

LabCollector

"Your Laboratory management solution"

User's guide

Stability Test Manager

Version 1.403 – April 2022



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1- INTRODUCTION

With LabCollector, you can now perform stability tests on products, e.g. drugs for post-market analysis, foods to check stability or expiry date, etc. The FDA also sets guidelines for conducting stability tests on drugs and products. These tests are basically carried out to check whether a product can be stored without changing its original chemical composition.

Stability tests are required for various reasons:

- Determination of intrinsic shelf life
- Storage conditions
- Elimination of impurities
- Development of the product
- Quality assurance
- Verification by regulatory authorities to obtain approval for marketing



Some examples of stability tests are below:

- Pharmaceutical products tend to change and release by-products during prolonged storage. Stability tests provide guidance on how certain medicines can be stored at room temperature and under controlled conditions.

- Food stability tests are done to determine the microbiological safety of the product or determination of shelf life.
- Cosmetic products to determine if they maintain the intended physical, chemical and microbiological quality.
- Medical device stability tests re performed to determine environmental influences such as temperature, humidity, light, moisture, pH, movement, gravity, etc. They are subjected to either real-time testing or accelerated stability testing.

2- GETTING STARTED

You can get the **Stability Test Manager add-on** by downloading from www.labcollector.com. LabCollector software has to be installed first as it contains the framework. LabCollector support documents for installation are available on our website. **Stability Test Manager add-on** can be installed on any operating system (Windows, macOS X, and Linux). Installation is performed by AgileBio on cloud-hosted instances.

As a general note, making a backup of LabCollector before installing or updating a new add-on is recommended.

A changelog is included in the download package. It is also available by navigating the browser URL on LabCollector at `*/stability_test_manager/changelog.txt`.

1/Manual mode:

Unzip and paste the **Stability Test Manager** add-on folder in the extra modules folder. For Windows, it would look like:

```
C:\Programs\AgileBio\LabCollector\www\lab\extra_modules\stability_test_manager
```

Open LabCollector, the **Stability Test Manager** add-on module is now activated. Click on the add-on icon, and enjoy your new add-on.

2/Automatic mode from LabCollector interface:

You can also add the **Stability Test Manager** add-on via the LabCollector Menu **Admin > Setup > Upload/Add Addons > Upload Add-on ZIP > Add Addon**

Return to the LabCollector homepage, the **Stability Test Manager add-on** module is now activated.

The add-on will remain in a 30 days free trial mode until you save the final license under **Settings > License**. To obtain a valid license, you have to copy and send the computer activation key to AgileBio. You may also use the client area of the labcollector.com website to obtain or update a license.

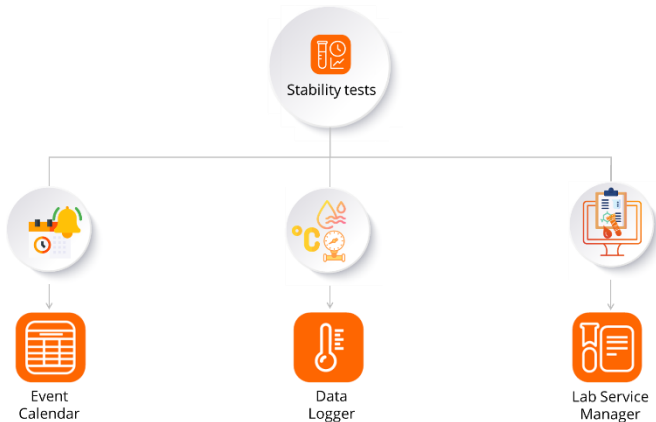
LabCollector is a copyrighted product from AgileBio.

3- SETTINGS/SETUP

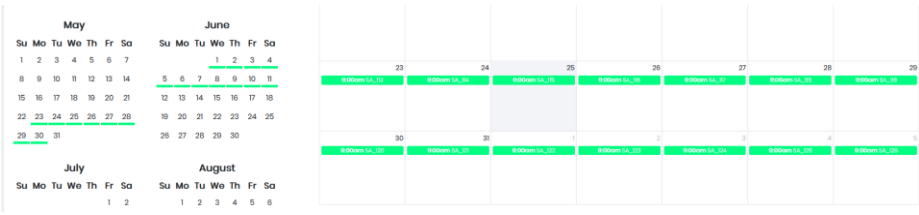
Only the super-administrator and the administrators can access this menu.


