GenXys™
PRESCRIBING SYSTEMS

LabGx™ User Manual

Precise Prescriptions. Every Time.

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Overview

Background

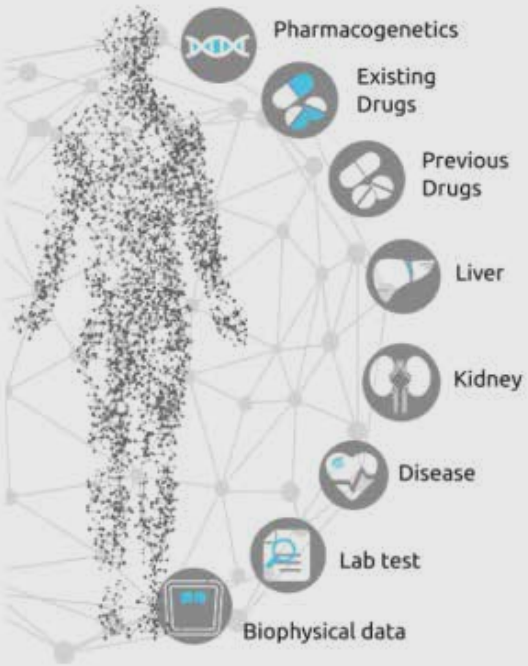
Over the past decade, pharmacogenetic testing has become increasingly available. However, its adoption in clinical settings remains slow. A significant barrier is the challenge healthcare providers face in interpreting and applying complex pharmacoge-netic reports. Many providers are unfamiliar with the specialized terminology or lack the time to navigate lengthy reports during patient consultations.

Clinical decision support systems (CDSS) have emerged as valuable tools to simplify the adoption of pharmacogenetic results. These systems integrate test results with other patient health information, offering clear, actionable insights. However, such systems are not always easily accessible to healthcare providers.

The GenXys platform, powered by its LabGx capability, provides molecular labs with a streamlined and comprehensive solution for embedding discrete lab results into GenXys' clinical decision support systems: TreatGx™ and ReviewGx™. These award-winning applications enable precision prescribing and automated medication reviews, supporting healthcare providers at every point of care.

Description

LabGx facilitates the implementation of pharmacogenetic results using evidence-based guidance, seamlessly integrating this information into the TreatGx and ReviewGx software. These tools offer clinicians real-time, multi-factorial medication optimization by combining relevant drug-gene interactions with other essential patient characteristics, enabling truly personalized precision medicine.



Platform Requirements

LabGx can be accessed via the country geo-contained cloud-based GenXys Portal through any supported web browser using validated login credentials.

A GenXys API gateway is also available for direct upload of data into LabGx.

File Requirements

PATIENT ORDERS

Contains ordering physician and patient demographics, along with specimen details, to link to raw genetic results files (may be batched; template provided by GenXys and populated via the lab's LIMS) [.json]

RESULT FILES

Result files may vary depending on the type of instrument used to generate output files:

- For ThermoFisher instruments, OpenArray files and CNV CopyCaller files are required.
- Star Allele data and SNP data files are required for Agena instruments.
- Unified Lab ResultTM (ULR) file with exported genotype data [.txt or .json converted to .ulr]

*GenXys can provide conversion to the ULR file type for certain types of data files. Contact your account representative for details.

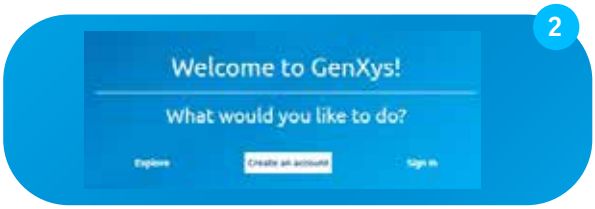
Creating a GenXys Portal Account

Creating a GenXys Portal Account

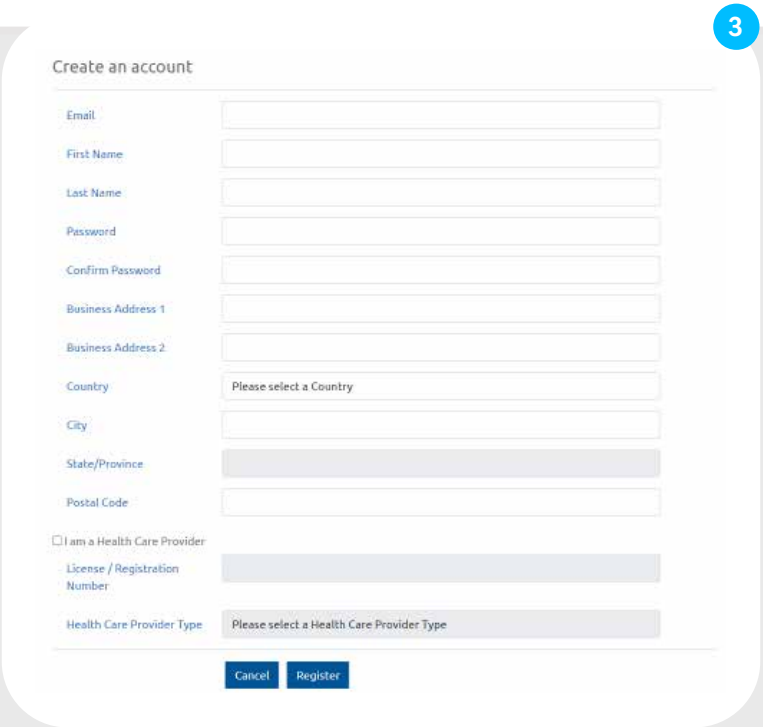
To access LabGx, users must have a GenXys Portal account and must have a valid GenXys license which includes access to the LabGx capability.

1. Visit the welcome page.

2. Select Create an account.



3. Enter the required information and select Register at the bottom of the page.

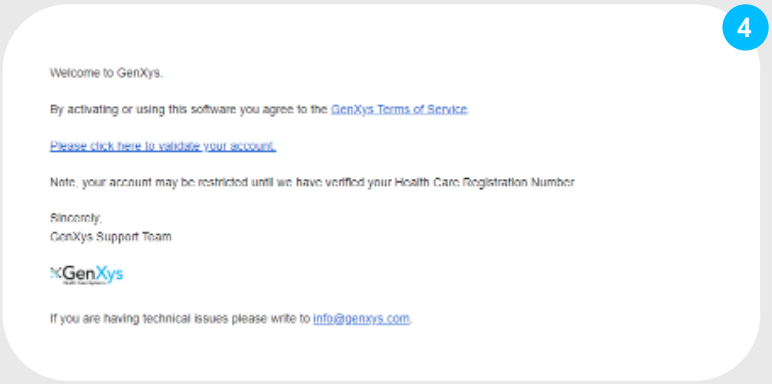


Creating a GenXys Portal Account

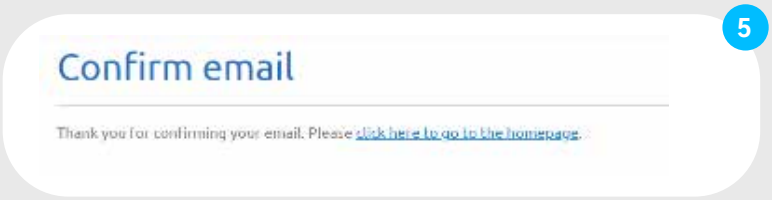
4. The next screen will display a registration confirmation message.

   An email will also be sent to the user's email from admin@genxys.com asking the user to confirm their email and agree to GenXys' Terms of Service.

   Follow the link to validate the email address and activate the account.

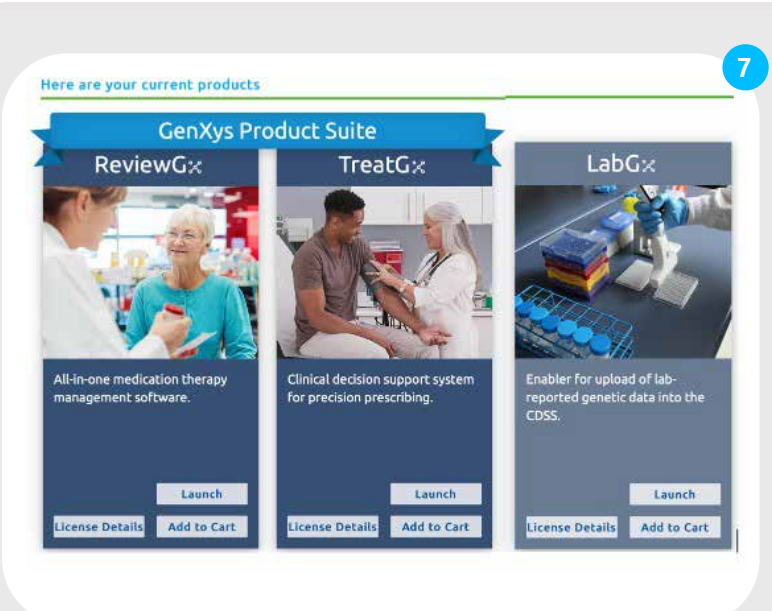


5. After landing on this page, the link to the homepage will prompt the user to log into their GenXys Portal account using their email and password.



