



PLA 3.0

FROM ASSAY SETUP TO INSIGHTS

Basic bioassay protocol

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CONTENTS

1 Basic bioassay protocol.....	3
1.1 Create and set up the protocol template.....	4
1.2 Create a protocol document.....	5
1.3 Generate the linked documents.....	5
1.4 Calculate the assays.....	7
1.5 Calculate the reportable values.....	8

1 BASIC BIOASSAY PROTOCOL

Use Basic bioassay protocol documents to set up a workflow for producing reportable values from multiple independent assay runs. Organize complex methods, retest scenarios, and report several products in a single assay.

What these documents do

Basic bioassay protocol documents let you create a closed structure of Quantitative response assay and Combination of assay results documents that you can use to efficiently perform assay analysis. You can configure separate templates for each assay, increase the number of included runs as needed, and perform complete assay evaluations efficiently and consistently.

What you will learn

In this topic, you will learn how to set up a protocol template that links together the assay and combination templates you created in the earlier steps. The template serves as a reusable blueprint for creating protocol documents, which you use to execute the actual workflow.

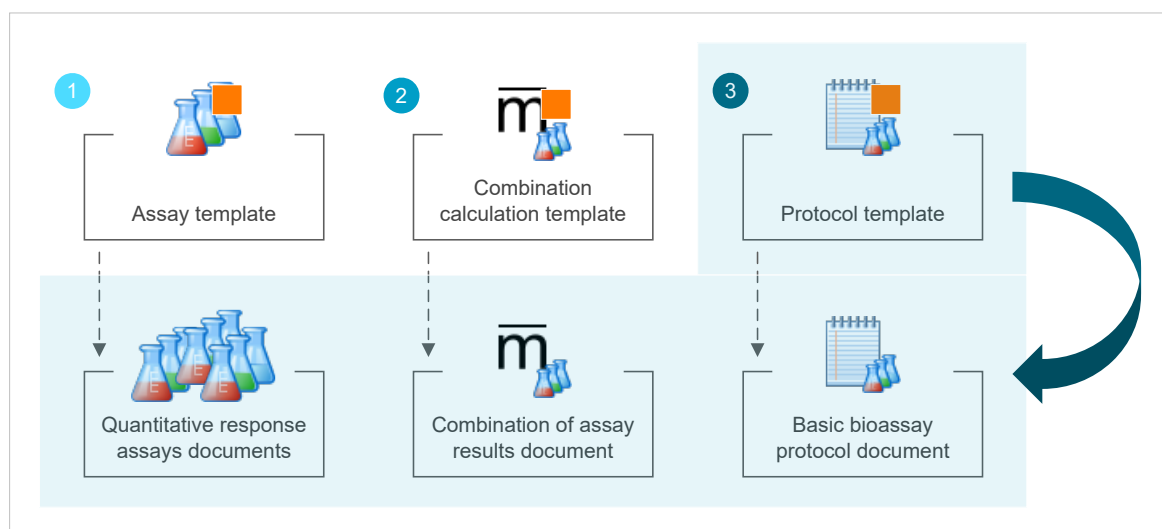


Figure 1-1 From plate to process step 3: Setting up a protocol template

This topic belongs to a three-part series that guides you through the complete setup process in PLA 3.0. Each part focuses on one stage of this process. This topic forms the third part and completes the setup.

The series is based on the '40 Basic Bioassay Protocol' demonstration data included in version 27 of the Biological Assay Package. You will learn how to set up the data and understand the purpose behind each setup step.

What the setup looks like

In this part, you create the protocol and define its properties. You can think of this as setting up a work list or work plan.

What you do step by step

The following table shows the tasks you need to perform to set up a Basic bioassay protocol document for this use case:

Step		Description	Task
1	Template setup	Create and set up the Basic bioassay protocol template.	Create and set up the protocol template
2	Protocol setup	Create a protocol out of the new template.	Create a protocol document
2	Document generation	Generate documents from the templates linked in the protocol document.	Generate the linked documents
3	Assay calculation	Enter the observation data and calculate the generated Quantitative response assay documents.	Calculate the assays
4	Reportable value calculation	Calculate the generated Combination of assay results document.	Calculate the reportable values

1.1 Create and set up the protocol template

Protocol templates serve as blueprints for your protocols. They let you link together assay and combination templates and define the number of assays you want to create. Create the protocol template required for this use case.

