



Genelex Corporation Fact Sheet

Company Name	Genelex Corporation
Company Websites	www.genelex.com www.YouScript.com
Founded	Genelex was founded in 1987 and is privately held
Number of Employees	60 (approximate)
Headquarters	3101 Western Ave., Ste. 100 Seattle, WA 98121 U.S.A.
Contact Information	800-TEST-DNA (800-837-8362) Email: info@youscript.com
Company Overview	<p>Genelex has grown from its early roots as a forensic and paternity testing laboratory to a CAP accredited and CLIA certified high-complexity molecular diagnostics laboratory offering healthcare providers pharmacogenetic testing (testing of gene variants that could have an impact on drug response) and analysis, together with clinical decision support software that enables safer, more targeted prescribing.</p> <p>Genelex currently offers more than 28 pharmacogenetic tests whose results can be interpreted by its YouScript® Personalized Prescribing Software.</p> <p>A patented medication management system, YouScript :</p> <ul style="list-style-type: none">• Is the first commercially-available software to assess the cumulative effect of a patient's genetics and their entire drug regimen, including multiple drugs, OTC, recreational medications and herbal supplements• Provides clinically-actionable prescribing guidance <p>Understanding which medications will work best for each patient has the potential to reduce adverse drug events (ADEs), reduce healthcare costs and improve patient outcomes.</p> <p>In 2014, The <i>Puget Sound Business Journal</i> named Genelex one of Washington's fastest growing companies for the second consecutive year and third time since 1995.</p>

Value to Healthcare Industry

The patented YouScript System makes personalized prescribing a reality. Using the technology, physicians can prescribe based on the science of genetic and metabolic variations, paired with individual patient test results, to:

- Improve patient care
- Ensure the right drug, and the right dose
- Ensure drug efficacy
- Reduce or eliminate side effects
- Avoid complications and re-admissions resulting from adverse drug events (ADEs)

Unlike some other initiatives undertaken to reduce healthcare costs in the long term, implementing YouScript can result in immediate cost-savings. Personalized Prescribing can impact costs:

- For individuals, by reducing treatment failures as well as the potential for drug-induced complications (or ADEs) and the additional care often required
- For physicians and the healthcare system as a whole, by identifying and better managing individuals at-risk for drug-gene interactions and potential ADEs, and by reducing hospital re-admissions

See [The Case for Pharmacogenetic Testing Fact Sheet](#) for related cost statistics, below.

Company History

Originally founded in 1987 by Howard Coleman and Tia Aulinkas as a forensics and ancestry genetic testing laboratory, Genelex performed thousands of tests internationally primarily for criminal and paternity cases. Seen as a highly-accurate, reliable lab, Genelex was often sought out for testing, consulting and testimony on high-profile cases.

The company turned its genetic testing and analysis expertise to the burgeoning field of pharmacogenomics in the late 1990s. The shift in focus was prompted by a [Fortune magazine story](#) about the death of Michael Adams-Conroy, a nine-year old boy who died of an adverse drug reaction resulting from his inability to properly metabolize Prozac.

In 2000, Genelex became one of the first labs in the U.S. to provide pharmacogenetic testing and interpretation. The company launched its medication management software, YouScript Personalized Prescribing Software, in 2012.

Pharmacogenetic Testing

Most commonly prescribed drugs are affected by genetic variations; multiple medications also can impact how a patient metabolizes individual drugs. Genelex offers 28+ pharmacogenetic tests that evaluate an individual's ability to metabolize various medications. Some tests are relevant to only specific drugs and conditions, but others, such as those testing the cytochrome P450 family of enzymes, have broad utility in that they test for variations in enzymes that help metabolize most of the medications we are likely to take in our lifetimes.

In 2015, Genelex introduced new tests for patients receiving care for several specific medical conditions (cardiac, psychiatric, ADHD, addiction, infectious diseases, cancer). Tests can be ordered individually or as a panel.

Tests determine if a patient:

- Is unable to process a drug favorably
- May have a negative or adverse reaction due to a drug-gene interaction
- Is likely to experience treatment failure, or
- Is at risk for toxic drug accumulation.

Genelex Corporation is accredited by the College of American Pathologists (CAP 1073709); certified under the Clinical Laboratory Improvement Amendments (CLIA No. 50D0980559); is Washington State Medical Test Site No. MTS-3919; New York State Department of Health license no. PFI 8201; and is licensed to perform high complexity clinical testing in all US states.

