

DIRECTIONS AND IMPORTANT INFORMATION

Intended Use: HydraTrend™ Test Strips are intended for self-monitoring of urine pH and specific gravity for hydration status monitoring.

Test Information & Procedure

Why you should monitor your urine for hydration status

- Dehydration can be highly dangerous, whether it results from exertion, environmental factors or health status.
- If you wish to maintain a healthy state of hydration, HydraTrend™ Test Strips can provide feedback so that you can fine-tune your fluid intake.
- Monitoring of urine specific gravity is a valuable tool in optimizing athletic and physical performance.
- Active Environmental Solutions recommends that you maintain a regular testing and reporting routine with the advice of your healthcare provider.

When to talk to your healthcare provider

- If you experience overheating, excessive fatigue, or other symptoms of heat stress.
- If you have kidney or urinary tract pain.
- If you experience symptoms such as: loss of attention, confusion, poor coordination, or behavior changes.
- If you need information about how much and what kinds of liquids you should drink each day.

What you should do if test results are hard to understand

- Check the expiration date printed on the label. Outdated test strips may give incorrect results.
- Test again with a test strip from a fresh bottle. (Use a bottle with an expiration date that has not passed).
- Check the test strips using Confirm™ Control Solutions.
- If a test result seems unclear or uncertain, call Active Environmental Solutions Customer Service on +61 3 9464 2300.

How to handle and store HydraTrend™ Test Strips:

- Store in a dark, dry place at 10°C–26°C (50°F–80°F)
- Keep the bottle closed unless removing a test strip.
- Throw away unused test strips 60 days after the first time you opened the bottle. Throw away unused test strips after the expiration date has passed. Record the date the bottle was first opened in the space provided on the label.
- Do not place the test strips or bottles in direct sunlight.
- Do not put test strips in any other container. Do not combine test strips from more than one bottle in any container.
- Do not use the test strips after the expiration date has passed. Even if the test strips are in a sealed bottle, they will expire. **Expired test strips may give incorrect results.**
- Throw away used test strips. Test strips cannot be re-used.
- Do not use test strips that appear spotty or uneven in colour. Compare the colours of an unused test strip to the test strip icon on the bottle label. If the colour is different, do not use the test strip.

IMPORTANT: Keep the unused test strips away from moisture, humidity, light, or heat. These conditions may reduce the effectiveness of the test strip. Discolouration of a test pad may affect that the test strip will give an incorrect result. If the test strips give results that do not match the chart, or give an unusual result, test with Confirm™ Low and Confirm™ High. If the test strips continue to give unusual results, throw away the bottle and test strips. Then test your urine again using a fresh test strip from a new bottle.

How to collect a urine sample

You may collect a urine sample in one of two ways. One way is to collect urine in a specimen sample container or cup. If the container will be reused, rinse it well three or four times with water and dry completely. **Do not use soap.** Even tiny amounts of soap or detergent can cause incorrect results. Test the urine sample immediately. Do not store a urine sample because pH and specific gravity of a sample can change over time.

The second way to collect a urine sample is to pass the test strip directly through the urine stream while urinating.

IMPORTANT: Please read all test directions before using!

What you need and how to perform the test

- Timer or watch that counts seconds
 - Clean, dry, container or cup to collect sample
 - Test strip
 - Colour charts (on bottle label)
- Check the expiration date printed on the bottle label. Do not use the test strips if the expiration date has passed. Outdated test strips may give incorrect results.
 - Decide which of the two ways will be used to collect the sample: either in the sample collection cup or by passing the test strip through a urine stream. If you choose to use the urine stream method, skip to step 4.
 - Collect the urine sample in a clean, dry sample container.
 - Remove a test strip from the bottle. Close the bottle immediately to preserve the rest of the test strips.
 - Dip the test pads of the test strip in the urine sample completely for 1 to 2 seconds, then remove. Or you may pass the test pads on the strip through the urine stream for 1 to 2 seconds. Do not leave the test strip in contact with the urine more than 1 to 2 seconds.
 - Do not leave the test strip soaking in the sample container. As you remove the test strip from the sample container gently draw the edge of the test strip across the edge of the sample container to remove excess liquid. Do not draw the side with test pads across the sample container edge.
 - Begin timing right away. Allow the colours to develop for 30 seconds before reading. Read the test strip between 30 and 60 seconds after starting the test.
 - Compare the developed pH test pad to the pH colour chart on the bottle label to get a result. The pH test pad is at the end of the strip. (See picture below.)
 - Compare the developed specific gravity test pad to the specific gravity colour chart on the bottle label to get a result. The specific gravity test pad is closer to the handle of the strip. (See picture below.)
 - Record test results.

