

Clearblue[®]

Menopause Stage Indicator

Helps her understand her
menopause journey



Healthcare Professional Brochure
Menopause



About Clearblue[®]

Clearblue[®] is the world's #1 selling brand in home pregnancy and fertility tests.^a Consumers trust the Clearblue[®] brand because it delivers the accurate information they want. Clearblue[®] product range is built on a strong foundation of peer-reviewed science and consumer understanding. Clearblue[®] is supported by over 35 years of expertise, quality, and innovation in consumer diagnostics.

If you are a healthcare professional and wish to contact a member of Clearblue[®] support team about any product in the Clearblue[®] range, please send an email to:
spdproductsupport@spdspark.com.

^a Based on international sales compiled using independent market research data.

Clearblue® Menopause Stage Indicator

Helps her understand her menopause journey^b



The average age of menopause is 51 years,¹ but perimenopause can last many years and symptoms can overlap with those of other health issues. A woman may not link her symptoms to menopause directly and might delay getting the help she needs. She can be left confused and wondering 'is this menopause or something else?'

Clearblue® Menopause Stage Indicator is the only at-home test that tracks her personal follicle stimulating hormone (FSH) levels and combines them with her age and cycle history in an easy-to-use app in order to indicate her likely menopause stage: premenopause, early perimenopause, late perimenopause, or postmenopause.^b

Clearblue® Menopause Stage Indicator is in line with the Stages of Reproductive Aging Workshop + 10 (STRAW+10) criteria,² which is a recognized framework for assessing female reproductive aging in research and clinical contexts.

The insight she gains from Clearblue® Menopause Stage Indicator is designed to enable a more productive and effective conversation between a woman and her healthcare professional, in order to help her get the support she needs, discuss symptom relief, and decide on next steps.



^b A confirmed menopause stage diagnosis can only be made by a healthcare professional after all clinical and laboratory findings have been evaluated.

Stages in the menopause journey

The menopausal transition

Menopause refers to a milestone day, which marks 12 months since a woman's last menstrual period. Tens of millions of women in the USA are approaching this day, but each woman's journey to menopause is unique and not always easy, meaning it can be difficult for her to fully understand the changes she is experiencing.

During the years leading to menopause (also called perimenopause), her menstrual cycles may become irregular, with more than 7 days difference in length between consecutive cycles or with cycles lasting longer than 60 days.² Perimenopause is often characterized by symptoms, such as fatigue and irritability,³ and it can be challenging to try and separate symptoms related to other health conditions from those associated with the transition to menopause. For instance, the prevalence of vasomotor symptoms such as hot flashes and night sweats, more commonly associated with the menopause, tend to be less common in younger women (≤ 45 years old),⁴ meaning that they are less likely to consider themselves in the menopausal transition and may delay seeking help from their healthcare professional.

Defining the menopause stage²

The STRAW+10 classification is one of the most recognized frameworks for defining stages of menopause.

Figure One: Schematic overview of menopause stages (based on STRAW+10 classification)²

		MENARCHE (FIRST PERIOD) ↓			MENOPAUSE ^a ↓			
Stage	REPRODUCTIVE			PERIMENOPAUSE		POSTMENOPAUSE		
	Early	Peak	Late	Early	Late	Early	Late	
Duration	Variable			Variable	1-3 years	2 years	3-6 years	Remaining lifespan
PRINCIPAL CRITERIA								
Menstrual cycle	Variable	Regular	Regular	Subtle changes in flow/length	Variable length persistent ≥ 7 -day difference in length of consecutive cycles	Cycle length ≥ 60 -day		
SUPPORTIVE CRITERIA								
<i>Hormone levels</i>								
FSH			Normal	Variable	\uparrow^b Variable	≥ 25 mIU/mL ^c	\uparrow^b Variable	Stabilizes
AMH			Low	Low	Low	Low	Low	Very low
Inhibin B			Low	Low	Low	Low	Low	Very low
DESCRIPTIVE CHARACTERISTICS								
Symptoms						Vasomotor symptoms likely	Vasomotor symptoms most likely	Increasing symptoms of urogenital atrophy

^a Menopause is defined as 12 months since last period.