The company's fully accredited laboratory facilities feature state-of-the-art robotic DNA extraction and testing equipment to ensure high accuracy and low errors; proprietary test platforms and methodologies; test validation across multiple platforms and dedicated customer support. Visit

www.genelex.com/pharmacogenetic-tests for full information.

YouScript® Personalized Prescribing Software

This clinical decision support software puts the latest clinical knowledge about drug metabolism at the fingertips of physicians, and provides clinically-actionable prescribing guidance for individual patients, improving care and reducing the potential for drug-related adverse events.

Features include:

- Cloud-based software that interprets each patient's genetic test and provides individualized prescription guidance via its Risk Analysis Dashboard, which details drug level changes due to

drug, gene or cumulative interactions

- Alternates Selector, which suggests safer drug alternatives when indicated, and permits the physician to audition alternates for adverse effects before prescribing
- Population risk analysis and management
- Detailed pharmacokinetic and pharmacodynamics effects and changes
- Interaction notes with detailed management and dosing guidance
- Clinical evidence and literature links
- HIPAA compliant
- APIs for EHR integration

YouScript is an Allscripts Development Program Certified Application, and conforms to RxNorm medication interoperability standards.

Costs

For Patients:

Medicare coverage varies by plan; Medicare Advantage covers in many instances and traditional Medicare covers testing in some select cases.

Most private insurance covers the testing in many diagnostic situations, including adverse drug reactions or lack of response to medication, pain management, cancer management, and management of many co-morbid conditions.

The ability to order tests individually and panels costing less than \$1000 makes testing both affordable and cost-effective for most.

Genelex also offers a generous Financial Assistance Plan for those in need.

For Providers:

YouScript clinical decision support software can be licensed annually for \$295.

Target Customers

- Healthcare providers, especially primary care practitioners, geriatricians, cardiologists, psychiatrists and pain management specialists
- Hospitals
- Pharmacists
- Long term care and skilled nursing facilities
- Managed and accountable care organizations
- IT professionals within healthcare organizations
- Consumers

Management Team

- Howard C. Coleman, Chairman and Chief Executive Officer
- Tia Aulinkas, PhD, Laboratory Director, Chief Scientific Officer and Board Member
- Gregory Alderson, CPA, Executive Vice President and Board Member
- John Nelson, M.D., MPH, Medical Director
- Bob Patterson, M.D., Chief Information Officer
- Kristine Ashcraft, Chief Operating Officer
- Rajeev Pany, Director of Software Engineering
- Janet Carbary, Chief Financial Officer
- Paul Seesman, Director of Payer Relations

Board Members

- Howard C. Coleman, Chairman
- Gregory Alderson
- Tia Aulinkas, PhD
- John Derr
- Dave Garets

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The Case for Pharmacogenetic Testing Fact Sheet

Clinical studies and recent healthcare industry research enumerate compelling facts in support of pharmacogenetic testing and analysis at the point of care.

The data points below are drawn from reports in a range of areas including Adverse Drug Events (ADEs), genetics, prescription medications, adherence and medical specialties.

Roughly **75% of the U.S. population** does not metabolize medications normally¹

Genetics can account for 20-95% of the variability in an individual's response to drugs²

2.2 million severe Adverse Drug Events (ADEs) occur in the U.S. every year³

ADEs:

- Are the **fourth leading cause of death** in the U.S.³
- Account for approximately **\$3.5 billion in extra medical costs annually**⁴

Medicare fined three-quarters of eligible hospitals for re-admissions in 2014⁵

As many as **33% of all potentially clinically significant drug interactions, one of the possible causes of ADEs, are caused by drug-gene and drug-drug-gene interactions** and may be missed by drug-drug interaction analysis alone⁶

FDA guidance:

- Drug-gene interactions should be considered **similar in scope to drug-drug interactions**⁷
- **More than 100 medications known to have drug-gene interactions** require FDA warnings on the labels, with recommendation for pharmacogenetic testing prior to use⁷

Drug related problems, such as non-adherence, sub-optimal prescribing, drug administration and diagnosis could cost the U.S. **as much as \$290 billion per year**⁸

Cytochrome variants impact more patients than common genetic disorder testing (for conditions such as breast cancer, cystic fibrosis, Downs syndrome, psychiatric, cardiac, pain)⁹

