Online Product Performance Reporting Training Guide

Electronic product performance reporting

• Simple online entry and submission
• Easy-to-save forms with image upload option and printing capabilities
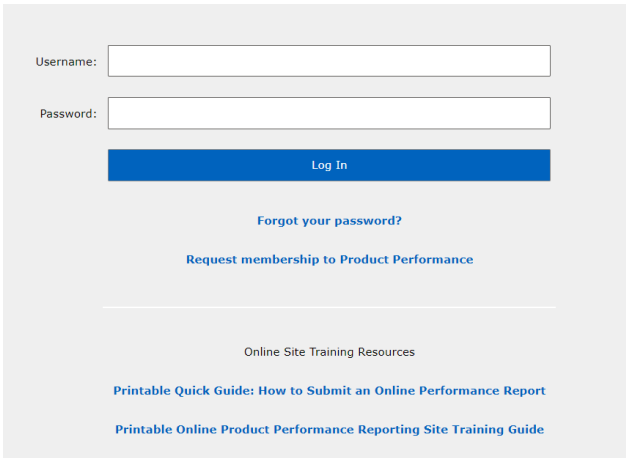• Reporting feature provides historical reviews and status updates

Getting Started

Step 1 – Go to the following link: https://productperformance.FreseniusKabiUSA.com
Step 2 – Click on "Request membership to Product Performance"
Step 3 – Complete enrollment screen (shown below). Ensure you include the correct phone number and address, so you are associated with the correct account
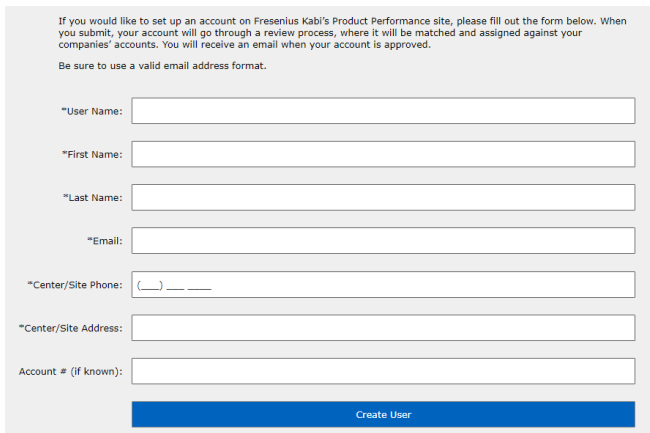Step 4 – Receive email confirmation with username and password

Request Membership:

Username:	
Password:	

Log In

Forgot your password?

Request membership to Product Performance

Online Site Training Resources

Printable Quick Guide: How to Submit an Online Performance Report

Printable Online Product Performance Reporting Site Training Guide

Enrollment Screen:

If you would like to set up an account on Fresenius Kabi's Product Performance site, please fill out the form below. When you submit, your account will go through a review process, where it will be matched and assigned against your companies' accounts. You will receive an email when your account is approved.

Be sure to use a valid email address format.

*User Name:	
*First Name:	
*Last Name:	
*Email:	
*Center/Site Phone:	(___) ___ ____
*Center/Site Address:	
Account # (if known):	

Create User

Entering a Report: Account Information and General Incident Information

1. Select your Account Number (any field with an * is required for submission)
2. Complete the required General Incident Information. Add any additional
   information you choose to report.
If you click yes to report an adverse event, an additional field will populate. Complete the field with
a description of the event.

Account Information:

* Account:	Select An Account
Customer Reference Number:	
If desired, provide your internal identifier number within this field	
QA Contact:	
Please provide the name of the person who has knowledge of the report and is able to provide additional information if requested.	