6. Each GenXys Portal account also needs to be approved by GenXys and linked to the appropriate lab account. This may result in a slight delay between account creation and ability to activate a product license.

7. After logging into the GenXys Portal, the available software proucts will be displayed. External molecular lab users who have signed a license agreement with GenXys will see LabGx on their dashboard once their account has been approved. Individual users do not need to purchase or add LabGx to their cart; a license will be shared with them by their LabGx administrator .



8. To view and update account details, click on the Account icon at the top right of the screen.
This allows users to update contact information, licence/registration number, address, email, and password.

9. Selecting the Manage icon displays the Manage pages with patient case invitations, available product licenses, and pharmacogenetic tests that have been ordered for patients. Product licenses can be activated, renewed, assigned, disabled, and re-assigned from this page.

A. Admin accounts will have all licenses owned by the admin account listed on this page, and can see which licenses are assigned, in use, and available.

B. Individual users will have their assigned license visible on this page, but the license may be owned by the admin account.

Managing LabGx Licenses

Managing LabGx Licenses

- Every lab will have an administration account, which controls all the LabGx licenses for their lab.
- The LabGx licenses can be viewed under Licenses within the Manage pages.
- Product licenses can be activated, assigned, disabled, and re-assigned from this page.
- To purchase or renew LabGx licenses, please contact a GenXys account manager.

To assign or re-assign a product license:

1. Click the Edit icon that corresponds to the license.
2. Add the user's email to assign the license and click Assign License.
3. The license assignee will receive an email from sales@genxys.com inviting them to activate their GenXys product license.

   If the user does not yet have a GenXys Portal account, they will need to create one before they are able to activate the LabGx license.

If the lab also has affiliate TreatGx and ReviewGx licenses, these can be viewed, assigned, and disabled from the License section of the Manage page.

Once a license has been assigned to a user outside the license owner's organization, the licenses cannot be re-assigned to a user at a different organization.

Under the Assigned To user email, the GenXys identifiers needed to link pharmacogenetic results to individual GenXys portal user accounts are displayed (clinicID/clinicType/clinicInstance); these identifiers can be entered in the order JSON file before uploading into LabGx.

Activating a LabGx License

Activating a LabGx License

License invitations will be emailed to those who have had a license assigned to them via an administrative account.

To activate a license:

1. Open the email from sales@genxys.com entitled “GenXys Product License Invitation.” Follow the directions in the email.
2. Users must have a GenXys Portal account before they can activate their product license.
3. GenXys must also approve the account and link it to the appropriate lab before a LabGx license can be activated. If users can see LabGx on their. Explore page when they login, GenXys has completed this approval.
4. After the GenXys Portal account has been created and LabGx is visible on the Explore page, click on the link in the email to activate the LabGx license, log into GenXys Portal, and confirm the activation.
5. Alternatively, license invitations can be viewed and activated from the Manage tab in the GenXys Portal account.
6. After the license has been activated, GenXys will ensure the correct user permissions are added for each user. If user permissions aren’t available as expected, please contact a GenXys account manager.

Account Types

Account Types

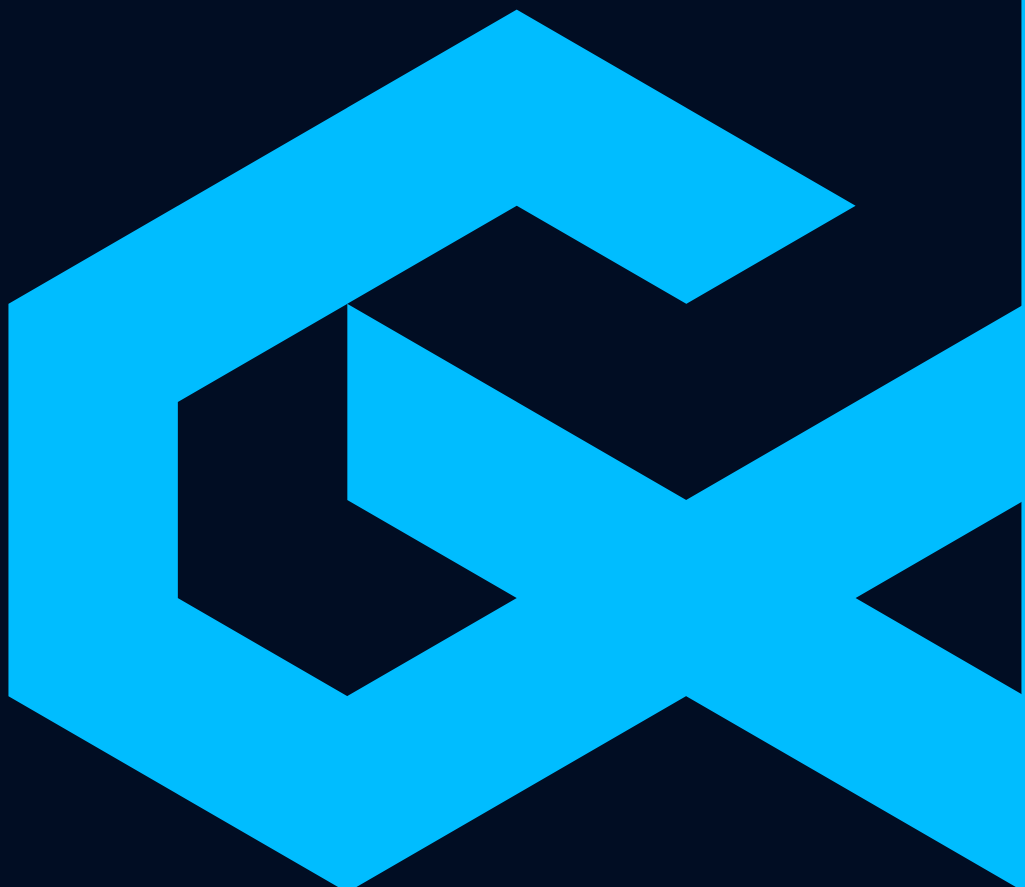
There are several account types within the GenXys Portal that determine permissions within each product.

These account types are assigned by GenXys in collaboration with each molecular lab. For LabGx, the relevant user types are:

1. **Health Care Provider (HCP)** – general user permissions for the TreatGx & ReviewGx software products (these products can be purchased by non-HCPs but the license will not activate for non-HCPs)
2. **Lab User** – general user permissions for LabGx (upload orders & results)
3. **Lab QA Signoff** – permissions for completing the QA sign off
4. **Lab Director Signoff** – permissions for completing the Lab Director sign off (LD Signoff)
5. **Lab Branding**– Permission to update report preferences

Users can have more than one user type.
User types and permissions are administered through the preferences tab, which can be accessed through the license owner account.

The LabGx™ Dashboard



The LabGx™ Dashboard

1. To enter the LabGx Dashboard, select Launch on the LabGx module from the GenXys Portal Explore homepage.

2. The Dashboard displays current patient orders. Orders are uploaded via one of three methods:

   a. Order JSON file is uploaded via the drag and drop interface.

   b. Order JSON file is uploaded via the GenXys API gateway.

   c. Order is populated via an associated healthcare provider (HCP) creating a patient profile and clicking the Order Pharmacogenetic Test button in the GenXys patient profile of TreatGx or ReviewGx.

3. Use the Start Date and End Date filter to limit the number of orders appearing on the page.

4. Use the Search bar to search for specific orders.

5. The Case Provider is by default the user who uploaded the patient order, unless the patient's HCP has been identified through one of three ways:

   a. The patient's HCP ordered the pharmacogenetic test directly from their GenXys Portal account.

   b. The patient's HCP's GenXys identifiers (clinicIdentifier, clinicInstance, clinicType) were included in the order JSON file that was uploaded into LabGx by the lab.

   c. The patient's HCP was added via the Edit icon and search from the Case Provider field in the LabGx dashboard.

