

# MENOPAUSE

## MENOPAUSE STAGE INDICATOR FSH TEST

Instruction  
Manual

Diagnox

## CARE TO KNOW

The life of an adult female can broadly be classified into three phases: the reproductive phase, the menopausal transition, and postmenopause.

Menopause is a natural and inevitable part of aging for women. It is officially diagnosed after 12 consecutive months without a menstrual period, marking the end of reproductive fertility.

Transitioning to menopause is often a gradual and incremental process. Hormonal changes and associated symptoms, such as hot flashes, mood swings, or sleep disturbances, may begin even before noticeable changes in menstruation occur. This transition typically unfolds over several years, sometimes extending over a decade. It's important to remember that every woman experiences her menopause journey uniquely, progressing through its stages at her own pace. Experiencing fluctuations in symptom intensity is normal, with some periods being more challenging than others.

### AT WHAT AGE DOES ONE REACH MENOPAUSE?

Most women experience menopause between the ages of 40 and 58, with the average age being around 51. However, physical changes begin years before the final menstrual period, during a transition phase known as perimenopause. This phase can last from 4 to 8 years and typically starts with changes in the menstrual cycle length, culminating a year after the final period. Smoking and genetics are two factors that can influence the timing of natural menopause. Medical interventions, such as ovarian surgery or cancer treatment, can induce menopause early.

### COMMON MENOPAUSE SYMPTOMS:

Menopause can bring a variety of symptoms, varying in intensity for each individual. Commonly experienced symptoms include:

**Hot Flashes:** Sudden feelings of warmth, most intense over the face, neck, and chest, leading to sweating and redness.

**Night Sweats:** Intense sweating during sleep, similar to hot flashes, often disrupting sleep.

**Irregular Periods:** Changes in the menstrual cycle's length and flow, ending with the cessation of periods.

**Mood Swings:** Emotional fluctuations, such as irritability, anxiety, and depression.

**Vaginal Dryness:** Decreased moisture in the vaginal area, causing discomfort or pain during sexual activity.

**Sleep Problems:** Trouble falling or staying asleep, often related to night sweats.

**Decreased Libido:** A reduction in sexual desire or interest.

**Weight Gain:** Increased weight, especially around the abdomen, due to hormonal changes.

**Thinning Hair:** Hair becoming thinner and dryer.

**Dry Skin:** Reduced skin elasticity and moisture, causing dryness and itching.

**Memory Problems:** Difficulties with memory or concentration, often referred to as "brain fog."

**Joint Pain:** Increased discomfort or pain in joints, not linked to another medical condition.

## MENOPAUSE STAGES:

**Perimenopause:** This stage marks the years leading up to menopause, characterized by decreasing estrogen production by the ovaries. It ends at menopause, when the ovaries stop releasing eggs. Common symptoms include irregular periods, hot flashes, mood swings, brain fog, and fatigue. These signs can be mistaken for other medical conditions, sometimes delaying the realization that they are menopausal changes. Perimenopause can be further divided into two stages:

- **Early Perimenopause:** This initial phase features irregular menstrual cycles and milder symptoms like mood fluctuations and hot flashes. Fertility begins to decrease, but pregnancy is still possible. Hormone levels, especially FSH, may vary greatly.
- **Late perimenopause:** In these final years before menopause, menstrual irregularities become more pronounced, and symptoms like severe hot flashes and sleep disturbances may intensify due to a substantial decrease in estrogen. FSH levels significantly increase as estrogen levels drop.

**Menopause:** Defined as the point when a woman has not had a menstrual period for a year. The ovaries have ceased releasing eggs and producing most estrogen.

**Postmenopause:** The years following menopause are referred to as postmenopause. Most women often see a reduction in menopausal symptoms; however, the decrease in estrogen raises the risk of various health issues. FSH levels remain elevated in this stage.

