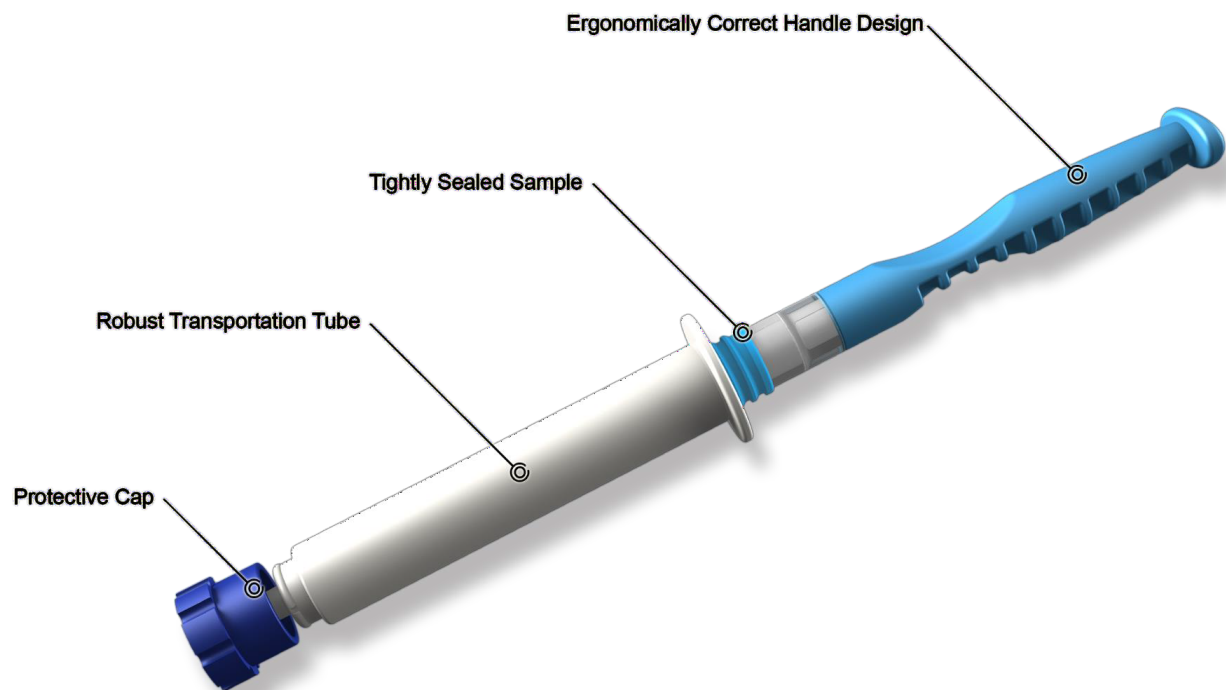


Fem•Collect™

Cervico-Vaginal Sample Collection System

Oasis Diagnostics® Catalog Number CVGL-301



Intended Use

The Fem•Collect™ Cervicovaginal Specimen Collection Device is intended for the safe and non-invasive collection of cells / DNA from the vaginal canal. The Fem•Collect™ is used for sample collection only and does not diagnose any disease.

Under appropriate conditions, sample collection may be performed by subjects in the privacy of their own homes.

For research use only in the United States. The performance characteristics of this device have not been evaluated by the FDA.

Introduction

A number of bodily fluids are available for the detection of biomarkers, drugs, and other analytes. These include blood, serum, cerebro-spinal fluid and others which are invasive for patients. There is a significant interest in the use of less invasive sample types including saliva, urine, tears, sweat, hair and specimens collected from the vagina.

Vaginal specimens collected using minimally invasive tools such as the Fem•Collect™ device may represent a means of self-collection, streamlining research protocols and at the same time presenting a more comfortable and private process for the subject.

Principles of the Device

The Fem•Collect™ Cervicovaginal Specimen Collection Device uses a very safe, highly absorbent pad to gently harvest cells / DNA from the vaginal canal to be used for research purposes.

Cells / DNA adhere to the absorbent pad component of the Fem•Collect™ in a short collection process lasting 5 minutes. Upon removal of the device from the cervicovaginal canal the sample pad is immediately protected with an opaque compression tube that preserves the integrity of the sample during transportation to a laboratory where downstream testing may be performed. A cap is placed on the Compression Tube of the device to seal the unit, which is then ready for transportation to a laboratory.

Materials Provided

1. Fem•Collect™ Saliva Collection Device.
2. Opaque Plastic Compression Tube.

Materials Required but not Provided

1. Timer
2. One Standard Collection Tubes (several options available).

Instructions for Use

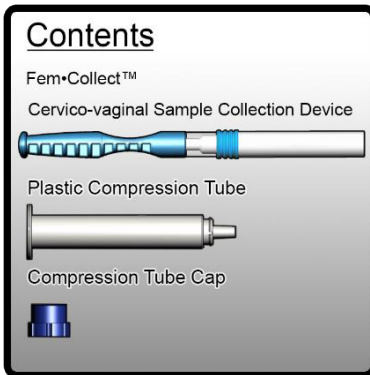
PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT A SPECIMEN USING THE FEM•COLLECT™ DEVICE. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE LESS THAN SATISFACTORY RESULTS.

