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PRESCRIBING SYSTEMS

LabStudio

CUSTOMIZABLE **LAB** WORKSPACE

User Manual

www.genxys.com

LabStudio

CUSTOMIZABLE **LAB** WORKSPACE

Lab Studio is a powerful tool designed to enhance your report customization experience. With Lab Studio, you can create, modify, and save multiple report templates, giving you greater flexibility and efficiency in generating reports that meet your specific needs.

This user manual will guide you through the features and functionalities of Lab Studio, including:

- Creating and Managing Report Templates
- Customizing Report Layouts and Data Fields
- Saving and Applying Templates for Future Use
- Tips for Optimizing Your Workflow

Whether you're new to report customization or an experienced user, this guide will help you get the most out of Lab Studio.

Let's get started!

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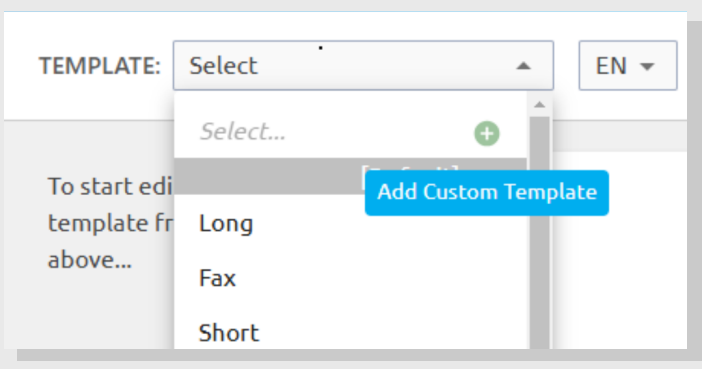
Templates

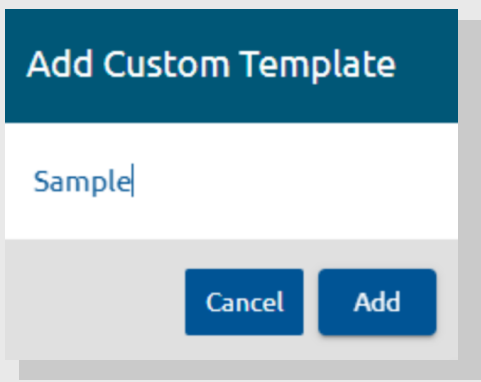
Lab Studio allows you to design and save multiple report templates, making it easier to generate reports that meet your specific requirements. Follow these steps to create, customize, and manage your templates efficiently.

Creating New Template

1. **Access Lab Studio**
   Navigate to the Lab Studio section from your LabGx dashboard.

2. **Start a New Template**
   Click on '+' /Create New Template" to begin designing your report :





3. **Save the Template**
   Click "Add " by giving it a recognizable name for easy access later.

4. **Customize Report Layout**
   Add or remove sections, adjust formatting, and select the data fields you want to include for Long, short and Fax versions independently.

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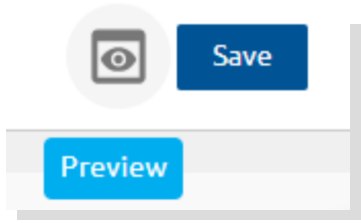
Templates

5 **Preview Your Template**
Review your changes to ensure the report appears as expected .



6 **Save the Template**
Click ”Save ” to retain the changes

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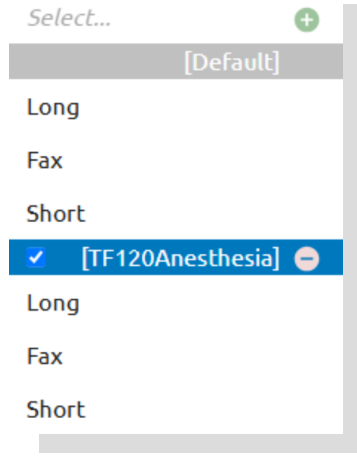
Managing your Templates

Editing an Existing Template:

Select a saved custom template, make the necessary changes, and save the updated version.

Applying a Template:

Select a template by checking the box beside each template name. One template can be activated at a time and if no templates are selected, the “Default” templates will be used.



Deleting Unused Templates:

Remove outdated templates to keep your workspace organized by clicking “–“ beside the template name.

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Using Custom Templates in Lab Studio

Labs can utilize custom templates in multiple ways to generate reports tailored to their needs. Below are the different methods for applying templates:

1 Activating a Template (Default Method)

The simplest way to use a custom template is to activate it. When a template is activated, all reports will be generated using either:

- The default template (if no other template is active).
- The active template (if one has been selected).

2 Specifying a Template in the Order JSON File

For more flexibility, users can specify a template directly within the order JSON file:

In the order file, include a tag with the desired template name.

Example: ”panel”:”panel_ID”,

”tag”:”Template name”,

When the report is generated, it will follow the specified template.

If no tag is present, the report will default to the active or default template. The tag will override the active template selected if different.

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Using Custom Templates in Lab Studio

3 Using Panel ID for Unique Report Configurations

If the lab utilizes Panel IDs and wants reports to follow a unique configuration:

- The lab can create a template specifically associated with a Panel ID. The template should be named identically to the Panel name.
- When an order includes a Panel ID, the system will map it to the corresponding template, ensuring that the correct format and settings are applied. The template will override the active template selected if different, and the template will override any tags as well.