General Incident Information:

Did the issue occur during a donation?
(check if yes) ☐

Was there an adverse event or injury?
(check if yes) ☑

* Please describe the event:

	Yes	No	N/A
* Was the procedure successfully completed?	☐	☐	☐
* If no, was the procedure stopped due to a soft goods incident?	☐	☐	☐
* Was the product lost?	☐	☐	☐

Entering a Report: Correspondence Information (if applicable)
1. Check box if you do NOT require a response letter
2. If you do require a letter, enter the email address IF different from the person submitting the performance report

Correspondence Information:

Check box if you do NOT require a response letter: ☐

* E-mail address of letter recipient: ☐ N/A

If different from person submitting the report (if the same, check N/A):

Entering a Report: Product Details

1. Enter in the Incident Date, Product Code, and Lot Number
2. Complete additional required and optional fields (as applicable)

Product details section will vary depending on product line selected

Product Details:

* Incident Date:	
* Product Code:	No available products. Please select a suitable account
	(i) Add a Product Code
* Lot Number:	
* Re-enter Lot Number:	
* Number of Incidents:	1
Instrument Serial Number:	
Software Version:	
Product Collected (ml):	
Donor Bleed Number:	

Entering a Report: Problem Details

1. Select when problem occurred (drop down menu)
2. Select what the issue was (drop down menu). If the choice you select states "Please Specify" please enter the issue that occurred in the empty field

Problem Details:

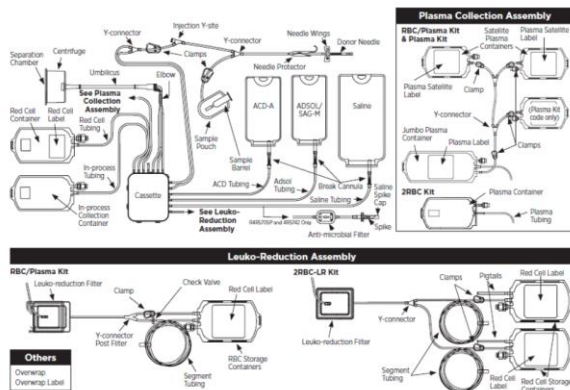|	
* When was the problem detected?	
* Identify the problem type:	

Entering Report: Problem Location

1. In the diagram below, click on the name of the area where the problem happened.

This diagram will vary depending on the product line chosen

2. If the location is unknown or not on the diagram, please select the checkbox at the top of the diagram and include the location in the "Additional Incident Description" box below the diagram

Entering Report: Additional Incident Description
1. If there is any additional information you'd like to provide please enter it in the "Additional Incident Description" box as seen below

Additional Incident Description:

Entering Report: Product Return Details
1. If you would like to return the sample, check the Yes box next to "Is a sample available for evaluation?"
2. When the Yes box is checked, the following question will populate "Is a sample return box needed?" along with a note concerning return labels (see below)
3. When the sample needed box is checked, the following statement will populate "If the address to ship the box to is different than the account address, ACCOUNT ADDRESS, please provide the ship to address:"
4. If you have pictures of the incident, you can upload them by clicking on browse

Product Return Details:

* Is a sample available for evaluation?	☑ Yes	☐ No	☐ Not Required
Is a sample return box needed? (check if yes)	☑		

If the address to ship the box to is different than the account address : Fresenius Kabi - Lake Zurich - Three Corporate Drive please provide the ship to address:

If no box is required, a new return label will be emailed to you separately once the complaint is processed. If a sample box is required, a return label will be included in the sample return box.

If you have pictures of the defective product, please attach them: No Files Chosen

Browse

Report Submission
1. Click "Submit" to submit your report
2. The following screen will populate. The submission number can be found under the submission details

Alyx System Kit Performance Report

Submit a new form   Print

Account Details
Account
Account Name
Account Address
QA Contact
Submitted By   Nissa Riemer
Work Phone   (847) 550 2865
Fax
Email   Nissa.riemer@fresenius-kabi.com

Submission Details
Submission Number   70
Submission Date   03/09/2022
Incident Date   03/09/2022
Customer Ref. Number
Notification Number
Status   Submitted

General Incident Information
Did the issue occur during a donation?   No
Was there any adverse event or injury?   No
Was the procedure successfully completed?   No
Was the procedure stopped due to a soft goods incident?   No
Was the product lost?   No

Product Information
Product Line   Alyx
Product Code   X4R5720
Lot Number   fn21f45342
Number of Incidents   1
Instrument Serial Number
Software Version
Product Collected (ml)
Donor Bleed Number

Product Return Details
Email address for letter recipient
Is a sample available for evaluation?   Yes
Is a sample return box needed?   No
Ship To address   Enter ship to address here. If applicable.