The LabGx™ Dashboard

6. Specimen details (SampleID, Type & Date Collected) can be uploaded via the order JSON file, or edited directly on the LabGx dashboard.:

a. The SampleID is a required field when uploading the order JSON file, but it can be edited from the LabGx dashboard if needed.

b. The Specimen Type can be set to a default value specified by the lab, uploaded as part of the order JSON file, or selected via the dropdown in the LabGx dashboard. For specific specimen types beyond Saliva, Swab & Whole Blood, enter a free text specimen type within the order JSON file.

7. Barcodes can be uploaded with the order JSON file, or manually updated in the LabGx dashboard before results are uploaded. The barcode field for the order must match the barcode or identifier field in the uploaded results files to generate a medication report.

8. The Action Log shows the history for each order, including the user responsi ble for the action. If a new report has been generated, these will be labeled by their revision number, as R1, R2 etc.

9. The Status of each order indicates what stage each order is at.

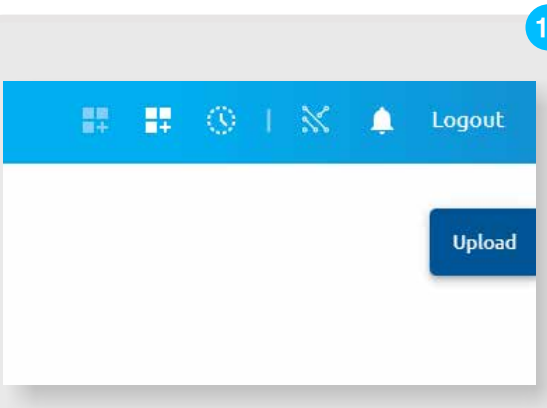
- **Awaiting Patient Sample** – For orders that do not yet have results uploaded.
- **Pending** – For orders with uploaded result files that are in the process of generating reports.
- **Awaiting QA signoff** – Orders that have generated reports that are waiting for QA signoff.
- **Awaiting LD Signoff** – Orders that have completed QA and are awaiting fina signoff.
- **Awaiting Concepts** – Transitory state where patient results are being uploaded to the GenXys patient profile for access in TreatGx & ReviewGx (no action required).
- **Complete** – All sign–offs are completed and the report PDFs are finalized and ready for download .

**Orders that are complete will disappear from the LabGx Dashboard and moved to the Historical Enterprise Orders page.

The LabGx™ Dashboard

10 Orders will be highlighted in pale orange if there was an issue with generating the patient report – the Status report will specify the specific issue.

11 The Up (Upload) tab in the upper right-hand corner is where result files will be uploaded in order to generate patient PGx interpretations.



12 In the top menu bar, there are links to **Historical Enterprise Orders** (where completed orders & reports are stored), the GenXys Portal home page **(Explore)**, Notifications, and to Logout.

LabGx
Medications Reports

LabGx
Medications Reports

1. Patient reports are available to download in PDF form once the Status changes to Complete.

   Completed reports are available in the **Historical Enterprise Orders page.**

2. Click the report icon to view and download the available report PDFs:

   - Long
   - Short (EN)
   - Short (Fax)
   - Raw report
   - Status report

3. Where applicable, patients also have the ability to access their completed reports by creating an account on the GenXys Patient Dashboard and clicking on **View your PGx Reports**

LabGx Medications Reports Long Report

The Long report is the complete medication report with references.

The sections in the Long report include:

Current Medications Impacted

A summary of the relevant pharmacogenetic markers that are associated with the patient's current medications *only appears if patient medication list is uploaded with patient orders in the format specified by GenXys

Medication Report

The longest section of the report that provides detailed information, sources and evidence levels on how a patients' lab results may affect each medication included in the report.

Medication Summary

A list of all medications included in the report, organized by their therapeutic area, and further stratified by the level of severity of the drug–gene interaction.

Table of Available References

A table of references available for each drug–gene interpretation.

Overview

An explanation of each section of the report and information on how to use the Medication Report, including a definition of the sources and evidence levels.

References

A list of the references used within the report.

Signoff Page

A section that includes the Methods, Limitations, and Liability Disclaimer from the laboratory performing the testing, and the signature of the report signatory (often the laboratory director).

Laboratory Report

A technical table of genetic test results reported from the lab and a summary of the relevant phenotypes.

LabGx Medications Reports Short Report

The short report includes a summary of the genetic lab data and phenotypes, as well as an overview of the drug–gene interaction severity for each medication included in the report.

Cover Page(s):

Includes highlighted serious drug–gene interactions, the laboratory methods, limitations, liability disclaimer, a summary of important data and the patient's phenotype results, and the report signatory's credentials and signature.

Content Pages

A summary table of medications included in the report, sorted alphabetically by therapeutic area, that displays the severity of each drug–gene interaction based on the patient's lab results.

LabGx Medications Reports Short (Fax) Report

- This report is similar to the Short report above but formatted in a black & white–friendly format to facilitate fax transmission.
- This PDF includes a summary of the patient's lab and phenotype results for select important genes, as well as a breakdown of medications with serious, moderate, and mild/no known gene–drug interactions.

LabGx Medications Reports Raw Report

The raw report refers to the unprocessed, foundational dataset of the report, presented in JSON (JavaScript Object Notation) format.

This format structures the data in a readable and organized way, using key–value pairs and nested objects, making it easy for both humans and systems to interpret.

The raw report serves as the primary source of truth, containing all the essential data points and metadata before any filtering, formatting, or analysis is applied.

It is often used for backend processing, integration with other systems, or generating refined, user–friendly reports.

Below is an example of data that a raw report may contain


```
{
 "Identifier": "41231050519977SMS",
 "HLAs": [],
 "CopyNumbers": [
  {
   "Gene": "CYP2D6",
   "Referance": "NG_008376.3 exon 9",
   "Result": "2"
  },
  {
   "Gene": "CYP2D6_intron2",
   "Referance": "NG_008376.3 intron 2",
   "Result": "2"
  },
  {
   "Gene": "CYP2D6_intron6",
   "Referance": "NG_008376.3 intron 6",
   "Result": "2"
  }
 ],
 "Genotypes": [
  {
   "Gene": "ABCB1",
   "RSID": "rs1045642",
   "HGVS": "c.3645G>A",
   "HGVSReferance": "NC_000007.14",
   "GenotypeConverted": "",
   "GenotypeOriginal": "A/G"
  },
```

LabGx Medications Reports Status Report

The status report highlights any errors that may have occurred while generating the pharmacogenetic interpretations.

Errors are usually the result of issues with the results input files.

Generally, orders will also be highlighted on the LabGx dashboard if an error or issue occurred during the pharmacogenetic interpretation

Customizing LabGx Reports

Key Features & Customization Options

- **Multiple Report Templates:** Create, edit, save, and activate custom templates for different reporting needs.
- **Flexible Report Layouts:** Customize sections, formatting, and data fields for Long, Short, and Fax versions.
- **Template Management:** Edit, apply, or delete saved templates to keep reports organized.
- **Order-Based Template Selection:** Apply templates dynamically using Order JSON file or Panel ID mapping for automation.
- **Global Settings:** Configure lab-wide settings, including:
  - Time Zone – Adjust report timestamps to match lab location.
  - Specimen Type – Define sample type (Swab, Whole Blood, Saliva).
  - Webhook URL & Notifications – Set up alerts for LD signoff, phenotype translation issues, and more.
- **Medication Summary & Interpretation:** Customize medication recommendations, therapeutic areas, and sources of evidence (CPIC, FDA, DPWG, PharmGKB).
- **Header & Footer Customization:**
  - Upload logos (max 400px, .PNG or .SVG).
  - Set a custom report title.
  - Enable patient profile links to TreatGx or ReviewGx.
  - Include footer logos and optional notes.
- **Technical & Lab Data Control:** Manage genomic location display, reporting methods, and signatory details (including name, title, and signature image).
- **Reference Management:** Include, reposition, or remove references and evidence sources.
- **Compliance & Accreditation Support:** Labs can add regulatory logos (CAP, CLIA, ISO, SANAS) and disclaimers.

***For a detailed step-by-step guide on using Lab Studio, refer to the LabGx QuickStart Guide.**

Patient Orders

Updating 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. 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.

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

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

5. The order file must use a specific JSON template, which can be populated with information from the laboratory information system (LIMS).

6. After orders have been uploaded into LabGx by uploading the JSON order file, they will appear in the LabGx Dashboard with an Awaiting Patient Sample status.