11. Throw away the used test strip. To reuse the sample container, wash it thoroughly with water and dry it completely before doing another test.

12. **Do not use soap.** The urine sample collection container must not have any soap or other residue. Contact with soap or detergent may cause incorrect test results. **Do not use the sample container for food or drinks.**



Quality Control There are two (2) levels of quality control solutions from Active Environmental Solutions. Confirm™ Low and Confirm™ High, which are included in the HydraTrend™ package. Confirm™ Low and Confirm™ High Control Solutions are made of salts, buffers, and detergents dissolved in water. Control solutions are used in place of a urine sample to check the system, which includes the accuracy of the test strip and how well you have performed the test and read the results. When you first begin to use the HydraTrend™ Test Strips, perform the test with the Confirm™ Low and Confirm™ High controls. Practise with the Confirm™ Low and Confirm™ High controls until you get valid results before testing your own sample. If you get unusual or unclear results with a urine sample, always test with the Confirm™ Low and Confirm™ High controls. When you begin to use a new bottle of test strips always test with the Confirm™ Controls to check performance.

TECHNICAL INFORMATION

Summary Test Principle

Specific Gravity: This test is based on a colour change of dyes in response to specific gravity. (Specific gravity is the density of dissolved substances in a liquid.) The developed colours range from blue in dilute urines, to blue-green, to yellow-green in urines of high concentration.

pH: This test is based on the response of a combination of two dyes that change colour with pH. The dyes produce easily distinguished colours from pH 5.0 through pH 8.0. The colours range from orange (5.0) to yellow, green-yellow, blue-green, and blue (8.0).

Results: After you dip a HydraTrend™ Test Strip in urine, or use Confirm™ Control Solutions, compare the developed test pads to the colour chart on the bottle label. The result of a test is the number under the colour on the colour chart that is closest to the colour of the developed test pad. If the colour of the developed test pad is between two colour blocks, the best result is halfway between the two numbers represented by the colour blocks. For example, an orange colour block represents pH 5.0, and a yellow colour block represents pH 6.0. If the developed test pad is yellow-orange, the pH is 5.5.

Limitations of the Procedure

- HydraTrend™ Test Strips are for diagnostic use outside the body only.** This test is not a treatment. This test is a means of keeping track of the urine specific gravity as a means of tracking hydration status.
- Certain medications and nutritional supplements may affect urine colour. These include Pyridium™, Azo Gantrisin™, Azo Gantano™, and riboflavin (a B vitamin).

These medications can result in an intense yellow or orange urine colour that may make the test results hard to interpret.

- Diet may affect urine colour. Particularly diets high in carotenoids. Carotenoids are found in leafy green vegetables and carrots.
- If you have colour blindness or impaired vision, ask for help reading the test strips.
- As with any laboratory test, medical decisions must not be based on a single test result.
- Do not change your medication without talking to your healthcare provider.
- Track trends in test results by recording results.
- Read the test results between 30 and 60 seconds after wetting the test strip. Compare the developed test pads to the colour charts on the bottle label.
- Specific gravity may be affected by a urine pH of 7.0 or higher. Therefore, if the pH is 7.0 or higher, the specific gravity result will appear low. **Add one colour block to the specific gravity test result when the pH is 7.0 or higher.**
- There are disease states in which the specific gravity does not reflect the state of hydration. Individuals with diabetes insipidus, renal failure, and certain hormonal disturbances may be dehydrated, but still have a low specific gravity. In these conditions, urine specific gravity is **not** a valid way to monitor hydration status. (1, 2)
- Urine specific gravity measurements indicate hydration status **only** for the time period since the last voiding of urine. Therefore, tracking specific gravity throughout the day can give a better indication of overall hydration status than individual or infrequent measurements.
- Being overhydrated can cause a dilution of sodium in the blood. This is called hyponatremia. Hyponatremia can be just as serious as dehydration. Individuals who have hyponatremia may continually have low urine specific gravity (less than or equal to 1.005).

