

ORA Partners Portal (ORAPP) Sample Collections Errors and Corrections Knowledge Article (KA)

Audience

This article is intended for ORA Partners Portal (ORAPP) users who performed a Sample Collections submission that received errors.

Summary

The ORAPP Sample Collections capability enables regulatory partners to share state-collected sample data with FDA via the Sample Collections Excel template. During submission, errors can occur preventing data from reaching FDA. This article provides guidance on how to view and correct Sample Collections submission errors.

Submission Error Causes

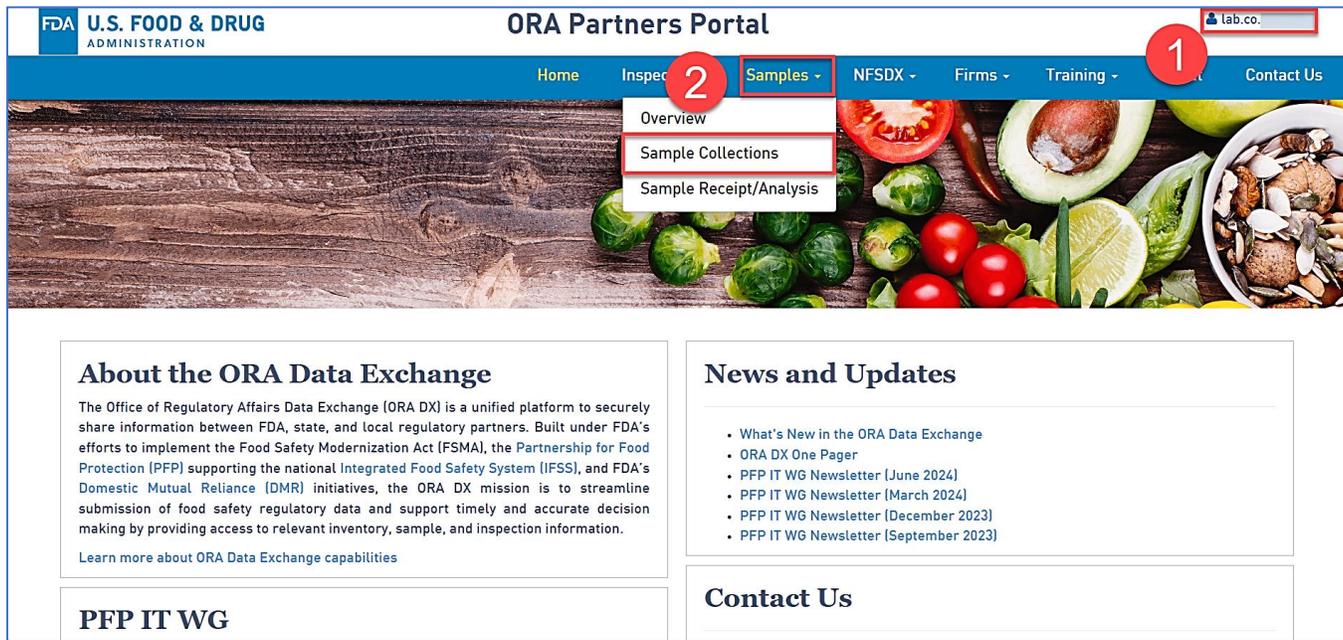
Submission errors occur when the submission file or data within the submission file has:

- improperly formatted data
- fields that exceed the maximum character limit
- prohibited template changes (i.e., deleted template columns)

Viewing and Correcting Submission Errors

To view and correct submission errors:

1. **Log in** to ORAPP.
2. Hover over the **Samples** tab and select **Sample Collections** on the menu to access the Sample Collections Data Exchange page.



- The **Status Summary** column displays the number of successfully processed sample collections and the number of sample collections returned with errors as highlighted in the image below.
- The **Status Column** will display “**Errors**” if any sample collections were returned for errors. Select the **eye** icon to view additional details about the submission results.

Sample Collections Data Exchange

Submit results using the Sample Collections Excel Template that is available to download below.