3-1. Add-ons setup



The Stability test manager can be connected to other add-ons offered by AgileBio:



- [Event Calendar add-on](#) provides a calendar system for LabCollector. Each user can create and share several calendars to manage single and recurring events. A general shared calendar is visible to all lab members for common events. Connected to the stability test manager, staff will see in a calendar view all the tasks that need to be done.



 VIEW EVENT

 John Pierce  Patricia Perez

Title SA_115


Start date 25/05/2022 09:00:00

End date

All day event No

Description Auto-generated with Stability Test Manager add-on

Recurring Once

Color 

Linked URLs https://labcollector.online/agilebio/extra_modules/stability_test_manager/index.php?action=view_plan&plan_id=6#action-view-test-112

Links to LabCollector data

- [Data logger add-on](#) is a network-based application for day-to-day control of storage equipment temperature, humidity, CO2 and other data centralized in LabCollector LIMS. Connected to the stability test manager, any data from the logger associated with the plan will be recorded with each sample.
- [Lab Service Management \(LSM\) add-on](#) allow to deal with a variety of tests, follow a precise workflow and create a final PDF report. Connected to the stability test manager, the LSM remote (the portal) helps the staff to send test requests, perform the tests step by step and produce a complete certificate of analysis.




To do the connection, these add-ons need to be purchased and installed on your current LabCollector instance. Please contact our Sales office for more details.

3-2. Settings

If you want to receive emails from the add-on to alert you of an available event like below, please check the box.

Stability tests event(s) available



2022-05-25 09:00
Powered by LabCollector

Only the owner and collaborators of the plan will receive it. Please see [section 4-1-5](#).

3-3. List

Under this menu, plan types can be defined. On the homepage, will be able to filtered by plan type.

| Plan types | |
|--|------------------------------------|
| <input type="text" value="Physical"/> | × |
| <input type="text" value="Chemical"/> | × |
| <input type="text" value="Microbiological"/> | × |
| <input type="text"/> | <input type="button" value="Add"/> |

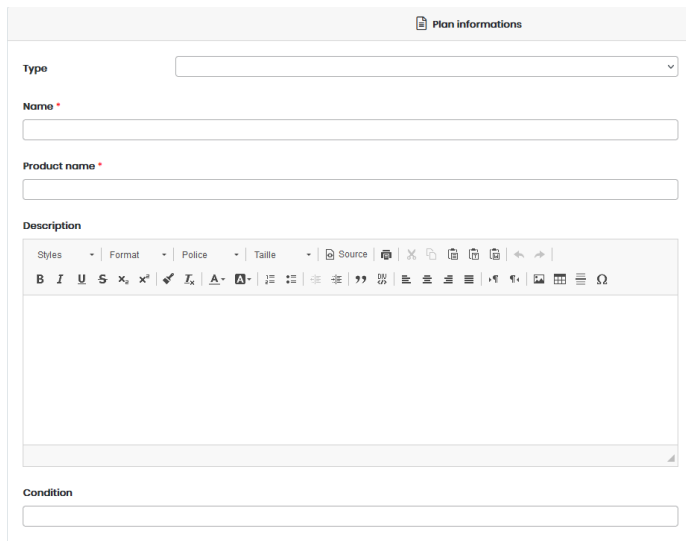
4- PLANS

The plan will be the key element of this add-on. Creation, modification, validation, execution will be seen in this section.

4-1. Plan creation

Create a plan can be done directly with the button on the top left of the homepage. Any users (except visitor) can create a plan even if staff and user will have to wait for an administrator approval before to process the plan ([see section 4-4-1](#)).