7. 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).**

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

Sending Patient Orders via GenXys API Gateway

1. GenXys will set up an API proxy user for the lab if they wish to send files to LabGx via the API gateway.
2. Patient orders need to be sent in JSON format, as described in "Uploading Patient Orders via Order File" above.
3. Orders can be sent alone, or with associated results files.

Creating an Order via the GenXys portal

1. Users of the TreatGx and ReviewGx software can order pharmacogenetic tests via the GenXys platform if this functionality is configured.

2. Lab affiliate users can have their lab preference set to a specific lab, and when the health care provider clicks "Order Pharmacogenetic Test" from an existing patient profile, the order will populate the selected lab's LabGx dashboard.

3. Labs then use the patient information on the LabGx order dashboard to proceed with a pharmacogenetic test order. The barcode and specimen type is editable by the lab; other patient information must be edited and re-uploaded in a new order.

4. If a pharmacogenetic test is ordered via the GenXys Portal, results will automatically be sent back to the ordering health care provider.

Linking Patient Orders & Results to the Ordering Health Care Provider (HCP)

In the Uploaded Order JSON

1. In the JSON order file, there are three fields that allow the patient's results and interpretation to be linked to a health care provider's TreatGx and ReviewGx account:

   - **"clinicIdentifier"** *required
     Analogous to the organization the HCP is a part of; the broadest identifier.

   - **"clinicType"** *optional
     Analagous to the location within the organization that the HCP is a part of; this is the level of identifier that is used when designating HCPs who will share a patient case load.

   - **"clinicInstance"** *optional
     Analagous to the HCP's unique identifier, and often the NPI is utilized for this most-specific identifier.

2. Each health care provider is assigned these three identifiers by GenXys when they sign up for a TreatGx or ReviewGx account. If labs are signing up affiliate HCPs, they may request specific identifiers to be used for these HCPs so that they are consistent with the lab's identifiers.

3. GenXys can provide ordering labs with these identifiers for HCPs who order tests through the lab, so that the lab can enter these identifiers into the patient order file. Labs can also see these identifiers in the **Licenses** section of the **Manage** page, if the lab has assigned an affiliate TreatGx or ReviewGx license to the HCP.

Linking Patient Orders & Results to the Ordering Health Care Provider (HCP)

4. If only the clinicIdentifier is included in the patient order (clinicType and clinicInstance JSON fields are empty), the results and report will be saved to the account of the user who uploaded the orders to LabGx. If the user doesn't have a TreatGx or ReviewGx account, the results will only be accessible via LabGx.

5. If the identifiers do not match any existing accounts, an error will occur and prevent the JSON order file from populating the LabGx dashboard.

6. If the lab has a clinical team who will be reviewing the patient results and using TreatGx or ReviewGx as part of patient care, a clinic account can be set up for the results to be sent to. As a default, these three identifiers can be set to the lab's clinic account, and then changed as needed to send results to an individual HCP.

Via the LabGx Dashboard

1. Once an order is uploaded into the LabGx dashboard, and before a report is generated, the Case Provider can be edited using the edit (pencil) icon next to the health care provider's email.

2. HCPs with existing GenXys Portal account can be searched for and results will be shared directly with them via TreatGx and ReviewGx.

Via the LabGx Historical Orders Page

1. Once a report is complete, it moves to the Historical Enterprise Orders page.

2. From here, HCPs can be invited to access the patient case in the GenXys Portal via a search of the GenXys HCP database, or via email invitation if the HCP does not yet have a GenXys Portal account.

Via the LabGx Portal

1. If a pharmacogenetic test is ordered via the GenXys Portal, results will automatically be sent back to the ordering health care provider.

Lab Data
Upload

To facilitate interoperability between genetic lab companies and the decision support capabilities within the GenXys platform, a common and consistent import format has to be used. This is called the Unified Lab Result (ULRTM).

The ULR represents a standardized form of 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.

For labs using ThermoFisher's OpenArrayTM or Agena Bioscience's Veridose Core Panel®, GenXys has developed a proprietary tool that converts the instrumentation data output files into the required ULR format.

ULR File Structure

*GenXys can provide conversion to the ULR file type for certain types of data files. Contact your account representative for details.

GenXys will provide a ULR template. See Appendix 1 for a sample of the ULR format. The structure of the files is specified in the following tables:

ULR (root)

Mandatory	Name	Type	Description
Y*	Genotype	Array of <Genotype> (see 2)	Genotype results
Y*	StarAllele	Array of <StarAllele> (see 3)	Star Allele results
Y*	PhenoType	Array of <Phenotype> (see 4)	Phenotype results
Y*	AllelePresence	Array of <AllelePresence> (see 5)	Allele presence results
Y*	CopyNumber	Array of <CopyNumber> (see 6)	Copy number results
Y*	SupplementaryResults	Array of <SupplementaryResult> (see 7)	Any other result not specified herein above

*The array can be empty, depending on the type of information the lab samples.

ULR File Structure

Genotype

Mandatory	Name	Type	Description	Example
Y	RSID	String	RSID identifier	rs2231142
Y	Genotype	String	Genotype result	G/G

StarAllele

Mandatory	Name	Type	Description	Example
Y	Gene	String	Gene identifier	CYP2D6
Y	Value	String	Star Allele result	*5/*6, (*5/*6)4N or *5/*6x3
Y	GeneticTestsDerivedFrom	Array of string	Details of translation underlying items	CYP2D6_CopyNumber rs1065852 rs59421388 rs5030867 rs28371706 rs5030655 rs3892097 rs35742686 rs5030656 rs16947 rs28371725 rs1135840

ULR File Structure

Phenotype

(Only mandatory if lab partner sends phenotype results)

Mandatory	Name	Type	Description	Example
Y	Gene	String	Gene identifier	CYP2C19
Y	Value	String	Phenotype result	PM
Y	Guideline	String	Guideline used in translation	CPIC

AllelePresence

Mandatory	Name	Type	Description	Example
Y	Gene	String	Gene identifier	HLAA
Y	Allele	String	Allele identifier	3101
Y	Presence	String	Presence/Absence	Possible values are: Absence, Presence

CopyNumber

Mandatory	Name	Type	Description	Example
Y	Gene	String	Gene identifier	CYP2D6
Y	CopyNumber	String	Copy number value	3

SupplementaryResult

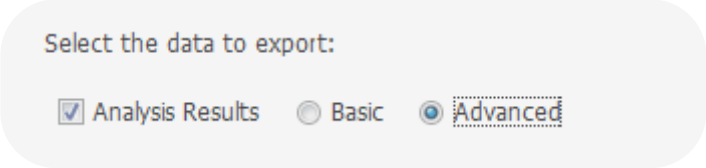
Mandatory	Name	Type	Description	Example
N	ResultType	String	Result description	Current possible values are: SangerSequencing, Long Range PCR (LRPCR)
N	Key	String	Identifier (such as an RSID or a Gene)	“rs1065852”
N	Value	String	Result	“A”

ThermoFisher
Instrumentation Results Files

To download the required ThermoFisher instrumentation files:

1. 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).

   i. Select Export > Analysis Data from the menu on the left-hand side
   ii. Under "Select data to export", check only "Analysis Results"
   iii. Ensure "Advanced" is selected:



   iv. Complete the "File name" and "File location" fields. For "File Type", select .txt
   v. Select "Export Preview", then "Start Export"

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

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

3. 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.

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

Agena Biosciences
Instrumentation Results Files

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

- PGxReport_combined.csv
- PGxReportSNPDetailsLong.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.

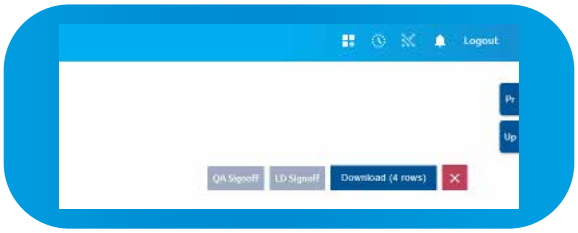
Type of file	Original extension	LabGx extension
Star Allele data	.csv	.srt
SNP data	.csv	.snp

Uploading Patient Result Files

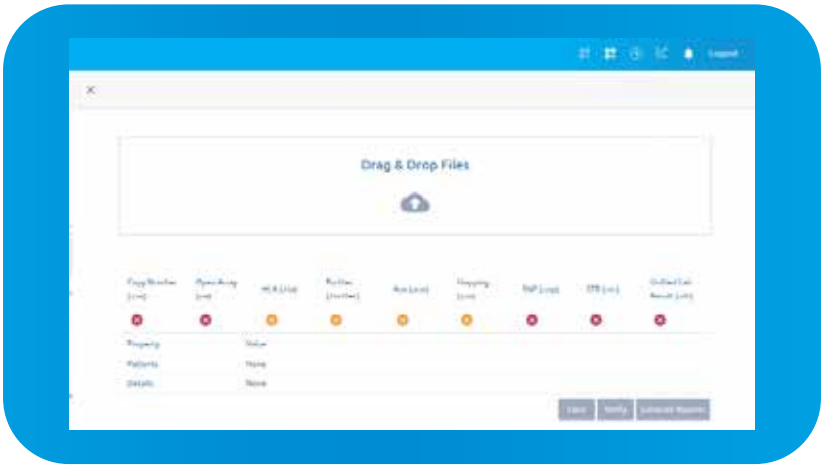
Uploading Patient Result Files

1. After the patient orders have been uploaded into the LabGx Dashboard, patient results can be uploaded into LabGx via drag and drop Alternatively, results files can be sent with the order file via the GenXys API Gateway.