Step-by-Step Instructions

General Note:

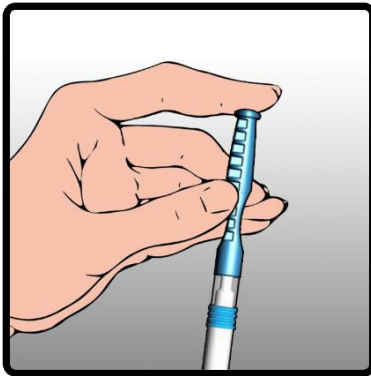
Allow at least 30 minutes after taking a shower or washing the vagina to collect specimens using the Fem•Collect™ Device.

1.



In preparation for cervicovaginal collection, place contents on a clean and dry surface.

2.



In a comfortable position, take the Fem•Collect™ Sample Collection Device in the dominant hand. Following the above picture hold the handle between the thumb and middle finger, with the index finger free above the base of the handle.

3.



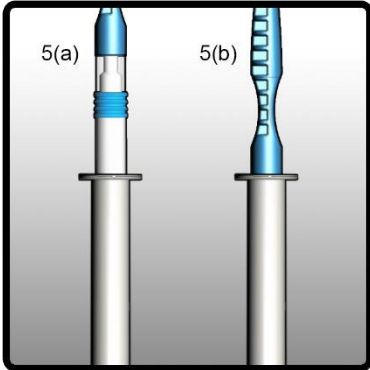
With the other hand hold open the skin folds of the large and small lips, to open the vaginal canal.

4.



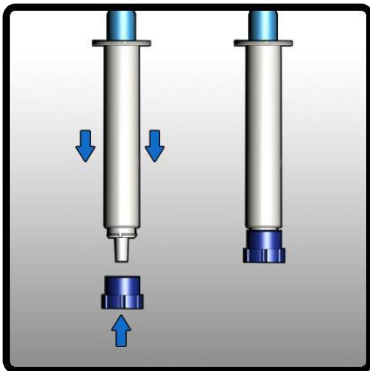
Align the absorbent pad with the vaginal canal. Gently press the Fem•Collect™ into the vaginal canal and twist the device in a circular motion for a period of 5 minutes. After collection is complete, gently remove the Fem•Collect™ from the vaginal canal. Do not touch the sample pad, and keep the pad clear of any other objects.

5.

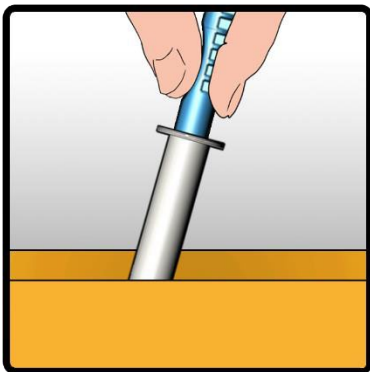


Immediately place the white absorbent pad end into the Plastic Compression Tube holding the Fem•Collect™ Sample Collection Device in an upright and vertical position as in 5(a) and firmly push the plunger down until the blue handle just enters the plastic Compression Tube as in 5(b).

6.



Attach the blue Compression Tube Cap provided to the base of the Plastic Compression Tube firmly.



Process immediately or place the complete Fem•Collect™ Device in a shipping / mailing envelope and mail the sample to the laboratory.

KIT COMPONENTEN

<u>Catalog Number</u>	<u>Item</u>
CVGL-301	Fem•Collect™ Universal Saliva Collection Device
MAIL-001	Mailing Envelope

OPTIONAL KIT COMPONENTS

<u>Catalog Number</u>	<u>Item</u>
MFGT-301	Standard 1.5 mL Microfuge Tubes
EPDF-201	Standard 2.0 mL Eppendorf Tubes
Note	The Fem•Collect™ may be used with either of the above collection tubes or other options for sample collection upon receipt at the laboratory.

Precautions and Notes

1. DO NOT REUSE OR SUBSTITUTE DEVICE COMPONENTS
2. Devices are for single use only. Used devices and samples should be treated as potentially infectious and disposed of in appropriate biohazardous waste containers.
3. Do not use devices beyond the expiration date printed on the pouch.
4. Prior to use, record patient / subject information on each of the Microfuge Collection Tubes.
5. The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
6. Fem•Collect™ Cervico-Vaginal Sample Collection Systems are provided in non-sterile form but may be provided in sterile form upon request.
7. Store at room temperature (15-30°C) until the expiration date written on the exterior of the pouch.
8. The Fem•Collect™ Cervico-Vaginal Sample Collection System does not diagnose any disease.

Ordering Information

Fem•Collect™ Collection Devices are sold in units of 15 collection devices per box and 10 boxes (150 devices) per shipping box (see Ordering Information below).

Fem•Collect™ Cervico-Vaginal Sample Collection System

Catalog Number: CVGL-701

Qty: 15/150

Optional Components

Tube Rack

Catalog Number TRAC-001

Qty: 1

1.5 mL Microfuge Tubes

Catalog Number MFGT-301

Qty: 100/500

2.0 mL Eppendorf Tubes

Catalog Number EPDF-401

Qty: 100/500

Final Note

Fem•Collect™ Devices are manufactured for Oasis Diagnostics® Corporation in the United States

This device is protected by US and EU Patents including US Patent Numbers
7,618,591
7,927,548
8,273,305 and others

Rev: 20160428

TECHNICAL SUPPORT

For Technical Support [available between 8.00 a.m. and 5.00 p.m. Pacific Standard Time] Monday through Friday, please call Oasis Diagnostics® Corporation at (360) 546-1563.

Technical support may also be obtained by sending details of any requirements by e-mail to info@4saliva.com.



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