GenXys™
PRESCRIBING SYSTEMS

LabGx
Quick Start Guide

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Introduction

LabGx facilitates the integration of pharmacogenetic results into clinical practice through evidence-based guidance. It seamlessly incorporates this data into the TreatGx and ReviewGx clinical decision support software, empowering clinicians with real-time, multi-factorial medication optimization. By combining relevant drug-gene interactions with essential patient characteristics, the software supports informed, personalized treatment decisions for precision medicine.

Testing labs use LabGx to translate genotype data into phenotype interpretations and generate medication recommendations. This guide is designed to help labs quickly get started with LabGx, ensuring a smooth and efficient implementation process.

During the onboarding phase, LabGx ensures seamless integration through a validation process designed to map genetic data to phenotypic interpretations and verify the lab's data format. This process begins with assessing the lab's genetic data format to ensure compatibility with LabGx's specifications, followed by genotype-to-phenotype mapping to confirm accurate translation of genetic markers into actionable insights. Sample datasets are then tested to validate medication recommendations, ensuring alignment with pharmacogenetic guidelines. Any discrepancies are addressed collaboratively, and final approval is granted once validation is successfully completed. This phase minimizes integration risks, ensures data accuracy, and establishes a reliable foundation for labs to confidently utilize LabGx in their workflows.

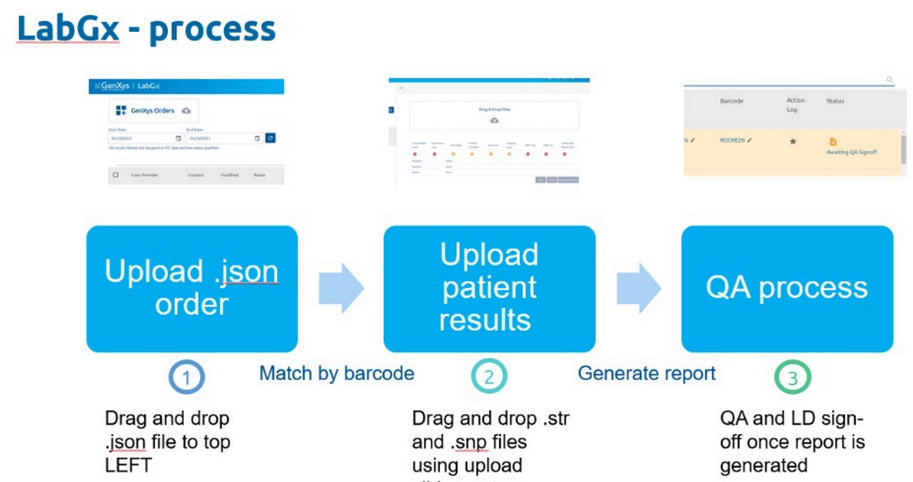
Three stage process

LabGx can generate a comprehensive report from raw data in just three easy steps

1. **Create a Patient Profile/ order:**
   Build a patient profile using the standardized JSON structure, capturing key demographic information, sample barcode and current medications. This step ensures data consistency and alignment with LabGx's requirements for downstream processing.

2. **Upload the Lab Data:**
   Upload the lab's genetic data into LabGx, where it will be mapped to phenotypic interpretations. The system automatically validates the data format and checks for completeness, flagging any inconsistencies for review.

3. **Run QA and Approve:**
   Perform a Quality Assurance (QA) review to validate data accuracy and ensure medication recommendations meet pharmacogenetic guidelines. If discrepancies arise, necessary edits can be made, and final approval can be granted through a Lab Director override (if required).



Folders and Files* Included with LabGx:

***For optimized viewing, open GenXys text or json files using notepad+**

1. Lab order folder: GenXys lab order specification, sampleorder file

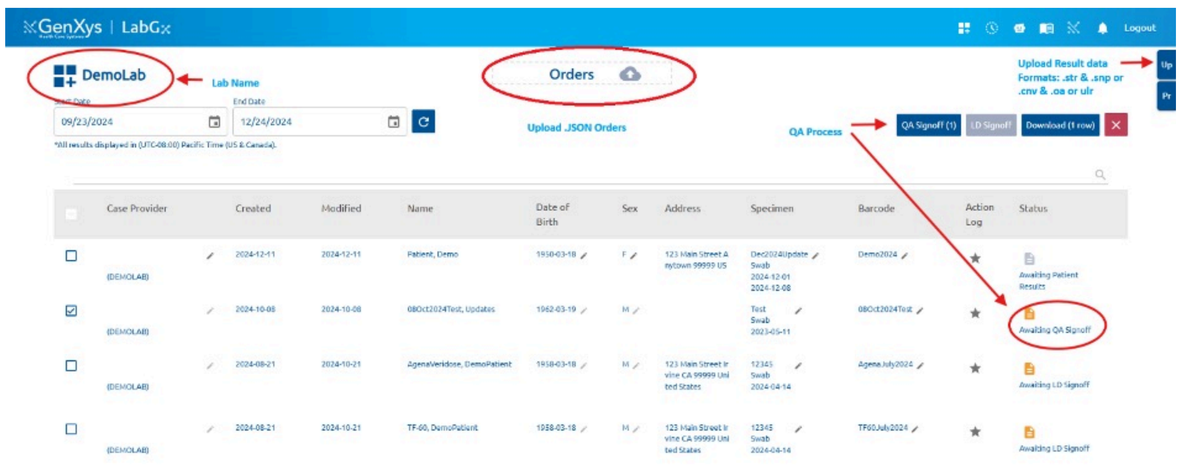
2. Rename extensions folder: readme.txt, drag & drop extension renamers

The user must rename the .batzzz extension to .bat after receiving the files

3. Report customization folder: images folder, data file

4. Genetic Results Folder: Specific information regarding genetic data formats for uploading

5. **LabGx API Folder: GenXys API Specification, GenXys API Overview (optional)**



