

clinLGX
RU_Allergic?
PREDICT VALIDATE DECIDE

Patient Decision Support Tool (PDST) User Guide

Software Version 1.0

March, 2023

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Product Notice

This guide describes features that are common to RU_Allergic?. Some features may not be available at this time.

Software Terms

By using this software, you agree to be bound by the terms of the clinLGX, LLC End User License Agreement (EULA).

Revision History

NOTE: The revision history cycle begins once changes or enhancements are requested after the document has been baselined.

Date	Revision	Description	Author
02/17/2023	1.0	Initial Documentation Release for RU_Allergic? PDST v1.0.0.	Mo Diop
03/27/2023	2.0	Update to Initial Documentation Release for RU_Allergic? PDST v1.0.	Mo Diop
03/27/2023	2.1.1	Update to Initial Documentation Release for RU_Allergic? PDST v1.0.	David Lee Scott Jr
03/28/2023	2.1.2	Update to Initial Documentation Release for RU_Allergic? PDST v1.0.	David Lee Scott Jr
03/28/2023	2.1.3	Update to Initial Documentation Release for RU_Allergic? PDST v1.0	Mike Fair
04/02/2023	2.1.4	Ensure the Initial Documentation Release for RU_Allergic? PDST v1.0 guide is user-friendly and formatted properly for the best patient-user experience.	Tanya A. McGhee

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Welcome to RU_Allergic? Patient Decision Support Tool (PDST)



The RU_Allergic? Patient Decision Support Tool (PDST) introduced by clinLGX, LLC provides the patient with relevant data to better understand their adverse reaction to a food and the underlying recommendation and how to tailor care to best suit their own unique values. This tool aids in predicting, validating and deciding how to best meet the challenges associated with your allergies and food intolerance needs, whether it be through a simple change in diet, over-the-counter (OTC) medication, prescription medication or herbal supplementation.

Adverse food reactions are clinically complex and heterogeneous, making evidence-based clinical diagnosis very challenging. The first landing point for most patients suffering from an adverse food reaction is a general practitioner, who often lack the knowledge, confidence, or resources to meet their specific needs due to insufficient training. Furthermore, complicating matters is the disproportionate number of practitioners trained to diagnose and manage patients suffering from adverse food reactions upon referral is generally quite low and varies widely across countries. Computer-aided decision support concept becomes, in this context, a potentially valuable tool to assist the practitioner in improved diagnosis of adverse food reactions and document the decision rationale in the patient's health record.

The RU_Allergic? Patient Decision Support Tool (PDST) software will:

- Allow the patient to view relevant data regarding the potential diagnostic on adverse reaction to food, that assists the decision on dietary changes or extensive medical diagnostics.
- Provide Classification of Adverse Reaction through evidence-based and prior information algorithms.
- Target medication recommendations to treat symptoms triggered by the adverse food reaction.
- Generate a structured text report of the displayed results that can be downloaded.

References and Resources

To learn more about RU_Allergic? PDST, please visit the following website address:

<https://www.clinlgx.com>

Enterprise Service Desk and Organizational Contacts

For issues related to RU_Allergic? PDST that cannot be resolved by this manual or the site administrator, please contact the RU_Allergic? PDST Service Desk at info@clinlgx.com.



Figure 1: RU_Allergic? PDST Homepage Menu

The RU_Allergic? website menu features four sections:

- **Home** – Hyperlink to the Home Page.
- **Order RU_Allergic?** – RU_Allergic? PDST Login and Ordering Portal.
- **Dashboard** – RU_Allergic? PDST Login and Results Portal.
- **Login** – Portal for account login and other information changes.

