TPA Network
Research Consortium

HERO
Health Economics Research Opportunities

Sample Test Results for Genetic/Genomic (DNA) Tests Focused on Medication

An Overview of the TPA and Self-Funded Market, Description of Our Study Approach and Insight into the Resources and Capabilities of TPA Network

To learn more about the **Research Consortium**
contact Richard Nicholas @ (858) 395-4114 or Richard@ResearchConsortium.org or see www.ResearchConsortium.org

Genetic Testing and Clinical Research

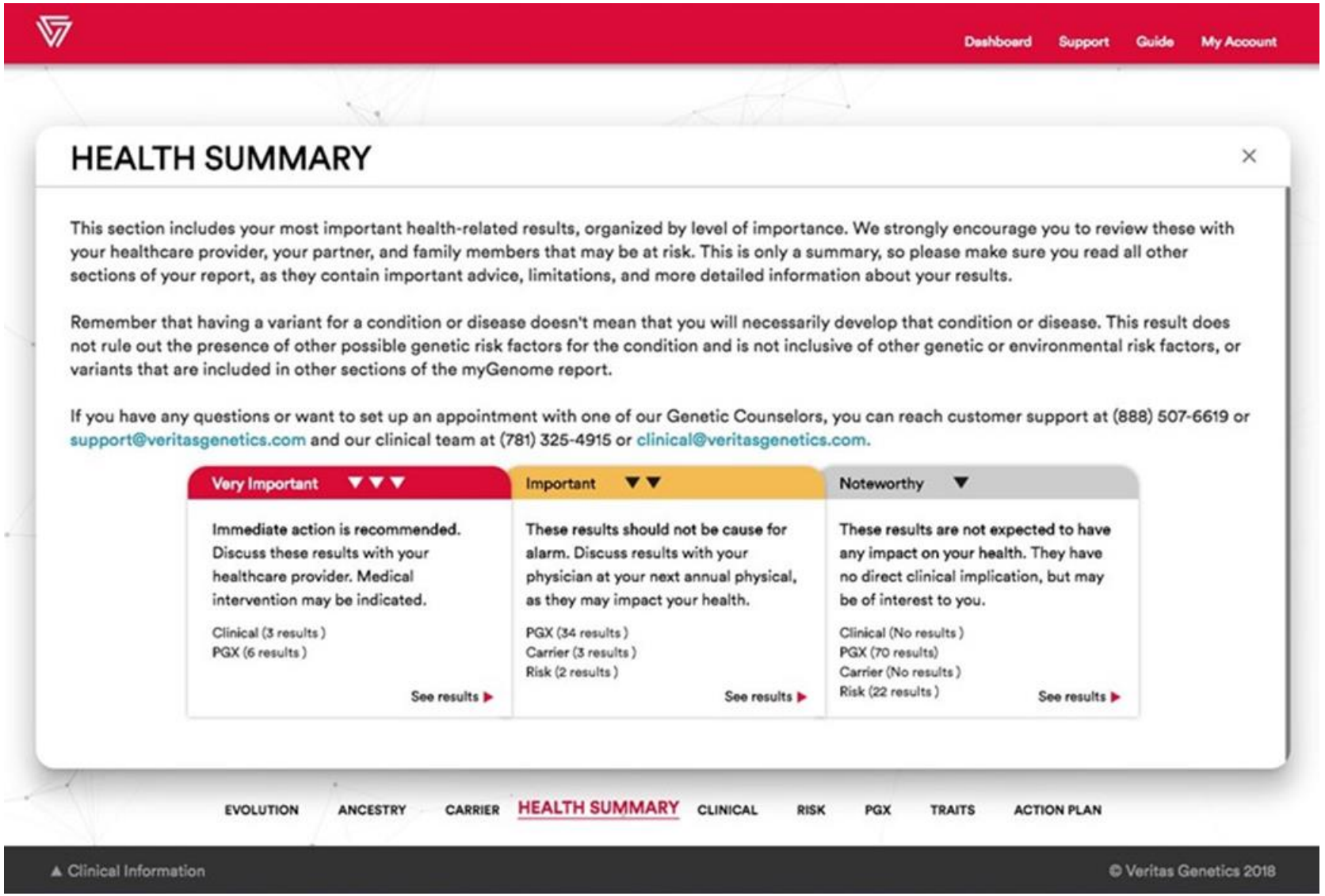
Recognizing their great value, more and more pharmaceutical, academic and foundational researchers are incorporating genetic (DNA) tests into their clinical research study regimens. Genetic tests explore a person's DNA to identify changes in chromosomes, genes, or proteins and are used by physicians for diagnostic, prognostic and predictive purposes. Genetic tests can confirm or rule out vulnerabilities to inherited diseases; or help determine a person's chance of developing or passing on a genetic disorder. Pharmacogenomic (PGx) tests determine the influence of genetic variation on drug response to determine which and what dosage would be the safest and most beneficial given the person's unique DNA (so that they don't have to try several medications before they find the right one). A perfectly healthy person can also benefit from obtaining medically actionable genetic data to learn more about what they can do to remain healthy or to become aware of what's to come for them health-wise so that they can take action to prevent certain disorders for which they might be more susceptible (from simply wearing more sunscreen to undergoing a preventative mastectomy).

