# ORA Partners Portal (ORAPP) Sample Receipt and Analysis Errors and Corrections Knowledge Article (KA)

## Audience

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

#### **Summary**

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

#### Submission Error Causes

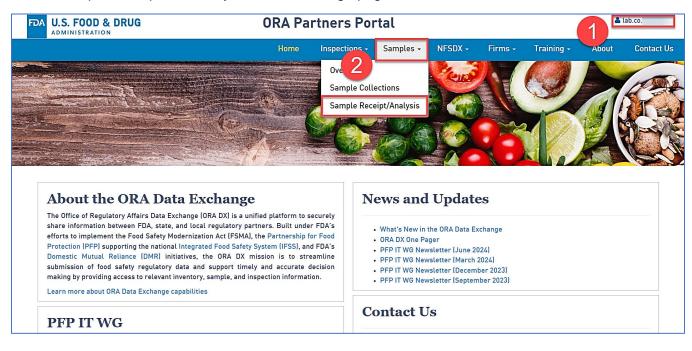
Submission errors occur when the submission file or data within the submission file has:

- 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 Receipt/Analysis** on the menu to access the Sample Receipt and Analysis Data Exchange page.





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

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nit results using the Sample Receipt and Analy _				
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- 5. The populated window displays two sections: **Successes** and **Errors**. Within each section, results are grouped by **Sample Receipts** and **Sample Analysis** as highlighted in the image below.
  - a. Successfully processed sample receipts and/or analyses data displays the FDA Sample Number and an acknowledgment of the successfully processed record.
  - b. Sample receipt and/or analysis data that received submission errors displays the FDA sample number and error message details.

**Note**: Error message details may contain pertinent instructions for corrections or business rules impacting the errors.

- Select the Download to Excel button to download the Info Excel file which should be used for reference during correction.
- 7. Close the window, by clicking on the "X" in the upper right corner, to return to the Sample Receipt and Analysis Data Exchange page.

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17_0_SC_NIF_SN.xlsx	Successes:	late, re-enter the data in one tab only without
	Sample Receipts:	ng tabs. Resubmit using a new filename. See more information on how to resubmit a file.
Sample Receipt Example Multiple Samples_SNTest	EDASampleNumber, 4968806:: The Sample Receipt submission was successfully processed ([PAF:ANT, PAC:04F800]).	receipts and/or analyses were processed ye icon in the Status column or refer to your FDA Sample Number(s) associated with the
Sample Receipt and Analysis Excel Template_SNTe	Sample Analysis: FDASampleNumber, 4968806   PAF, ANT   PAC, 04F800:: The Sample Analysis submission was successfully processed.	receipts and/or analyses were processed ye icon in the Status column or refer to your FDA Sample Number(s) associated with the
Sample Receipt Example Multiple Samples_SNTest	Errors:	receipts and/or analyses were processed ye icon in the Status column or refer to your FDA Sample Number(s) associated with the
Sample Receipt and Analysis Excel Template_SNTe	Sample Analysis: FDASampleNumber, 4968806   PAF, ANT   PAC, 71003K:: LBS-ERR-BV-239: The [ProblemAreaFlag] 'ANT' [ProgramAssignmentCode] '71003K' combination is incorrect for this [SampleNumber] '4968806'.	accessfully processed due to validation error(s), nalyses were processed successfully and 2 b be corrected. Click on the eye icon in the our email to review the error(s) associated with
	FDASampleNumber. 4968806   PAF, ELE   PAC. 04019A:: LBS-ERR-BV-239: The IProblemAre 6 LE Download to Excel	necessary corrections and resubmit the file iccessfully processed due to validation error(s), nalyses were processed successfully and 2 be corrected. Click on the eve icon in the



8. On the Sample Receipt and Analysis Data Exchange page, select the **Download File** button next to the submission file that contains errors. The **submission 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 to begin corrections.

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10. Open the previously downloaded Info Excel file.

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11. The **Info Excel file** contains two tabs: **Sample Receipts Info** and **Sample Analyses Info**. Information regarding the submission successes and errors is provided within each tab.

FDA Sample Number	PAF	PAC	Test Run ID	Test Result ID	Information
uccesses					
4968479	ANT	04F800			The Sample Analysis submission was successfully processed.
4968476	ANT	04F800			The Sample Analysis submission was successfully processed.
4968476	ELE	04019A		-11	The Sample Analysis submission was successfully processed.
rrors					
4968479	ANT	71003K			LBS-ERR-EA-903: [Alertlustification] is missing, but is required when [EmailAlert] is 'Y'.
1144286	PES	04004A			LBS-ERR-BV-237: [SampleNumber] '1144286' is not associated with this lab.
1144285	PES	04004A			LBS-ERR-BV-101: [SampleNumber] '1144285' is invalid. Check the sample number assigned by FDA.
1144287	PES	04004A			LBS-ERR-BV-237: [SampleNumber] '1144287' is not associated with this lab.
Sample Receipts Inf	o Si	ample Ana	lyses Info	Ð	

12. Before starting corrections, identify the successfully processed data in both tabs of the Info Excel file, to be deleted before resubmitting the data. Take note of the FDA Sample Number, Problem Area Flag (PAF) (Sample Analyses Info Tab Only), and Program Assignment Code (PAC) (Sample Analyses Info Tab Only) fields. In the example highlighted below, FDA Sample Number: 4968476 successfully processed PAF: ANT and PAC: 04800 analysis data during the submission.