By leveraging these options, labs can maintain greater control over report customization and ensure that each report aligns with specific clinical and operational requirements.

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Best Practices for Template Management

- Name your templates clearly to differentiate them easily.
- Keep commonly used templates updated to reflect any changes in reporting needs.
- Templates can be used for Affiliates lab as well, your total number of custom templates includes any templates dedicated to your affiliates.
  For example, a Professional Lab with 5 custom templates included can utilize 3 for themselves, and use 1 each for their two affiliate labs.

  Each lab including affiliates gets a set of default templates included.

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Global Settings in Lab Studio

These settings apply to all templates and are not part of individual customizations. They serve as a foundational configuration for the lab.

Report Formats
Reports can be published in various formats, including Long, Fax, Short, and Raw.

Specimen Type
Labs can select from Swab, Whole Blood, or Saliva. If a different specimen type is preferred, it can be defined in the order JSON file under the specimen section.

Time Zone
The report's time zone can be set based on the lab's local time zone.

Webhook URL
A webhook URL can be entered to receive real-time notifications for specific events.

Email Notifications
Users can configure email alerts for: Awaiting LD signoff, Phenotype translation issues, and Star allele translation issues.

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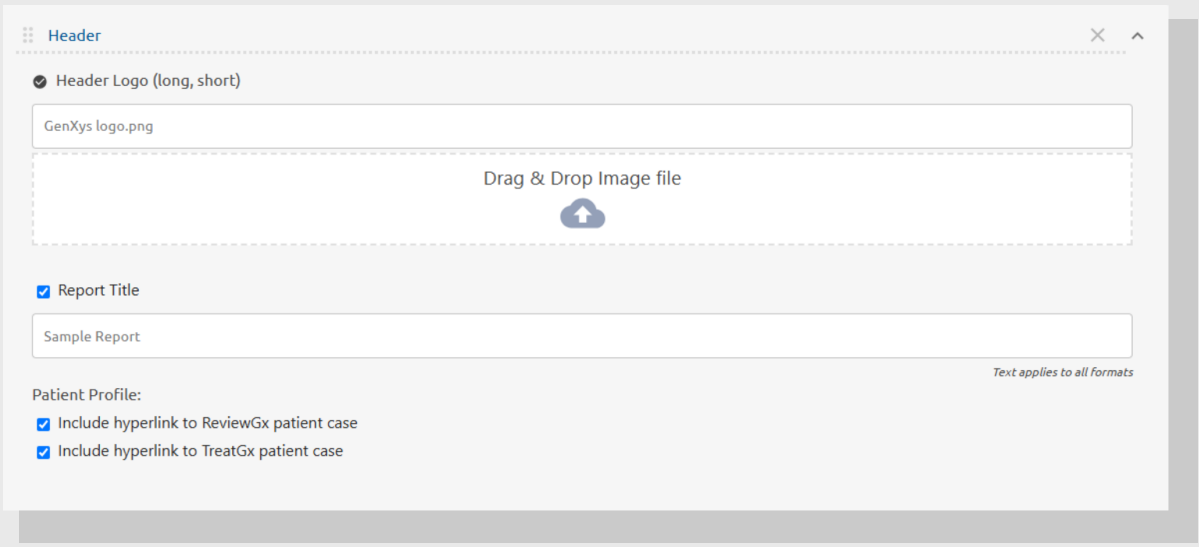
Template Customization

Customization is available for all the content sections. Some fields are applicable for all formats of the reports (Long, short, Fax) and some customizations are only exclusive to certain formats. If any feature is grayed out, it indicates the benefit is not under your current package. Please contact GenXys team to add any additional features.

Header



Header Logo

The Lab's logo can be uploaded here in .PNG or .SVG format. The logo should be below 400 Pixels in dimensions. The same logo will apply to the default template and all custom templates.

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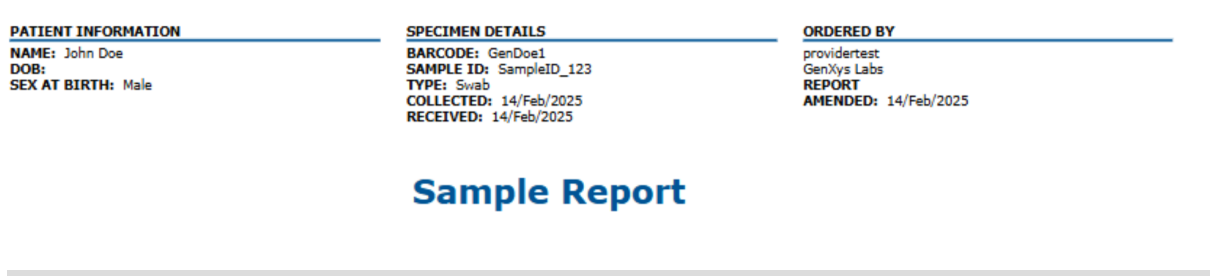
Template Customization

Report Title

If checked, any Custom report title can be provided which will be visible on top of the reports.