Sample DNA Report 1

One study participation benefit may be a valuable medical-grade DNA test and lifetime access to easy-to-use AI-based technology that enables patients and their physicians to "query" the genome to learn how it impacts everything from how drugs are metabolized to what foods are good and not good to eat; and much more.

Genome sequencing is employed for patients having cancer, serious genetic diseases or symptoms that can't be explained. It can identify genetic drivers of disease; aid in diagnosis; and guide treatment.

This Veritas genomic test report is representative of those often used by a genetic specialist or PharmD to counsel patients and providers.

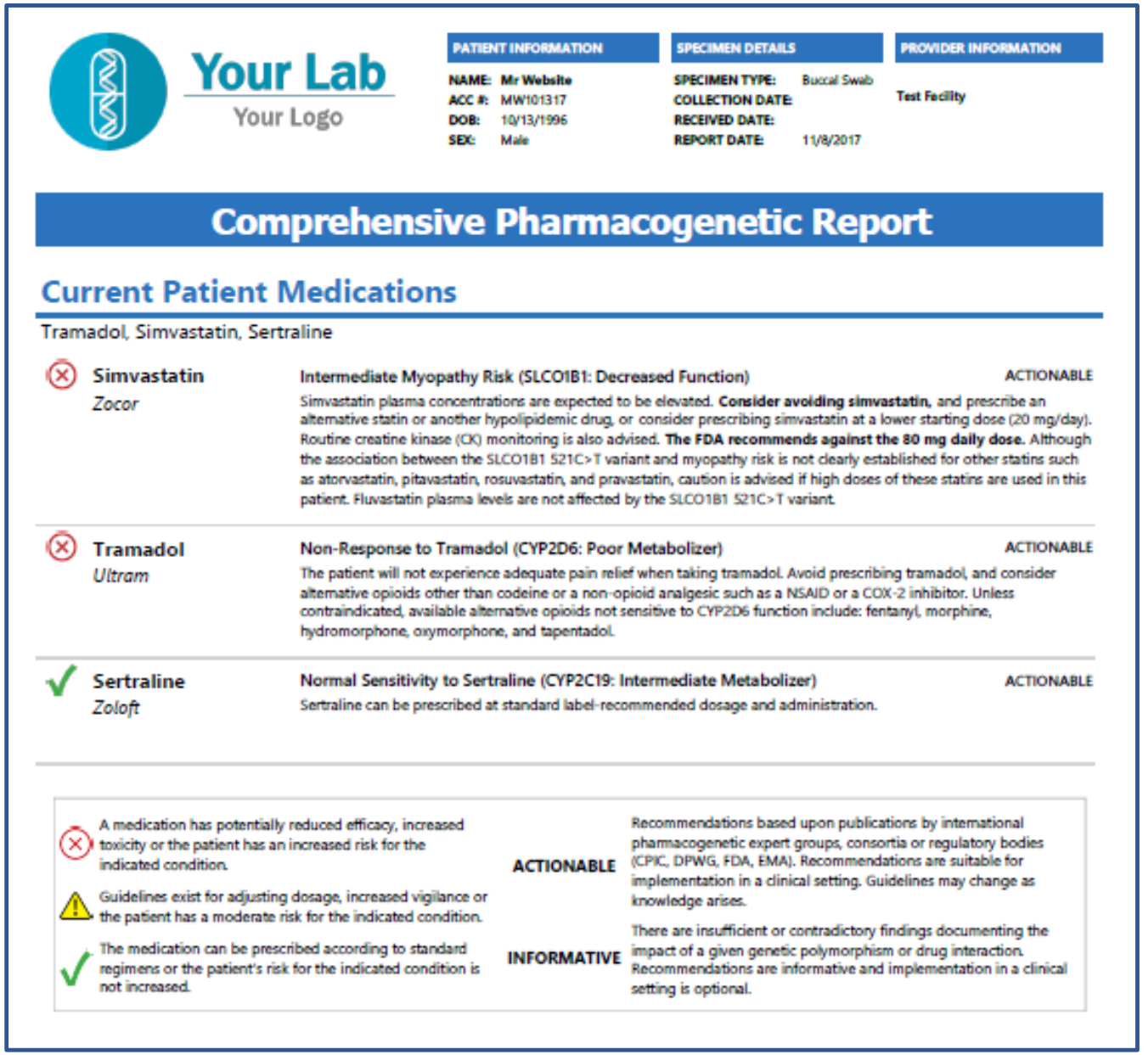


Sample DNA Test Report 2

Featured is a sample pharmacogenomic (PGx) test report from Translational Software, whose mission is to deliver precision medicine to every person and every clinical setting around the world.

The company believes in simplifying complex genetic data into actionable, evidence-based recommendations and platform-agnostic genomic decision support which empowers laboratories, clinicians, providers, and healthcare technology solution providers to confidently incorporate pharmacogenomics into care plans.

Essentially, the company transforms genetic test results into actionable information and, in turn, better medical outcomes. The company's web portal provides physicians with the power to provide better patient care with clinically-relevant pharmacogenomics information.



Your Lab
Your Logo

PATIENT INFORMATION		SPECIMEN DETAILS		PROVIDER INFORMATION
NAME:	Mr Website	SPECIMEN TYPE:	Buccal Swab	Test Facility
ACC #:	MW101317	COLLECTION DATE:		
DOB:	10/13/1996	RECEIVED DATE:		
SEX:	Male	REPORT DATE:	11/8/2017	

Comprehensive Pharmacogenetic Report

Current Patient Medications