^b \uparrow = elevated (blood draw on cycle days 2-5).

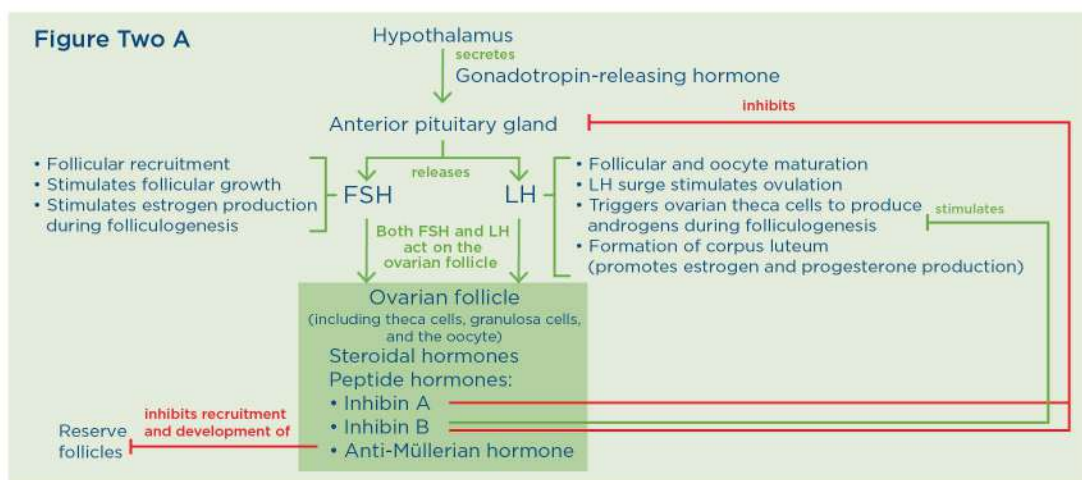
^c Approximate expected level based on assays using current pituitary standards.^{2,5-7}

Adapted from: Harlow SD, et al. Executive summary of the Stages of Reproductive Aging Workshop + 10: addressing the unfinished agenda of staging reproductive aging. Menopause. (2012) 19: 387-395.

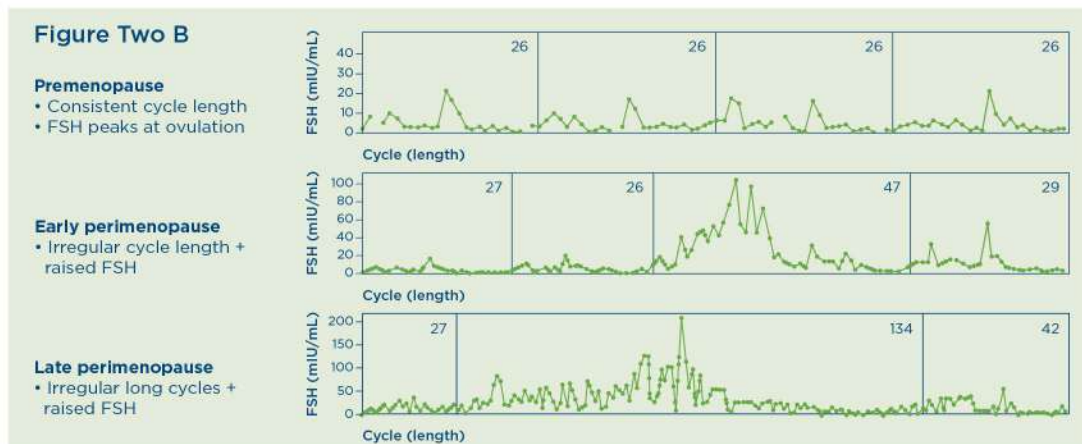
Reproductive endocrinology of the menopausal transition