[Download Sample Collections Excel Template_v1.6](#) |
 [Download Guidance Materials](#)

To submit Sample Collections data for processing, **DO NOT**:

- Password-protect the file
- Reuse a previously submitted filename
- Use a filename longer than 75 characters or containing * " : ? | \ < >
- Upload more than 10 files at one time
- Upload a file more than 2 MB in size

Click the Refresh icon to view the latest processing information for the submitted files.
Processed files can be downloaded by clicking the Download icon. The processed files will be available for download for one year from the Submission Date.

Select Files Refresh

Colorado Department of Public Health				
Filename	Submission Date	Submitted By	Status	Status Summary
Samples Collection Example_SN_24(2).xlsx	5/31/2024	Sharlitta Nipper	Errors	The submission was not successfully processed due to validation error(s). 1 sample collections and/or PAF/IPAC additions were processed successfully and 1 returned errors that need to be corrected. Click on the eye icon in the Status column or refer to your email to view the list of the Lab Sample Number(s) and the corresponding FDA Sample Number(s) and to review the error(s) associated with the submission. Make any necessary corrections and resubmit the file using a new filename.
Samples Collection Example_SN_24.xlsx	5/31/2024	Sharlitta Nipper	Errors	The submission was not successfully processed due to validation error(s). 1 sample collections and/or PAF/IPAC additions were processed successfully and 1 returned errors that need to be corrected. Click on the eye icon in the Status column or refer to your email to view the list of the Lab Sample Number(s) and the corresponding FDA Sample Number(s) for success(es) and to review the error(s) associated with the submission. Make any necessary corrections and resubmit the file using a new filename.

- The populated window displays two sections, highlighted in the example below: **Successes** and **Errors**.
 - Successfully processed sample collections data displays the **lab sample number** included in the submission, the newly assigned **FDA sample number**, and an **acknowledgement of successful submission**.
 - Sample collections data with errors displays the **lab sample number**, **error message**, and **instructions on how to correct the error**.
- Select the **Download to Excel** button to download the **Info Excel file** which should be used for reference during correction.
- Close the window, by clicking on the “X” in the upper right corner, to return to the Sample Collections Data Exchange page.

Sample Collections Data Exchange

Submit results using the Sample Collections Excel Template that is available to download below.

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Processed files can be downloaded by clicking the Download icon.

Select Files Refresh

Samples Collection Example_SN_24.xlsx

Successes:

LabSampleNumber, 1011115-0SN | FDASampleNumber, 1259062: The Sample Collection submission was successfully processed. (PAF:DEC, PAC:03R801).

Errors:

LabSampleNumber, 1011115-0S: SMP-ERR-001: Required Field - A value is missing for the "ProductCode" column. Scroll through the values in the column until you find a blank cell and populate with a value. (PAF:DEC, PAC:03R801).

Download to Excel

Filename	Submission Date	Submitted By	Status	Status Summary
Samples Collection Example_SN_24(2).xlsx	5/31/2024	Sharlitta Nipper	Errors	The submission was not successfully processed due to validation error(s). 1 sample collections and/or PAF/IPAC additions were processed successfully and 1 returned errors that need to be corrected. Click on the eye icon in the Status column or refer to your email to view the list of the Lab Sample Number(s) and the corresponding FDA Sample Number(s) and to review the error(s) associated with the submission. Make any necessary corrections and resubmit the file using a new filename.
Samples Collection Example_SN_24.xlsx	5/31/2024	Sharlitta Nipper	Errors	The submission was not successfully processed due to validation error(s). 1 sample collections and/or PAF/IPAC additions were processed successfully and 1 returned errors that need to be corrected. Click on the eye icon in the Status column or refer to your email to view the list of the Lab Sample Number(s) and the corresponding FDA Sample Number(s) for success(es) and to review the error(s) associated with the submission. Make any necessary corrections and resubmit the file using a new filename.
17_0_SC_NIF_SN (5-31-24).xlsx	5/30/2024	Sharlitta Nipper	Errors	The submission was not successfully processed due to validation error(s). 0 sample collection and/or PAF/IPAC additions were processed successfully and 1 returned errors that need to be corrected. Click on the eye icon in the Status column or refer to your email to view the error(s) associated with the

8. On the **Sample Collections Data Exchange** home page, select the **Download File** button next to the file that contains errors. The file will appear in the Downloads folder within the browser.

Note: The location of the Downloads folder will vary based on the browser.

9. Open the downloaded **submission file** and the previously downloaded **Info Excel file** to begin making corrections.

