

YONI Egg

Instruction for Use – English

Professional Use Only

Please read this user manual carefully before using the test

INTENDED USE

YONI Egg is an in vitro diagnostic kit intended to be used for the collection and preservation of Vaginal swab samples for quantitative analysis of vaginal microbiome using genetic methods. This kit has not been evaluated for home use. The patient-collected swab specimen application is limited to health care facilities where support/counseling is available to explain the procedures and precautions. This kit can be used to give information about vaginal microbiome composition but should not be the sole basis for diagnostic; confirmatory and additional testing are required.

SUMMARY

The vaginal microbiome composition has been analyzed for several reasons, among those reasons we have the potential influence of it in the recurrent vaginal infections and woman infertility. The female tract microbiota can vary greatly in composition depending on various aspects of each woman's life. There are several gynecological diseases that can be impacted by the vaginal microbiome. Among those the most prevalent are Vaginal Candidiasis and Bacterial Vaginosis. The fungal infections can have as a symptom the vaginal itching, burning, hyperemia and dyspareunia. Bacterial Vaginosis is commonly associated with greyish or greenish vaginal discharge, with or without bubbles and with fetid odor. The correlation with infertility of undefined cause is still being researched but there are consistent data in the literature that indicates a correlation between the host vaginal microbiome and the recurrent implantation failure diagnostic.

KIT COMPONENTS

Components	Quantity per kit
Individually wrapped, sterile vaginal swab	1
Tube containing Specimen Transport Medium	1 x 2 ml
Biological transport bag and box	1
Instructions for use	1

Note: The components of kits cannot be exchanged

STORAGE CONDITIONS AND SHELF LIFE

Store the YONI Egg kit before use at 5-25°C. The expiry date of the kit is printed on the label.

After vaginal sample collection, store the kit at 5 to 25°C and return to the address stated no later than 3 weeks after sampling.

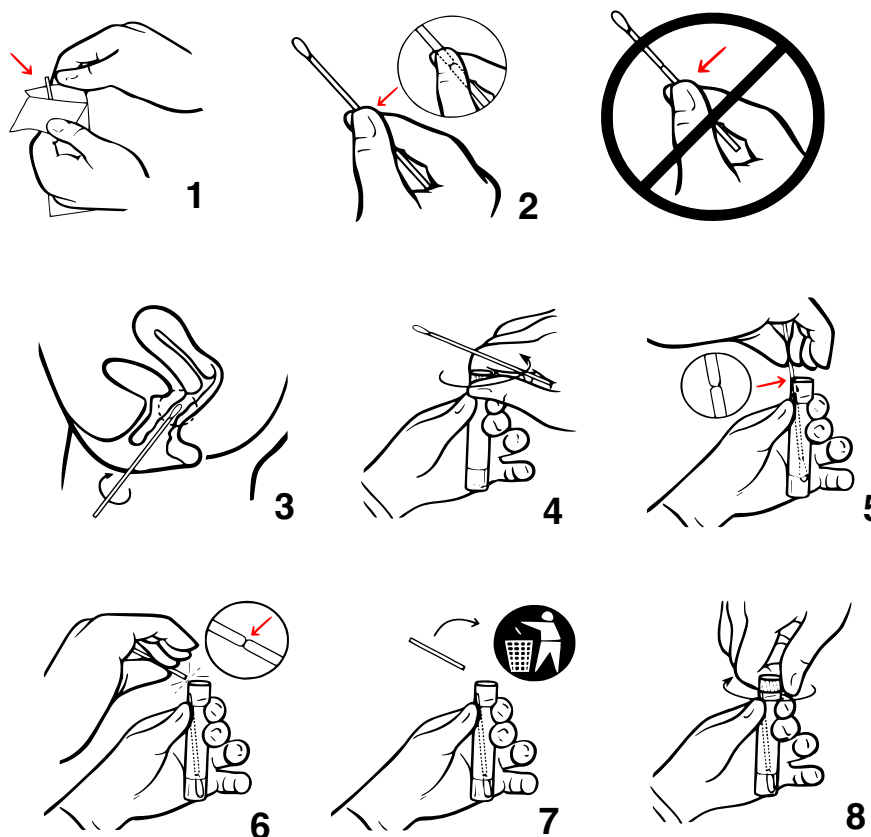
SPECIMEN COLLECTION

Note: For patient-collected vaginal swab specimen collection, ensure that patients read the *Patient Collection Instructions* before providing them with a collection kit.

Collect samples only 48 to 72 hours after sexual intercourse.

Instructions for vaginal swab specimen collection:

- Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new swab.
- Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
- Carefully insert the swab into the vagina about 5 cm past the introitus and gently rotate the swab for 5 to 10 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin. If you are using a speculum, avoid using a lubricant on the tip of the speculum, applying only to the exterior sides of the speculum.
- While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new YONI Egg kit.
- Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- Carefully break the swab shaft at the score line against the side of the tube.
- Immediately discard the top portion of the swab shaft.
- Tightly screw the cap onto the tube.

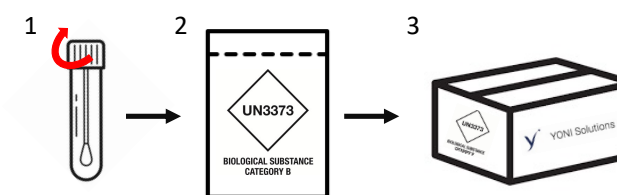


SPECIMEN TRANSPORT AND STORAGE

Vaginal swab specimens must be transported to the laboratory in the provided swab specimen transport medium and tube.