FSH in the menopausal transition

While it is not unusual for FSH levels to vary across the menstrual cycle (with peaks normally reached during ovulation),⁸ regularly elevated FSH levels can be an indication that a woman is approaching menopause, or in postmenopause.^{2,8,9} The increase in FSH across the menopausal transition has been studied and reported in large population-based studies, including the 2004 Study of Women's Health Across the Nation (SWAN) conducted in the USA.⁸



Overview of reproductive endocrinology showing that the gonadotropin-releasing hormone triggers the anterior pituitary gland to produce FSH, which targets the ovaries in females. The ovary produces inhibin B, which is responsible for suppressing FSH levels.¹⁰



Schematic graph showing how FSH levels fluctuate throughout cycles, with higher levels being more common once perimenopause is reached.

The level of FSH typically correlates with the number of follicles remaining in a woman's ovaries.¹¹ As women age, they have fewer remaining follicles; therefore, their body produces less inhibin B, which is responsible for suppressing FSH levels.¹⁰ This means that the pituitary gland continues to produce increasing amounts of FSH, as the body tries harder to grow and mature the remaining follicles. As the number of follicles drops, the level of FSH increases,¹⁰ which is what makes FSH a useful tool in detecting the transition to menopause.

Why indication of menopause stage is important

Although stage classification criteria (such as STRAW+10)² are explored in research settings and used in clinical practice, they are not consistently used in medical practice. Often, healthcare professionals may initiate conversations about menopause based on the patient's age, menstrual cycle changes, and the presence of 'typical' menopause symptoms.

A 2023 survey found that 49% of women confuse the cause of their symptoms with other conditions such as stress, flu, or even pregnancy.¹² In addition, 63% of women haven't spoken to a healthcare professional when they think they could be on their menopause journey.¹²

Recent data have shown that owing to a lack of education on the menopausal transition and inadequate medical care, 65% of women do not feel fully prepared for the menopausal transition.¹³ According to an AARP survey of more than 400 women between 50 and 59 years, 84% said their symptoms interfered with their daily lives, with 12% reporting that their symptoms interfered "a great deal" or are debilitating.¹⁴

Even when menopause symptoms occur, nearly three out of four women with significant menopause symptoms seeking medical attention are left untreated.^{14,15} One study including more than 500,000 women in various stages of menopause found that women with untreated vasomotor symptoms (hot flashes) indirectly lost 57% more work productivity days than women without any vasomotor diagnosis.¹⁵

An at-home solution to indicate a woman's likely stage^b of menopause to facilitate her diagnosis and discussion

Clearblue® Menopause Stage Indicator uses serial FSH measurements and combines them with age and cycle information in a free-to-download app, to indicate her likely stage on the menopause journey.^b

Clearblue® Menopause Stage Indicator is in line with criteria outlined in STRAW+10.² Using the information she inputs and the FSH test results, this product is designed to indicate her likely menopause stage:^b premenopause, early perimenopause, late perimenopause, or postmenopause.

She can generate a personalized report detailing her stage, her personal information, FSH results, and up to 6 weeks of symptoms she may have logged (she can also log up to 19 common symptoms of menopause on a daily basis). She can choose to share this report with her healthcare professional to provide them with more insights about her personal situation and obtain any support needed.

Clearblue® Menopause Stage Indicator empowers women during their menopause journey allowing them to have more productive and effective conversations with their healthcare professional.

^b A confirmed menopause stage diagnosis can only be made by a healthcare professional after all clinical and laboratory findings have been evaluated.

Introducing Clearblue® Menopause Stage Indicator

Who is Clearblue® Menopause Stage Indicator for?

This product is for women who may be experiencing some symptoms of perimenopause or changes to their menstrual cycle and wondering 'is this menopause?'