4-1-1. Plan information



The screenshot shows a web form titled "Plan informations". It contains the following fields and components:

- Type:** A dropdown menu.
- Name *:** A text input field with an asterisk indicating it is mandatory.
- Product name *:** A text input field with an asterisk indicating it is mandatory.
- Description:** A rich text editor with a toolbar containing options for Styles, Format, Police, Taille, Source, and various text formatting icons (bold, italic, underline, strikethrough, text color, background color, bulleted list, numbered list, link, unlink, indent, outdent, undo, redo, help, and a search icon).
- Condition:** A text input field.

In this section, only Name and product name are mandatory.

The type field is linked to the List that need to be configured first. It can help to organize the plan view and filter easily.

The condition is a free text field, in addition to the description, it can help to summarize the physico-chemical conditions of the plan.

| | |
|---|--------------------------|
| #2 | Long term stability plan |
| Condition: 25°C ± 2°C/60% RH ± 5% RH | |
| No description | |

4-1-2. Planning

The planning section offers 2 different options.

Planning

Start date * 2021-12-01 **End date *** 2022-12-31

1 **Cycle *** 1 **Per *** day **At *** ex.: 09:30
ex.: 1 time a day at 9:30

2 **Every *** 30 **days** 0 **days**
ex.: every 30 days +/- 3 days

Planning preview ▾

Nb backup samples 0

The first option is based on a time cycle. The number of sampling per day, week or month needs to be set up.

When the interval is per week, the day(s) need(s) to be selected.

Cycle * 1 **Per *** week **At *** 15:30
ex.: 1 time a day at 9:30

Choose 1 day(s) *

Monday Tuesday Wednesday Thursday Friday Saturday Sunday

When the interval is per month, the day and the week need to be selected.

Cycle * 1 **Per *** month **At *** 15:30
ex.: 1 time a day at 9:30

On *

Monday 1st week of month

The second option is based on an exact repetition of days between each sample, with the possibility to have a window in days to be able to sample.

Every * days +/- * days
ex: every 30 days +/- 3 days

In both case, after the settings, a calendar preview is generated with all the sampling dates, from which you can reject dates by clicking on it. The excluded date turns red/inactive.

Planning preview ^

You can click on a date to exclude it from plan:

| 2021-12 | | | | | | |
|---------|----|----|----|----|----|----|
| Mo | Tu | We | Th | Fr | Sa | Su |
| | | 1 | 2 | 3 | 4 | 5 |
| 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| 20 | 21 | 22 | 23 | 24 | 25 | 26 |
| 27 | 28 | 29 | 30 | 31 | | |

| 2022-01 | | | | | | |
|---------|----|----|----|----|----|----|
| Mo | Tu | We | Th | Fr | Sa | Su |
| | | | | | 1 | 2 |
| 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 |
| 31 | | | | | | |

| 2022-02 | | | | | | |
|---------|----|----|----|----|----|----|
| Mo | Tu | We | Th | Fr | Sa | Su |
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | | | | | | |


4-1-3. Backup/Spare tube

The configuration allows to create spare tube in case of tube failure or for any reason. These spare tubes will be not linked to a proper date, they can be used at any moment.

4-1-4. Plan general configuration

In this section, a project from the [Project Code](#) list of LabCollector can be selected. It allows to filter on the homepage.

As a mandatory option, a module needs to be selected among the default Samples module and all the [custom modules](#). It's in this module that all the samples will be created with their storage pending for the sampling action.

 Plan configuration

Project

Module *

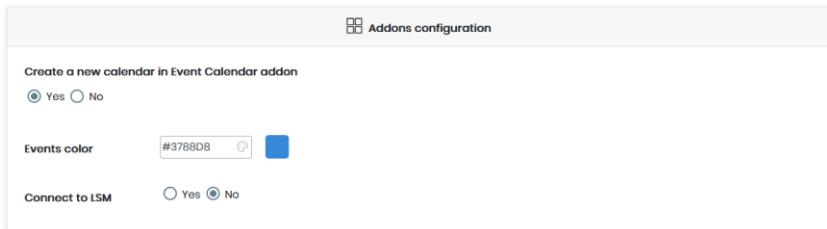
4-1-5. Plan collaborators

The last section of the plan creation is to set up the owner and the collaborators of the plan. Only the owner is mandatory. Only the owner and the collaborators of the plan will be able to edit it and run it.