Note: The [Resources](#) section of this article contains a list of additional resources to help with error corrections.

The screenshot shows the ORA Partners Portal interface. At the top, there is a navigation bar with the FDA logo and the text "ORA Partners Portal". Below this is a sub-navigation bar with links for Home, Inspections, Samples, NFSDX, and Firms. The main content area is titled "Sample Collections Data Exchange" and contains instructions for submitting data, including a "Download Sample Collections Excel Template_v1.6" button and "Download Guidance Materials" link. A list of instructions for submission is provided, such as "Password-protect the file" and "Do not upload more than 10 files at one time". A "Refresh" button is located at the bottom right of the instructions. Below the instructions is a table with the following columns: "Filename", "Submission Date", "Submitted By", "Status", and "Status Summary". The table contains one entry: "Samples Collection Example_SN_24(2).xlsx" with a submission date of "5/31/2024" and submitted by "Shariitta Nipper". The status is "Errors" with a red triangle icon. A red circle with the number "8" is overlaid on the "Download File" button (a download icon) next to this entry. A browser download history popup is visible in the top right corner, showing a recent download of "Samples Collection Example_SN_24(2)(1).xlsx" (412 KB, 1 minute ago). A red circle with the number "9" is overlaid on the "Recent download history" popup.

10. In the **Info Excel file**, identify the successfully processed data to be deleted before resubmitting the data. Take note of the **lab sample number** and the details in the **Information** column. Successfully processed data should be deleted from the submission file when performing corrections. In the highlighted example below, lab sample number: **TS02-5** was successfully processed and assigned an **FDA Sample Number**.

Lab Sample Number	FDA Sample Number	Information
Successes		
TS02-1	4874091	The Sample Collection submission was successfully processed ([PAF:ANT, PAC:04F800]).
TS02-1	74091	A PAF/PAC was successfully added to the Sample Collection ([PAF:ANT, PAC:71003K],[PAF:ANT, PAC:04F800]).
TS02-5	4874092	The Sample Collection submission was successfully processed ([PAF:PES, PAC:04004A]).
Errors		
TS02-3		LBS-ERR-SC-043: [FEINumber] OR the [LegalName] and address is required when [RespFirmType] is not 'D' AND [IsDealerConsumer] is not 'Y'.
TS02-3		LBS-ERR-SC-069: The submitted FEI or address returned no match; therefore, the data could not be successfully processed. Contact your State Liaison for assistance.
TS02-2		LBS-ERR-SC-041: The [SampleDeliveredDate] '2019-07-01T00:00:00Z' is invalid. It cannot not be earlier than the [CollectionDate] of '2019-07-18T00:00:00Z'.
TS02-2		LBS-ERR-SC-041: The [SampleDeliveredDate] '2019-07-01T00:00:00Z' is invalid. It cannot not be earlier than the [CollectionDate] of '2019-07-18T00:00:00Z'.
TS02-4		LBS-ERR-SC-029: The [ProgramAssignmentCode] '04BB4A' is invalid. It must be in the list of reference values. (LabPAFID=1_4) ([PAF:PES, PAC:04BB4A]).

11. In the **submission file**, locate and delete the rows (highlighted below) for all successfully processed data on each data entry tab (**Sample Collection, Firms, Analysis Assignment, and Manufacturing Codes**). Highlighted in the example below, the submission data for lab sample number: **TS02-5** will be deleted from all four tabs of the submission file.

Note: When submitting multiple data for a single lab sample number and a **Program Assignment Code (PAC)/Problem Area Flag (PAF)** assignment received errors, do not delete any submission data for that lab sample number in the file. Even if the sample collection data was successfully processed, that data should remain in the file for resubmission after all errors have been corrected.

LabSampleNumber	Program1	EON	SampleFlagCode	CollectionDate	CollectionRemarks	IsDealerConsumer
TS02-1	Food Contract		DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable apple juice.	N
TS02-2	Food Contract		DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable apple juice.	N
TS02-3	Food Contract		DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable apple juice.	N
TS02-4	Food Contract		DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable apple juice.	N
TS02-5	Food Contract		DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable apple juice.	N

12. Once all successfully processed data submissions are deleted, begin performing corrections. In the **Info Excel file**, identify the submission data that received errors and take note of the **lab sample number** and error details in the **Information** column. Highlighted in the example below, lab sample number: **TS02-2** received an error that the **Sample Delivered Date was invalid because it is an earlier date than the Sample Collection Date**. The error must be corrected in the submission file.