It might also be used by a woman who has no outward signs or symptoms of approaching menopause, but simply wants to understand where (or if) she is on her menopause journey. Some women do not know about the different stages of the menopausal transition. This product can help them to understand their journey by giving personalized information that allows them to own their stage and even embrace it.

This product is not suitable for women who are pregnant, breastfeeding, or taking hormonal birth control, hormone replacement therapy, or medications affecting FSH, those who have PCOS, or after surgical procedures that affect their cycle. It is not for contraceptive use.

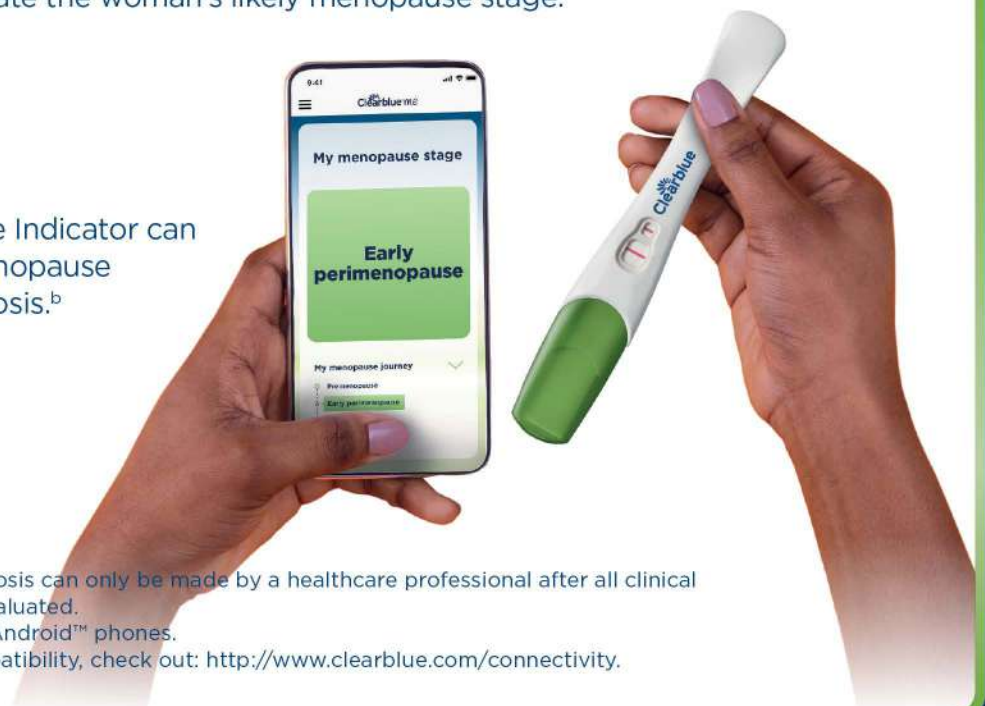
How does Clearblue® Menopause Stage Indicator work?

Each pack contains five easy-to-use urine FSH test sticks to be used alongside a free-to-download app available for both Apple (iOS) and Android devices.^c The app asks her to enter some basic information (including date of birth and cycle history in the last 12 months) and then guides her on how and when to test. She tests her urinary FSH level on alternate days, inputting her result into the app each time as positive or negative. The app contains useful images to guide her.