4-2. Extra Add-ons configuration

4-2-1. Event Calendar

It's a quick configuration. First, at least one calendar in the Event Calendar add-on needs to be done. Then from the plan creation, once the option is enabled, a color for the events can be configured.




The screenshot shows a configuration window titled "Addons configuration". It contains three sections:

- Create a new calendar in Event Calendar addon:** Radio buttons for "Yes" (selected) and "No".
- Events color:** A text input field containing "#3788D8" and a color selection button (a blue square).
- Connect to LSM:** Radio buttons for "Yes" and "No" (selected).

4-2-2. LSM

Before to configure the section LSM in the Stability test manager add-on, the LSM needs to be configured. Please refer to the [manual](#) and the [Knowledge Bases](#). Here you need, the URL of the LabCollector instance and a token generated from Admin > Other > Setup > Webservices. Once this information has been populated, the system will allow to retrieve the tests, the sample type and the model of the LSM.

 Addons configuration

Connect to LSM Yes No

LSM URL domain * **LSM API token *** **Group LSM orders by plan** Yes No

The first part of your LSM url, before extra_modules A token to allow LSM connection

✔ LSM remote URL found


LSM tests **LSM sample type** **LSM model**

Enter at least 3 characters Enter at least 3 characters Enter at least 3 characters

#2 Appearance ✘ #2 Drug Powder ✘
 #3 Color ✘
 #4 pH test ✘

Once this setup done, the portal to do the test request will be ready.

4-2-3. Data logger

 Plan configuration

Project

Module *

Link sensor(s)

Programmable resolution thermometer °C (Large Stability Chamber) ✘
Smart battery monitor %RH (Large Stability Chamber) ✘

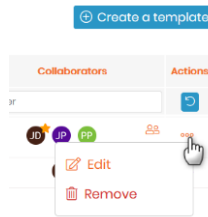
Into the plan configuration section, a list of sensors will be available. The list displays the probe name followed by the equipment associated with it. This configuration needs to be done in the Data logger add-on (the manual is [here](#)).

4-3. Templates

Once the plan is completed and ready to go, it can be saved as a template instead of running it immediately. Like that with a few clicks, you can generate a new plan quickly and easily by modifying the conditions for example or the date of execution.

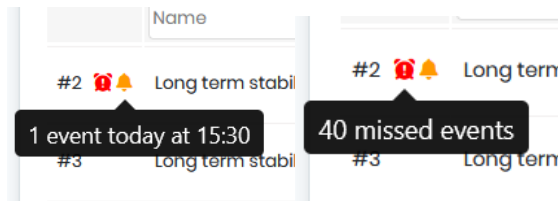
A template can be selected at the beginning of the plan creation form and automatically, the form is populated.

On the template page, the templates can be filter like the plans (by type, project, collaborators...) and modification or deletion are available.



4-4. Run a plan

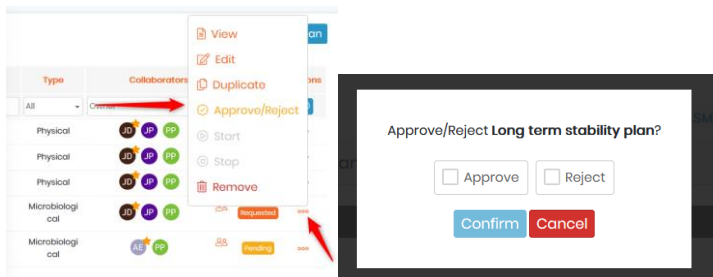
Only the owner or the collaborators can run a plan. On the homepage, you can filter by status, by default pending and processing plan are displayed. Pending events are displayed with a yellow bell icon whereas missed events are displayed with a red clock icon.



4-4-1. Approval

When a user of any level permission creates a new plan, before to be started, the plan needs to be approved (or rejected). An administrator can auto approve his plan. Plans of staff and users need to be approved before use.

For all plans with the status REQUESTED, an administrator needs to select the approve/reject action. Each action of rejection or approval will be recorded in the log like all the other actions.



If a plan is rejected, its status turns to rejected and it is displayed under the Old plan menu.