PATIENT INFORMATION
NAME: John Doe
DOB:
SEX AT BIRTH: Male

SPECIMEN DETAILS
BARCODE: GenDoe1
SAMPLE ID: SampleID_123
TYPE: Swab
COLLECTED: 14/Feb/2025
RECEIVED: 14/Feb/2025

ORDERED BY
providertest
GenXys Labs
REPORT
AMENDED: 14/Feb/2025

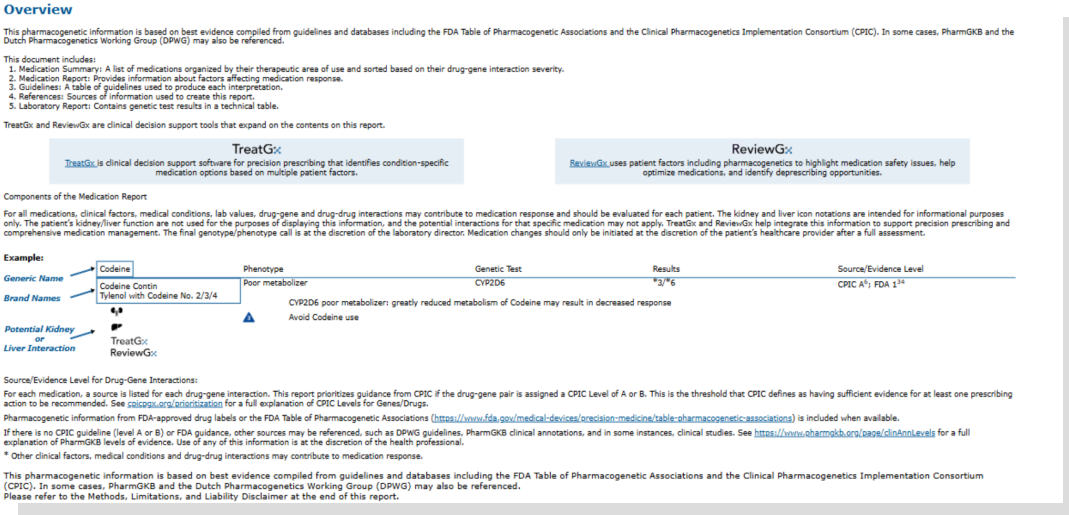
Sample Report

Patient Profile

If enabled, a hyperlink to the patient's case will be included in the report, allowing users to directly access the patient profile. Clicking the link will open either TreatGx or ReviewGx, depending on the selected workflow.

Overview

The report overview can be included/ excluded or repositioned. The report overview includes the content of the report, components of the medication report and an explanation of the evidence level of DGIs.



Overview

This pharmacogenetic information is based on best evidence compiled from guidelines and databases including the FDA Table of Pharmacogenetic Associations and the Clinical Pharmacogenetics Implementation Consortium (CPIC). In some cases, PharmGKB and the Dutch Pharmacogenetics Working Group (DPWG) may also be referenced.

This document includes:
1. Medication Summary: A list of medications organized by their therapeutic area of use and sorted based on their drug-gene interaction severity.
2. Medication Report: Provides information about factors affecting medication response.
3. Guidelines: A table of guidelines used to produce each interpretation.
4. References: Sources of information used to create this report.
5. Laboratory Report: Contains genetic test results in a technical table.

TreatGx and ReviewGx are clinical decision support tools that expand on the contents on this report.

TreatGx
TreatGx is clinical decision support software for precision prescribing that identifies condition-specific medication options based on multiple patient factors.

ReviewGx
ReviewGx uses patient factors including pharmacogenetics to highlight medication safety issues, help optimize medications, and identify deprescribing opportunities.

Components of the Medication Report

For all medications, clinical factors, medical conditions, lab values, drug-gene and drug-drug interactions may contribute to medication response and should be evaluated for each patient. The kidney and liver icon notations are intended for informational purposes only. The patient's kidney/liver function are not used for the purposes of displaying this information, and the potential interactions for that specific medication may not apply. TreatGx and ReviewGx help integrate this information to support precision prescribing and comprehensive medication management. The final genotype/phenotype call is at the discretion of the laboratory director. Medication changes should only be initiated at the discretion of the patient's healthcare provider after a full assessment.

Example:

Generic Name → Codeine
Brand Names → Codeine Contin, Tylenol with Codeine No. 2/3/4
Potential Kidney or Liver Interaction → TreatGx, ReviewGx

Phenotype	Genetic Test	Results	Source/Evidence Level
Poor metabolizer	CYP2D6	*3/*6	CPIC A[5]; FDA 1[14]

CYP2D6 poor metabolizer: greatly reduced metabolism of Codeine may result in decreased response
Avoid Codeine use

Source/Evidence Level for Drug-Gene Interactions:

For each medication, a source is listed for each drug-gene interaction. This report prioritizes guidance from CPIC if the drug-gene pair is assigned a CPIC Level of A or B. This is the threshold that CPIC defines as having sufficient evidence for at least one prescribing action to be recommended. See cpicpgx.org/prioritization for a full explanation of CPIC Levels for Genes/Drugs.

Pharmacogenetic information from FDA-approved drug labels or the FDA Table of Pharmacogenetic Associations (https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations) is included when available.

If there is no CPIC guideline (level A or B) or FDA guidance, other sources may be referenced, such as DPWG guidelines, PharmGKB clinical annotations, and in some instances, clinical studies. See https://www.pharmgkb.org/page/clinAnnLevels for a full explanation of PharmGKB levels of evidence. Use of any of this information is at the discretion of the health professional.