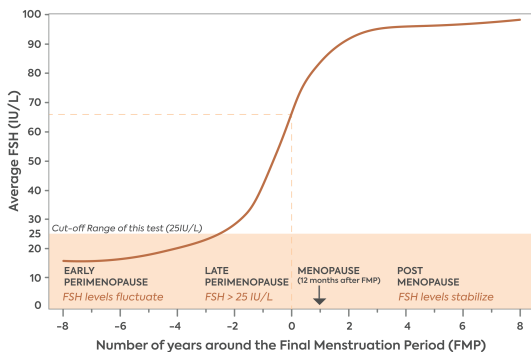
The STRAW (Stages of Reproductive Aging Workshop) staging system<sup>2</sup> is widely considered the gold standard for characterizing reproductive aging through menopause. Here is a simplified overview of the STRAW menopause stages:

Remember, menopause is not an illness, nor a phase you simply have to endure. With the right information, you can make informed choices that will usher you into an exciting new chapter in life, filled with joy and great health. Embracing this stage with knowledge and positivity can transform your experience of menopause.

	REPRODUCTIVE	EARLY PERIMENOPAUSE	LATE PERIMENOPAUSE	POSTMENOPAUSE
DURATION	Variable	Variable	1 - 3 years	Remaining lifespan
MENSTRUAL CYCLE	Regular	Variable length. Persistent $\geq 7$ -day difference in length of consecutive cycles	Cycle length $\geq 60$ -day	None
PHYSICAL SYMPTOMS	None	Mild	Pronounced	Vary person-to-person Health risks increase
FSH LEVELS	Normally low	Fluctuate throughout the menstrual cycle	$> 25$ mIU/mL	Stabilize to a high level about 2 years after menopause.

## FSH IN THE MENOPAUSAL TRANSITION

Fluctuating levels of Follicle Stimulating Hormone (FSH) throughout the menstrual cycle are normal, typically peaking during ovulation. However, consistently high levels of FSH can signify that a woman is nearing menopause or has entered postmenopause. This pattern of rising FSH levels throughout the menopausal transition has been documented in extensive population studies, such as the Study of Women's Health Across the Nation (SWAN) in the United States<sup>3</sup>.



Changes in mean FSH concentrations in relation to time before and after the Final Menstruation Period (FMP) – Adapted from Randolph JF et al.<sup>3</sup>

## WHY KNOWING YOUR MENOPAUSAL STAGE IS IMPORTANT?

Recognizing your menopausal stage is crucial for various reasons. According to a 2023 survey, 49% of women mistakenly attributed their menopausal symptoms to other causes such as stress, illness, or even pregnancy, and 63% did not consult healthcare professionals upon suspecting the onset of menopause<sup>1</sup>.

Current data reveals that due to a lack of education on menopausal transition and inadequate healthcare support, 65% of women feel unprepared for menopause. Among women aged 50 to 59, 84% reported significant disruption to their daily lives due to menopausal symptoms, with 12% finding these symptoms extremely limiting.

Despite widespread menopausal symptoms, many affected women do not seek medical help. For instance, among those experiencing severe symptoms, 75% remain untreated. Research involving over half a million women demonstrated that untreated vasomotor symptoms (such as hot flashes) lead to greater loss of work productivity compared to women without these symptoms.

Post-menopause, women face an increased risk of various health conditions, including osteoporosis (weakening of the bones), cardiovascular disease, type 2 diabetes, urogenital problems, vaginal atrophy (drying and thinning of vaginal tissues), and dementia. Proactive health management is essential to maintaining a good quality of life during this stage. This includes adopting a healthy diet, maintaining an active lifestyle with regular exercise, and having consistent consultations with healthcare providers to monitor and address any health concerns effectively.

## WARNINGS AND PRECAUTIONS

1. Keep this product out of reach of children.
2. Read this instruction manual carefully to understand the scope and limitations of this test. Use only as directed.
3. Use each test device only once.
4. Do not touch the test area of the strip.
5. Dispose of used tests after use.
6. Do not use the test kit beyond the expiration date (see the date on the box).
7. Do not use the test if the pouch is punctured or poorly sealed.
8. Always consult your doctor before starting any treatment or therapy based on the test result.