Expected Values

Specific Gravity: An average adult on a normal diet, including normal fluid intake, can produce urine with specific gravity between 1.005 and 1.035 (1). Urine specific gravity in healthy people varies depending on fluid intake, diet, activity, and environmental factors. Drinking more water will generally prevent or alleviate symptoms of dehydration and heat stress. Dehydration can result in a high urine specific gravity. Therefore, it is prudent to maintain a specific gravity of less than 1.010 (2). Specific gravity measurements taken before exercise are an indication of starting hydration status and indicate the hydration status for the previous few hours. *It is prudent to take multiple measurements during periods of intense exertion or heat stress.*

Specific Gravity	State of Hydration (2)
Less than 1.010	Very Good
1.010 to 1.015	Good
1.015 to 1.020	Fair
Greater than 1.020	Poor

pH: Urine pH in healthy people can range from 4.6 to 8.0 (1). However, urine pH in healthy people is usually between 5.5 and 7.0. Urine pH can vary depending on diet, whether a person is awake or asleep, and when a person last ate. High-protein diets are associated with acid urine, while vegetarian diets produce more alkaline urine (3). Urine pH is not directly relevant to hydration status. However, if urine is alkaline, it is necessary to adjust for the effect of pH on the specific gravity test. See "Limitations of the Procedure" above.

pH	Meaning (3)
Less than 7.0	Acid
7.0	Neutral
Greater than 7.0	Alkaline

Performance Characteristics

Specific Gravity: This test determines urine specific gravity between 1.000 and 1.030. In a study performed for Active Environmental Solutions, untrained participants tested their own urine samples. Professional medical technicians tested those same samples. 76.7% of participant specific gravity results agreed with professional results.

pH: This test determines urine pH between 5.0 and 8.0. In a study performed for Active Environmental Solutions, untrained participants tested their own urine samples. Professional medical technicians tested those same samples. 90.3% of participant pH results agreed with professional results.

Availability

HydraTrend™ Test Strips are available in 50-test strip bottles included in the HydraTrend™ package.

Contact Information

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Works Cited

- (1) *Clinical Diagnosis and Management by Laboratory Methods*, John Henry, M.D., 1996
- (2) Dr. Stephen W. Leslie, M.D., F.A. C.S., personal communication (March 2004)
- (3) *Modern Urine Chemistry*, edited by Helen M. Free, M.A., published by Bayer Corporation, 1996

Additional Reading:

- *The Team Physician's Handbook, 2nd Edition*, edited by Morris B. Mellion, M. D., W. Michael Walsh, M.D., Guy L. Shelton, M.A., PT, ATC, Hanley & Belfus, Inc., Philadelphia, 1997
- *How to Train for and Run Your Best Marathon*, Gordon Bakoulis Bloch, Simon & Schuster, New York, 1993
- *Exercise and Fluid Replacement, from Medicine & Science in Sports & Exercise (MSSE, 28:1, 1996, pp i-vii)*
- *Water: The Beverage for Life, by the American Dietetic Association, Chicago, IL., 2002*

HydraTrend™ Confirm™ Low and Confirm™ High Control Solutions

DIRECTIONS AND IMPORTANT INFORMATION

Intended Use: HydraTrend™ Confirm™ Low and Confirm™ High Control Solutions are intended for use with HydraTrend™ Test Strips only. HydraTrend™ Confirm™ Low and Confirm™ High Control Solutions are used to check how well the HydraTrend™ Test Strips are performing.

Principle: Confirm™ Low and Confirm™ High Control Solutions are liquids with known pH and specific gravity values. Confirm™ Low and Confirm™ High Control Solutions contain a buffer that contain a buffer to keep the pH at the known value. They also contain salts to give known levels of specific gravity. This provides known responses for HydraTrend™ Confirm™ Low and Confirm™ High Control Solutions do not contain any biological or hazardous material. HydraTrend™ Confirm™ Low and Confirm™ High Control Solutions are designed to give values at or near extremes of the test range.

Test Information & Procedure

How to handle and store Confirm™ Low and Confirm™ High Control Solutions

- store in a dark, dry place at 10°C–26°C (50°F–80°F)
- keep bottles closed unless in use
- throw away unused control solutions after the expiration date of the bottle has passed
- do not place bottles in direct sunlight
- do not put control solutions in any other container
- do not combine control solutions from more than one bottle in any container
- do not use the control solutions after the expiration has passed. Even if the bottle has never been opened, the solutions will expire. **Expired control solutions may give incorrect results.**
- do not remove the dropper tip from the bottles of Confirm™ Control Solutions
- do not dip the test strips into the bottles of Confirm™ Control Solutions

IMPORTANT: Keep unused Confirm™ Low and Confirm™ High Control Solutions away from heat. Heat may reduce the effectiveness of Confirm™ Low and Confirm™ High Control Solutions. If test strips give results that do not match the chart or give an unusual result, throw away the bottle and test strips. Then test again using a fresh test strip from a new bottle.