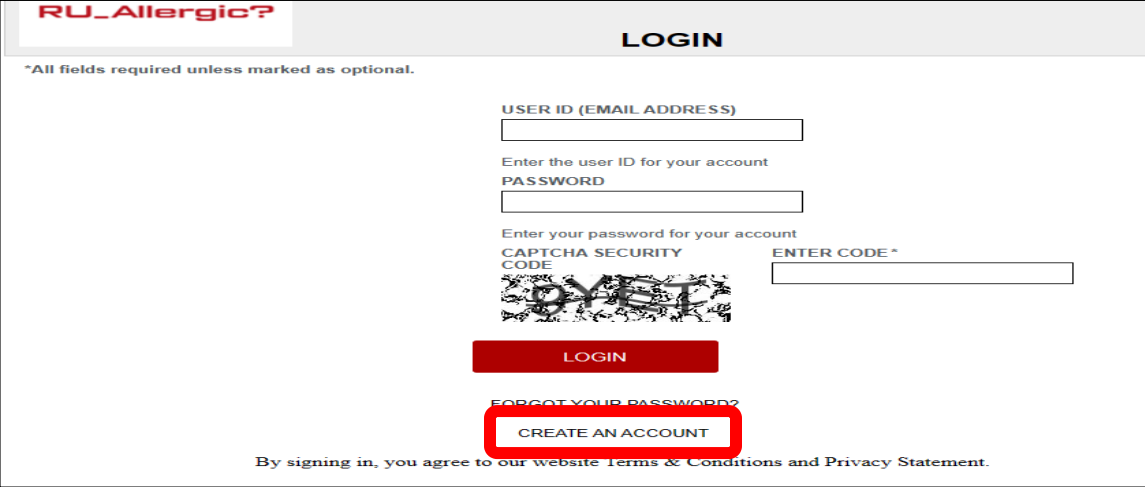
Registering and Creating an Account for RU_Allergic? Login Credentials

Before logging into the RU_Allergic? Home Page:

- Users must complete the registration process at <https://ruallergic.com/> to access the RU_Allergic? PDST Patient Portal to obtain their Unique Patient ID (UPI) login credentials for RU_Allergic?
- For the best user experience, Users must have Google Chrome 2016 or later for Windows 10, Google Chrome for Mac or Google Chrome for Android, Microsoft Edge v111.0.1661.41 or later for Windows 11 installed on their device.

Action Steps: Registering and Creating an Account in the RU_Allergic? Patient Portal:

1.	Open your browser and enter the following web address to navigate to the Home Page of the RU_Allergic? Patient Portal: https://ruallergic.com
2.	Click the LOGIN link located at the top of the page. 

3.	Click the CREATE AN ACCOUNT link located near the bottom of the page to get to the Registration page. 
4.	Fill in all required fields as denoted by an asterisk (*): • Name – Patient's name. • Date of Birth – Patient's date of birth. • Email – Patient's or guardian's email. • Password – Patient's password. • Phone – Patient's phone number. • Zip Code – Patient's zip code. • Security Code – This section is provided by clinLGX Digital Front Door Registration Panel and must be filled in order to complete registration. Hit the SUBMIT button. NOTE: Upon successful completion of the registration process you will receive a text message with your Unique Patient Identifier (UPI) number that has been assigned to you. Record this number in a secure location as it will be required to order RU_Allergic?™. The clinLGX Digital Front Door will provide you with information about advanced ordering options, test results notification, billing, and other services.

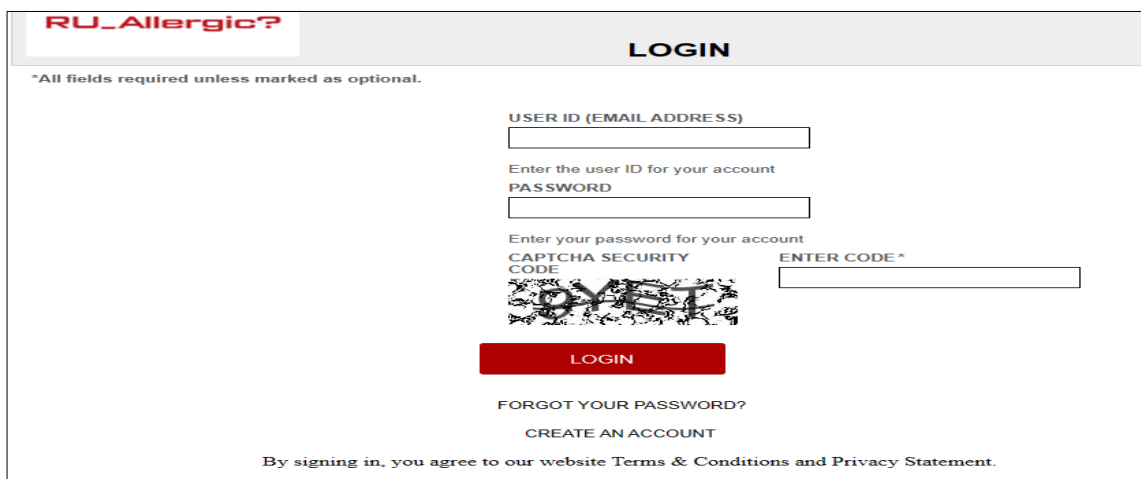
Logging into your RU_Allergic? Account

After the account creation, the user will access the RU_Allergic? PDST by navigating in your browser to the RU_Allergic? Home Page.

