

Clinical Research Coordinator SOPs: Stool kit assembly

Last updated: October 18, 13

This SOP outlines the purchasing of supplies and assembly of stool collection kits

Materials for ONE fecal collection kit:

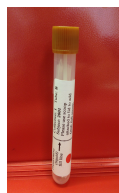
- A. (2) Sarstedt stool collection tube with scoop
- B. (1) Stool collection tube label w/ **red** dot indicating **ethanol**
- C. (1) Stool collection tube label w/ **blue** dot indicating **no preservative**
- D. (1) 5 mL of ethanol (EtOH)
- E. (1) Stool collection date/time label
- F. (1) Biohazard bag
- G. (1) Small (6"x6") easy fold *return* shipper
- H. (1) Large (14"x14") easy fold *outgoing* shipper
- I. (1) Printed **Dietary Recall And Activity Index**
- J. (1) Category 3 in exempted quantity label
- K. (1) Fed-Ex clinical pak
- L. (1) FedEx shipping label
- M. (1) Stool collection hat + collection cup/lid
- N. (1) Pair of gloves

- At the screening colonoscopy, subjects will be given 1 stool collection kit to be used for collection 1.
- At the baseline visit, subjects will be given 5 stool collection kits to be used for collections 2-6. Healthy controls who prefer to complete screening and baseline visits on the same day should be given 6 kits.
- At the baseline visit, subjects will be given a pre-completed **Stool Collection Calendar**.
- At each visit, subjects will be given a copy of the **Instructions Stool** document.
- At the *month 3 visit, subjects will be given 6 new collection kits to be used for collections 7-12.
- At the month 6 visit, subjects will be given 6 new collection kits to be used for collections 13-18.
- At the *month 9 visit, subjects will be given 6 new collection kits to be used for collections 19-24.

**Healthy controls will be mailed 6 stool collection kits by their research coordinator at month 3 and again at month 9.*

Instructions for Kit Assembly: *Coordinator should plan to assemble approx. 20 kits per week*

1. Fill 1 of the stool collection tubes (A) with 5mL of **ethanol** (D). Place 1 label with a **red** dot (B) on the tube.



2. Place 1 label with blue dot (C) on the other stool collection tube (A). This tube should contain no preservative.



3. Sample IDs with barcode labels will be provided to each site and should be adhered to the tubes.
4. Place stool collection date/time label (E) on front of biohazard bag (F).
5. Place both labeled stool collection tubes inside biohazard bag.



6. Assemble small easy fold return shipper (G) and large easy fold outgoing shipper (H).



(small= return shipper)



(large= outbound)

7. Fold **Dietary Recall And Activity Index** questionnaire (I) in half then in half again and place in front pocket of biohazard bag.
8. Place biohazard bag (with included tubes & questionnaire) on top of 1 FedEx preprinted return shipping label and close the return shipper (G).



9. Number the outside of the return Shippers (Ex: Collection #1-6 OR Collection #7-13) according to the label on the front of the biohazard bag.

10. Fill in *shippers address and "3" on category 3 in exempted quantity label (J) and place label on outside of Fed-Ex clinical pak (K).

* Write a large "3" on this label along with your name and office address with a black permanent marker.



11. Repeat steps 1-10 **six times** as subjects will need enough supplies to last 3 months or 6 collections.

12. Place the following supplies inside the large easy fold outgoing shipper (H) as follows:



















(bottom layer) ->



(upper layer)

- All six Fed-Ex clinical paks (with attached category 3 exempted quantity labels)
 - All 6 stool collection hats
 - All six return shippers (G) (which now include questionnaires, biohazard bags, and stool collection tubes) stacked side by side in 2 columns of 3 each.
 - All six sets of stool collection collection cup + lid. (note: Stack 3 collections cups inside each other and then rest 3 lids on top of the stack. Repeat for the remaining 3 cups/ lids)
 - All six pairs of gloves can be placed through the remaining empty space to keep contents from shifting.
13. Close outgoing shipper (H) and either mail to patient or give to patient at their next visit to take home with them. If mailing to subject, ***be sure to use shipping tape to seal the box completely.***

		Vendor	Catalog Number	Description	UOM	Price
A		Sarstedt	80.623	Faeces container w/ screw cap, sterile (500 tubes) www.sarstedt.com	BX	132.80
B,C		Staples	440728	Avery 5520 White WeatherProof Address Labels 1,500/Box www.staples.com	BX	54.49
D		Fisher	BP28184	Fisher Scientific: Molecular Biology Grade Ethanol www.fishersci.com	EA	191.32
E		Staples	479877	Staples White Inkjet/Laser Shipping Labels 1,000/Box www.Staples.com	BX	25.99
F		Fisher	0180003	Fisher Scientific: Biohazard Bag 6X9 (case of 1000= \$102) www.fishersci.com	CS	102.25
G		Uline Inc	S-16642	6 x 6 x 1 1/4" White Literature Mailers (return) www.uline.com	EA	0.38
H		Uline Inc	S-16944	14 x 14 x 5" White Literature Mailers (outbound) www.uline.com	EA	1.88
J		Labelmaster	L350R	Dangerous Goods in Excepted Quantities Label www.labelmaster.com	RL	30.10
K		FedEX	NA	Clinical Paks 1-800-Go-FedEx	-	FREE
L		FedEX	NA	Preprinted shipping labels 1-800-Go-FedEx	-	FREE
M		Fisher	02544208	Fisher Scientific: SPECIMEN COLLECTION SYST 60/CS www.fishersci.com	CS	115.13
		Vendor: Owens&Minor MFG: Becton Dickinson	*MFG#: 366643	Blood Vacutainer EDTA Tube (100 tubes) 10mL. www.catalog.bd.com	BX	7.21
		Vendor: Owens&Minor MFG: Becton Dickinson	*MFG#: 367988	SST Tube 8.5 PLBL RD/GR BX/100EA (\$17 per 100 tubes) www.catalog.bd.com	EA	0.16
		Qiagen	*76154	RNeasy TissueProtect Tubes 50 X 1.5 M www.qiagen.com	ST	233.70
		USA Scientific	*1420-9700	2mL Tube Bag /500EA www.usascientific.com	BG	47.50
		Fisher	*G33500	Fisher Scientific: Glycerol Certified ACS 500ML www.fishersci.com	EA	23.86

*supplies are for blood and/or biopsy collection and should not be included in stool collection kits.