4-4-2. Event execution/action







Once the plan is validated, the status turns to Pending and the plan can be started by the owner or the collaborator. In processing mode, samples can be taken and/or tests performed.

Once a plan is started, the samples and their storage that will be used to perform the tests need to be generated in the module of your choice. Five steps will be followed to do that: choice of the box model, choice of the equipment and the rack, choice of the prefix of the boxes, in case of backup, a storage needs to be selected too and at least the confirmation.

Box model > Storage location > Boxes prefix > Backup storage > Start

- 1 | Box 100 tubes (100 positions)
 - 2 | Large stability chamber (+25°C), Rack1_6
 - 3 | Long_term_plan_2022-1_
 - 4 | Large stability chamber (+25°C), undefined
 - 5 | **Confirm plan start:**
 4 samples will be created in **Stability test** module.
 2 backup samples will be created in **Stability test** module.
 4 events will be created in **Long term stability plan** calendar (Event Calendar addon).
- Start
Cancel

Next events will be automatically displayed in the Available events menu in addition to the missed events. From this menu, you will be able to enter in the plan or generate the test. From the plan view, all the missed events can be exported in CSV format.

| Available events | | | | | |
|------------------|--------------------------|--------------|--|---|---|
| Missed events | | | | | |
| | Name | Product name | Available event | Actions | |
| #2 | Long term stability plan | Product A | 20/06/2022 event missed (late for 5 days) |  |  |
| #2 | Long term stability plan | Product A | 17/06/2022 event missed (late for 8 days) |  |  |
| #2 | Long term stability plan | Product A | 13/06/2022 event missed (late for 12 days) |  |  |

Do the sampling/test
 Enter in the plan

If the alerts are set up, an email is sent to the collaborators. On the homepage and in the plan, along the events.

Long term stability plan: You have an event today at 15:30 (late for 2 hours and 12 minutes)

| ne | Start date | End date | Frequency | Project | Type |
|----|------------|----------|-----------|---------|------|
| | | | | | |

In the plan view, a color code is applied on the date points.

Start date: 31/12/2021 **End date:** 31/12/2022 **Frequency:** 2 times per week on tuesday, friday at 15:30 **Number of events:** 104
Excluded day(s): 14/01/2022

Legend: Executed events (green), No executed events (red), Missed events (red with X), Pull event (red with star), Next events (grey)

20 21 22 23 24 25 26

27 28 29 30 31

17 18 19 20 21 22 23

24 25 26 27 28 29 30

31

21 22 23 24 25 26 27

28

2022-05

| Mo | Tu | We | Th | Fr | Sa | Su |
|----|----|----|----|----|----|----|
| | | | | | | 1 |
| 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| 16 | 17 | 18 | 19 | 20 | 21 | 22 |
| 23 | 24 | 25 | 26 | 27 | 28 | 29 |
| 30 | 31 | | | | | |

2022-06

| Mo | Tu | We | Th | Fr | Sa | Su |
|----|----|----|----|----|----|----|
| | | | 1 | 2 | 3 | 4 |
| 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| 19 | 20 | 21 | 22 | 23 | 24 | 25 |
| 26 | 27 | 28 | 29 | 30 | | |

2022-07

| Mo | Tu | We | Th | Fr | Sa | Su |
|----|----|----|----|----|----|----|
| | | | | 1 | 2 | 3 |
| 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 25 | 26 | 27 | 28 | 29 | 30 | 31 |

For next events, the user by clicking on the date can see the sample information

×

Plan: Long term stability plan

28/10/2022 Pending

Box Long_term_plan_2022-1_1

Stability test SA_2 (A2)

For the missed(s) or the pull events, user can perform action following the configuration.

✕

Plan: Long term stability plan

01/05/2022 Refresh

| | |
|-----------------------|-------------------------|
| Box | Long_term_plan_2022-1_1 |
| Stability test | SA_1(A) |

⚠ event missed (late for 23 days)

Order LSM test

Mark executed
Mark not executed

As soon as an event is marked as executed or not executed a log is generated.