Tramadol, Simvastatin, Sertraline

Simvastatin *Zocor*

Intermediate Myopathy Risk (SLCO1B1: Decreased Function) — ACTIONABLE

Simvastatin plasma concentrations are expected to be elevated. **Consider avoiding simvastatin,** and prescribe an alternative statin or another hypolipidemic drug, or consider prescribing simvastatin at a lower starting dose (20 mg/day). Routine creatine kinase (CK) monitoring is also advised. **The FDA recommends against the 80 mg daily dose.** Although the association between the SLCO1B1 521C>T variant and myopathy risk is not clearly established for other statins such as atorvastatin, pitavastatin, rosuvastatin, and pravastatin, caution is advised if high doses of these statins are used in this patient. Fluvastatin plasma levels are not affected by the SLCO1B1 521C>T variant.

Tramadol *Ultram*

Non-Response to Tramadol (CYP2D6: Poor Metabolizer) — ACTIONABLE

The patient will not experience adequate pain relief when taking tramadol. Avoid prescribing tramadol, and consider alternative opioids other than codeine or a non-opioid analgesic such as a NSAID or a COX-2 inhibitor. Unless contraindicated, available alternative opioids not sensitive to CYP2D6 function include: fentanyl, morphine, hydromorphone, oxymorphone, and tapentadol.

Sertraline *Zoloft*

Normal Sensitivity to Sertraline (CYP2C19: Intermediate Metabolizer) — ACTIONABLE

Sertraline can be prescribed at standard label-recommended dosage and administration.

- A medication has potentially reduced efficacy, increased toxicity or the patient has an increased risk for the indicated condition.
- Guidelines exist for adjusting dosage, increased vigilance or the patient has a moderate risk for the indicated condition.
- The medication can be prescribed according to standard regimens or the patient's risk for the indicated condition is not increased.