Procedure

To create the protocol template:

1. In the **Navigator**, select the folder in which you want to create the document.
2. From the context menu, select  **New**.
3. In the **Create a new document** dialog, on the **Available document types** tab, go to **Biological Assay Package > Basic bioassay protocol**.
4. You can create protocol templates from scratch or using another template. For this use case, you create a template from scratch. Select 'New Basic bioassay protocol.'
5. At the bottom of the dialog, select the **Create as template** option.
6. To confirm your selection and create the template, select **Create**.
Result: The **Content** editor opens, displaying your new template.
7. As the template name, enter Product X Protocol.

To set up the protocol template:

8. Expand the **Mode: Assay replicate** element.
9. As the **Number of replicates**, enter 3.
10. Expand the **Templates > Assay templates > Assay template** element.
11. As the **Template**, select the assay template you created.
12. Expand the **Combination calculation templates > Configuration** element.
13. As the **Template**, select the combination template you created.
14. Save the template.

What to do next

Create a protocol document.

1.2 Create a protocol document

Create a protocol document based on your template.

Before you begin

You have created and set up a protocol template.

Procedure

To create a protocol document:

1. In the **Navigator**, select the folder in which you want to create the document.
2. From the context menu, select  **New**.
3. In the **Create a new document** dialog, on the **Available document types** tab, go to **Biological Assay Package > Basic bioassay protocol**.
4. Select 'Product X Protocol.'
5. To confirm your selection, select **Create**.
Result: The **Content** editor opens, displaying your new document.
6. Save the document.

What to do next

Generate the linked documents.

1.3 Generate the linked documents

Use the protocol document to generate the Quantitative response assay and Combination of assay results documents from the linked templates.

Before you begin

You have created a protocol document.

Procedure

To generate the linked documents, on the action bar, select  **Generate**.

Result

PLA 3.0 executes the protocol:

- It uses the assay template to create the number of assay documents you defined as replicates (orange arrows). In this use case, this are three Quantitative response assay documents.
- It uses the combination calculation template to create a Combination of assay results document (blue arrow).