Action Steps: Logging into your RU_Allergic? Account:

1.	Open your browser and enter the following web address to navigate to the Home Page of the RU_Allergic? Patient Portal: https://ruallergic.com
2.	Click the LOGIN link located at the top of the page.

3. Fill in the required fields: User ID (Email Address), Password and CAPTCHA Security Code and hit the **LOGIN** button to access the Patient Dashboard.



The RU_Allergic? PDST Dashboard

The RU_Allergic? PDST Dashboard allows the patient to order tests, view test results, medication recommendations, and update patient information.

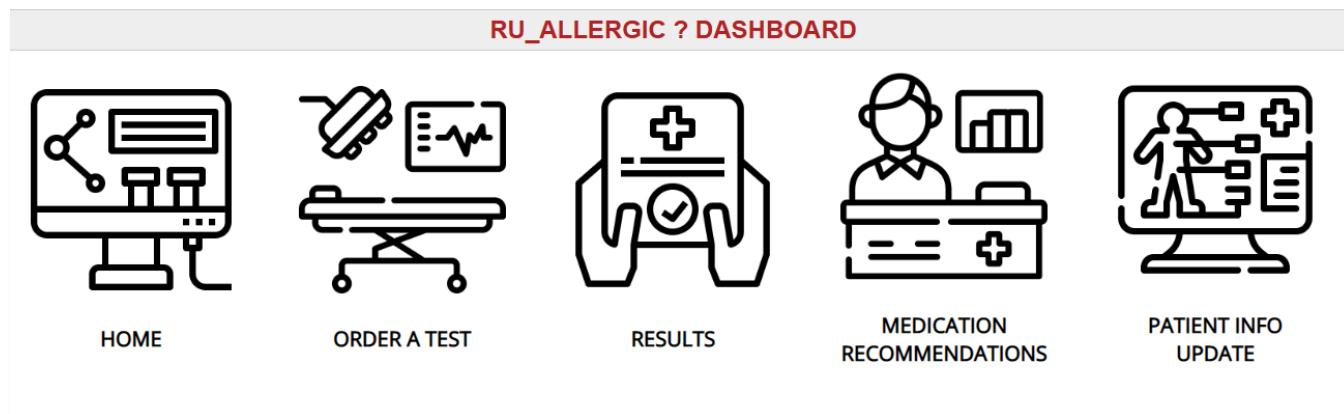


Figure 2: RU_Allergic? PDST Dashboard

Ordering RU_Allergic? PDST Tests



This section is the payment portal that restricts access to the RU_Allergic? PDST results until completion of payment. These fields must be filled in properly and payment processing completed before moving forward. The User will enter:

- **Unique Patient Identifier (UPI) Number:** UPI is provided via a text to the user's mobile phone upon completion of the registration process.
- **Test Code & Price:** User selects the test(s) of their choice.
- **Credit Card number, security code, expiration date and ZIP code.**

PRODUCT CODE
RUA_001

The Intended use of the RU_ALLERGIC? Patient Decision Support Tool (PDST) is to assist patients in better understanding of their specific adverse food reaction is a food allergy or a food intolerance.

*RU_ALLERGIC? is a Trademark of clinLGX, LLC;

PURCHASE THIS PRODUCT ☐ YES ☐ NO ☐ PROMO

PAYMENT

Name On Card*

Credit Card*

Expiration Date*

Security Code*

XXXX XXXX XXXX XXXX

MM/YY

XXX

Powered by **stripe**

CAPTCHA Security Code

Please type the CAPTCHA Security Code here: *

26C43

Figure 3: RU_Allergic™ PDST Order Page

Action Steps: Ordering a RU_Allergic? PDST Test:

1.	Click on the Order A Test button.
----	--

2.	Make your desired product test selection, fill in the required payment information, CAPTCHA Security Code and click the PAY NOW button. After successful payment is received, the browser will be re-directed to the RU_Allergic? PDST page where patient medical history and information on adverse food reactions will be entered.
----	---

RU_Allergic? PDST Entry of Patient Data and Medical History:

Patient information can be input in the RU_Allergic? PDST application from any device that has access to the internet, to help make informed decisions about a patient's adverse reaction to food(s). This section provides for entry of Patient Permission, Data Entry, Medical History, Adverse Food Reaction(s) and Accepting Terms of Service



The RU_Allergic? Patient-Centered Clinical Decision Support Tool (PC_CDST) has the potential to support patient-centered care by helping clinicians and patients make the best decisions given each individual's circumstances and preferences in the diagnosis and classification of adverse food reactions.