LabGx - .JSON Order

```
"orders": [{
    "resourceType": "patient",
    "orderedBy": "providertest",          <-- Ordering Physician
    "clinicIdentifier": "DemoLab",        <-- Lab Name
    "clinicType": "DemoLab-LAB",
    "clinicInstance": "",
    "barcode": "BC 1_B",                  <-- Must match sample ID in result files
    "panel": "",
"payload": {
    "identifier": "PGx 1_B",
    "firstName": "Test",
    "lastName": "One",
    "demographics": {
        "dob": "1999-01-01",
        "sexAtBirth": "F",
        "email": "Test.One@genxys.com",
        "address": {
            "addressLine1": "100 Main Street",
            "addressLine2": "Unit 300",
            "city": "Anytown",
            "region": "California",
            "postalCode": "90210",
            "country": "US"
        }
    },
    "specimen": {
        "sampleId": "1_B",
        "type": "Swab",
        "date": "2022-06-08",
        "received": "2022-06-06"
    },
    "notes": "this is a sample note.",
"medicalSummary": {
    "currentMedications": [{
            "name": "ACH-ATORVASTATIN 40 MG TABLET",
            "dosage": "1 Tablet, QD",
            "coding": {
                "system": "DIN",
                "code": "2457776"
            },
            "indication": {
                "name": "Attention Deficit Hyperactivity Disorder",
                "coding": {
                    "system": "ICD9",
                    "code": "314.01"
```

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Uploading Patient Orders via Order file

1. To upload patient orders, drag and drop the required json file onto the **[Lab Name] Orders box in the top middle of the LabGx Dashboard or click on [Lab Name] Orders and select the file.**

2. The lab can also select the performing lab if the primary lab has any affiliated lab listed.

3. Patient orders are in JSON format. Commas are used to separate different orders with no indentation; no comma is used at the end of the last order.

4. After uploading, a popup box will confirm the number of orders to be uploaded.

5. If there is an issue with the order file, a red error banner will show at the bottom of the window. See the Troubleshooting section for more information.

6. The order file must use a specific json template,

7. The order file can be populated with information from the laboratory information system (LIMS).

8. After orders file have been uploaded into, they will appear in the LabGx Dashboard with an **Awaiting Patient result status.**

9. Uploaded orders may be cleared from the dashboard, and re-uploaded if necessary. Once results are associated with an order, the order cannot be deleted. Clearing orders with a generated report will move the order to the **Historical Enterprise Orders** page with a status of **Complete (not signed off).**

10. Some order information can be edited within LabGx, including the barcode, DOB and specimen details; other information must be edited in the data files and re-uploaded to correct errors or issues.

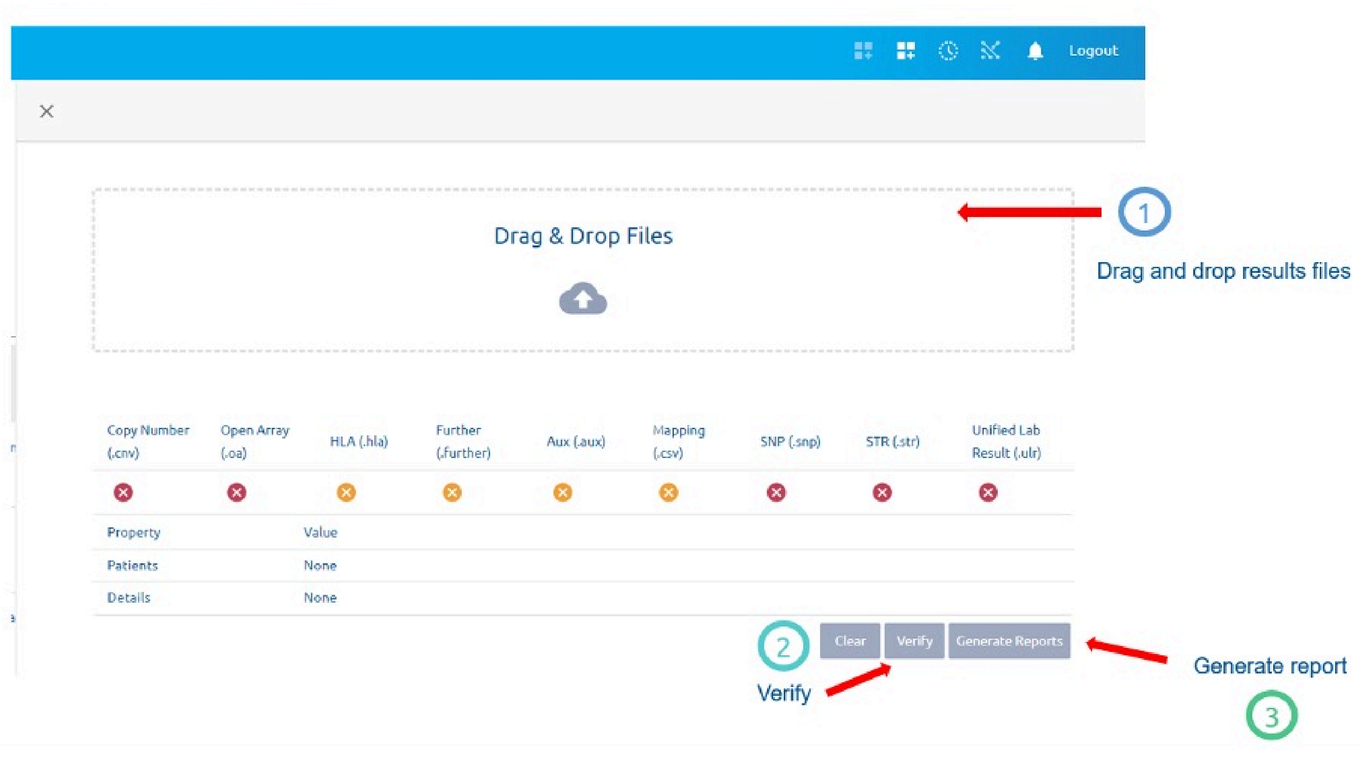
LabGx Results Files

A ULRTM (unified lab result) file, has been developed by GenXys to promote interoperability with any lab. The ULR represents a genetic result from any lab and can be accepted by GenXys systems for further processing. External labs will be given a ULR template and detailed instructions on how to generate the necessary file for use in LabGx.