2. Click on the **Up** (Upload) tab in the top right-hand corner of the dashboard.



3. Click on the **Up** (Upload) tab in the top right-hand corner of the dashboard.



Refer to the file specifications in the previous section. The following files are applicable in ULR uploads:

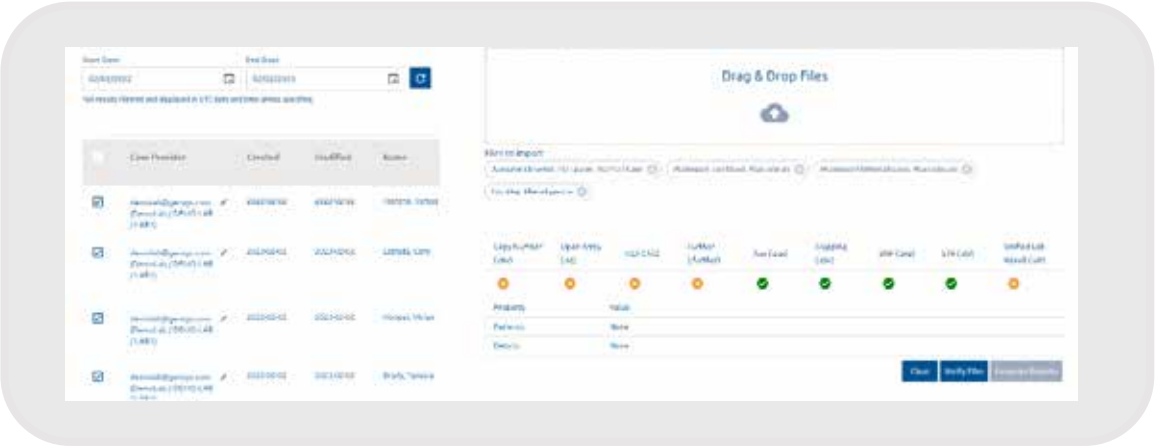
Type of file	Original extension	LabGx extension
ULR	.txt or .json	.ulr
Auxiliary file (uploaded by GenXys*)	.json	.aux

*Auxiliary files are required for all external labs. Auxiliary files are configuration files created by the GenXys lab team and contain panel-specific information on alleles, translation, and phenotypes. GenXys will create and upload the Auxiliary file for each lab as part of the implementation process.

Uploading Patient Result Files

4 ULR files are uploaded for a single case at a time. Select the desired case on the left side, this will enable the Verify ULR button at the bottom of the Upload screen:

Uploaded results files in the upload side bar



Click the **Verify ULR** button. This will confirm the case the ULR data is being associated to, as well as the number of results uploaded:

Verification of results files in the upload side bar

5 If uploading other file types, follow the same process and click Verify Files to ensure there are no errors that will prevent report generation.

Generating Patient Reports

Generating Patient Reports

1. Once the files have been verified in the Upload sidebar, the **Generate Reports** button will become active. Click this button to upload the files to LabGx.
A pop-up screen will show if there were any issues during the upload – these should be outlined in the **Details** section.

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

   i. **Awaiting QA** signoff if no major errors are detected. Minor issues with the report will result in the order being highlighted in pale orange. Go to the next step if this is the case.

   ii. **Error** if an error is detected and the report generation cannot be completed. Click on the report icon and select the **Status Report** in the dropdown menu. This report explains in detail the type of error that prevented the system from generating a PGx interpretation. After errors are resolved, reupload the genetic data files if required to generate a new report. If support is required to resolve the error, please contact GenXys for support, using the contact information at the end of this manual.

3. 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.

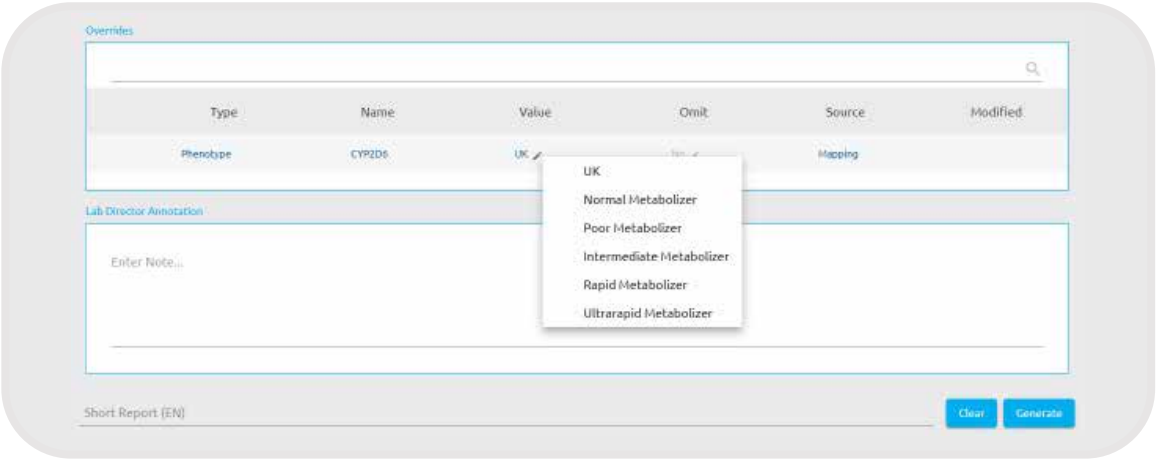
   i. Orders will also be highlighted in orange on the LabGx dashboard if there was an issue with the report generation. Viewing the Status Report will help identify the specific issue.

4. 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.

Generating Patient Reports

5 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 HCP via the GenXys Portal.

6 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.



Retracting or Re-generating Reports

Retracting or Re-generating Reports

1. Once reports are Complete (QA & LD signoff is complete), they may be "retracted" from the GenXys Portal by resetting the patient case. This will remove the PDF report from the patient profile and the lab data from the clinical decision support software, TreatGx and ReviewGx.

2. To reset a patient case, first save the existing report PDFs if they have not already been downloaded by the lab. Resetting the case removes the report from LabGx, and reverts the order to **Awaiting Patient Sample.**

3. Select the patient case to reset, and then click the red button at the top of the Historical Orders page called **Reset Lab Results**. The report will disappear from the Historical Orders page, and appear on the LabGx Dashboard with a status of **Awaiting Patient Sample.**

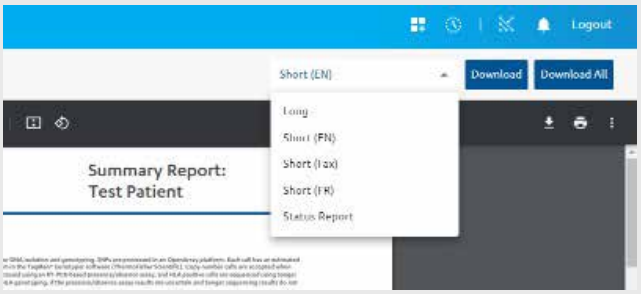
4. Return to the LabGx Dashboard and re-upload results with the same barcode as the patient case to re-generate the report. Continue with the usual QA and LD signoff process.

Report Quality Assurance (QA) Check

Report Quality Assurance (QA) Check

1. The Quality Assurance (QA) check is required to ensure that the expected results in the PGx interpretations generated by LabGx are all present so that the correct phenotype is reported for each applicable gene.

2. The user in charge of the QA check should first notice if there are any orders on the LabGx dashboard that are highlighted in orange. This indicates that there was an issue with the report generation.
Next look at the Status Report.
Open this report by clicking on the report icon in the Status column of the LabGx dashboard, and then selecting the Status Report from the dropdown at the top of the PDF viewer.