* Other clinical factors, medical conditions and drug-drug interactions may contribute to medication response.

This pharmacogenetic information is based on best evidence compiled from guidelines and databases including the FDA Table of Pharmacogenetic Associations and the Clinical Pharmacogenetics Implementation Consortium (CPIC). In some cases, PharmGKB and the Dutch Pharmacogenetics Working Group (DPWG) may also be referenced.
Please refer to the Methods, Limitations, and Liability Disclaimer at the end of this report.

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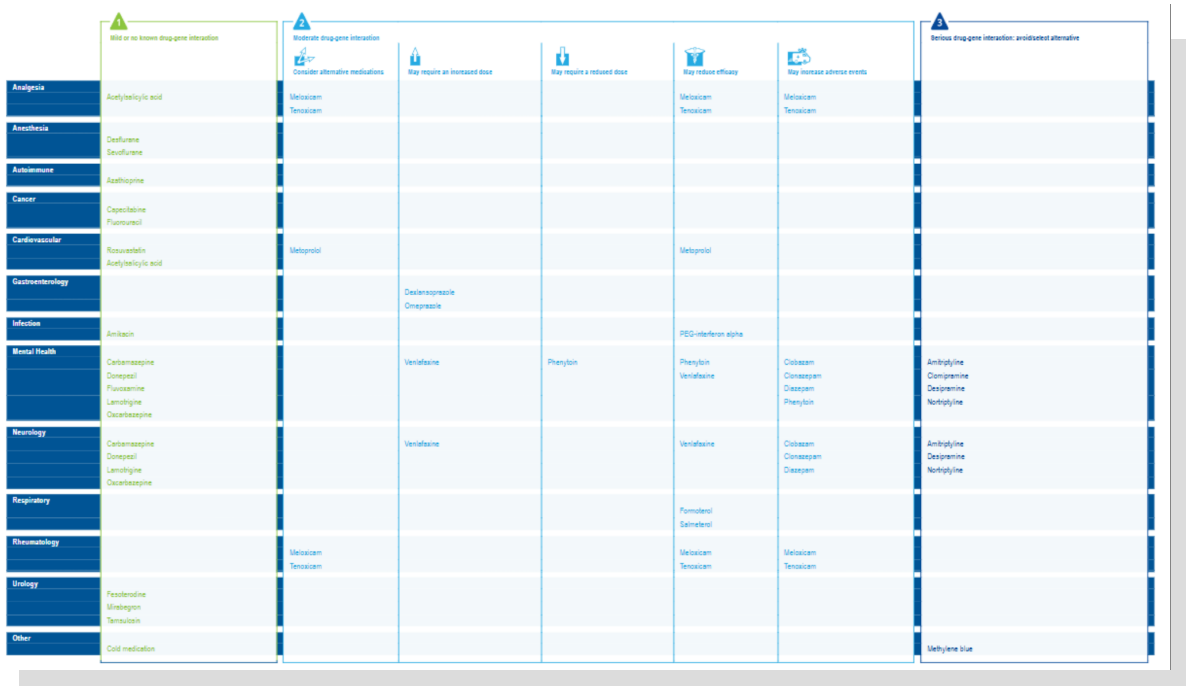
Template Customization

Medication Summary Table

The Medication Summary Table lists medications with pharmacogenetic associations, categorized by therapeutic area and the severity of drug–gene interactions. Some medications may appear in multiple columns within the moderate drug–gene interaction category due to varying effects or associations with multiple genes. The highest severity level (moderate/severe) is prioritized, considering all relevant sources and gene interactions for each medication. This section also can be included/excluded/ repositioned in the report.



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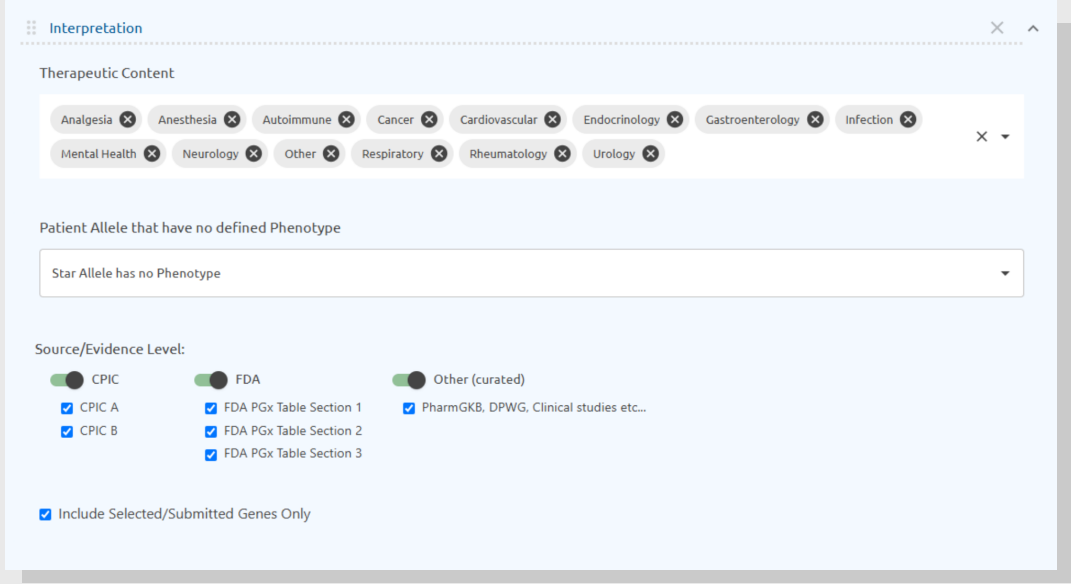
Template Customization

Medication Summary

The Medication Summary lists medications with pharmacogenetic associations, categorized by therapeutic area and drug–gene interaction severity. The highest severity level (moderate/severe) is prioritized based on all relevant sources and gene interactions for each medication. This section also can be included/excluded/ repositioned in the report.