At the end of the testing regime, the algorithm in the app uses all the information entered to indicate the woman's likely menopause stage:

- **Premenopause**
- **Early perimenopause**
- **Late perimenopause**
- **Postmenopause**

Clearblue® Menopause Stage Indicator can give an indication of the menopause stage, not a definitive diagnosis.^b



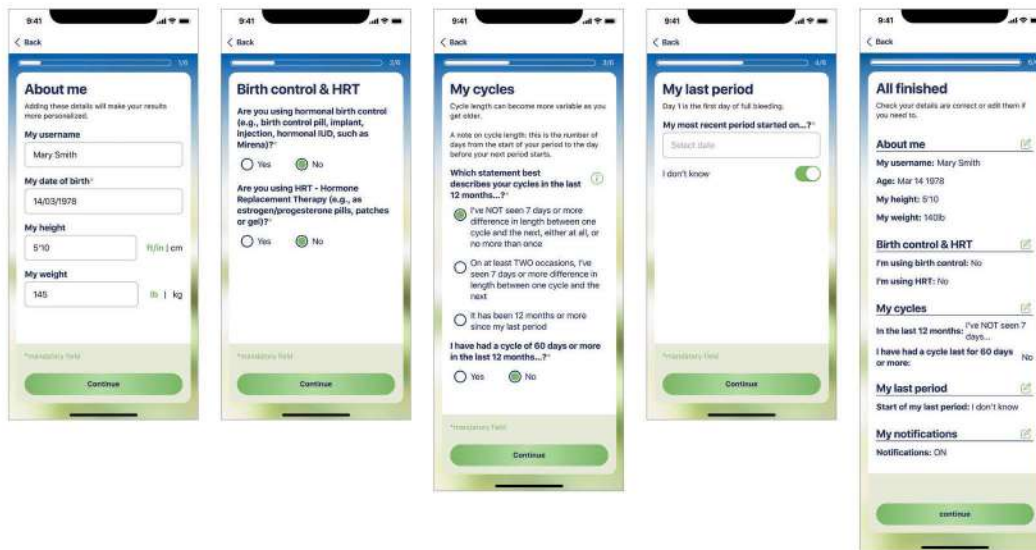
^b A confirmed menopause stage diagnosis can only be made by a healthcare professional after all clinical and laboratory findings have been evaluated.

^c Compatible with most iPhones® and Android™ phones.

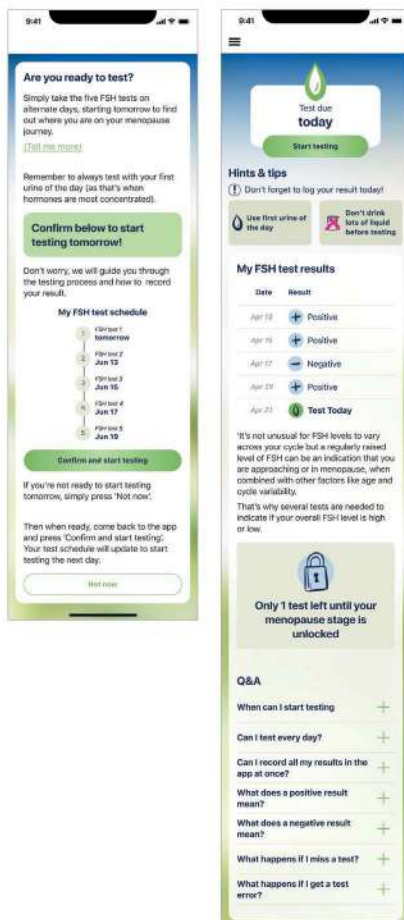
For more information on phone compatibility, check out: <http://www.clearblue.com/connectivity>.

A guide on the 'Menopause Stage - Clearblue® me' app

After downloading the app from meno.clearblue.com/app (or search the App Store or Google Play store), she simply creates an account as directed.



She can start testing from the day after account set-up and at any time in her cycle, with the app reminding her when to test.



She must use the free-to-download app to get her menopause stage result. Otherwise, she will only get her FSH test results

The 'Menopause Stage - Clearblue® me' app offers a range of features:

- **Smart algorithm** – uses her cycle information, FSH results, and age to indicate her likely menopause stage^b
- **Simple to use** – in-app step-by-step instructions
- **Easy testing routine** – a countdown timer indicates when to read the test result
- **Symptom tracking** – 19 symptoms can be logged and tracked
- **Cycle tracking** – periods and historical cycles can be logged and tracked
- **Educational content** – information on her likely stage and articles about the menopause journey in general
- **Personalized report** – an easy-to-read report can be generated and shared with her healthcare professional

^b A confirmed menopause stage diagnosis can only be made by a healthcare professional after all clinical and laboratory findings have been evaluated.

