

3. Right to an Accounting of Disclosures

You may request a list of certain disclosures we have made of your PHI over the past **six years**, excluding disclosures made:

- For treatment, payment, or healthcare operations
- To you directly
- Under your authorization

Your first request in a 12-month period is free. Additional requests may incur a reasonable fee.

4. Right to Request Restrictions

You may ask us to restrict:

- How we use or disclose your PHI for treatment, payment, or healthcare operations
- Disclosure of PHI to a health plan if you pay out-of-pocket in full for the service

While we are not required to agree to all requested restrictions, we will always honor restrictions required by law or involving self-paid services.



5. Right to Confidential Communications

You may request that we:

- Contact you using alternative methods (e.g., by mail only, no phone calls)
- Send PHI to an alternate address or phone number

We will accommodate all reasonable requests, unless legally prohibited or administratively infeasible.

6. Right to a Copy of This Notice

You may request a printed copy of this Notice of Privacy Practices at any time, even if you agreed to receive it electronically. It is also available online at:

https://www.advanta.com/privacy

Right to Complain About Privacy Practices

You have the right to file a complaint if you believe your privacy rights have been violated or if you are dissatisfied with how your Protected Health Information (PHI) has been handled.

Advanta Genetics takes all privacy concerns seriously and will investigate each complaint thoroughly. We will not retaliate against you for filing a complaint or exercising any of your rights under HIPAA.

How to File a Complaint with Advanta Genetics

You may submit a complaint in writing, by email, or by phone to:

Privacy Officer – Advanta Genetics 10935 CR 159 Tyler, TX 75703 903-805-9955 privacy@advanta.com

You May Also File a Complaint with the U.S. Department of Health and Human Services (HHS)

Office for Civil Rights (OCR) – HHS https://www.hhs.gov/hipaa/filing-a-complaint/index.html

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No Retaliation Guarantee

Whether your complaint is made to Advanta or directly to HHS, you are fully protected by law from any form of retaliation, denial of service, or discrimination as a result of your complaint.

Our Responsibilities and Changes to This Notice

Advanta Genetics is required by federal law to:

- Maintain the privacy and security of your Protected Health Information (PHI)
- Provide you with this Notice of Privacy Practices explaining our legal obligations and privacy practices
- Abide by the terms of this Notice currently in effect
- Notify you in the event of a breach of your unsecured PHI, as required under the HIPAA Breach Notification Rule

We Reserve the Right to Revise This Notice

We may change our privacy practices at any time, as permitted or required by law. If we make a material change to this Notice, we will:

- Update the Effective Date listed at the top of the Notice
- Make the new Notice available upon request, in our office, and on our website: https://www.advanta.com/privacy

Unless prohibited by law, all changes to this Notice will apply to all PHI we maintain, including information collected prior to the effective date of the revised Notice.