<sup>1</sup>MENOPAUSE HABITS & PRACTICES STUDY. CATALYX, 2023. 1,004 US WOMEN 40-55 Y.O.

<sup>2</sup>HARLOW, S. D., ET AL., (2012). EXECUTIVE SUMMARY OF THE STAGES OF REPRODUCTIVE AGING WORKSHOP + 10: 19(4), 387-395.

<sup>3</sup>RANDOLPH JF, ET AL., CHANGE IN FOLLICLE-STIMULATING HORMONE AND ESTRADIOL ACROSS THE MENOPAUSAL TRANSITION: EFFECT OF AGE AT THE FINAL MENSTRUAL PERIOD. J CLIN ENDOCRINOL METAB. 2011;96:746-754.

## BACKGROUND

Follicle Stimulating Hormone (FSH) is a hormone essential for managing egg development and ovarian function. It plays a key role in women's fertility, serving as an indicator of ovarian reserve and a criterion for assessing menopause stages.

During the reproductive years (premenopause), women typically experience regular menstrual cycles and maintain low FSH levels. As menopause approaches, these cycles become irregular and FSH levels rise. Often referred to as perimenopause, this transitory phase can span several years and typically includes physical symptoms like hot flashes, sleep disturbances, vaginal dryness, hair loss, anxiety, mood swings, memory issues, and fatigue. A woman is considered to have reached menopause after 12 consecutive months without a menstrual period, marking a natural transition to a stage where natural pregnancy is no longer possible. Postmenopause, FSH levels remain elevated and stabilize.

Nearly half of women may mistakenly attribute perimenopausal symptoms to other health conditions, which may lead to misdiagnosis and unnecessary anxiety<sup>1</sup>. Accurate FSH level testing can clarify a woman's stage in her menopausal journey, enabling proactive health management. This understanding is crucial for preventing misdiagnoses and reducing risks associated with menopause, such as osteoporosis, increased blood pressure and cholesterol levels, and a heightened risk of heart disease.

## INTENDED USE

The FSH Menopause Rapid (Midstream) Test is a rapid test for the qualitative detection (presence or absence) of Follicle-Stimulating Hormone (FSH) levels in urine to aid assessment of a woman's likely menopause stage.

## TEST PRINCIPLE:

The FSH Menopause Rapid (Midstream) Test is a rapid, lateral flow chromatographic immunoassay. It qualitatively detects human Follicle Stimulating Hormone (FSH) in urine with a sensitivity of 25 mIU/mL. This test uses a combination of antibodies, including a specific monoclonal anti-FSH antibody, to selectively identify increased FSH levels without interference from related hormones like hCG, hLH, and hTSH at their normal high levels. By measuring FSH and considering menopausal symptoms, the test helps to determine the likely stage of menopause.

To perform the test, immerse the test device in a urine sample, allowing the sample to enter the device's specimen well. Capillary action then draws the sample across a membrane, where it interacts with a colored conjugate pre-applied to the membrane.

If significant levels of FSH are present in the specimen, they bind to the colored conjugate, forming a visible line in the Test Line Region of the membrane. The intensity of this line should match or exceed that of the Control Line Region. A line in the Control Line Region will also appear, acting as a procedural check. This confirms that the correct volume of the specimen has been added and the test is functioning correctly due to proper membrane absorption.

## WHO SHOULD USE THIS TEST?

The Diagnox Menopause FSH Test is designed for women experiencing potential perimenopausal symptoms, such as changes in their menstrual cycle, and seeking to understand if they are entering menopause.

It is also suitable for women who may not have noticeable menopausal symptoms but are interested in assessing their menopausal status. As many women are not fully aware of the stages of menopause, this test serves as a tool to help them comprehend and navigate their menopausal journey more effectively.