Interpretation

The positioning of this section relative to others will determine the location of the Medication Report – detailed drug–gene interaction information for each medication.



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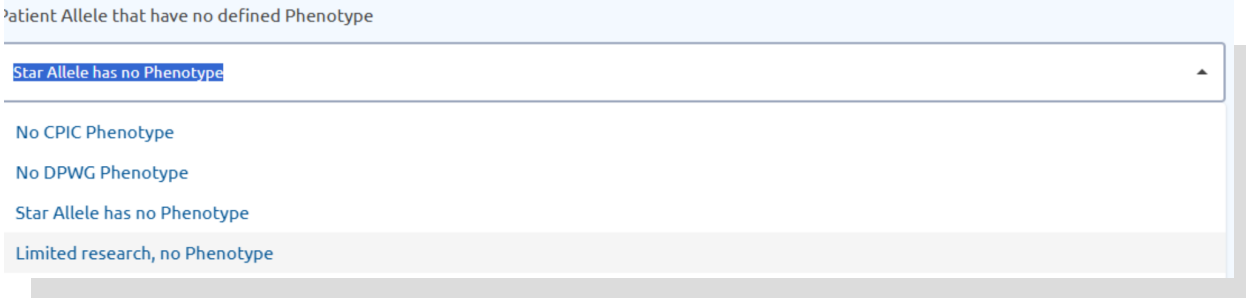
Therapeutic Content

The medication recommendation in the report is generated based on the selected therapeutic areas. As shown in the medication summary or the medication summary table, all the medications are divided into different therapeutic areas, reports can be customized by selecting/deselecting appropriate areas. Based on the selection, the report will include the medication recommendations. Certain medications are included in multiple therapeutic areas depending on their use.

Patient Allele that have no defined phenotype

If the phenotype is undefined based on the Star Alleles found, the Lab Director can select the preferred message to include in the report.



Sources/Evidence level

This setting allows for customization of preferred PGx evidence source/guideline and levels of evidence. If all categories are kept selected, there will be no changes to current content. This is available to users with Lab Director or Branding permission. The selected preferences will apply to any LabGx PDFs completed after the preferences are saved.

Template Customization

More Details on Sources

CPIC Guidelines: https://cpicpgx.org/genes-drugs/

CPIC Level A

Clinical context
Genetic information should be used to change prescribing of affected drug.

Level of evidence
Preponderance of evidence is high or moderate in favor of changing prescribing.

Strength of recommendation
At least one moderate or strong action (change in prescribing) recommended.

CPIC Level B:

Clinical context
Genetic information could be used to change prescribing of the affected drug because alternative therapies/dosing are extremely likely to be as effective and as safe as non-genetically based dosing.

Level of evidence
Preponderance of evidence is weak with little conflicting data.

Strength of recommendation
At least one optional action (change in prescribing) is recommended.

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FDA Table of PGx Associations:

https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations

Section 1
Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations

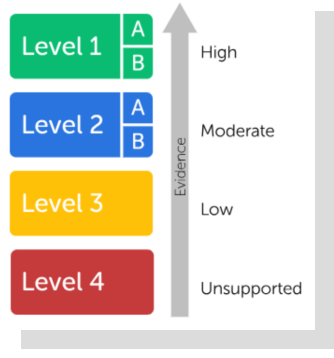
Section 2
Pharmacogenetic Associations for which the Data Indicate a Potential Impact on Safety or Response

Section 3
Pharmacogenetic Associations for which the Data Demonstrate a Potential Impact on Pharmacokinetic Properties Only. The impact of these genetic variants or genetic variant inferred phenotypes on the safety or response of the corresponding drug has not been established.

Other

This category is "curated" as drug-gene interactions have been selected based on requests and does not represent the full content in each category (unlike CPIC and FDA Table full content).

PharmGKB:
Pharmacogenomics Knowledge Base that encompasses clinical information including clinical guidelines and drug labels, potentially clinically actionable gene-drug associations and genotype-phenotype relationships. The following levels are defined for PharmGKB Clinical Annotations:
https://www.pharmgkb.org/page/clinAnnLevels



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Product Monographs:
FDA product monograph guidance, not necessarily included in the FDA Table of PGx Associations. We use PharmGKB's Drug Label PGx Level as a standard to assess level of evidence: https://www.pharmgkb.org/fdaLabelAnnotations https://www.pharmgkb.org/page/drugLabelLegend#pgx-level

Testing Required:
The label states or implies that some sort of gene, protein or chromosomal testing, including genetic testing, functional protein assays, cytogenetic studies, etc., should be conducted on the gene or gene product mentioned in the annotation before using this drug. This requirement may only be for a particular subset of patients. If the label states a test "should be" performed, this is interpreted as testing required.