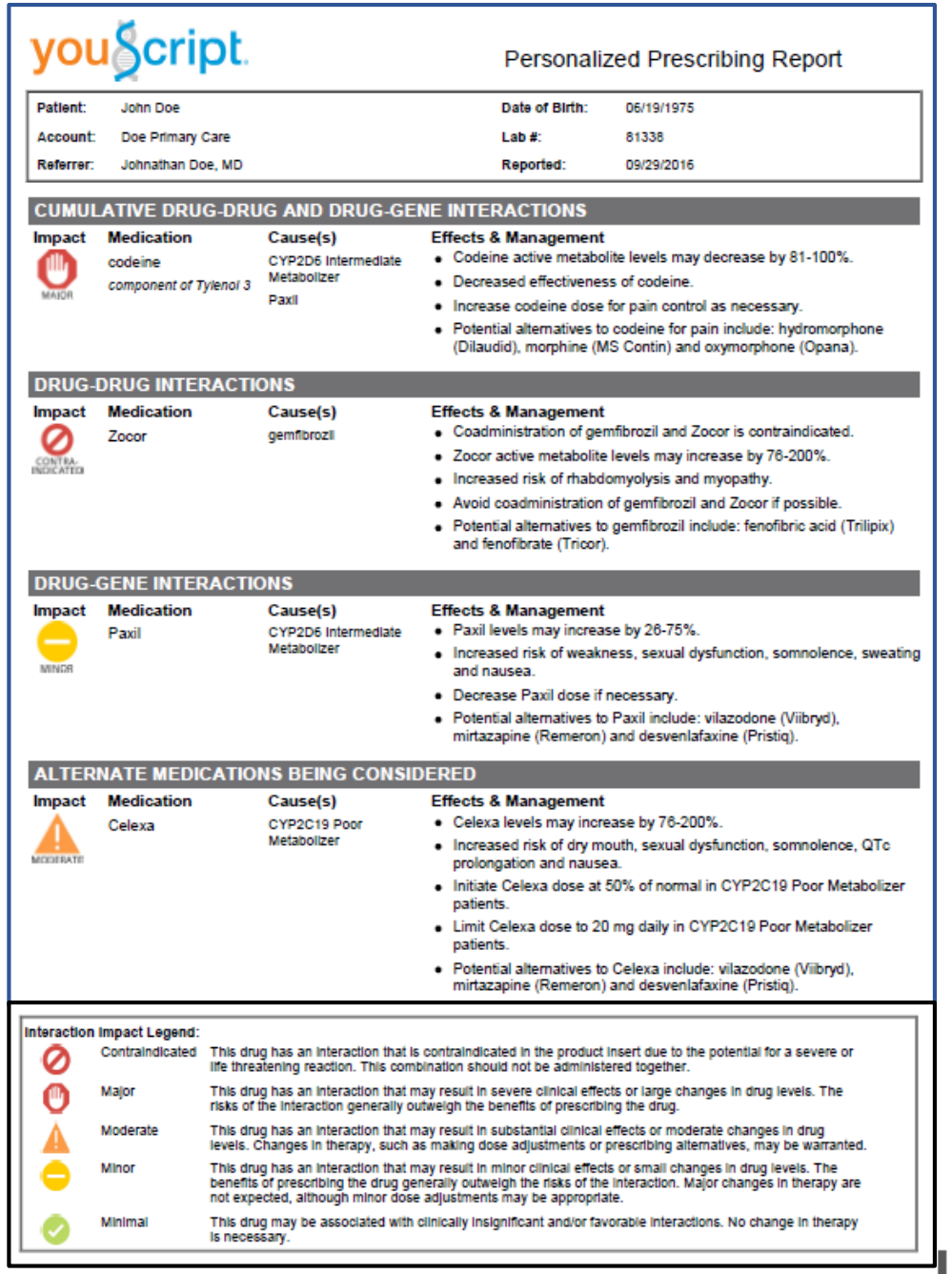
ACTIONABLE — Recommendations based upon publications by international pharmacogenetic expert groups, consortia or regulatory bodies (CPIC, DPWG, FDA, EMA). Recommendations are suitable for implementation in a clinical setting. Guidelines may change as knowledge arises.