HOME | ORDER RU_ALLERGIC? | RESULTS

PLEASE READ

In case of a life threatening emergency, immediately call 911. Information on this site is not intended or implied to be a substitute for professional medical advice, diagnosis or treatment. All content contained on or available through this site is for general information purposes only. By using this website and sending us your information, you are giving us permission to contact you.

The intended use of the RU_ALLERGIC? CDST patent pending (USPTO Application No. 63/384,968) clinical decision support tool (CDST) is to provide end-users, medical professionals and patients, with insights into an individual's food hypersensitivity profile which is a growing health care burden. The patient specific data insights provided in RU_ALLERGIC? CDST final report is not proof of medical necessity. Medical necessity can only be determined by a trained professional proficient in the management of food allergies and food intolerances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications.

RU_ALLERGIC? CDST can enhance clinician and patient decision making by clearly describing and appraising the scientific evidence and reasoning (the likely benefits and harms) behind clinical recommendations, making them relevant to the individual patient encounter. The RU_ALLERGIC? CDST integrates into its clinical decision making platform guidelines published by the following organizations: American Academy of Allergy, Asthma, and Immunology (AAAAI) and American College of Allergy, Asthma, and Immunology (ACAAI); Canadian Society of Allergy and Clinical Immunology (CSACI); Centers for Medicare and Medicaid Services (CMS); European Academy of Allergy and Clinical Immunology (EAACI).

The information gained using the RU_ALLERGIC? PC_CDST is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. ClinLGX, LLC and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at <https://www.clinlgx.com>.

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PERMISSIONS

I give permission for my specimen(s) and clinical information to be used in de-identified studies at clinLGX, LLC and for publication, if appropriate. My name or other personal identifying information will not be used in or linked to the results of any studies and publications.

TEST CODE

RU_ALLERGIC?

INSTRUCTIONS

To begin go to the patient section, select yes for if the patient has a clinLGX Unique Patient ID (UPI) and then type in your UPI. The system will collect information on your medical history, the specific food that triggered the adverse reaction and the presenting symptoms. Upon submission of this information the system will predict the type of adverse food reaction and make testing recommendations to validate the prediction. The system will send messages every four hours until you have acknowledged review of your results. To acknowledge results please click on the pencil icon to the right of the order number, select test review and click on the update button. The status will change from a red "0" to a green "1".

PATIENT DATA ENTRY

Does the patient have a ClinLGX Unique Patient Identifier (UPI)? ☐ Yes ☐ No

If you selected yes please type in the patient's UPI ID

Patient First Name

Patient Middle Name

Patient Last Name

Patient DOB

Patient Zip Code

Figure 4: RU_Allergic? PDST Data Entry Page

Action Steps: Entering Patient Medical History and Adverse Food Reactions into the RU_Allergic? PDST:

1.	Fill in and complete each section of this page with as much detail as possible: • Permission – This section provides the user an option to accept or decline their participation on clinLGX de-identified studies. • Patient Data Entry – This section allows a patient to order a prediction, the user must complete all the required fields in the section. The required fields are denoted by an asterisk. • Patient Medical History – This section contains required fields regarding the user's medical history. • Adverse Food Reaction(s) – This section contains required fields regarding the user's history of adverse food reactions. If there is more than one instance/symptom of an adverse food reaction, multiple entries can be made here. • Terms of Service – The user must read and accept all terms of service to continue.
2.	Click the SUBMIT button. After submission, the browser will be re-directed to the ruallergic.com Patient Dashboard Home Page. After 20 mins or so, you will be able to view the results. To exit RU_Allergic? PDST, close out of the browser window. NOTE: Any information not submitted will be lost.

Acknowledging Review of RU_Allergic? PDST Test Results



This section provides information on viewing and acknowledging the results of the prediction of potential adverse food reaction the User may suffer from based on the information provided in the RU_Allergic? ordering portal.