One-size prescribing can lead to treatment failures and a high cost of care. For

example, **cancer drugs are ineffective in an average of 75% of patients**¹⁰

Medical Specialties:

Cardiology - The FDA has included pharmacogenomic information in the labels of **16 cardiology and hematology drugs**¹¹ Nine of these drugs are processed through the body's highly variable CYP450 pathways.¹¹

Geriatrics - **40% of individuals over 65** take five or more medications.¹² One out of five elderly Americans take medications that "may adversely affect coexisting conditions"¹³

Pain - Persistent pain impacts 116 million adults and **costs the U.S. \$560-\$635 billion annually**^{14a}; most pain medications (opioids) are metabolized by CYP450 enzymes, thus patients with variations to these genes are at an increased risk of ADEs or treatment failure^{14b}

Psychiatry - Reduced metabolic function is associated with an **increased risk of adverse effects in patients taking antidepressants**¹⁵

References

¹ Villagra D, Goethe J, Schwartz HI, Szarek B, Kocherla M, Gorowski K, et al. Novel drug metabolism indices for pharmacogenetic functional status based on combinatory genotyping of CYP2C9, CYP2C19 and CYP2D6 genes. *Biomarkers in medicine*. 2011;5(4):427-38. Epub 2011/08/25. doi: 10.2217/bmm.11.32. PubMed PMID: 21861665; PubMed Central PMCID: PMC3225004.

² Belle DJ and Singh H. Genetic Factors in Drug Metabolism. *Am Fam Physician*. 2008 Jun 1; 77(11):1553-1560.

³ Lazarou J, Pomeranz, BH, Corey PN. Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies. *JAMA*. 1998 Apr; 279 (15):1200-1205.

⁴ U.S. Center for Disease Control and Prevention; *Journal of the American Medical Association*

⁵ Rau J. Medicare Fines 2,610 Hospitals In Third Round Of Readmission Penalties [Online News Service]. *Kaiser Health News*; 2014 [cited 2014]. Available from: <http://kaiserhealthnews.org/news/medicare-readmissions-penalties-2015>

⁶ Verbeurgt P, Mamiya T, Oesterheld J. How common are drug and gene interactions? Prevalence in a sample of 1143 patients with CYP2C9, CYP2C19 and CYP2D6 genotyping. *Pharmacogenomics*. 2014;15(5):655-65. Epub 2014/05/07. doi: 10.2217/pgs.14.6. PubMed PMID: 24798722.

⁷ www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM337169.pdf

⁸ Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease. A NEHI Research Brief - August 2009: NEHI; 2009.

⁹ Cystic Fibrosis Foundation; www.BreastCancer.org; National Down Syndrome Society; Genelex14K+ patients and hundreds of published reference papers; Administration on Aging, CVS Pharmacy; Wall Street Journal / Medco Health Solutions; Centers for Disease Control.

¹⁰ www.personalizedmedicinecoalition.org/sites/default/files/files/Case_for_PM_3rd_edition.pdf

¹¹ Table of Pharmacogenomic Biomarkers in Drug Labels Silver Spring, MD: FDA; 2013 [cited 2014 2/14/14]. Available from: www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm

¹² Qato DM, Alexander GC, Conti RM, Johnson M, Schumm P, Lindau ST. Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. *Jama*. 2008;300(24):2867-78. Epub 2008/12/26. doi: 10.1001/jama.2008.892. PubMed PMID: 19109115; PubMed Central PMCID: PMC3934884.

¹³ Lorgunpai SJ, Grammas M, Lee DS, McAvay G, Charpentier P, Tinetti ME. Potential therapeutic competition in community-living older adults in the u.s.: use of medications that may adversely affect a coexisting condition. *PLoS One*. 2014;9(2):e89447. doi: 10.1371/journal.pone.0089447. PubMed PMID: 24586786; PubMed Central PMCID: PMC3934884.

^{14a} Institute of Medicine Committee on Advancing Pain Research, Care, and Education. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington, DC: National Academies Press; 2011.

^{14b} Smith HS. Opioid Metabolism. *Mayo Clin Proc*. 2009;84 (7):613-624. PubMed PMID: 19567715.

¹⁵ Ingelman-Sundberg M, Sim SC, Gomez A, Rodriguez-Antona C. Influence of cytochrome P450 polymorphisms on drug therapies: pharmacogenetic, pharmacoeconomic and clinical aspects. *Pharmacol Ther*. 2007; 116:496-526.