TRAINING REQUIREMENTS FOR PHYSICIANS USING THE COOK® CHORIONIC VILLUS SAMPLING SET

Chorionic villus sampling (CVS) is a procedure requiring technical dexterity and a well-equipped team. We recommend that CVS be performed only by physicians with adequate training in the technique at well-equipped centers with an experienced support team.

To assess the adequacy of training, COOK will require a certification from each institution or physician ordering the device that each physician using the COOK CVS Set is adequately trained. This training shall be certified under one of the following categories.

1. The physician(s) who will use the COOK CVS Set shall have performed at least 25 CVS procedures previously using an approved CVS device.
2. If a physician has not performed at least 25 CVS procedures, he/she must use an approved CVS device to sample chorionic villus tissue from at least 25 patients under the direction of a physician experienced in the CVS technique before using the COOK CVS Set independently.
3. Investigators participating in the clinical trial of the COOK CVS Set are exempt from the above training requirements.

Each physician intending to use the COOK CVS Set must complete the COOK CVS Set Training Certification Form below and return it to COOK by one of the following methods: by mail (COOK Medical Incorporated, 1025 Acuff Road, Bloomington IN 47402-4195), fax (800.554.8335) or e-mail (orders@cookmedical.com).

COOK® CVS TRAINING CERTIFICATION FORM

Customer Acct. No. _____

In accordance with FDA approval of this device, COOK requires that each physician using the COOK CVS Set receive adequate training prior to use. Please certify that you meet one of the following three qualifying criteria by checking the appropriate box:

- ❑ I have performed at least 25 CVS procedures previously using an approved CVS device.
- ❑ I will use an approved CVS device to sample chorionic villus tissue from at least 25 patients under the direction of a physician experienced in the CVS technique before using the COOK CVS Set independently.
- ❑ I was an investigator in the clinical trial of the COOK CVS Set, and therefore I am exempt from the above training requirements.

Physician Name Last First

Institution

Address

City, State, Zip City State Zip

Phone Number - -

E-mail Address

Today's Date Month Day Year

✘ Physician Signature