## WHO SHOULD AVOID USING THIS TEST?

This test is not recommended for:

- Women who are pregnant or breastfeeding.
- Those using hormonal birth control or hormone replacement therapy.
- Individuals on medications, such as estrogen supplements, that affect FSH levels.
- Women diagnosed with Polycystic Ovary Syndrome (PCOS).
- Those who have undergone surgeries impacting their menstrual cycles.

Additionally, it is crucial to understand that this test should not be used as a method of birth control. It is specifically designed to assess menopausal status and does not provide information regarding fertility or contraception.

## ON WHAT DAYS SHOULD I USE THIS TEST?

To accurately determine your menopause stage, it is essential to conduct two tests, spaced one week apart. This approach accounts for within-cycle hormonal fluctuations during the perimenopausal stage.

### IF YOU ARE STILL HAVING MONTHLY PERIODS:

**First Test:** During the first week of your menstrual cycle (Days 2-7, with Day 1 being the first day of menstruation).

**Second Test:** One week after the first test.

### IF YOU ARE NO LONGER HAVING REGULAR PERIODS:

**First Test:** At any time during the month.

**Second Test:** One week after the first test.

#### **Important Notes:**

*Always use the first-morning urine for testing. It's most concentrated and ensures consistency. If testing during your period, avoid days of heavy bleeding.*

## DIRECTIONS FOR USE

### Before Performing the Test:

- Wash your hands thoroughly.
- Ensure your hands are dry before handling the test.

### Sample Collection:

- Collect the urine specimen in a clean, dry container or directly urinate on the test tip.
- Use the first morning urine because it contains the highest FSH concentration.

### Test Procedure:

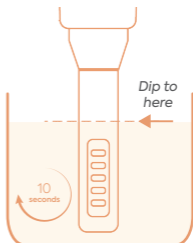
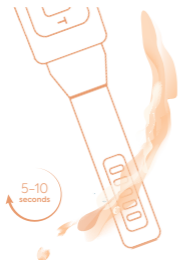
#### DIP

Remove the test device from the foil pouch. Take off the cap and either:

Place the exposed tip in the urine stream for 5-10 seconds, ensuring it's thoroughly wet.

or

Dip the tip into a container of urine for at least 10 seconds.



*Note: Avoid urinating on the Test and Control windows.*

#### WAIT FOR 5 MINUTES

After removing from the urine, replace the cap. Place the test on a flat surface with windows facing up, then start timing.



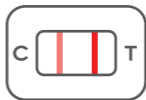
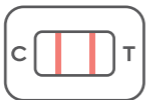
As the test begins to work, you may notice a light red flow moving across the Test and Control windows. Read the result at exactly 5 minutes. Do not interpret results after 5 minutes.

*Note: If no flow is observed, the specimen amount might be insufficient. Review the instructions and repeat with a new test device.*

## READING THE RESULTS

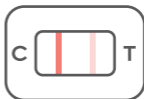
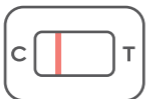
### POSITIVE

- Two lines are visible, and the line in the Test Line Region (T) is as dark as or darker than the line in the Control Line Region (C).
- This indicates the FSH level is higher than normal.
- Record the results and consult the next section for interpretation.



### NEGATIVE

- Either two lines are visible with the Test Line Region (T) line being lighter than the Control Line Region (C) line, or only one line is visible in the Control Line Region (C) with no line in the Test Line Region (T).
- This indicates that the FSH level is not elevated at this time.
- Record the results and refer to the next section for interpretation.



### INVALID

- If no line appears in the Control Line Region (C) after 5 minutes.
- The test is invalid and should be repeated using a new device.
- Common causes include an insufficient urine sample or incorrect test administration.
- Review the instructions before retesting.





## UNDERSTANDING THE RESULTS

The following table summarizes the test results.