Quality Control Confirm™ Low and Confirm™ High Control Solutions are used in place of urine sample to check the test system which includes the accuracy of the test strips and how well you perform the test and read the results. When you first begin to use HydraTrend™ Test Strips, perform the test with Confirm™ Low and Confirm™ High Control Solutions. Practice until you get valid results with a urine sample. If you get unclear or unusual results with a urine sample, check test strips from the same bottle with Confirm™ Low and Confirm™ High Control Solutions. When you open a new bottle of test strips, test with Confirm™ Low and Confirm™ High Control Solutions to check the test strips.

IMPORTANT: please read all test directions before using!

What you need and how to perform the test:

- Timer or watch that counts seconds
 - Two (2) test strips, one for each Confirm™ Control Solution
 - Colour charts (on test strip bottle label)
 - Confirm™ Low and Confirm™ High Control Solutions
1. Check the expiration date printed on the test strip bottle and Confirm™ Low and Confirm™ High bottle labels. Do not use strips or solutions if the expiration dates have passed. **Expired strips or solutions may give incorrect results.**
 2. Remove two test strips from test strip bottle. Close the test strip bottle immediately to preserve the rest of the test strips.
 3. Remove the cap from Confirm™ Low. Squeeze only one drop of solution onto each test pad on one test strip. Do not allow the tip of the squeeze bottle to touch the test pads. Do not allow any liquid that has touched the test strip to flow back into the dropper tip of the bottle. To remove any excess Confirm™ Low Control Solution from the test pads, gently touch only the edge of the test strip to a clean, absorbent material such as a tissue. Replace the cap immediately.
 4. Remove the cap from Confirm™ High Control Solution. Repeat step 3 above with Confirm™ High and the second test strip.
 5. Begin timing right away. Allow colour to develop for 30 seconds before reading.
 6. Read the test strips between 30 and 60 seconds after starting the tests.
 7. Compare the developed pH test pad on both strips to the pH colour chart on the bottle label to get results. The pH test pad is at the end of the strip (see picture below).
 8. Compare developed specific gravity test pads on both test strips to the specific gravity colour chart on the bottle label to get results. The specific gravity test pad is close to the handle of the strip (see picture below).
 9. Throw away the used test strips.



Results: Get results with HydraTrend™ Test Strips by comparing the developed test pads to the colour charts on the bottle label. The result of a test is the number under the colour block on the colour chart that is close to the colour of the developed test pad. If the colour of the developed test pad is between two colour blocks, the best result is halfway between the two numbers represented by the colour blocks. For example, an orange colour block represents pH 5.0, and a yellow colour block represents pH 6.0. If the developed test pad is yellow-orange, the pH is 5.5

Interpreting Confirm™ Low and Confirm™ High Test Results

- There is a range of expected values for each level of Confirm™ Control Solutions (see the table below). The result of the test should be within that range of values. Results may vary, but all results should be within the given range.
- For results that are out of range or difficult to interpret, call Active Environmental Solutions on +61 3 9464 2300 for help before testing urine samples.

Acceptable ranges for Confirm™ Control Solutions

	Confirm™ Low	Confirm™ High
pH	5.0-6.5	7.0-8.0
Specific Gravity	1.000-1.010	1.014-1.025

Limitations of Procedures

- If you have colour blindness or impaired vision, ask for help in reading the test strips.
- Confirm™ Low and Confirm™ High are for diagnostic use outside the body only. This process is not a treatment; it is a means of keeping track of the effectiveness of HydraTrend™ test strips.
- Confirm™ Low and Confirm™ High Control Solutions are intended for use with HydraTrend™ Test Strips only. The Confirm™ Low and Confirm™ High Control may give incorrect results when used with any other product.
- Read test results between 30 and 60 seconds after wetting the test strips. Compare the developed test pads to the colour charts printed on the bottle label.

Availability:

Confirm™ Low and Confirm™ High Control Solutions in 2.5ml bottles are included in the HydraTrend™ package. One 2.5ml bottle provides enough solution for approximately 25 tests.

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