LabGx report viewer

3. Check for any Translation or Compilation Issues. Translation Issues mean that phenotype mapping was not successful for one or more genes – either due to missing data or issues with the translation file. Compilation Issues indicate an issue with certain medications in the report – this should be brought to the Lab directors' attention.

Report Quality Assurance (QA) Check

GenXys PRESCRIBING SYSTEMS

4 If there is a Translation issue, open the Long version of the PGx interpretation, and scroll to the Laboratory Report at the end of the report. The first table of the Laboratory Report contains a list of all the SNPs required to determine the phenotype of a gene. Ensure there is a result in every row.

Laboratory Report

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

Gene	rsID	HGVS	HGVS Reference	Result
ABCG2	rs2231142	c.421C>A	NM_001257386.1	G/T
ADRB2	rs1042713	c.46A>G	NM_000024.5	A/G
ANKK1	rs1800497	c.2137G>A	NM_178510.1	A/G
CYP2B6	rs28399499	c.983T>C	NC_000019.10	T/T
CYP2B6	rs3211371	c.1459C>T	NC_000019.10	C/C
CYP2B6	rs34223104	g.-82T>C	NC_000019.10	T/T
CYP2B6	rs2279343	c.785A>G	NC_000019.10	A/A
CYP2B6	rs3745274	c.516G>T	NC_000019.10	G/G
CYP2C	rs12777823	g.96405502G>A	NC_000010.10	G/A
CYP2C19	rs12248560	c.-806C>T	NM_000769.2	C/C
CYP2C19	rs12769205	c.332-23A>G	NM_000769.1	A/G
CYP2C19	rs28399504	c.1A>G	NM_000769.1	A/A
CYP2C19	rs41291556	c.358T>C	NM_000769.1	UK
CYP2C19	rs4244285	c.681G>A	NM_000769.1	G/A
CYP2C19	rs4986893	c.636G>A	NM_000769.1	G/G
CYP2C19	rs72552267	c.395G>A	NM_000769.1	G/G
CYP2C19	rs17884712	c.431G>A	NM_000769.1	G/G
CYP2C19	rs56337013	c.1297C>T	NM_000769.1	C/C
CYP2C19	rs6413438	c.680C>T	NM_000769.1	C/C
CYP2C19	rs72558186	g.19294T>A	NM_000769.1	T/T

A) If there is a UK (unknown value), this is due to missing data (results) in the .oa, .snp file or ULR file.

Gene	rsID	HGVS	HGVS Reference	Result
CYP2D6	rs5030655	c.454delT	NM_000106.5	A/A
CYP2D6	rs5030656	c.841_843delAAG	NM_000106.5	TCT/TCT
CYP2D6	rs5030867	c.971A>C	NM_000106.5	T/T
CYP2D6	rs59421388	c.1012G>A	NM_000106.5	C/C
CYP2D6	rs5030862	g.124G>A	NM_000106.5	C/C
CYP2D6	rs5030865	g.1758G>T,G>A	NM_000106.5	C/C
CYP2D6	rs769258	g.31G>A	NM_000106.5	C/C
CYP2D6	rs201377835	g.883G>C	NM_000106.5	C/C
CYP2D6	rs774671100	g.137-138insT	NM_000106.5	A/A
CYP2D6	rs72549356	1864_1865ins	NM_000106.5	-/-
CYP2D6	rs267608319	g.4042G>A	NM_000106.5	C/C
CYP2D6	rs72549346	g.3259_3260insGT	NM_000106.5	-/-
CYP2D6	rs1135822	g.1611T>A	NM_000106.5	A/A
CYP2D6	rs79292917	g.2939G>A	NM_000106.5	C/C

B) If there is a "–/–" this indicates a deletion/deletion result

c)

DPYD	rs55886062	c.1679A>C	NC_000001.11	A/A
Factor II	rs1799963	c.*97G>A	NM_000506.4	G/G
Factor V	rs6025	c.1601G>A	NM_000130.4	Unreported
HTR2A	rs7997012	c.614-2211T>C	NM_000621.5	G/G

d)

CYP2D6	rs5030862	c.124C>T	NC_000022.11	C/C
CYP2D6	rs201377835	c.181-1C>G	NC_000022.11	C/C
CYP2D6	rs774671100	c.137->A	NC_000022.11	A/A (-/-)[1]
CYP3A4	rs35599367	c.522-191G>A	NC_000007.14	G/G
CYP3A5	rs10264272	c.624G>A	NM_000777.4	C/C
CYP3A5	rs776746	c.219-237G>A	NM_000777.4	C/C
CYP3A5	rs41303343	c.1035_1036->A	NC_000007.14	A/A (-/-)[1]

5 If all SNPs have a result, move on to the Copy Number Variation table, and ensure all genes have a result.

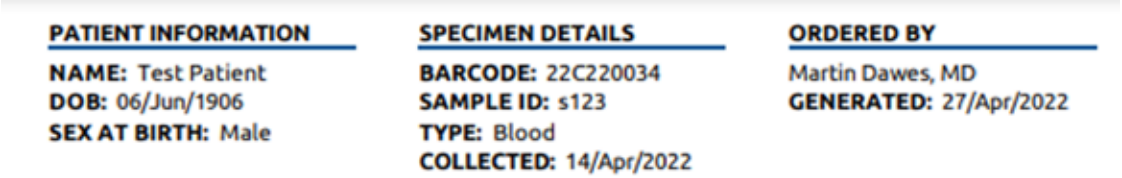
6 The Phenotype table in the Laboratory Report contains key genes, their star allele diplotypes, and corresponding phenotype. The star allele diplotypes are determined by the mapping file that GenXys creates for each panel. If there is a missing result in this final result table, please contact GenXys for support. Phenotypes are determined based on relevant guidelines for each gene. If there is an Undetermined star allele result (due to missing SNP data), the Phenotype Result will be Inconclusive. The phenotype may also be Inconclusive if there is no literature to support the phenotype translation from the star allele result (contact GenXys if you have any questions about this).
All pharmacogenetic information (results, phenotypes, interpretations) is the same across all PGx interpretations for a given patient order. If the pharmacogenetic information is correct in the Laboratory Report in the Long interpretation, the other PDFs will contain the same information.

Phenotype Table

Gene	Allele Result	Phenotype Result
CYP2D6	*1/*9	Normal Metabolizer
CYP2C9	*1/*2	Intermediate Metabolizer
CYP2C19	*1/*1	Normal Metabolizer
TPMT	*1/*1	Normal Metabolizer
SLCO1B1	*1/*1	Normal Function
CYP2A6	*1/*9	Normal Metabolizer
CYP3A5	*3/*3	Poor Metabolizer
DPYD	*1/*1	Normal Metabolizer
NUDT15	*1/*1	Normal Metabolizer

7 If there is missing information or an unknown phenotype, the lab director can override the report before final signoff. Using the Override option while viewing the report, the lab director can manually assign a phenotype and add annotations or comments, which will be displayed in the top section of the report.

8 In addition to checking the Laboratory Report in the Long PGx interpretation, also ensure that the information at the top of each PDF appears correctly:



PATIENT INFORMATION
NAME: Test Patient
DOB: 06/Jun/1906
SEX AT BIRTH: Male

SPECIMEN DETAILS
BARCODE: 22C220034
SAMPLE ID: s123
TYPE: Blood
COLLECTED: 14/Apr/2022

ORDERED BY
Martin Dawes, MD
GENERATED: 27/Apr/2022

9 The report signatory name, Methods, Limitations, Liability Disclaimer, lab logo, and lab contact information in the footer of the report are all based on the preferences and customizations from each external lab partner during the implementation process. If this information is correct for one patient in the batch of orders, it will be correct for all.