To convert a .txt or .json file to the ULR extension, use the drag-and-drop extension converter provided by GenXys (in Rename Extension folder). The converter file extension must first be changed from .batzzz to .bat.

Type of file	Original extension	LabGx extension
ULR	.txt or .json	.ulr

LabGx also contains a proprietary, integrated ULR Generator that can be used to convert ThermoFisher OpenArrayTM and Agena Biosciences MassARRAY Veridose CoreTM data files into ULR format.



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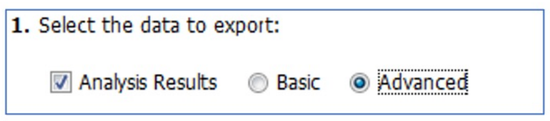
ThermoFisher

To download the required ThermoFisher instrumentation files:

- For the OpenArray data – Export results from TaqMan Genotyper software using advanced setting that includes a genotype base pair call (e.g. A/A; A/G; G/G).

1. Select **Export > Analysis Data** from the menu on the left-hand side
2. Under “Select data to export”, check only “Analysis Results”
3. Ensure “Advanced” is selected:



4. Complete the “File name” and “File location” fields. For “File Type”, select .txt
5. Select “Export Preview”, then “Start Export”

- For the CNV data – Export from the CNV CopyCaller software; label Target as gene name (e.g. CYP2D6).

1. Select **File > Export** to export the results. Save the file in a .txt format.

- To convert the .txt files to the required .oa or .cnv extension, use the drag and drop extension converters provided by GenXys (in Rename Extension folder). The converter file extensions must first be changed from .batzzz to .bat. Next, drag and drop the .txt files onto the OA_DragDropExtensionRenamer or CNV_DragDropExtensionRenamer.

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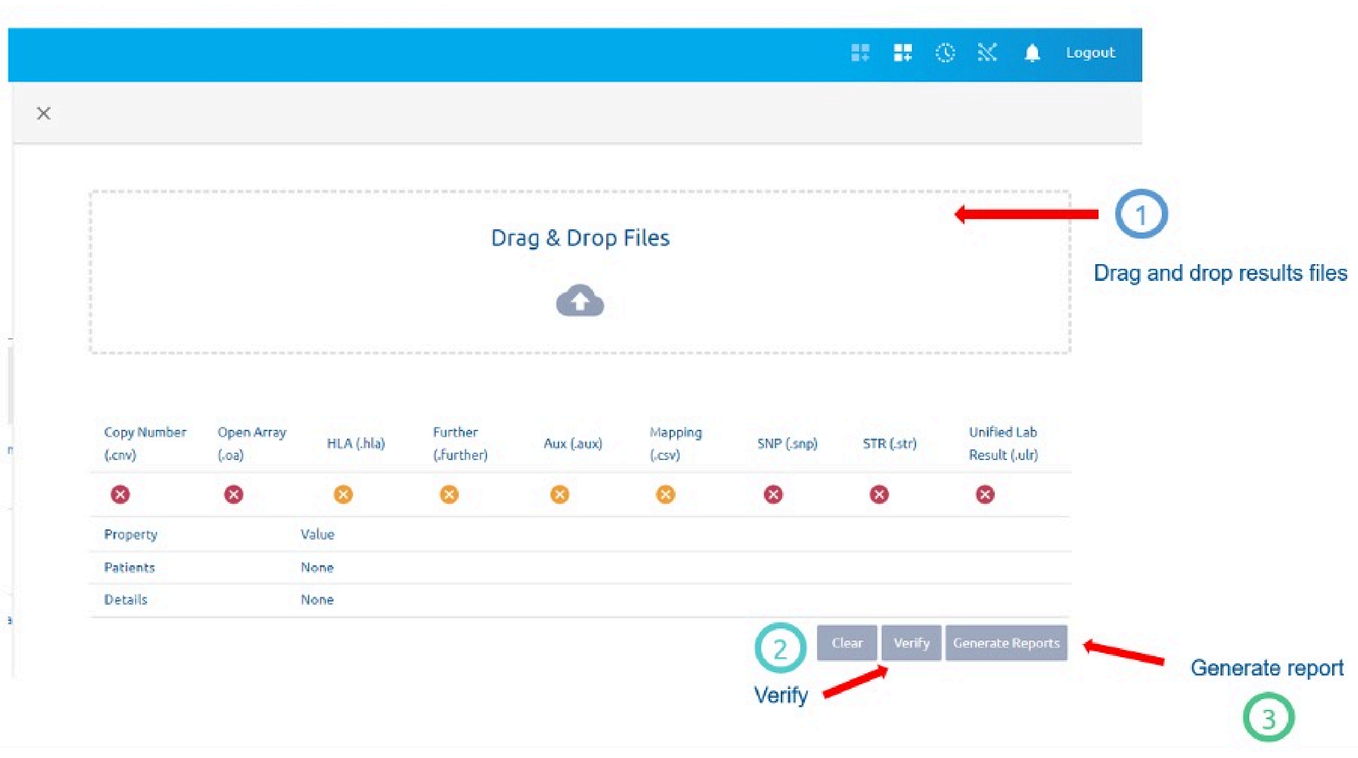

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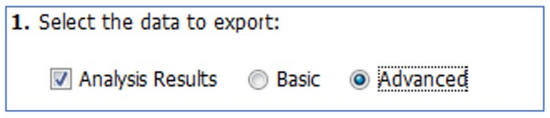

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Type of file	Original extension	LabGx extension
OpenArray data	.txt	.oa
OpenArray data	.txt	.cnv

Agena Bioscience

Agena Biosciences Veridose CoreTM files:

• The following files will need to be downloaded as CSV files and converted to the accepted LabGx extension:

oPGxReport_combined.csv

oPGxReportSNPDetailsLong.csv

• To convert the .csv files to the required .str or .snp extension, use the drag-and-drop extension converters provided by GenXys (in Rename Extension folder). The converter file extensions must first be changed from .batzzz to .bat. Next, drag and drop the .txt files onto the STR_DragDropExtensionRenamer or SNP_DragDropExtensionRenamer.