Testing Recommended:
The label states or implies that some sort of gene, protein or chromosomal testing, including genetic testing, functional protein assays, cytogenetic studies, etc., is recommended to be carried out on the gene or gene product mentioned in the annotation before using this drug. This recommendation may only be for a particular subset of patients. PharmGKB considers labels that say testing "should be considered" or "consider genotyping or phenotyping" to be recommending testing.

Actionable PGx
The label discusses a dose adjustment, contraindication or alternate drug recommendation, or other guidance for patients with a particular genotype or metabolizer phenotype, if known. However, the label does not require or recommend genotype or phenotype testing before using the drug.

DPWG:
Dutch Pharmacogenetics Working Group published guidelines, often overlap with CPIC content. https://www.pharmgkb.org/guidelineAnnotations

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Template Customization

Include Selected/Submitted Genes only

If the lab wants to hide the unsubmitted genes from the report, this check box can be selected.

Available References

A table of available references will be auto-generated based on the evidence sources, drug and genetic data. This section can be repositioned but must be included.

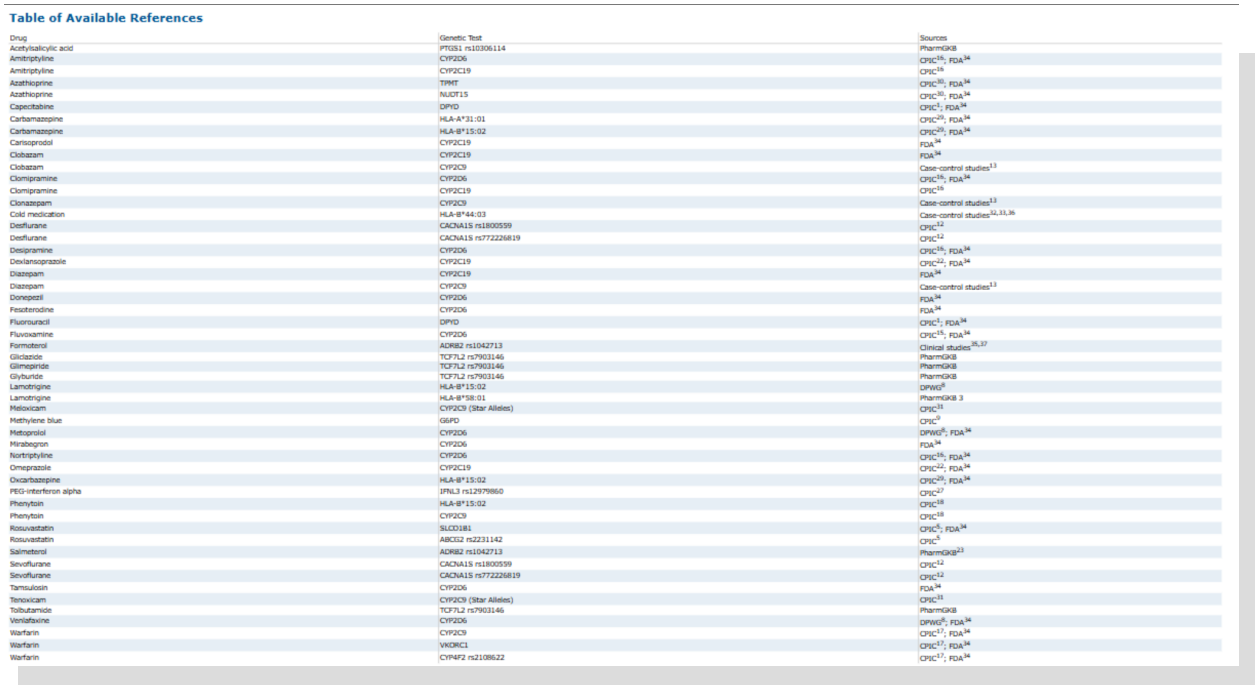

Table of Available References

Drug	Genetic Test	Sources
Acetylsalicylic acid	PTGS1 rs10306114	PharmGKB
Amitriptyline	CYP2D6	CPIC[16]; FDA[34]
Amitriptyline	CYP2C19	CPIC[16]
Azathioprine	TPMT	CPIC[30]; FDA[34]
Azathioprine	NUDT15	CPIC[30]; FDA[34]
Capecitabine	DPYD	CPIC[1]; FDA[34]
Carbamazepine	HLA-A*31:01	CPIC[20]; FDA[34]
Carbamazepine	HLA-B*15:02	CPIC[20]; FDA[34]
Carisoprodol	CYP2C19	FDA[34]
Clobazam	CYP2C19	FDA[34]
Clobazam	CYP2C9	Case-control studies[13]
Clomipramine	CYP2D6	CPIC[16]; FDA[34]
Clomipramine	CYP2C19	CPIC[16]
Clonazepam	CYP2C9	Case-control studies[13]
Cold medication	HLA-B*44:03	Case-control studies[32,33,36]