Clearblue® Menopause Stage Indicator FSH tests are:

- **Ergonomic** - a curved, long easy-grip handle
- **Easy to use** - a wide 18mm tip to help her sample and unique Floodguard™ technology to make it easy to test correctly
- **Easy to test** - an easy testing routine that consists of five tests on alternate days with step-by-step instructions and reminders on test days in the app
- **Easy to read** - a large easy-to-read result window
- **Accurate** - >99% accuracy when tested with positive FSH ($\geq 25\text{mIU/mL}$) and negative FSH urine samples by trained technicians in laboratory conditions
- **Better than single, one-off measurements** - by taking serial FSH tests on alternate days, normal cyclical fluctuations in FSH can be accounted for and a more accurate indication of her FSH levels can be determined. The tests that measure a one-time snapshot of FSH levels may be subject to normal cyclical fluctuations of FSH, potentially giving a positive result around the time of ovulation. These fluctuations in FSH are normal and not due to perimenopause

The test must be conducted with the first urine of the day and can be used by either holding the test stick in the urine stream for 5 seconds or dipping it in a collected urine sample for 20 seconds.



Results from the FSH test sticks must be read **within 8 minutes** of testing. Two lines indicate a positive result, no matter how faint or dark the lines are. One line indicates a negative result. A **control line must always be seen in the control window** to indicate the test has worked.



FSH test results should be recorded in the app after testing, by pressing either the positive or negative button, depending on the observed test result. She can input her result up until midnight on the day of testing.



What are the different stages identified by Clearblue® Menopause Stage Indicator?

After she has inputted her age and cycle history, and completed all five FSH tests, the smart algorithm will indicate her likely menopause stage:^b

Premenopause

Premenopausal women experience periods and are still considered fertile or in the reproductive phase of life.

Early perimenopause

A variable follicular phase is due to changing levels of FSH.

The woman experiences menopause symptoms, but her period has not stopped yet or it has been less than a year since the last period.

Late perimenopause

Menstrual cycles become more irregular in length and hormonal levels go through extreme changes. There is a space of >60 days between each period. Women have more cycles in which an egg is not released at all (anovulation) and FSH levels are elevated at this stage.

There is an increased likelihood of vasomotor symptoms during this stage (50-82% of women in the USA experience vasomotor symptoms).¹⁶

Postmenopause

After menopause, the next stage is postmenopause. Women may still experience some of the perimenopause symptoms, but often these will improve and resolve with time.



^b A confirmed menopause stage diagnosis can only be made by a healthcare professional after all clinical and laboratory findings have been evaluated.