PATIENT DECISION SUPPORT TOOL RESULTS HOME DASHBOARD					
Note: The system will send messages twice a day until you have acknowledged review of your results. To acknowledge results please click on the pencil icon to the right of the order number, select test review and click on the update button. The status will change from a "NO" to a "YES".					
					Sort by
	DATE OF SERVICE	TEST STATUS	ADVERSE FOOD REACTION CLASSIFICATION	TEST REVIEW	
1	2/25/2023	COMPLETE	FOOD ALLERGY	Yes	
2	2/25/2023	COMPLETE	FOOD ALLERGY	Yes	
3	2/25/2023	COMPLETE	FOOD ALLERGY	Yes	
4	4/2/2023	COMPLETE	FOOD ALLERGY	No	
5	4/2/2023	COMPLETE	FOOD ALLERGY	No	
6	4/2/2023	COMPLETE	FOOD ALLERGY	No	
7	4/2/2023	COMPLETE	FOOD ALLERGY	No	

Figure 5: RU_Allergic? PDST Test Results Example

NOTE: The User will receive a text message indicating the availability of the results to acknowledge when the RU_Allergic? PDST releases them. The system will send messages twice a day until you have acknowledged review of your results.

Action Steps: Acknowledging RU_Allergic? PDST Test Results:

1.	After receiving a text message indicating the availability of the results, click on the Results button to display the list of available results.
----	---

2. Select the desired test result you wish to view. In the **TEST REVIEW** column, if there is a 'NO' displayed, that means the results has not been acknowledged. To acknowledge results please click on the pencil icon to the right of the desired test results line item, checkmark the box in the test review and click on the **Update** button. The status will change from a 'NO' to a 'YES'.

PATIENT DECISION SUPPORT TOOL RESULTS

[HOME](#) | [DASHBOARD](#)

Note: The system will send messages twice a day until you have acknowledged review of your results. To acknowledge results please click on the pencil icon to the right of the order number, select test review and click on the update button. The status will change from a "NO" to a "YES".

Sort by ▼

	DATE OF SERVICE	TEST STATUS	ADVERSE FOOD REACTION CLASSIFICATION	TEST REVIEW	
1	2/25/2023	COMPLETE	FOOD ALLERGY	Yes	
2	2/25/2023	COMPLETE	FOOD ALLERGY	Yes	
3	2/25/2023	COMPLETE	FOOD ALLERGY	Yes	
4	4/2/2023	COMPLETE	FOOD ALLERGY	☒	UPDATE CANCEL
5	4/2/2023	COMPLETE	FOOD ALLERGY	Yes	

3. Click on the **View** icon in the last column to view the results.

NOTE: To download a PDF of the results, click on the **Download PDF** link at the top left-hand side of the page.

Download PDF

PRODUCT CODE
RUA_P001

PRODUCT DESCRIPTION
The intended use of the RU_ALLERGIC? Patient Decision Support Tool (PDST) is to promote collaboration between healthcare professional and patients in the diagnosis of adverse food reactions (food allergies and food intolerances).

Order Number
5348

Date Of Service
4/2/2023

PATIENT INFORMATION

CLINLX UP# MSCONJ27	Patient Name Tanya McChae	Patient Age 22
------------------------	------------------------------	-------------------

CLASSIFICATION ADVERSE REACTION TO FOODS

Classification Of Adverse Food Reaction FOOD ALLERGY	Classification Subclass IgE
Trigger Food Pecan	Trigger Food Category Seeds & Nuts
Foods That May Trigger A Similar Adverse Reaction Peanut, Navy Bean, Lima bean, Green Pea, Chick Pea, Lentil, English Walnut or Soybean	
Date Of Last Adverse Reaction 3/31/2023	Route Of Exposure Ingestion
Severeness Of Adverse Reaction 2	

RECOMMENDED TESTING TO VALIDATE PREDICTIONS

Food allergy, in the form of skin testing may be selected to confirm Pecan triggered the FOOD ALLERGY. Food specific IgE blood tests can be used as a substitute for skin testing where skin testing is not possible or is not reliable. Food specific IgG testing has no value in the diagnosis of FOOD ALLERGY as reflected in a number of society practice guidelines.* Food-specific IgG is currently understood to represent a normal immunological response to food consumed in the diet and a reflection of foods one consumes. Please consult a qualified healthcare provider to validate that the adverse food reaction that triggered the Trouble Breathing was caused by the Ingestion of Pecan.