Desflurane	CACNA1S rs1800559	CPIC[12]
Desflurane	CACNA1S rs772226819	CPIC[12]
Desipramine	CYP2D6	CPIC[16]; FDA[34]
Dexlansoprazole	CYP2C19	CPIC[22]; FDA[34]
Diazepam	CYP2C19	FDA[34]
Diazepam	CYP2C9	Case-control studies[13]
Donepezil	CYP2D6	FDA[34]
Fesoterodine	CYP2D6	FDA[34]
Fluorouracil	DPYD	CPIC[1]; FDA[34]
Fluvoxamine	CYP2D6	CPIC[16]; FDA[34]
Formoterol	ADRB2 rs1042713	Clinical studies[35,37]
Gliclazide	TCF7L2 rs7903146	PharmGKB
Glimepiride	TCF7L2 rs7903146	PharmGKB
Glyburide	TCF7L2 rs7903146	PharmGKB
Lamotrigine	HLA-B*15:02	DPWG[9]
Lamotrigine	HLA-B*58:01	PharmGKB 3
Meloxicam	CYP2C9 (Star Alleles)	CPIC[31]
Methylene blue	G6PD	CPIC[3]
Metoprolol	CYP2D6	DPWG[9]; FDA[34]
Mirabegron	CYP2D6	FDA[34]
Nortriptyline	CYP2D6	CPIC[16]; FDA[34]
Omeprazole	CYP2C19	CPIC[22]; FDA[34]
Oxcarbazepine	HLA-B*15:02	CPIC[20]; FDA[34]
PEG-interferon alpha	IFNL3 rs12979860	CPIC[27]
Phenytoin	HLA-B*15:02	CPIC[18]
Phenytoin	CYP2C9	CPIC[18]
Rosuvastatin	SLCO1B1	CPIC[5]; FDA[34]
Rosuvastatin	ABCG2 rs2231142	CPIC[5]
Salmeterol	ADRB2 rs1042713	PharmGKB[23]
Sevoflurane	CACNA1S rs1800559	CPIC[12]
Sevoflurane	CACNA1S rs772226819	CPIC[12]
Tamsulosin	CYP2D6	FDA[34]
Tenoxicam	CYP2C9 (Star Alleles)	CPIC[31]
Tolbutamide	TCF7L2 rs7903146	PharmGKB
Venlafaxine	CYP2D6	DPWG[9]; FDA[34]
Warfarin	CYP2C9	CPIC[17]; FDA[34]
Warfarin	VKORC1	CPIC[17]; FDA[34]
Warfarin	CYP4F2 rs2108622	CPIC[17]; FDA[34]

References

A full list of references is available for each interpretation. This section can be replaces with a hyperlink or repositioned but must be included.

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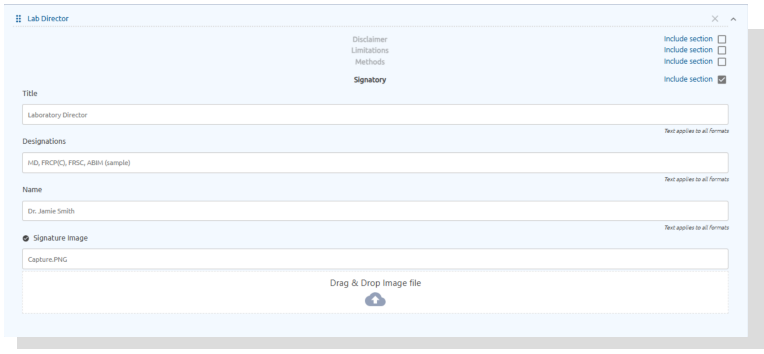
Template Customization

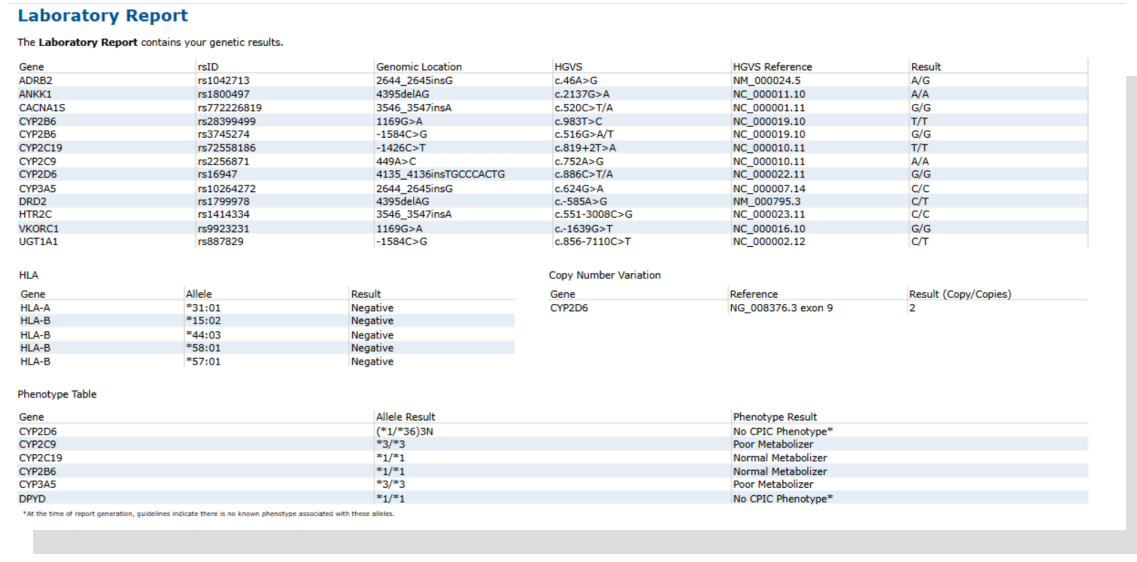
Lab Director

In this section, the reporting Methods, Limitations and Liability Disclaimer can be entered along with the signatory title, designations, name and signature image(.png <400 Pixels). All of the fields here are optional and can be selected/deselected or repositioned.