FDA Sample Number	PAF	PAC	Test Run ID	Test Result ID	Information
Successes					
4968479	ANT	04F800			The Sample Analysis submission was successfully processed.
4968476	ANT	04F800		2	The Sample Analysis submission was successfully processed.
4968476	ELE	04019A	<u> </u>		The Sample Analysis submission was successfully processed.
Errors					
4968479	ANT	71003K			LBS-ERR-EA-903: [AlertJustification] is missing, but is required when [EmailAlert] is 'Y'.
1144286	PES	04004A			LBS-ERR-BV-237: [SampleNumber] '1144286' is not associated with this lab.
1144285	PES	04004A			LBS-ERR-BV-101: [SampleNumber] '1144285' is invalid. Check the sample number assigned by FDA.
1144287	PES	04004A			LBS-ERR-BV-237: [SampleNumber] '1144287' is not associated with this lab.
Sample Receipts Inf	o Sa	ample Ana	lyses Info (+	Đ	: •

- 13. In the submission file, navigate to the appropriate PAF or Receipt tab.
- 14. Then, locate and delete the row that contains the FDA Sample Number, PAF (Sample Analysis Data Only), and PAC (Sample Analysis Data Only) from the successfully processed submission. In the example below, the highlighted row will be deleted. Repeat steps 12 14 until all successfully processed data has been deleted.

SampleNumber	LabSampleAnalysisID	ProgramAssignmentCode	ProblemAreaFlag	EmailAlert
4968479	1144284	04F800	ANT	Y
4968479	1144284	71003K	ANT	Y
4968479	1144284 14	71003K	ANT	Y
4968476	1000001	04F800	ANT	Y
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			13	
> ELE	PES MYC MIC VIR	PAR NUC DEC NAR	ANT NIS ··· + :	4



15. After all the successfully submitted data is removed from the submission file, begin correcting the errors. Identify the error(s) on the Info Excel file.

FDA Sample Number	PAF	PAC	Test Run ID	Test Result ID	Information
Successes					
4968479	ANT	04F800			The Sample Analysis submission was successfully processed.
4968476	ANT	04F800			The Sample Analysis submission was successfully processed.
4968476	ELE	04019A			The Sample Analysis submission was successfully processed.
Errors					
4968479	ANT	71003K		15	LBS-ERR-EA-903: [Alertlustification] is missing, but is required when [EmailAlert] is 'Y'.
1144286	PES	04004A		15	LBS-ERR-BV-237: [SampleNumber] '1144286' is not associated with this lab.
1144285	PES	04004A			LBS-ERR-BV-101: [SampleNumber] '1144285' is invalid. Check the sample number assigned by FDA.
1144287	PES	04004A			LBS-ERR-BV-237: [SampleNumber] '1144287' is not associated with this lab.
Sample Receipts Inf	o <b>S</b>	ample Ana	lyses Info 🦳 🤆	Đ	1 4

16. Take note of the FDA Sample Number, PAF (Sample Analyses Info Tab Only), and PAC (Sample Analyses Info Tab Only) fields to locate the correct sample data on the submission file. In the highlighted example below, FDA Sample Number: 4968479 received errors for the PAF: ANT and PAC: 71003K analysis data submission. The Information column indicates that the AlertJustification field on the submission file was empty which caused the error.

FDA Sample Number	PAF	PAC	Test Run ID	Test Result ID	Information
Successes					
4968479	ANT	04F800			The Sample Analysis submission was successfully processed.
4968476	ANT	04F800			The Sample Analysis submission was successfully processed.
4968476	ELE	04019A			The Sample Analysis submission was successfully processed.
Errors					
4968479	ANT	71003K			LBS-ERR-EA-903: [AlertJustification] is missing, but is required when
					[EmailAlert] is 'Y'.
1144286	PES	04004A		16	LBS-ERR-BV-237: [SampleNumber] '1144286' is not associated with this lab.
1144285	PES	04004A			LBS-ERR-BV-101: [SampleNumber] '1144285' is invalid. Check the sample
					number assigned by FDA.
1144287	PES	04004A			LBS-ERR-BV-237: [SampleNumber] '1144287' is not associated with this lab.
Sample Receipts Inf	o Sa	ample Ana	lyses Info (-	Ð	

- 17. In the submission file, navigate to the appropriate PAF or Receipt tab.
- Then, locate the appropriate row using the FDA Sample Number, PAF (Sample Analysis Data Only), and PAC (Sample Analysis Data Only) found in the Info Excel file and correct the error. In the highlighted example below, to correct the submission error received for FDA Sample Number: 4968479 PAF: ANT and PAC: 71003K, a justification must be added in the AlertJustification field on the row for that sample. Repeat steps 15 18 until all errors have been corrected.

SampleNumber	LabSampleAnalysisID	ProgramAssignmentCode	ProblemAreaFlag	EmailAlert	AlertJustification T	estRu
4968479	1144284	71003K	ANT	Y	Correction - add in justifi	7
4968479	1144284	71003K	ANT	Y	Post Sample	7
					•	
PES MYC N	AIC   VIR   PAR   NUC   DEC   N		: [4]			



19. Once all corrections are made, **save the file with a new file name**, and perform a resubmission. For detailed instructions on performing a submission, view the <u>ORA Partners Portal (ORAPP)</u> <u>Multi-File Submission for Sample Receipt and Analysis (KAPPSA1)</u> KA.

Resources	
Resource Name ad Location	Description
Sample Receipt and Analysis Guidance Materials (ORAPP Login Required)	Guidance materials are a collection of documents that support Sample Receipt and Analysis 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 Receipt and Analysis Data Exchange page after successful login.
Sample Receipt and Analysis e- Learning Courses	<ul> <li>The four non-interactive Sample Receipt and Analysis e- Learning courses available on the ORAPP e-Learning page provide: <ul> <li>Sample Receipt and Analysis Overview</li> <li>Sample Receipt and Analysis Guidance Materials Overview</li> <li>Sample Receipt and Analysis Submission</li> <li>Sample Receipt and Analysis Errors and Correction</li> </ul> </li> </ul>
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.