BACK

4. Click the **BACK** button to return to the listing of results and view additional test results.

Viewing RU_Allergic? Medication Recommendations



MEDICATION
RECOMMENDATIONS

This section displays the targeted medication recommendations that may be used to treat the symptoms caused by the adverse food reaction. The RU_Allergic? PDST computer-aided medication recommendations includes prescription strength, over the counter (OTC) and herbal supplements.

Download PDF

PRODUCT CODE
AR2_Rx

PRODUCT DESCRIPTION
The intended use of AR2F_Rx is to assist patient in identifying medication options available to treat symptoms caused by adverse food reactions.

Order number 5332	Date of service 2/25/2023
----------------------	------------------------------

PATIENT INFORMATION

CLINLGX UPI# CE8RRFYW	Patient Name Tanya McGhee
--------------------------	------------------------------

COMPUTER ASSISTED MEDICATION(S) RECOMMENDATIONS TO TREAT SYMPTOMS TRIGGERED BY THE ADVERSE FOOD REACTION

Prescription Antihistamines may be used to treat the Itching in the Mouth triggered by the Ingestion of Canned Vegetables. Herbal Supplements Honey or Chamomile may be used to treat the Itching in the Mouth triggered by the Ingestion of Canned Vegetables.	Over The Counter (OTC) Benadryl may be used to treat the Itching in the Mouth triggered by the Ingestion of Canned Vegetables.
---	---

[BACK](#)

Figure 6: RU_Allergic Medication Recommendations Example

Action Steps: Viewing RU_Allergic? Medication Recommendations:

1.	Click on the MEDICATION RECOMMENDATIONS button.
2.	Click on the View icon in the last column to view the recommendation. NOTE: To download a PDF of the medication recommendations, click on the Download PDF link at the top left-hand side of the page.
3.	Click the BACK button to return to the listing of results and view additional recommendations.

Patient Information Update



This section allows the User to make updates to their name, date of birth, email address and phone number.

INFORMATION UPDATE

Unique Patient ID (UPI)
CE8RRFYW

First Name

DOB

Email *

Phone *

Last Name

Zip Code

Confirm Email *

Confirm Phone *

Please type the Security Code shown below in the Enter Code* field.

Security code

Enter code *

Figure 7: Patient Information Update

Action Steps: Updating Patient Information:

1.	Click on the Patient Info Update button.
2.	Make your desired changes, enter the CAPTCHA Security Code and click the UPDATE button.

Troubleshooting

Input Entry Error

If the user enters incorrect information, an error message is displayed to the user, the error code is logged in the RU_Allergic? PDST database, the rest of the remote data calls are skipped, and the user cannot continue with the RU_Allergic? PDST workflow. The user must complete all required fields in order to submit an order.

The screenshot displays two sections of a web form: 'PATIENT DATA ENTRY' and 'PATIENT MEDICAL HISTORY'. Both sections contain several required fields, each marked with a red exclamation mark icon and the word 'Required'.

PATIENT DATA ENTRY

- Does the patient have a ClinLGX Unique Patient Identifier (UPI)? * ☐ Yes ☐ No (Required)
- If you selected yes please type in the patients UPI ID: CURR1YER
- Patient First Name: [Text Field]
- Patient Middle Name: [Text Field]
- Patient Last Name: [Text Field]
- Patient DOB: [Text Field]
- Patient Zip Code: [Text Field]

PATIENT MEDICAL HISTORY

- Select any skin conditions the patient may suffer from: * [Dropdown Menu] (Required)
- Does the patient suffer from any of the following conditions? * [Text Field] (Required)
- Does the patient have a history of allergies to any of the following: * [Dropdown Menu] (Required)
- Has the patient taking any of these medications in the last 2 weeks? * [Dropdown Menu] (Required)
- Does the patient notice their adverse reaction to foods worsen under any of the following conditions? * [Dropdown Menu] (Required)
- Because of your adverse reaction to food(s), how troublesome do you find that you must always be alert as to what you are eating? * ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 (Required)

Figure 8: RU_Allergic? PDST Input Error Handling

New Terminology, Acronyms and Abbreviations

Acronym	Definition
CLINLGX DFD	ClinLGX Digital Front Door
RU_ALLERGIC?_PDST	RU_ Allergic? Patient Decision Support Tool
UPI	Unique Patient ID

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