Accesing Patient PGx Interpretations

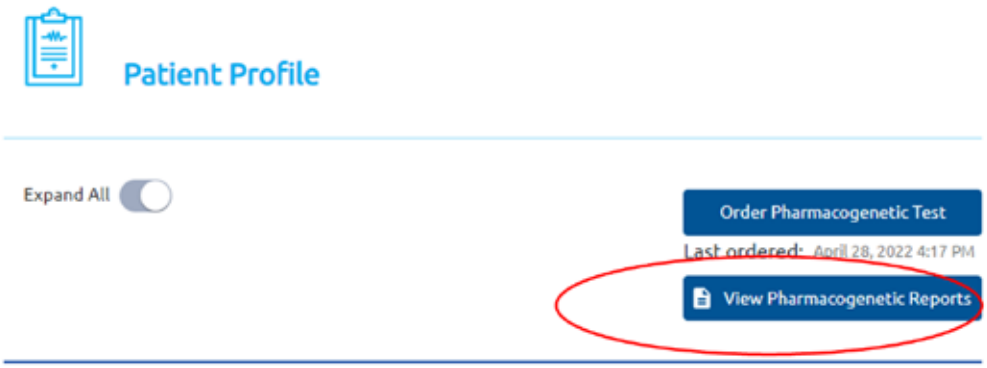
Accesing Patient PGx Interpretations

1. Patient reports can be viewed in the Historical Enterprise Orders tab, accessed by clicking the clock icon in the top right of the screen. The PDFs can be downloaded as required.

   a) Orders in the Historical Enterprise Orders tab can have the following statuses:

   i. **Complete:** Report is signed off and available for download
   ii. **Complete (not signed off)**: Report was generated but not signed off on (not released) but is available for viewing

2. **No report available:** There was an error in the report generation process, or a report was not generated (no report available to view or download) Lab results and the PDF report are also automatically sent to the health care provider's TreatGx/ReviewGx account who ordered the patient test (if they ordered directly via the GenXys portal or if they have a GenXys account and the lab has indicated the HCP as the case provider – see section on Linking Patient Orders & Results to the Ordering Health Care Provider (HCP)). The PDF reports can be accessed from the Patient Profile, either via TreatGx or ReviewGx.

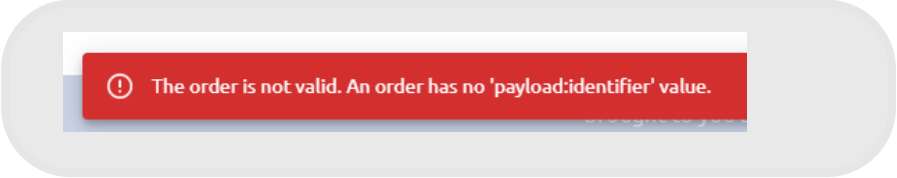


Patient Profile in ReviewGx & TreatGx

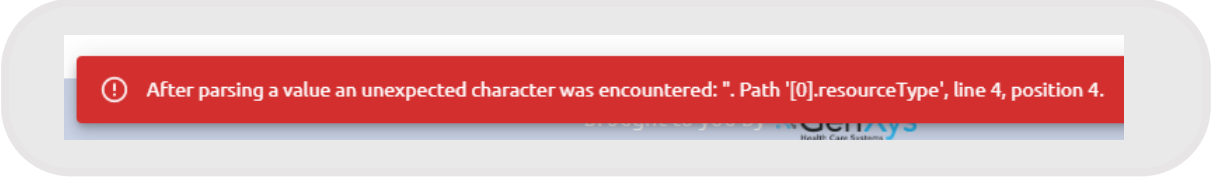
Troubleshooting

Errors that occur during order uploading

1. Missing information in the orders file.
This error indicates a missing required value (Identifier)



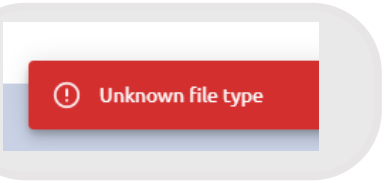
1. Error in the JSON formatting. This error indicates an error in the JSON file (that occurs after "resourceType" – in this case a missing comma). If one of these errors occur, update the order .json file and re-upload to the LabGx Dashboard.



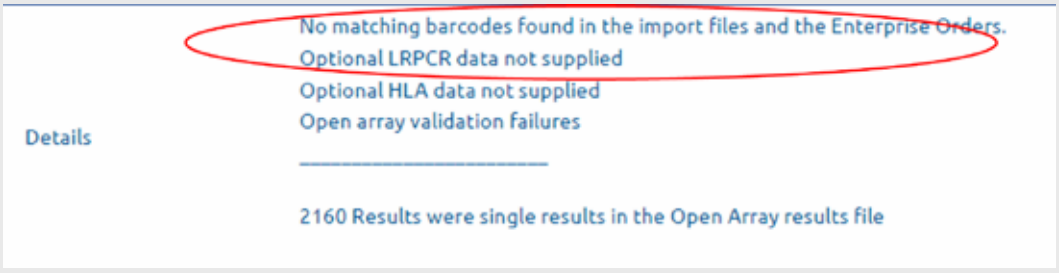
Troubleshooting

Errors that occur during results uploading & verification

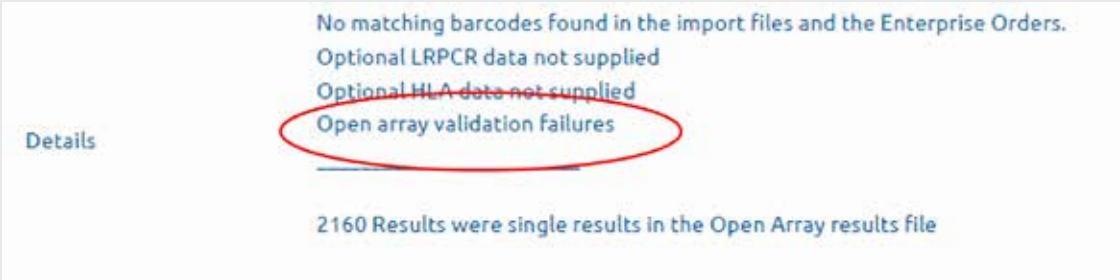
1. Unknown file type. Error message that indicates an unexpected file type (for example, a .txt file). Ensure the correct file format is used for orders (.json) and results (.ulr, .oa, .cnv, .snp, .str).



2. No matching barcodes found in the import files and the Enterprise Orders. File verification error message. This error occurs when the Identifier(s) in the results files (.oa & .cnv OR .ulr) does not match the identifier(s) of the uploaded order(s). Ensure the correct orders & results are being uploaded



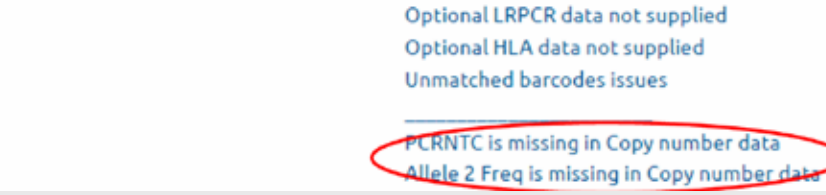
3. Open array validation failures. The LabGx software is looking for replicates and control data that has not been provided by the lab; however, a report can still be generated based on the data provided.



Troubleshooting

Errors that occur during results uploading & verification

4 Missing copy number data. The LabGx software cannot find information that it is looking for in the CNV data file (frequency), but this is not necessary for the report (this may occur due to different ways of exporting the results data). The sample identifier is in the open array result file but not in the cnv result file. This may or may not be relevant depending if these results relate to the order for which interpretations are being performed.



5 Missing data in the .oa or .cnv files. File verification error message.
This error occurs when data is missing for one or more patients (patient identifiers) in the the OpenArray result file. This may or may not be relevant depending if these results relate to the orders for which interpretations are being performed.

After correcting the issue in the relevant results file, re-upload to LabGx and click “Verify Files” to ensure no further issues remain.

Troubleshooting

Errors that occur during PGx Interpretation generation

1. **Requires Test**
LRPCR. This error message indicates that CYP2D6 phenotype is inconclusive based on the data provided and further testing is required, such as the LRPCR test to determine which of the *alleles are duplicated. A FurtherTests file may be required. If no further data is provided, the phenotype result will be Inconclusive.

2. **Requires Test**
SangerSequencing_or_intron2CNV. This error suggests the presence of possible CYP2D6 hybrid alleles. Additional assays may be required to resolve this genetic translation issue such as the CYP2D6 intron 2 CNV assay.

- To upload CNV intron 2 data, go to the CopyCaller software and export a single file containing the CYP2A6, CYP2D6 exon 9, and CYP2D6 intron 2 data. Re-upload this Copy Number file instead.
- To upload Sanger sequencing data, use the FurtherTest file. If no further data is provided, the phenotype result will be Undetermined.

3. **Unexpected errors:**
These errors will appear in a red box above the upload fields. If a red box error occurs, send a screenshot of the error to GenXys for troubleshooting support.

After errors are resolved, reupload the genetic data files to ensure that no issues are outstanding. Then proceed with generating the reports.

Troubleshooting

Errors that occur after Interpretation generation:

1. **Status reverts to Awaiting Patient Sample:**
If the status of a patient order reverts to Awaiting Patient Sample after reports are generated, try uploading the results files again and re-generate the affected patient PGx interpretation.