✕

Plan: Long term stability plan

24/05/2022 15:30 Executed

| | |
|--|----------------------------|
| Box | Long_term_stability_plan_1 |
| Stability test | SA_47 |
| Programmable resolution thermometer | 24.1875 °C |
| Smart battery monitor | 32.79 %RH |

Marked as Executed by Jane Doe on 24/05/2022 17:46:51.

If probes from data logger are linked to the plan, then the data from the probes are saved and can be retrieved directly from the sample record.

113 SA_113
🔍 📄 📁 📧 📧 📧 📧

Stability Tests

| | |
|---|---|
| Plan: | Short term stability plan |
| Test date: | 23/05/2022 |
| Status: | Executed (on 24/05/2022 18:02:54 by Jane Doe) |
| Programmable resolution thermometer | 23.875 °C |
| Temperature, Humidity, Barometric Pressure and Lig | 301 lux |

If the LSM is associated with the plan, Order LSM test is available and the LSM remote or portal opens with the configuration previously done.

If backup/spare tubes are available, they are all in the Backup samples table:

| Sample name | Location | Status | Pulled on/test date | Pulled by | Reason | Actions |
|-------------|--|--------|---------------------|-----------|--------|---------|
| SA_backup_5 | Room_1 > Large stability chamber > new_rack > Long_term_plan_2022-L_backup_1 | Pulled | | | | |
| SA_backup_6 | Room_1 > Large stability chamber > new_rack > Long_term_plan_2022-L_backup_1 | Pulled | | | | |

Their location in the dedicated room or stability chamber can be viewed and then they can be used as needed like with a scheduled sample.

| Sample name | Location | Status | Pulled on/test date | Pulled by | Reason | Actions |
|-------------|--|---------|---------------------|-----------|--|---------|
| SA_backup_5 | Room_1 > Large stability chamber > new_rack > Long_term_plan_2022-L_backup_1 | Pulled | 24/04/2022 15:58:08 | Jana Doe | Need a additional test, the plate broke. | |
| SA_backup_6 | Room_1 > Large stability chamber > new_rack > Long_term_plan_2022-L_backup_1 | Pulling | | | | |

Once the plan is finished, a PDF report can be exported which will contain all the information and actions performed during the plan.

ⓘ This plan has been automatically marked as finished on 2021-10-07 12:09:34.
1 test(s) have been marked Executed and 0 test(s) have been marked Not executed.

[Edit](#) [Duplicate](#) [Export PDF](#)

Type: No type Project: reagent Module: Stability Test Status: **Finished**

Under Old plans menu, all the stopped and rejected plans will also have a report generated.



Short term stability plan (#6)

| | |
|----------------------|--|
| Product name: | Product D |
| Type: | Microbiological |
| Project: | No project |
| Module: | Stability test |
| Condition: | 25°C ± 2°C/60% RH ± 5% RH |
| Status: | Stopped on 25/05/2022 13:43:14 by Jane Doe |

| | |
|-----------------------|--|
| Owner: | Jane Doe |
| Collaborators: | Albert Einstein John Pierce Patricia Perez |



| Tests | | | | |
|------------|----------------|----------|------------------------------------|--|
| Day | Stability test | Status | On/by | Sensor(s) |
| 23/05/2022 | SA_113 | Executed | on 24/05/2022 18:02:54 by Jane Doe | Programmable resolution thermometer: 23.88 °C Temperature, Humidity, Barometric Pressure and Lig: 391 lux |
| 24/05/2022 | SA_114 | Executed | on 24/05/2022 18:02:59 by Jane Doe | Programmable resolution thermometer: 23.88 °C Temperature, Humidity, Barometric Pressure and Lig: 391 lux |
| 25/05/2022 | SA_115 | Pending | | |

5- UPGRADING AND UPDATING

To update or upgrade the **Stability Test Manager Add-on** module, just download it from our website (www.labcollector.com). Then, unzip the folder and paste files in the following folder:

Ex. on Windows setup:

```
Programs\AgileBio\LabCollector\www\lab\extra_modules\stability_test_manager
```

As a general suggestion, we always recommend making a backup prior to performing an upgrade or update.

If your instance of LabCollector is cloud hosted with AgileBio, contact a sales or support representative to update.



<http://www.labcollector.com>
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