1 <sup>ST</sup> TEST	2 <sup>ND</sup> TEST	MENSTRUAL CYCLE	PHYSICAL SYMPTOMS	INTERPRETATION	STAGE
Negative	Negative	Regular	None	Most likely not experiencing perimenopause.	<b>Premenopause</b>
Negative	Negative	Regular	Mild menopause symptoms	Likely not experiencing perimenopause in this cycle. If symptoms continue, consider retesting next month or explore other potential causes for the symptoms.	<b>Premenopause</b>
Positive	Negative	Irregular Periods (varying flow and cycle duration, but periods have not stopped or it's been less than 12 months since the last one)	Menopause symptoms	Likely in the early stages of perimenopause. Consider consulting with a healthcare provider for further guidance.	<b>Early Perimenopause</b>
or					
Negative	Positive				
Positive	Positive	Period ongoing or less than 12 months since last period, with significant irregularity (e.g., gaps over 60 days between periods)	Pronounced menopause symptoms	Likely in the late stages of perimenopause. Discuss with a healthcare provider for personalized management and support.	<b>Late Perimenopause</b>
Positive	Positive	No menstrual periods for twelve consecutive months	Intensified menopause symptoms	Menopause is likely complete. While the test can be repeated for confirmation, it's important to discuss with your physician about managing post-menopausal health and considering supportive therapies.	<b>Post Menopause</b>

## LIMITATIONS OF USE

1. Taking the pill (oral contraceptives), using patch contraceptives, hormone replacement therapy (HRT), and estrogen supplements may result in false negative readings. Similarly, ovarian and pituitary tumors can decrease FSH levels, potentially causing false negatives. Although the test is highly accurate in detecting FSH concentrations at or above its threshold, rare instances of false results can still occur.
2. This test is not intended for assessing fertility or pregnancy. It is designed specifically for FSH detection and should not inform contraception decisions.
3. While the device does not contain any viable infectious agents, all urine samples must be treated as potentially infectious. Ensure that any spills are thoroughly cleaned using an appropriate disinfectant, and dispose of the specimen and all potentially contaminated materials safely.
4. If menopause symptoms are present but the result is negative, consult a physician for further evaluation.
5. A tumor in the hypothalamus may result in low FSH levels, impacting the test result.
6. Clinical diagnosis should not be based solely on this test. It should be made by a physician after evaluating all clinical and laboratory findings.
7. This product is not for diagnosing, curing, mitigating, preventing, or treating diseases or conditions and is not a substitute for professional medical advice, diagnosis, or treatment.







## STORAGE AND STABILITY

### TEST

1. Store the test within 36°F to 86°F (2°C to 30°C) in the original sealed pouch until the expiration date.
2. Keep the test away from direct sunlight, heat, and moisture to ensure accuracy.
3. Do not freeze.

### SAMPLE

1. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
2. Although freshly collected urine is recommended for testing, urine specimens may be stored between 2–8 °C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.
3. If using a refrigerated sample, allow it to reach room temperature (15°–30°C) before testing.

	Do not reuse		Keep dry	REF	Catalog Number
IVD	For in vitro diagnostic use only		Keep away from sunlight	LOT	Batch Number
	See instruction for use		Store between 36°F - 86°F		Expiry Date

## ABOUT DIAGNOX



We believe that promoting and sharing knowledge is a form of care. With this mission, we make it easy for people to take charge of their own health.

Listen to your body and get to know yourself to own yourself.

Being the protagonist of your well-being is having information at the palm of your hand. With that in mind, we provide innovative health tests that provide accurate results along with simple-to-understand information and all the support needed for you to connect the dots and be aware of your health. After all, good decisions come from good information.

It is knowledge from the inside out that guides us to look after ourselves and others around us, raising awareness for better health for all.

### Diagnox

Care to Know. Know to Care.

## QUESTIONS?

For questions, please contact us at:

[contact@diagnoxhealth.com](mailto:contact@diagnoxhealth.com)

Diagnox LLC, Plano, TX 75024 - USA

[DIAGNOXHEALTH.COM](https://diagnoxhealth.com)

### **This test's analytical accuracy is 99%**

as compared to other urine membrane FSH tests.  
(N=250, 95% CI)



SCAN THIS QR CODE  
TO LEARN MORE  
ABOUT THE MULTI-CENTER  
CLINICAL VALIDATION DATA.