Technical Report

This section contains the lab data that was uploaded with genetics results. If the genomic location option was selected in the interpretation section, the report will include that under the Laboratory report section. The technical report for the short report format includes phenotypes and HLAs if tested. The technical report for the long report format also includes genotypes and CNV results.



Laboratory Report

The **Laboratory Report** contains your genetic results.

Gene	rsID	Genomic Location	HGVS	HGVS Reference	Result
ADRB2	rs1042713	2644_2645insG	c.46A>G	NM_000024.5	A/G
ANKK1	rs1800497	4395delAG	c.2137G>A	NC_000011.10	A/A
CACNA1S	rs772226819	3546_3547insA	c.520C>T/A	NC_000001.11	G/G
CYP2B6	rs28399499	1169G>A	c.983T>C	NC_000019.10	T/T
CYP2B6	rs3745274	-1584C>G	c.516G>A/T	NC_000019.10	G/G
CYP2C19	rs72558186	-1426C>T	c.819+2T>A	NC_000010.11	T/T
CYP2C9	rs2256871	449A>C	c.752A>G	NC_000010.11	A/A
CYP2D6	rs16947	4135_4136insTGCCCACTG	c.886C>T/A	NC_000022.11	G/G
CYP3A5	rs10264272	2644_2645insG	c.624G>A	NC_000007.14	C/C
DRD2	rs1799978	4395delAG	c.-585A>G	NM_000795.3	C/T
HTR2C	rs1414334	3546_3547insA	c.551-3008C>G	NC_000023.11	C/C
VKORC1	rs9923231	1169G>A	c.-1639G>T	NC_000016.10	G/G
UGT1A1	rs887829	-1584C>G	c.856-7110C>T	NC_000002.12	C/T

HLA

Gene	Allele	Result
HLA-A	*31:01	Negative
HLA-B	*15:02	Negative
HLA-B	*44:03	Negative
HLA-B	*58:01	Negative
HLA-B	*57:01	Negative

Copy Number Variation

Gene	Reference	Result (Copy/Copies)
CYP2D6	NG_008376.3 exon 9	2

Phenotype Table

Gene	Allele Result	Phenotype Result
CYP2D6	(*1/*36)3N	No CPIC Phenotype*
CYP2C9	*3/*3	Poor Metabolizer
CYP2C19	*1/*1	Normal Metabolizer
CYP2B6	*1/*1	Normal Metabolizer
CYP3A5	*3/*3	Poor Metabolizer
DPYD	*1/*1	No CPIC Phenotype*

*At the time of report generation, guidelines indicate there is no known phenotype associated with these alleles.

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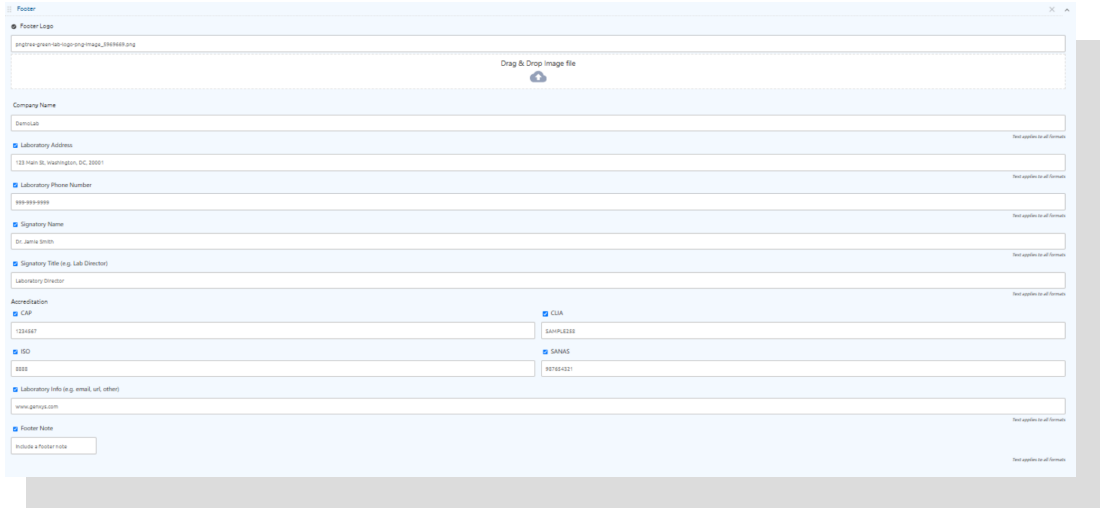
Template Customization

Footer



Labs can upload a footer logo that includes company or lab details and accreditation (CAP, CLIA, ISO, SANAS). An optional footer note section is also available for adding any additional information not covered in other sections of the report. The note will appear on the last page of the report