Problem Details
When was the problem detected?   Set Up
Identify the problem type   Broken
Problem Location   Sample Pouch

Attached Files

3. If you desire, you can print this page by clicking the "Print Page" button in the upper right corner, or you can click on "Submit a New Form" to submit another report

How to Search for Product Performance Reports

1. Click on Search

You can search by incident date or date range, product line, product code, lot number, submission number, your reference number, notification number, or donor bleed number.

2. Choose your account number,
3. Enter your search criterion.
4. Click search

Search Results

1. All the reports within the parameters you set will populate

Search Results

Submission #	Account #	Account Name	QA Contact	Product Line	Incident Date	Product Code	Product Description	Lot Number	Problem Detected	Problem Type	Status
60	60019464			Bioflex	03/01/2022	4B7891X	ACD-A IN 1000ML PLASTICCONTAINER	FM21L23422	Filtration	Illegible	Submitted
64	60039909			Amicus	03/01/2022	4B7898Q	ACD-A 500 ML (PACK FACTOR 24)	fa21f45342	Prime _____%	Other (Please Specify)	Submitted
65	60037587			Amicus	03/02/2022	4R2256	PLASMACELL-C DISPOSABLE SET	fa21f45342	Prime _____%	Particulate Matter	Submitted
67	60034710			Alyx	03/01/2022	4R2440	16G NEEDLE W/ PLASTIC MASTERGUARD	fa21f45342	Draw Cycle #	Restriction / No Flow	Submitted
69	60023365			Alyx	03/01/2022	FUM4092	4% ANTICOAGULANT SODIUM CITRATE,250ML	fa21f45342	Draw Cycle #	Restriction / No Flow	Submitted
70	60019431			Alyx	03/09/2022	X4R5720	ALYX 2RBC-LR KIT	fn21f45342	Set Up	Broken	Submitted

To start a new search, click here

Export to Excel

2. Click on the Submission Number if you wish to view the individual report in more detail
3. Click on Export to Excel if you wish to view the results in Excel

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
	Submissic	Account N	Account N	Status	Notificatic	Customer	QA Contac	Product Li	Adverse E	Adverse E	During Do	Donation	Product Lc	Soft Good	Infusion S	Incident D	Drug Adm	Drug Used	Is Cytotox	Manufactu
	60	60019464		Submitted				Bioflex	No		No	Yes	Yes	Yes		3/1/2022				
	64	60039909		Submitted				Amicus	No		No	Yes	Yes			3/1/2022	N/A			
	65	60037587		Submitted				Amicus	No		No	Yes	Yes			3/2/2022	N/A			
	67	60034710		Submitted				Alyx	No		No	Yes	Yes	Yes		3/1/2022				
	69	60023365		Submitted				Alyx	No		No	No	No	No		3/1/2022				
	70	60019431		Submitted				Alyx	No		No	No	No	No		3/9/2022				

Corrections

• If you need to make corrections to a report please call Product Complaint and Support (PCS) at 800-933-6925 or email PCS at mdcomplaintsupport@fresenius-kabi.com

• Provide the submission number, your full name, and changes that need to be made

Refer to Instructions for Use and Operator's Manual for a complete list of warnings and precautions associated with the use of this these products.

US Headquarters:
Fresenius Kabi
Three Corporate Drive
Lake Zurich, IL 60047

FRESENIUS KABI