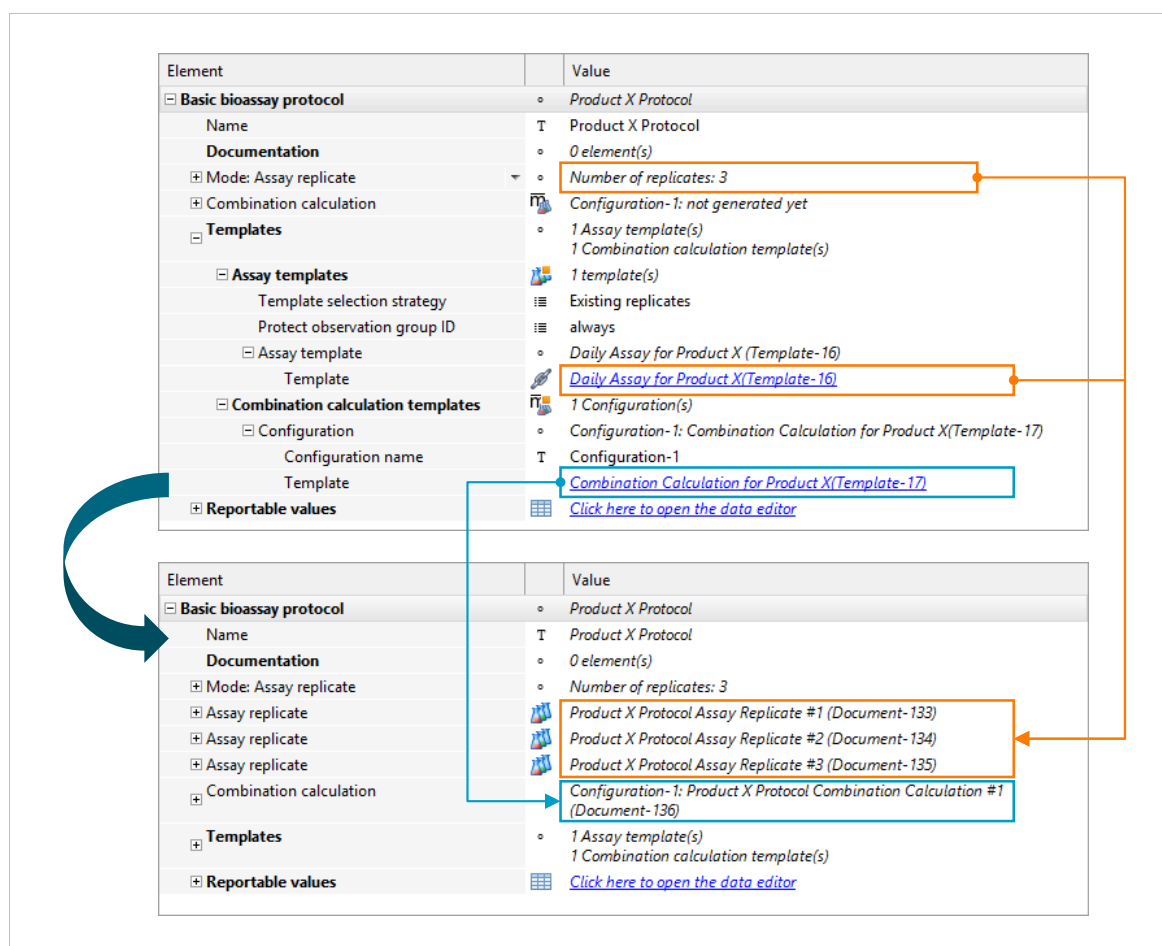


Figure 1-2 Protocol execution resulting in generated documents

What to do next

Calculate the assays.

1.4 Calculate the assays

Enter the observation data and calculate the generated Quantitative response assay documents.

Before you begin

You have generated the linked documents.

About this task

As assay data becomes available, enter it into the corresponding assay document and calculate the result. This lets you verify that each assay behaves as expected before proceeding to the next step. A common approach is to start with one assay on day one, evaluate it, and then continue with the other assays in the following days. This staged approach helps detect potential issues early.

This use case simulates a three-day workflow. Use the observation data provided for each day to complete and calculate the corresponding Quantitative response assay document.

1.4.1 Day 1

Procedure

1. Open the first Quantitative response assay document.
2. In the **By Position** editor, select **Response** as the primary display factor.
3. Copy and paste the following values. Leave the rest of the wells empty.

	1	2	3	4	5	6	7	8	9	10	11	12
A	2	3	4	6	10	20	30	31	32	33	33.5	34
B	1.9	3.4	3.9	5	9	23	30	31	32	32.5	33	34

4. Calculate the assay and evaluate the results:
 - a. On the action bar, select  **Calculate**.
 - b. Access the document dashboard to view a graphical summary of the calculation results: On the action bar, select  **Dashboard**.

1.4.2 Day 2

Procedure

1. Open the second Quantitative response assay document.
2. In the **By Position** editor, select **Response** as the primary display factor.
3. Copy and paste the following values. Leave the rest of the wells empty.

	1	2	3	4	5	6	7	8	9	10	11	12
A	2	3	4	6	10	19	29	31	32	33	33.5	34
B	1.9	3.4	3.9	6	10	22	30	31	32	32.5	33	34

4. Calculate the assay and evaluate the results:
 - a. On the action bar, select  **Calculate**.
 - b. Access the document dashboard to view a graphical summary of the calculation results: On the action bar, select  **Dashboard**.
5. Optional: After calculating the second assay, you can already run the combination calculation to see how the results compare. This helps identify outliers early. For details, see the [Calculate the reportable values](#) topic.

1.4.3 Day 3

Procedure

1. Open the third Quantitative response assay document.
2. In the **By Position** editor, select **Response** as the primary display factor.
3. Copy and paste the following values. Leave the rest of the wells empty.

	1	2	3	4	5	6	7	8	9	10	11	12
A	2	3	4	6	10	20	30	31	32	33	33.5	34
B	1.9	3.4	3.9	6	10	20	30	31	32	32.5	33	34

4. Calculate the assay and evaluate the results:
 - a. On the action bar, select  **Calculate**.
 - b. Access the document dashboard to view a graphical summary of the calculation results: On the action bar, select  **Dashboard**.

What to do next

Calculate the reportable values.

1.5 Calculate the reportable values

Use the generated Combination of assay results document to calculate the reportable values.

Before you begin

You have calculated the assays.

About this task

Once you have calculated at least two individual assays, you can use the Combination of assay results to calculate the reportable value. This merges the results of independent assay runs and produces a single value that you can use for decision-making, release testing, or trending.

Performing the combination calculation at this stage helps confirm that the assays behave consistently before continuing with additional runs.

Procedure

To calculate the reportable values:

1. Open Combination of assay results document.
2. On the action bar, select  **Calculate**.

Result

PLA 3.0 executes the combination calculation. After calculation, you see the result summary on the **Results** tab of the document dashboard.



Figure 1-3 Results of a combination calculation on the dashboard of a Combination of assay results document