Type of file	Original extension	LabGx extension
Star Allele data	.csv	.str
SNP data	.csv	.snp

Linking Patient Orders to Results

The “barcode” field in the Order file should match the patient identifier in the ULR file (or in the instrumentation files) for a given patient.

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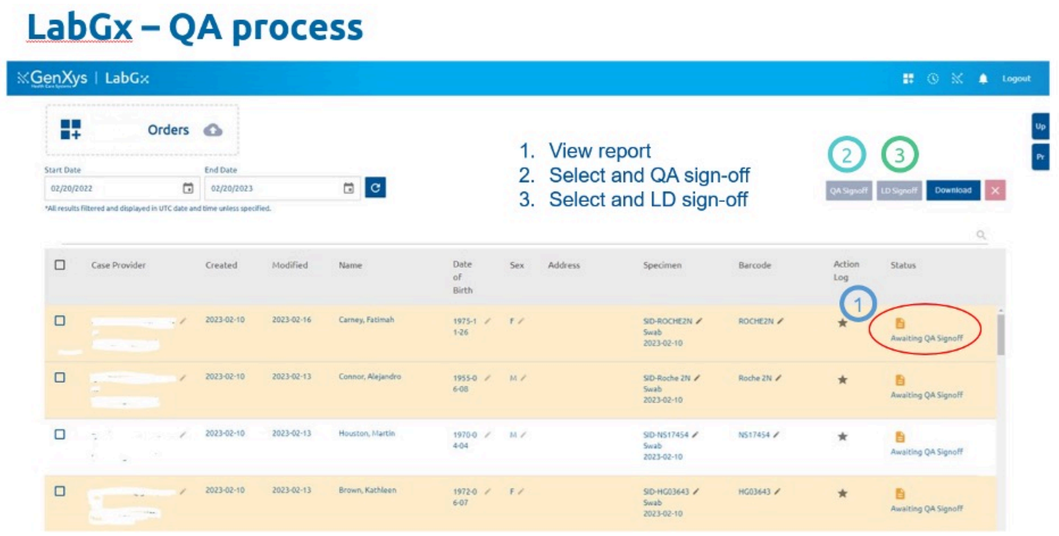
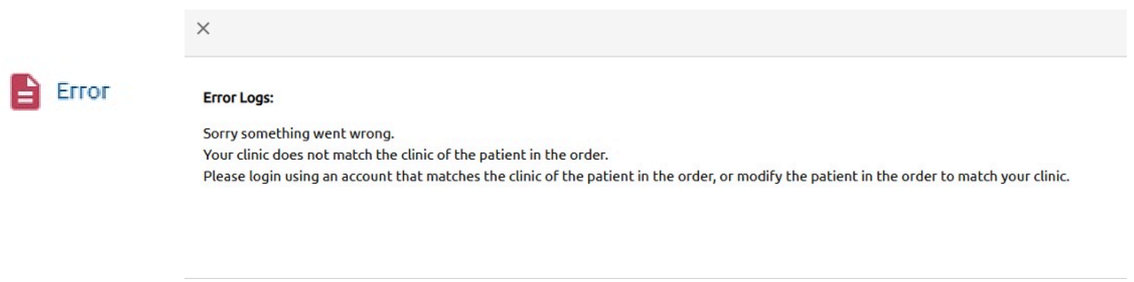
QA Process

1. After uploading, the Status of each patient order will change from **Awaiting Patient Sample to Pending**, and then to:

a. **Awaiting QA signoff** if no major errors are detected. Minor issues with the report such as an unreported phenotype will result in the order being highlighted in pale orange. Go to the next step and review the status report if this is the case



b. **Error** will appear if the report generation cannot be completed. Click on the report icon and view the Error Logs. This report explains in detail the type of error that prevented the system from generating a PGx interpretation. After errors are resolved, lab can reupload the genetic data files if required to generate a new report.



c. There is a lab director override where the lab director can manually enter star alleles if there is a an ambiguous result.

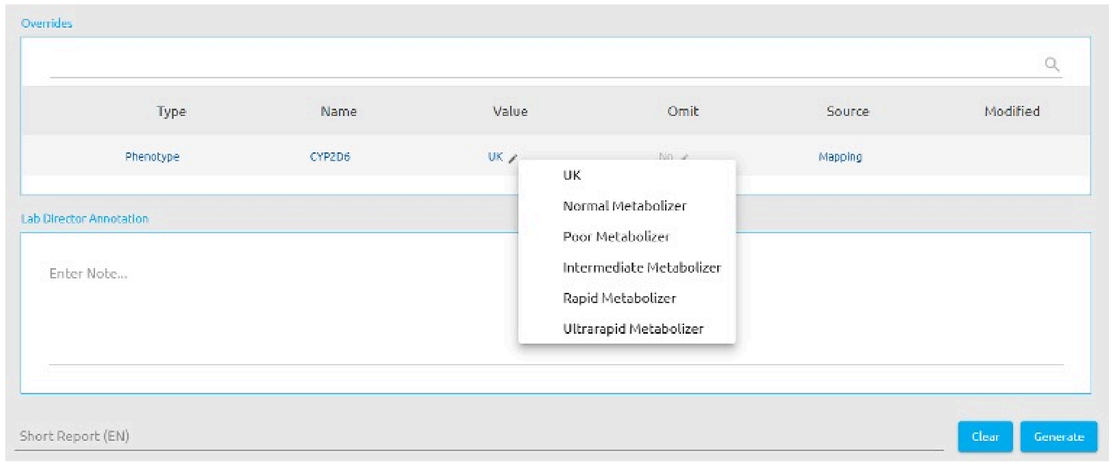
1. Notify the LabGX user in charge of Quality Assurance (QA) that reports are ready for QA review. The QA user will review the PDFs by clicking on the report icon . The PDF viewer will pop out and the different reports can be viewed by selecting them from the drop-down at the top. The Status Report summarizes which files were used to generate the patient reports, as well as any specific issues that occurred during report generation. See the Report Quality Assurance Check section below.

a. Orders will also be highlighted in orange on the LabGx dashboard if there was an issue with the report generation. Viewing the Status Report will help identify the specific issue.

