

988

AR 226 - 3403

Site Manual for DuPont PFOA Screening

This site manual contains instructions and forms to support collecting, processing, and shipping clinical samples for the DuPont PFOA quarterly screening project.

	<u>Page</u>
Sample Collection Supplies	2
Sample Processing Procedures.....	3
<i>Sample Processing for the PFOA Assay</i>	3
Packing and Shipping Frozen Samples.....	5
PFOA Sample Collection Record	6
Sample Collection Supply Reorder Form	7
Shipping Notification Form	8

Advion BioSciences contact:

Mr. David Hardwick
Director of Laboratory Operations
Advion BioSciences, Inc.
15 Catherwood Road
Ithaca, NY 14850

Phone: [REDACTED]

Fax: [REDACTED]

email: [REDACTED]

Company Sanitized. Does not contain TSCA CBI

Sample Collection Supplies

Sample collection supplies, sufficient for 24 subjects, are provided for each PFOA screening session. Supplies are labeled with the company name, study identification, and the expected month and year of screening. Because PFOA can be present in very low levels on some of the supplies, all supplies are tested at Advion before shipment. To minimize the possibility of extraneous contamination, please use only the materials supplied and discard unused supplies after each screening session.

Supplies include:

1. Tubes

Tubes are provided for collecting samples for PFOA analysis. Blood from the patient is drawn into red-top Vacutainer® tubes. Processed samples are transferred into polypropylene tubes. Each tube has an area to apply a label.

2. Labels

Blue paper labels are to be applied to the red-top Vacutainer tubes.

White nylon barcode labels are to be applied to the 12 x 75 mm screw-cap polypropylene sample tubes and have an area to write the subject ID, collection time, and collection date.

3. Needles

Needles are included for drawing blood. Needles are pre-tested by lot to determine their acceptability for use in this project.

4. Needle Holders

Needle holders are provided for sample collection.

5. Transfer Pipettes

Polypropylene transfer pipettes are provided to transfer the processed serum into the screw-cap sample tubes. Transfer pipettes are pre-tested by lot to determine their acceptability for use in this project.

6. Plastic Bags

Large and small zip-lock bags are provided to protect tubes and Sample Collection Records from leakage during transport back to Advion.

7. Site Manual

This Site Manual is included with your Sample Collection Supplies. Make copies of the Sample Collection Record (page 6) as needed for each day that samples are drawn.

IMPORTANT:

When all subjects have been recruited and blood samples collected, discard all remaining supplies. New supplies will be shipped for the subsequent screening session.

Sample Processing Procedures

During each screening session, samples will be collected for PFOA analysis. Please use the procedure listed below for sample processing.

Sample Processing for the PFOA Assay

Equipment and Supplies Required

- 4-mL (red-top) glass Vacutainer® blood collection tubes (supplied)
 - 21-gauge needles (supplied)
 - Needle holders (supplied)
 - Polypropylene tubes (12 x 75 mm) with caps (supplied)
 - Centrifuge
 - Transfer pipettes (supplied)
 - -20 ± 10 °C freezer
 - Labels (supplied)
- 

Procedures

1. Draw blood into a 4-mL (red-top) glass Vacutainer® blood collection tube using the 21-gauge needles supplied. Label the Vacutainer® with the blue paper label provided.
2. Allow blood to clot for 15 minutes (or until thoroughly clotted) at room temperature.
3. Centrifuge the blood sample for 15 minutes at 3000 rpm.
4. Remove the serum using the transfer pipettes provided and transfer the serum into a 12 x 75 mm polypropylene tube. Cap the tube tightly.
5. Label the sample with the white nylon barcode label provided. Write the patient ID, date, and time on the label using a Sharpie® permanent marker. Do not use ballpoint pen.



Example of PFOA sample label

Company Sanitized. Does not contain TSCA CBI

(Continued) Sample Processing for the PFOA Assay

6. Enter the last five digits of the barcode that appears on the white nylon label on the PFOA Sample Collection Record (page 6). Enter the date and 24-hour clock time of sampling on the same page.
7. Freeze immediately at -20°C . Please hold samples at -20°C and ship all accumulated samples at the end of each visit. If additional shipments are required, please contact Advion in advance.
8. When ready, ship the sample set overnight on dry ice to Advion BioSciences. See Shipping Instructions for more details.