Note: Specimens must be shipped in accordance with applicable national and international regulations. Shipment at room temperature.

- Make sure that the cap is tightly screwed onto the specimen tube.
- Place the tube in the Biological Substance Category B Pouch and close it.
- Place the Pouch in the YONI Egg Box provided and close the security sealer.
- Send the box to YONI Solutions partner Lab (address on the label of the box)



LIMITATIONS

- The test procedure, precautions, and interpretation of results for this test must be followed strictly when testing.
- The kit must be used only with vaginal swab samples. This kit is not intended to be used with other sample types.
- For patient self-collect, vaginal swab specimen collection is limited to health care facilities, where support/counseling is available to explain the procedures and precautions. Ensure that patients read the *Patient Collection Instructions* before providing them with a collection kit.
- The test is for professional use only and not for home testing or near-patient testing.
- The test results of this kit are for reference only and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in conjunction with their symptoms, medical history, other laboratory tests and treatment responses.

WARNING AND PRECAUTIONS

- Use the provided swab only. Failure to use the provided swab may invalidate the test results.
- Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- Specimens may be infectious. Use Standard Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.

- If the contents of the transport tube are spilled at any time during the collection procedure, use a new YONI Egg Kit. Failure to use a new kit may invalidate the test results.
- Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
- Do not use the kit after its expiry date to collect specimens.
- Do not use the test kit if the swab pouch or collection tube is damaged or if the Specimen transport media has turbidity.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

DEVICE PERFORMANCES

1. Cross-reaction

Unrelated bacteria (*Bacillus subtilis*) were added to the sample containing *Lactobacillus crispatus* and did not affect adversely Assay.

2. Interfering Substances

The following interfering substances were tested in the assay: Vaginal Estrogen gel (5%), Lubricant (1%), Semen (5%), Vaginal Hydrating Cream (5%), Urine (5%), Blood (5%) and Isoconazol (5%). Only the semen interferes with the assay due to the semen microbiota. The other substances did not significantly interfere with the analysis.

3. Repeatability and reproducibility of analysis

A standard deviation error of 1.4% was observed for reproducibility and the error associated with measurement is $\pm 4\%$.

4. Limit of detection and Hook effect

Bacteria samples were submitted to dilution series in the preservation buffer to determine the limit of detection. The LOD was determined at 100 CFU. No hook effect linked with the collecting device was observed.

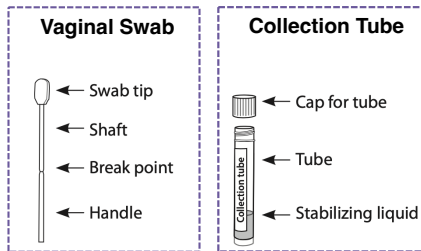
5. Clinical performance

A total of 38 vaginal swab sample were collected at the University Hospital Lausanne (Switzerland) and analyzed with reference method 16S sequencing. From the 38 samples, 20 had good concordance between 16S and YONI results. Which means that the main species detected by 16S was detected by YONI Device.

SYMBOLS

	Manufacturer		Expiry Date
	Do not reuse		Lot Number
	Authorized representative in EU		Caution
	Consult instructions for use		In vitro diagnostic medical device
	Temperature limitation		Catalog number
	Sufficient for <n> Test		CE-Marking
	Not for near patient testing (IVDR only)		Not for self-testing (IVDR only)

Kit Content



Warnings and Precautions

- Wash your hands with soap and water prior to starting the collection.
- Sit or stand in a comfortable position.
- Do NOT collect samples during your menstrual period.
- It is normal and not cause for concern if you notice a slight discharge or blood on the swab after collection.
- If you are pregnant, talk to your health care professional before using this collection kit.
- Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest.
- Do NOT spill the stabilizing liquid in the collection tube.
- Do NOT lay the swab tip down or touch any other surface once it is removed from the packaging.
- Small items may pose a choking hazard.

User Instruction

1 Open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new swab.

2 Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the break point. Do not hold the swab shaft below the break point.

3 Gently open the folds of skin at the vaginal opening and carefully insert the swab into the vagina 5 cm and gently rotate the swab for 20 seconds. Remove the swab carefully from the vagina, without touching the external skin.

4 While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube and do not touch the swab tip.

5 Immediately place the swab into the transport tube so that the score line is at the top of the tube. Carefully break the swab shaft at the score line against the side of the tube.

6 Tightly screw the cap onto the tube.

Discard packaging and swab handle in the garbage
Give the tube with the sample to your doctor and send the samples for analysis according to the transport instructions supplied by the manufacturer. Ship in accordance with the applicable regulations for transport of biological specimens.

REFERENCES

- Punzón-Jiménez et al. The impact of the female genital tract microbiome in women health and reproduction: a review. *J Assist Reprod Genet* 38, 2519–2541 (2021)
- Saraf et al. Vaginal microbiome: normalcy vs dysbiosis. *Arch Microbiol* 203, 3793–3802 (2021)
- Chen et al. Alterations of Vaginal Microbiota in Women With Infertility and Chlamydia trachomatis Infection. *Front Cell Infect Microbiol*. 2021
- Schoenmakers et al. The vaginal microbiome as a tool to predict IVF success. *Curr Opin Obstet Gynecol*. 2020 Jun;32(3):169-178

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EC REP