3. To perform the QA signoff after all reports are verified, the QA user is required to select each patient order, and then click the QA signoff button at the top. A prompt will appear to confirm the QA Signoff for the selected number of orders.

4. After the QA Signoff, the patient order Status will change to Awaiting LD Signoff (Lab Director signoff). This is the final signoff before the report is completed and released to the ordering health care provider (HCP) via the GenXys Portal.

5. As part of the process, the user with Laboratory Director permissions will receive an email notifying them that reports are ready for their signoff. The Laboratory Director will review the PDFs by clicking on the report icon . To perform the signoff, the Laboratory Director is required to select each patient order, and then click the LD signoff button at the top. The lab director has the option to override any phenotype or Star Allele before performing the LD signoff (if the report is highlighted with any unreported phenotype). Once the phenotype or star allele is assigned,(the Lab director can also share their Annotation by typing any notes in the same window.) LD can click on “Generate” to regenerate the report with the changes and momentarily the report status will go back to Awaiting QA Signoff again. The LD can then perform the QA and LD signoff to complete the report.



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LabGx Report Customization

Lab Studio

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.

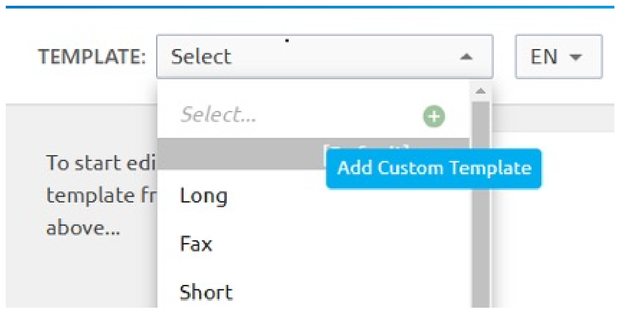
Let’s get started!

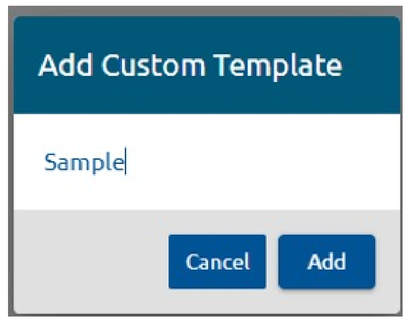
Lab Studio Templates

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 a 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.
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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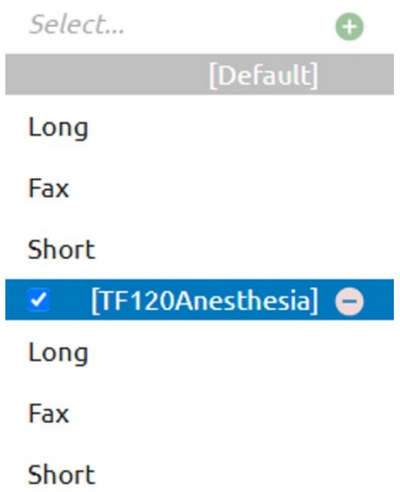
Managing Your Templates

- **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.



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.

- **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.
- 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.
- 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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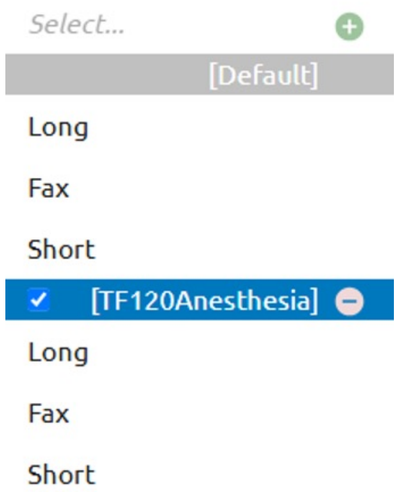

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Global Settings in Lab Studio

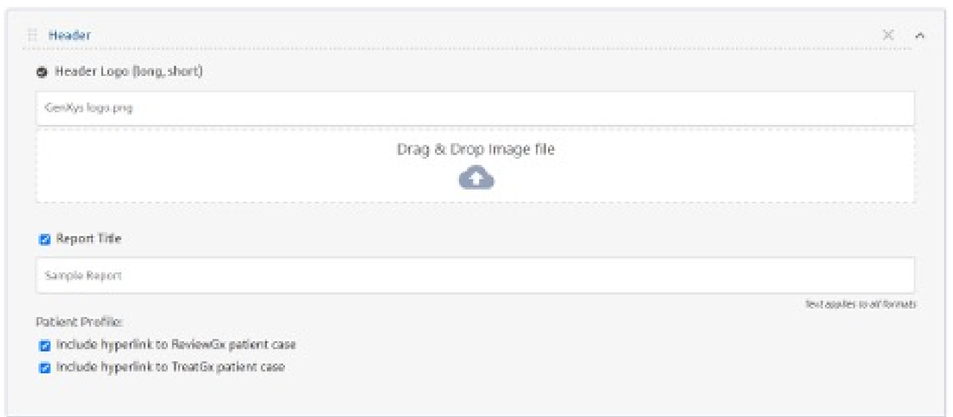
These settings apply to all templates and are not part of individual customizations. They serve as a foundational configuration for the lab.

- **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

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 avail any additional features.