Company Sanitized. Does not contain TSCA CBI

Packing and Shipping Frozen Samples

Prior to shipping the first set of samples call the courier (FedEx) to set up an account, if this has not been done previously. This will facilitate scheduling pick-ups even though your account will not be billed for the transportation of the samples. Request information on local service schedules and the latest time of day to arrange for pick-up.

Important: Please hold samples at -20°C and ship all accumulated samples at the end of each screening session. If additional shipments are required, please contact Advion in advance.

Ship samples to Advion BioSciences via FedEx overnight delivery. Your supplies include shipping Airbills pre-addressed to Advion BioSciences. Please write in your address and shipping information.

Samples should be shipped on Monday, Tuesday, or Wednesday, only.

Package the frozen, processed samples as follows:

1. Put all samples in a zip-lock bag.
2. Place a copy of all applicable Sample Collection Records in a second large zip-lock bag.
3. Place the zip-lock bags containing the frozen samples and the Sample Collection Records in the insulated shipping container provided by Advion.
4. Pack the samples with at least 10 pounds of dry ice and replace the foam lid.
5. Seal the shipping box securely.
6. Complete the FedEx Airbill and place the "Dry Ice" sticker on the box. Fill in the amount of dry ice in kg (10 lbs = 4.5 kg).
7. Telephone your local FedEx service to arrange for pickup.
8. When the agent arrives, sign the Airbill and keep the sender's copy. Maintain your copy, as this begins the audit trail that documents the shipping process.
9. Complete the Shipping Notification Form and fax the form to Advion BioSciences.

Nationally observed holidays may cause shipment delivery delays. Contact Advion BioSciences for holiday pick-up and delivery schedules.

Company Sanitized. Does not contain TSCA CBI

PFOA Sample Collection Record

Study: PFOA Screening	Site No.: 	Date of Sampling: Day Month Year
---------------------------------	--	--

PFOA Sample Collection:

Subject Initials	24-HOUR CLOCK TIME (HH:MM)	BARCODE (enter last five digits)	COMMENTS)
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	
		4140042	

Sample Collection Supply Reorder Form

Please use this form to reorder sample collection kits from Advion BioSciences.

Instructions:

1. Complete the reorder form.
2. Fax to the attention of [REDACTED]
3. Orders may also be phoned in to [REDACTED]

Requested By: _____

Study #: PFOA Screening

Date Requested: _____

Investigator's Name: _____

Telephone Number: _____

Date Supplies Needed: _____

ALL INFORMATION ABOVE IS REQUIRED TO COMPLETE ORDER

Additional Supplies

Supplies	Quantity Needed
4-mL red-top Vacutainer® tubes	_____
21 Gauge Needles	_____
Needle Holders	_____
Transfer Pipettes	_____
Blue paper Vacutainer® labels	_____
Barcoded Sample Labels*	_____
FedEx Airbills	_____
Dry Ice Shipping Labels	_____
Shipping Containers	_____

*Please contact Advion to discuss details.

Please allow 5 to 7 days for delivery of kits and supplies.

Company Sanitized. Does not contain TSCA CBI

15 Catherwood Road, Ithaca, NY 14850

[REDACTED]

Shipping Notification Form

When shipping samples, please complete this form and return by fax to Advion BioSciences at 607-266-0749.

FAX TRANSMISSION COVER SHEET

TO: NAME: [REDACTED]
COMPANY: Advion BioSciences
PHONE: [REDACTED]
FAX: [REDACTED]

TOTAL PAGES TRANSMITTED INCLUDING COVER:

FROM:

Investigator's Name: _____
Site Number: _____
Location/Address: _____
Telephone Number: _____
Fax Number: _____
Compound or Project: PFOA Screening
Ship Date: _____
FedEx Tracking Number(s): _____
Number of Shipping Containers: _____
Number of Samples Shipped: _____
Contact at Shipping Site: _____
Email Address: _____

CONFIDENTIALITY NOTE: The information contained in the facsimile message is privileged and confidential information intended only for the use of the individual or entity named below. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copy of this telecopy is strictly prohibited. If you have received this telecopy in error, please immediately notify us by telephone and return the original message to us at the address above via the United States Postal Service. Thank you.

Company Sanitized. Does not contain TSCA CBI