INFORMATIVE — There are insufficient or contradictory findings documenting the impact of a given genetic polymorphism or drug interaction. Recommendations are informative and implementation in a clinical setting is optional.

Sample DNA Test Report 3

YouScript Precision Prescribing software is among the most advanced and innovative drug interaction software available, synthesizing all evidence impacting drug response to reduce trial-and-error prescribing and support the right decision at the point of care, reduce costs and improve outcomes.

Clinically validated to reduce avoidable adverse drug events its database contains ~ 2,000 unique drugs, herbals, and OTC medications and 90+ phenotypes. Its clinical content team continuously evaluates new drugs, research, and data, and created a library of 17,000+ professionally curated published references and product inserts. It integrates PGx testing with comprehensive drug-gene / drug-drug interaction information to assess the cumulative impact of a patient's genetics and drug regimen, and their risk for adverse drug events. Information, alerts, and recommended medication alternatives are presented in an easy-to-understand, clinically actionable format.



youScript

Personalized Prescribing Report

Patient:	John Doe	**Date of Birth:**	06/19/1975
Account:	Doe Primary Care	**Lab #:**	81338
Referrer:	Johnathan Doe, MD	**Reported:**	09/29/2016

CUMULATIVE DRUG-DRUG AND DRUG-GENE INTERACTIONS

Impact	Medication	Cause(s)	Effects & Management
MAJOR	codeine *component of Tylenol 3*	CYP2D6 Intermediate Metabolizer Paxil	• Codeine active metabolite levels may decrease by 81-100%. • Decreased effectiveness of codeine. • Increase codeine dose for pain control as necessary. • Potential alternatives to codeine for pain include: hydromorphone (Dilaudid), morphine (MS Contin) and oxymorphone (Opana).

DRUG-DRUG INTERACTIONS

Impact	Medication	Cause(s)	Effects & Management
CONTRAINDICATED	Zocor	gemfibrozil	• Coadministration of gemfibrozil and Zocor is contraindicated. • Zocor active metabolite levels may increase by 76-200%. • Increased risk of rhabdomyolysis and myopathy. • Avoid coadministration of gemfibrozil and Zocor if possible. • Potential alternatives to gemfibrozil include: fenofibric acid (Trilipix) and fenofibrate (Tricor).

DRUG-GENE INTERACTIONS

Impact	Medication	Cause(s)	Effects & Management
MINOR	Paxil	CYP2D6 Intermediate Metabolizer	• Paxil levels may increase by 26-75%. • Increased risk of weakness, sexual dysfunction, somnolence, sweating and nausea. • Decrease Paxil dose if necessary. • Potential alternatives to Paxil include: vilazodone (Viibryd), mirtazapine (Remeron) and desvenlafaxine (Pristiq).

ALTERNATE MEDICATIONS BEING CONSIDERED

Impact	Medication	Cause(s)	Effects & Management
MODERATE	Celexa	CYP2C19 Poor Metabolizer	• Celexa levels may increase by 76-200%. • Increased risk of dry mouth, sexual dysfunction, somnolence, QTc prolongation and nausea. • Initiate Celexa dose at 50% of normal in CYP2C19 Poor Metabolizer patients. • Limit Celexa dose to 20 mg daily in CYP2C19 Poor Metabolizer patients. • Potential alternatives to Celexa include: vilazodone (Viibryd), mirtazapine (Remeron) and desvenlafaxine (Pristiq).

Interaction Impact Legend:

Contraindicated	This drug has an interaction that is contraindicated in the product insert due to the potential for a severe or life threatening reaction. This combination should not be administered together.
Major	This drug has an interaction that may result in severe clinical effects or large changes in drug levels. The risks of the interaction generally outweigh the benefits of prescribing the drug.
Moderate	This drug has an interaction that may result in substantial clinical effects or moderate changes in drug levels. Changes in therapy, such as making dose adjustments or prescribing alternatives, may be warranted.
Minor	This drug has an interaction that may result in minor clinical effects or small changes in drug levels. The benefits of prescribing the drug generally outweigh the risks of the interaction. Major changes in therapy are not expected, although minor dose adjustments may be appropriate.
Minimal	This drug may be associated with clinically insignificant and/or favorable interactions. No change in therapy is necessary.