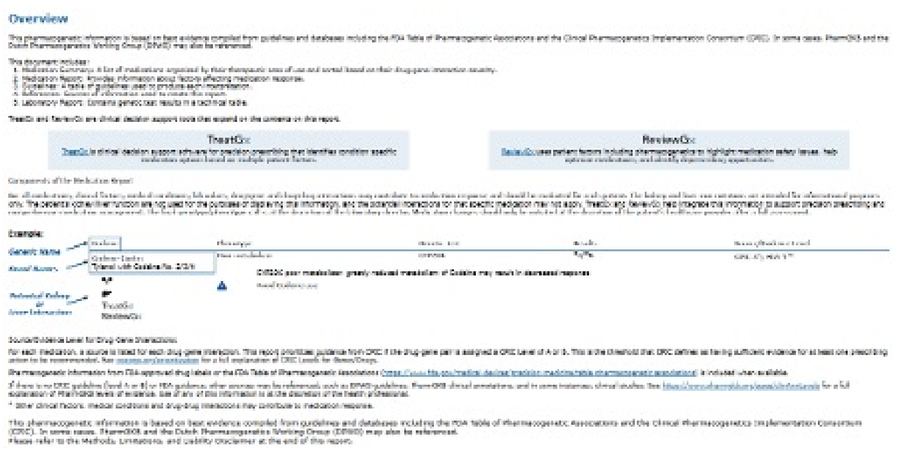
- **Header**
- **Header Logo:** The Lab's logo can be uploaded here in .PNG or .SVG format. The logo should be below 400 Pixels in dimensions.



- **Report Title:** If checked, any Custom report title can be provided which will be visible on top of the 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 repositions. The report overview includes the content of the report, components of the medication report and an explanation of the evidence level of DGIs.



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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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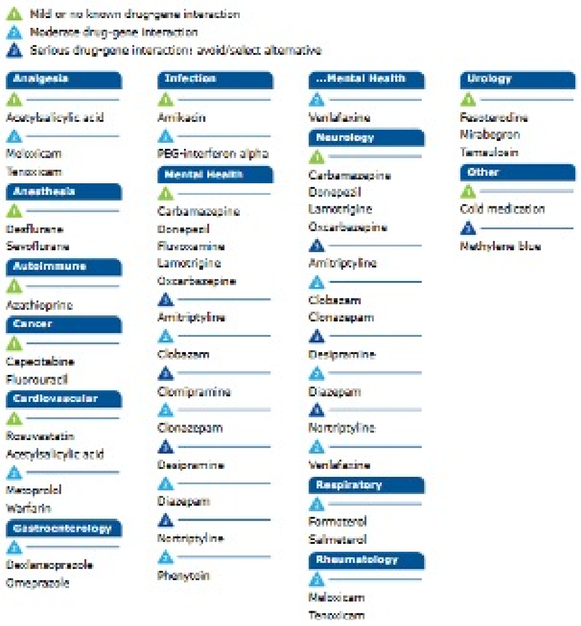
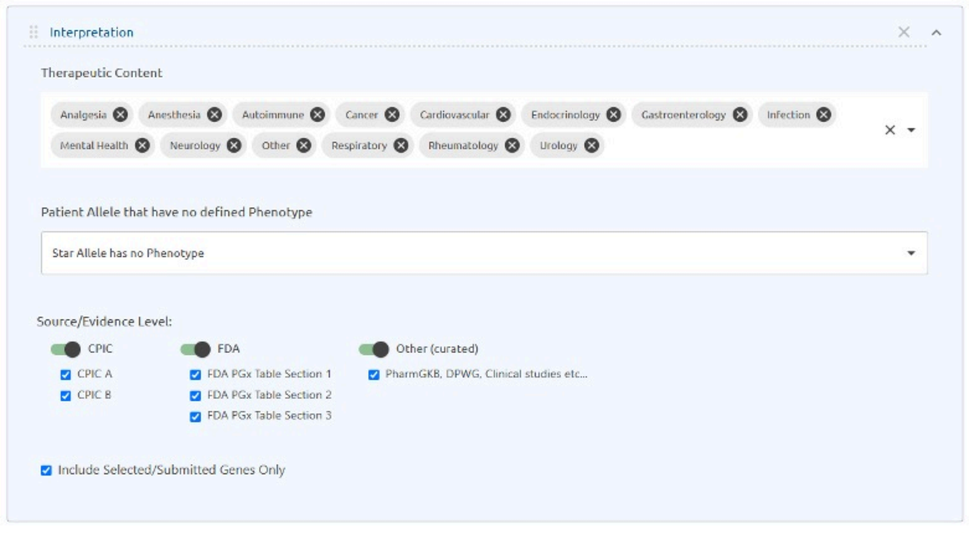


Interpretation



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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.

Patient Allele that have no defined phenotype

If the phenotype is undefined/ unreported, user can select the most appropriate message to include in the report

Sources/Evidence level

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.

Lab can select the level of evidence that they want to include in the report by selecting/deselecting the checkboxes.

Include Selected/Submitted Genes only

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

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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 or removed/included.