If issues arise during the use of LabGx, please contact:
info@genxys.com for support.

```
{
 "Genotype": [
  {
   "RSID": "rs2231142",
   "Genotype": "G/G"
  },
  {
   "RSID": "rs12769205",
   "Genotype": "A/A"
  },
  {
   "RSID": "rs1042713",
   "Genotype": "G/G"
  },
  {
   "RSID": "rs1800497",
   "Genotype": "G/G"
  },
  {
   "RSID": "rs28399504",
   "Genotype": "A/A"
  },
  {
   "RSID": "rs41291556",
   "Genotype": "T/T"
  },
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   "Genotype": "G/G"
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   "RSID": "rs4986893",
   "Genotype": "G/G"
  },
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  },
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   "Genotype": "A/G"
  },
  {
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   },
   {
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   },
   {
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    "Genotype": "T/T"
   },
   {
    "RSID": "rs267606617",
    "Genotype": "A/A"
   },
   {
    "RSID": "rs116855232",
    "Genotype": "C/C"
   },
   {
 "RSID": "rs1799971",
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    "Genotype": "C/C"
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   },
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    "Genotype": "C/C"
   },
   {
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    "Genotype": "C/C"
   },
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   "Genotype": "G/A"
  },
  {
   "RSID": "rs5030867",
   "Genotype": "T/T"
  },
  {
   "RSID": "rs1808682",
   "Genotype": "G/G"
  },
  {
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   "Genotype": "A/A"
  },
  {
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   "Genotype": "CTT/–"
  },
  {
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   "Genotype": "T/T"
  },
  {
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   "Genotype": "C/C"
  },
  {
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   "Genotype": "C/C"
  },
  {
   "RSID": "rs41303343",
   "Genotype": "–/–"
  },
  {
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   "Genotype": "C/C"
  },
  {
   "RSID": "rs28371725",
   "Genotype": "C/C"
  },
  {
   "RSID": "rs5030655",
   "Genotype": "A/A"
  },
  {
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  },
  {
   "RSID": "rs489693",
   "Genotype": "A/C"
```

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  "Genotype": "C/C"
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  "RSID": "rs9332131",
  "Genotype": "A/A"
 },
 {
  "RSID": "rs12248560",
  "Genotype": "T/T"
 },
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  "RSID": "rs16947",
  "Genotype": "G/G"
 },
 {
  "RSID": "rs7900194",
  "Genotype": "G/G"
 }
]
```

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"StarAlleles": [
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   "Value": "(*1/*1)3N",
   "GeneticTestsDerivedFrom": [
    "CYP2D6_CopyNumber",
    "rs1065852",
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    "rs5030655",
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    "rs35742686",
    "rs5030656",
    "rs16947",
    "rs28371725",
    "rs1135840",
    "rs59421388",
    "rs5030867"
   ]
  },
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   "Value": "*1/*1",
   "GeneticTestsDerivedFrom": [
    "rs1799853",
    "rs1057910",
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    "rs7900194",
    "rs28371685"
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  },
  {
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   "rs41291556",
   "rs12248560",
   "rs12769205"
  ]
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  "Value": "*1/*2",
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  "Gene": "SLCO1B1",
  "Value": "*1/*5",
  "GeneticTestsDerivedFrom": [
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  ]
 },
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  "Value": "*4/*4",
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   "rs28399454"
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   "rs10264272",
   "rs41303343"
  ]
 },
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   "rs67376798"
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  {
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   "Value": "PM"
  },
  {
   "Gene": "CYP2C19",
   "Guideline": "DPWG",
   "Value": "PM"
  },
  {
   "Gene": "CYP2C9",
   "Guideline": "",
   "Value": "NM"
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   "Guideline": "",
   "Value": "NM"
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   "Gene": "DPYD",
   "Guideline": "",
   "Value": "NM"
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  {
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   "Guideline": "",
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  {
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   "Guideline": "",
   "Value": "IM"
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   "Gene": "CYP2D6",
   "Guideline": "",
   "Value": "UM"
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   "Gene": "CYP2D6",
   "Guideline": "ActScore",
   "Value": "UM"
  }
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 "AllelePresence": [
  {
   "Gene": "HLAA",
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    "Presence": "Absence"
   },
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    "Gene": "HLAB",
    "Allele": "1502",
    "Presence": "Presence"
   },
   {
    "Gene": "HLAB",
    "Allele": "5801",
    "Presence": "Absence"
   },
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    "Allele": "4403",
    "Presence": "Presence"
   }
  ],
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    "CopyNumber": "3"
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    "Gene": "CYP2A6",
    "CopyNumber": "2"
   }
  ],
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   {
    "TestType": "LRPCR",
    "RSID": "rs1065852",
    "Genotype": "A"
   }
  ]
}
```

Linking results from LabGx into the GenXys portal for health care providers

Linking results from LabGx into the GenXys portal for health care providers

LabGx enables the upload of genetic data from labs into the GenXys Portal via LabGx. Once the genetic data is in the GenXys Portal, health care providers can utilize this and other patient information within the clinical decision support software, TreatGx and ReviewGx, to enable precision prescribing and comprehensive medication reviews.

There are 4 ways to enable health care providers to receive patient results directly from labs via LabGx:

1. Labs include the health care provider's 3 identifiers in the order JSON file that is uploaded into LabGx.
2. Labs manually search for and select the health care provider from the LabGx dashboard after the order has been uploaded into LabGx.
3. Labs can share the patient case and results with the health care provider from the Historical Orders page after the order is complete.
4. Health care providers can "order" pharmacogenetic tests via the patient profile in the GenXys Portal and this will automatically link the order to the health care provider within LabGx.

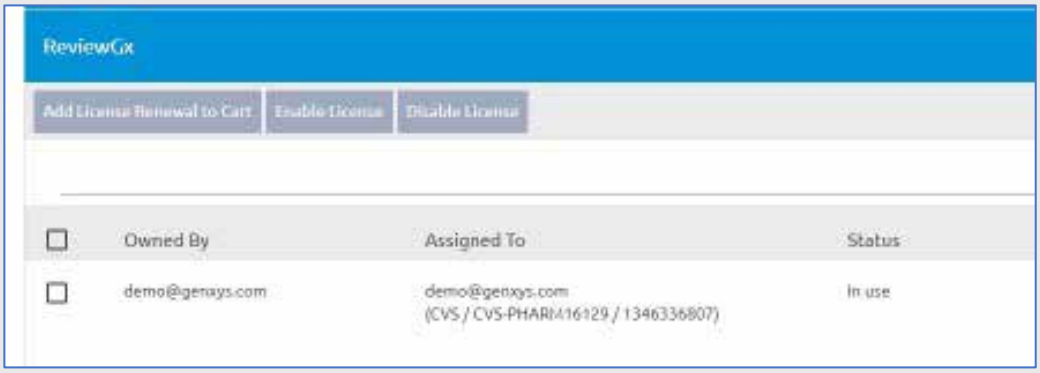
Identifiers
in Order JSON file

Each health care provider within the GenXys Portal is assigned a set of 3 unique identifiers by GenXys. These identifiers can be entered in the order JSON by the lab to link results to the health care provider's GenXys account as soon as results are complete. GenXys can share a list of these identifiers for relevant health care providers with labs, and labs can also see a list of these identifiers for any health care providers they have shared licenses with via the Manage page for their GenXys admin account.

For example, a pharmacist with license #1346336807, working at CVS pharmacy at location 16129 would be assigned the following GenXys identifiers, and these would be entered within the order JSON file:

```
"clinicIdentifier":"CVS",
"clinicType":"CVS-PHARM16129",
"clinicInstance":"1346336807",
```

Identifiers are viewable from the "Manage Page" under Licenses:



Manual linking
from LabGx Dashboard (incomplete orders)

Once an order is uploaded into the LabGx dashboard via the order JSON, the Case Provider can be updated by clicking the Edit (pencil) icon. Health care providers who have a GenXys account are searchable within the dropdown search window.

Manual linking
from LabGx Dashboard Historical Orders (complete orders)

Once an order is complete (ie. the report is signed off), it will move from the LabGx dashboard into the Historical Orders page. Results can still be shared with health care providers in the GenXys Portal at any time by clicking the Invite (envelope) icon. Health care providers with GenXys Portal accounts can be invited via the search function, and health care providers without GenXys accounts can be invited via email.

Direct Ordering via the GenXys Portal Patient Profile

This option is only available if health care providers have an agreement with a lab that uses LabGx and this workflow has been approved and tested.

Health care providers can initiate a LabGx order via a patient profile in the GenXys Portal, and this will automatically link the results back to the health care provider's account once they are complete.