Lab Sample Number	FDA Sample Number	Information
Successes		
TS02-1	4874091	The Sample Collection submission was successfully processed ([PAF:ANT, PAC:04F800]).
TS02-1	4874091	A PAF/PAC was successfully added to the Sample Collection ([PAF:ANT, PAC:71003K],[PAF:ANT, PAC:04F800]).
TS02-5	4874092	The Sample Collection submission was successfully processed ([PAF:PES, PAC:04004A]).
Errors		
TS02-3		LBS-ERR-SC-043: [FEINumber] OR the [LegalName] and address is required when [RespFirmType] is not 'D' AND [IsDealerConsumer] is not 'Y'.
TS02-3		LBS-ERR-SC-069: The submitted FEI or address returned no match; therefore, the data could not be successfully processed. Contact your State Liaison for assistance
TS02-2		LBS-ERR-SC-041: The [SampleDeliveredDate] '2019-07-01T00:00:00Z' is invalid. It cannot not be earlier than the [CollectionDate] of '2019-07-18T00:00:00Z'.
TS02-2		LBS-ERR-SC-041: The [SampleDeliveredDate] '2019-07-01T00:00:00Z' is invalid. It cannot not be earlier than the [CollectionDate] of '2019-07-18T00:00:00Z'.
TS02-4		LBS-ERR-SC-029: The [ProgramAssignmentCode] '04BB4A' is invalid. It must be in the list of reference values. ([LabPACID=1_A]/[PAC-PES_PAC:04BB4A])

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13. In the **submission file**, navigate to the appropriate tab and locate the **lab sample numbers** for the identified errors to make the necessary corrections. Highlighted in the example below, the **Sample Delivered Date** for Lab Sample Number: **TS02-2** must be changed to a date after the **Sample Collection Date**.

LabSampleNumber	Program1	SampleFlagCode	CollectionDate	CollectionRemarks	SampleDeliveredDate
TS02-1	Food Contract	DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable apple juice.	6/15/2024
TS02-2	Food Contract	DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable apple juice.	6/13/2024
TS02-3	Food Contract	DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable apple juice.	6/15/2024
TS02-4	Food Contract	DV	6/14/2024	Twelve 128-ounce subsamples of ready to drink nonperishable a	6/15/2024

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14. Once all corrections are made, save the file with a new file name, and perform a resubmission. For additional instructions on how to perform a submission, view the [ORA Partners Portal \(ORAPP\) Multi-File Submission for Sample Collections \(KAPPSC1\)](#) KA.

Note: Files that were successfully processed during the previous submission should not be resubmitted.

Resources

Resource Name and Location	Description
Sample Collections Guidance Materials <i>(ORAPP Login Required)</i>	Guidance materials are a collection of documents that support Sample Collections data submissions by providing template and submission instructions, example submission files, list of values, data elements, and business rules information via the state mapping file, in addition to other resources that provide guidance for a successful submission. A link to download the guidance materials is available on the ORAPP Sample Collections Data Exchange page after successful login.
Sample Collections e-Learning Courses	The four non-interactive Sample Collections e-Learning courses available on the ORAPP e-Learning page provide: <ul style="list-style-type: none"> Sample Collections Overview Sample Collections Guidance Materials Overview Sample Collections Submission Sample Collections Errors and Correction
Sample Data Sharing KAs	The four Sample Data Sharing KAs provide step-by-step instructions with images on how to perform Sample Collections and Sample Receipt and Analysis Submissions in ORAPP in addition to how to correct submission errors.
Product Code Builder	The Product Code Builder is a tool used to properly generate a product code for samples included in a submission. The Product Code Builder allows users to enter descriptive information which will be used to generate the correct product code that should be entered on the template. The generated product code can be copied and pasted directly into the template.

Contact Us

For assistance with ORAPP or ORA DX, contact the ORA DX Team via the ORAPP Contact Us page: https://orapartners.fda.gov/webcenter/portal/ORAPARTNERS/pages_contactus.