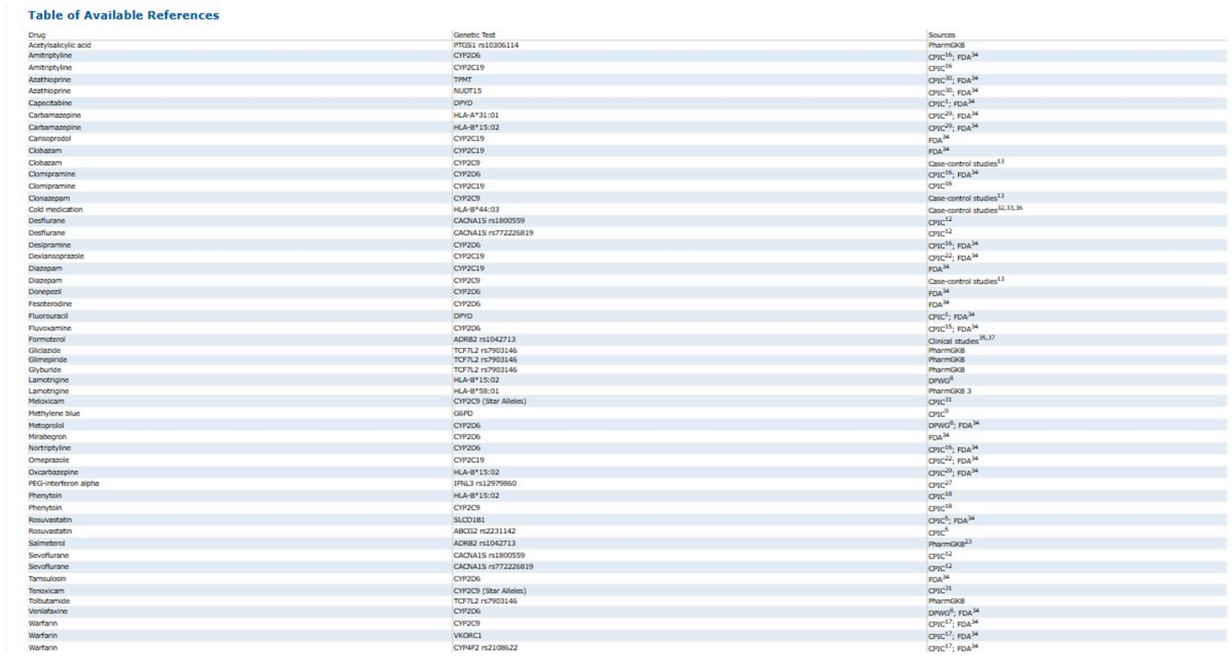


Table of Available References

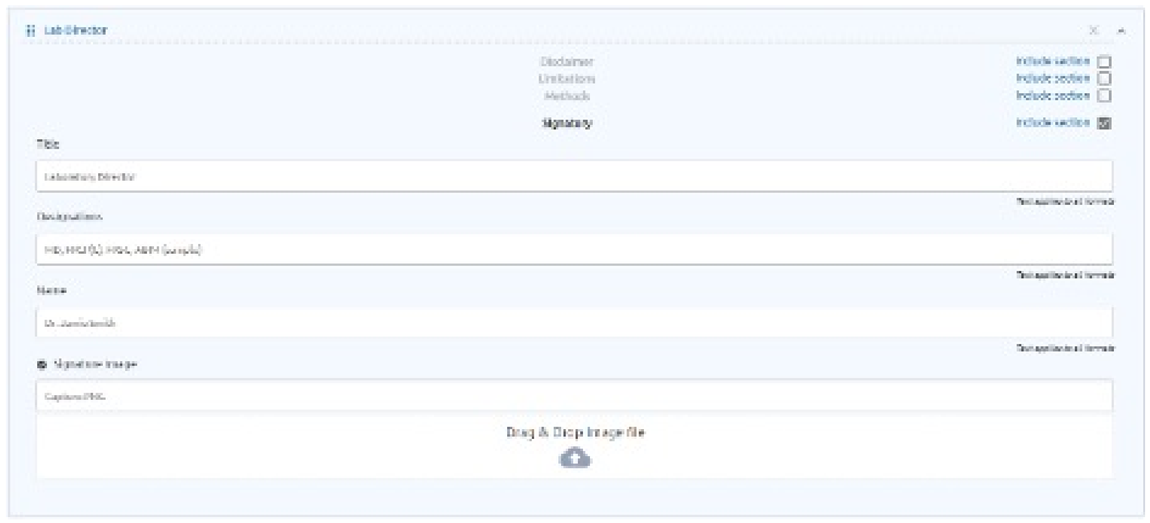
Drug	Genetic Test	Sources
Acetylsalicylic acid	PTGS1 rs10306114	PharmGKB
Amitriptyline	CYP2D6	CPIC[16]; FDA[34]
Amitriptyline	CYP2C19	CPIC[16]
Azathioprine	TPMT	CPIC[30]; FDA[34]
Azathioprine	NUDT15	CPIC[30]; FDA[34]
Capecitabine	DPYD	CPIC[1]; FDA[34]
Carbamazepine	HLA-A*31:01	CPIC[29]; FDA[34]
Carbamazepine	HLA-B*15:02	CPIC[29]; 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[15]; FDA[34]
Formoterol	ADRB2 rs1042713	Clinical studies[26,37]
Gliclazide	TCF7L2 rs7903146	PharmGKB
Glimepiride	TCF7L2 rs7903146	PharmGKB
Glyburide	TCF7L2 rs7903146	PharmGKB
Lamotrigine	HLA-B*15:02	DPWG[8]
Lamotrigine	HLA-B*58:01	PharmGKB 3
Meloxicam	CYP2C9 (Star Alleles)	CPIC[31]
Methylene blue	G6PD	CPIC[3]
Metoprolol	CYP2D6	DPWG[8]; FDA[34]
Mirabegron	CYP2D6	FDA[34]
Nortriptyline	CYP2D6	CPIC[16]; FDA[34]
Omeprazole	CYP2C19	CPIC[22]; FDA[34]
Oxcarbazepine	HLA-B*15:02	CPIC[29]; 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[8]; 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/ removed.