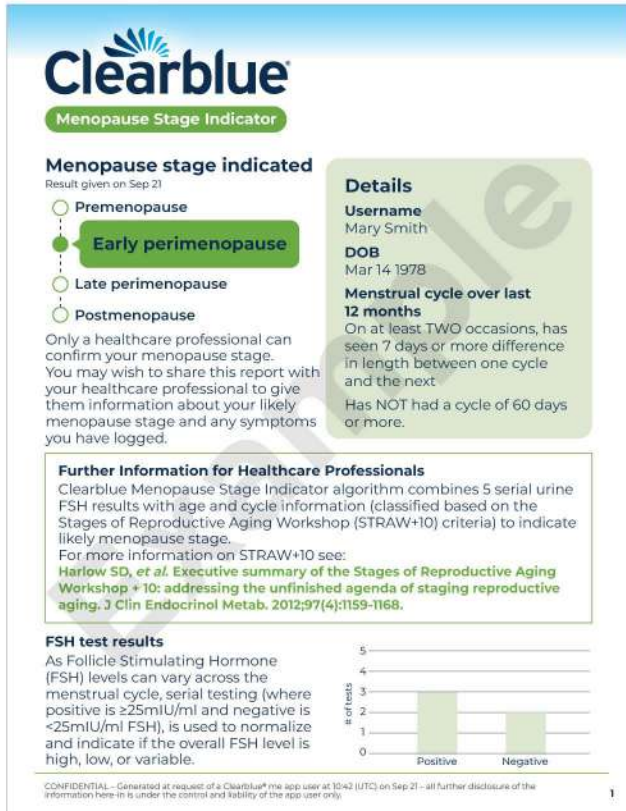
Symptom and cycle tracking

The app allows her to track the frequency and intensity of up to 19 symptoms as well as provide information about her cycle, such as duration and period flow.



A helpful report to facilitate communication with her healthcare professional

An easy-to-read personalized report can be generated and shared with her healthcare professional. The report includes her likely menopause stage, FSH test results, and up to 6 weeks of logged symptoms.



Advantages of Clearblue® Menopause Stage Indicator for her

- Unique smart algorithm in line with clinical criteria for assessment of reproductive aging
- Uses five FSH tests on alternate days to account for any potential mid-cycle FSH elevation, allowing her to test at any time in her cycle
- Personalized results based on the user's FSH levels, age, and cycle data
- Simple testing routine
- Allows comfortable at-home testing using urine instead of invasive blood draws
- Includes FSH tests featuring >99% accuracy at detecting FSH in laboratory conditions
- Enables tracking of symptoms and their intensity
- A personalized summary report can be generated, detailing her likely menopause stage and how it was determined, to share with her healthcare professional. It also shows up to 6 weeks of symptoms logged

Advantages of Clearblue® Menopause Stage Indicator for her healthcare professional

This product is not intended to replace the care provided by healthcare professionals, but rather to provide women with a tool to educate, engage, and empower them on their menopause journey. The information she gains from Clearblue® Menopause Stage Indicator can be used to facilitate a more positive and effective conversation between a woman and her healthcare professional. A study conducted by Egg Strategy on behalf of Clearblue® showed that healthcare professionals believe Clearblue® Menopause Stage Indicator can allow a meaningful and informed partnership with their patients:

“This educational tool empowers women to be more engaged in understanding and tracking what is going on with their bodies as they transition through menopause. In doing so, they can have a more meaningful and informed partnership with their doctor.”

Benefits for healthcare professionals:

- **Empowers patients with a personalized report** – allowing for more productive discussions during time-restricted consultations
- **Accountability** – creating engagement and allowing women to take control of their menopause journey
- **Scientifically supported** – classification of likely menopause stage is in line with the STRAW+10 classification criteria²
- **Symptom tracking** – symptom history can provide a foundation for discussions and potential next steps



Important considerations

- A confirmed menopause stage diagnosis should only be made by a healthcare professional after all clinical and laboratory findings have been evaluated
- The manufacturer's instructions regarding any medication should be read before conducting the test
- When testing, women should use the first urine of the day, when hormone levels are most concentrated
- Excessive fluid intake should be avoided prior to testing
- Women are advised to discuss their results with a healthcare professional

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Clearblue® Menopause Stage Indicator

Innovative – the first of its kind at-home test that tracks personal FSH levels and combines them with age and cycle data in an easy-to-use app

Easy to use – urine tests featuring an ergonomic design, wide tip, and a large result window, and an app with step-by-step instructions

Simple testing routine – five at-home urine FSH tests taken on alternate days

Personalized report – results can be compiled into a personalized report and shared with healthcare professionals



Follow the QR code to visit our website and learn more about Clearblue® Menopause Stage Indicator.

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For more information about Clearblue® Menopause Stage Indicator, please visit our websites:

www.clearblue.com

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