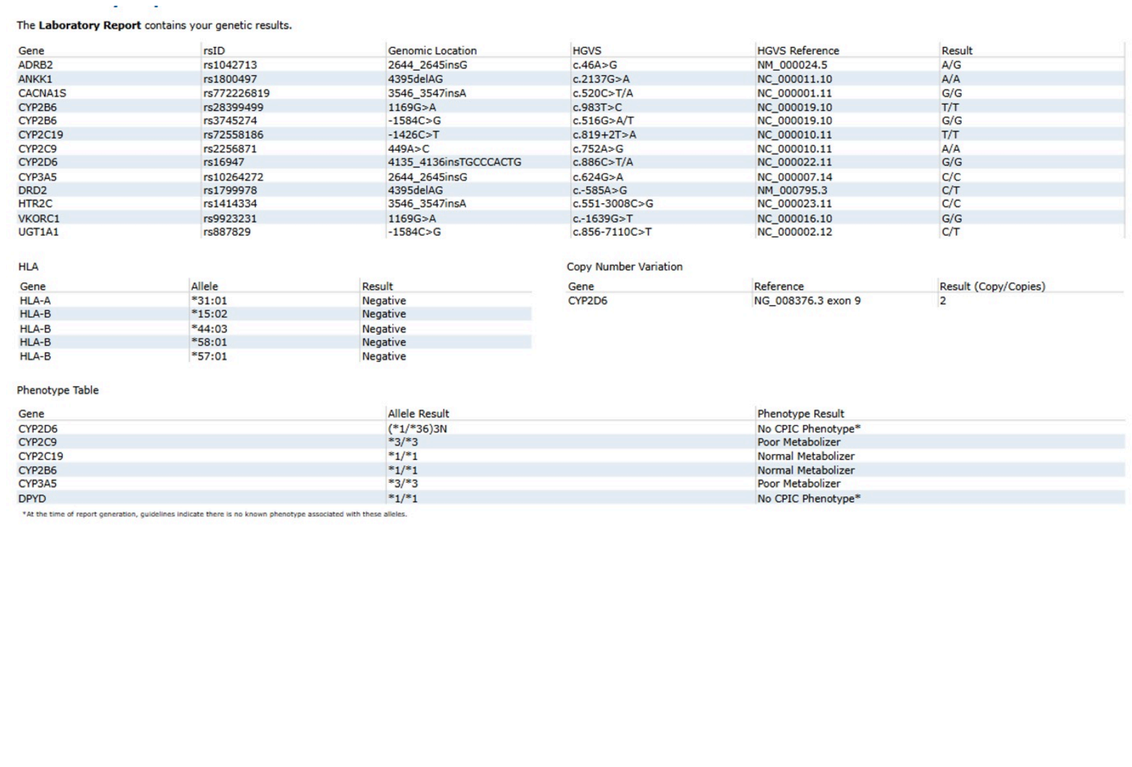
Lab Director

In this section, the reporting Methods, limitation and liability disclaimer can be entered along with the signatory title, designations, name and signature image(.png <400 Pixels). All 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 **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

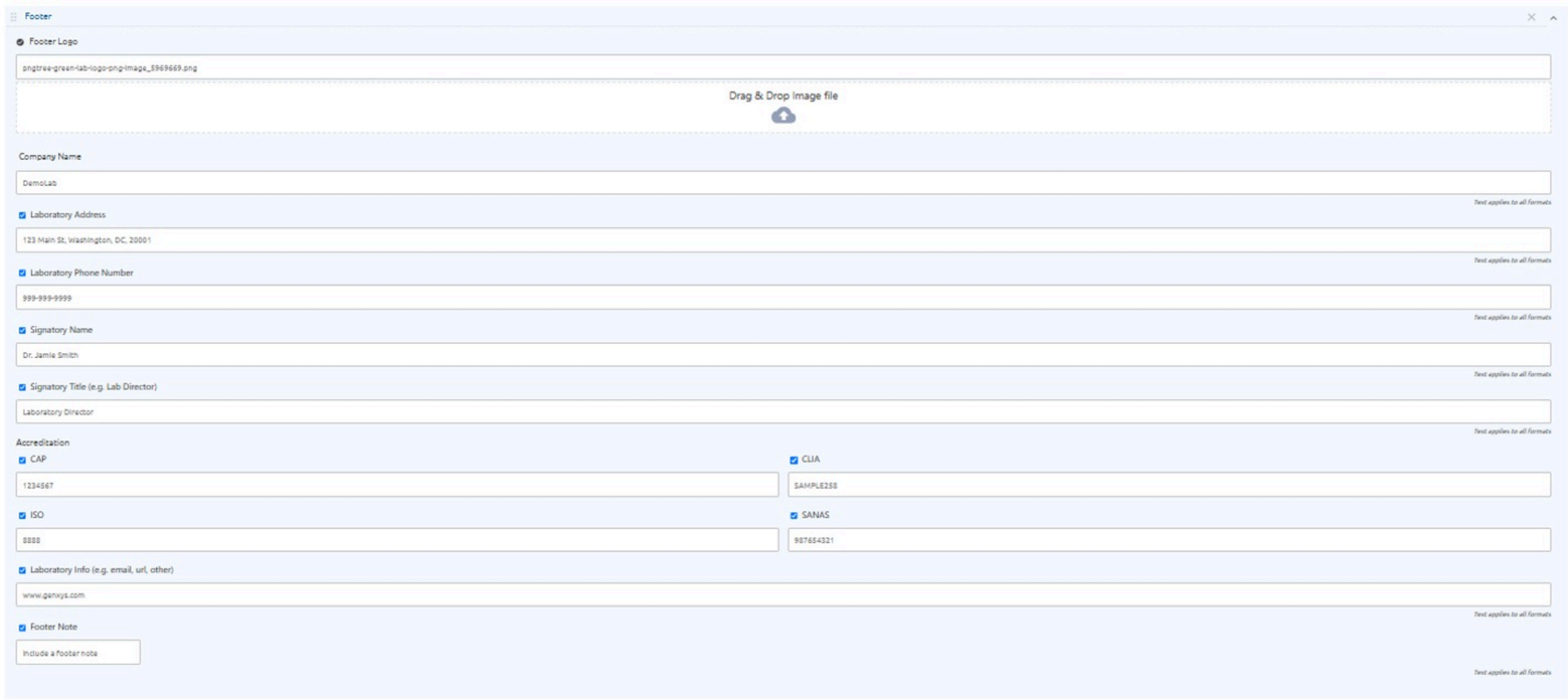
Phenotype Table

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.

LabGx
Quick Start Guide

Footer



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