Contour next
Blood Glucose Test Strips

For use with CONTOUR®NEXT meters

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Intended Use: The CONTOUR NEXT test strips are intended for use with the CONTOUR NEXT family of blood glucose meters for self-testing by persons with diabetes and for near-patient testing by health care professionals to quantitatively measure glucose in venous blood and fresh capillary whole blood drawn from the fingertips. Check your meter user guide for alternative site testing from the palm. Check your meter user guide for neonatal and arterial use.

Material Provided: Blood glucose test strips.

Materials required but not provided: Compatible blood glucose meter, lancets, and a lancing device.

Storage and Handling:

- Store the strips at temperatures between 0ºC and 30ºC.
- **Store the test strips in their original bottle only. Always close the lid immediately and tightly after removing a test strip.**

CAUTION: Do not use the test strips after the expiry date. The expiry date is printed on the test strip carton and bottle label.

- If the meter and/or test strips are moved from one temperature to another, allow 20 minutes for them to adjust to the new temperature before performing a blood glucose test. The operating temperature range of the test strip is 5°C to 45°C, 10% to 93% relative humidity (RH). Your user guide will identify the appropriate operating temperature range for the meter you are using.
- Ensure that the test strip bottle has not been previously opened. Examine the product for missing, damaged, or broken parts. Contact Customer Service at 1-800-289-312 for replacement parts and assistance.

The test strips are for single use only. **Do not reuse test strips.**

Number of test strips included.

Test Procedure: Before testing, see your meter user guide and additional instructions included in the meter carton for details on test strip handling, testing, measurement range and limitations. Your user guide will identify the appropriate operating conditions for the meter you are using.

Test Results: See your meter user guide for details on test results and clinical performance data related to your compatible meter. Your meter has been preset to display results in mmol/L (millimoles of glucose per liter) or mg/dL (milligrams of glucose per deciliter). Results in mmol/L will **always** have a decimal point (e.g., 5.3 mmol/L); results in mg/dL will **never** have a decimal point (e.g., 96 mg/dL). If your test results are not displayed correctly in mmol/L or mg/dL, contact Customer Service at 1-800-289-312.

Health Care Professionals: See your meter user guide for instructions specific to health care professionals.

Target Ranges: See your meter user guide for target ranges.

Questionable or Inconsistent Results: See the meter user guide for problem solving. If attempts to correct a problem fail, contact Customer Service at 1-800-289-312.

Quality Control: You should perform a control test if you think your test strips may be damaged, if you think your meter may not be working properly or if you have repeated, unexpected blood glucose test results. Health care professionals should follow quality control testing requirements established by their facility. **Use only CONTOUR®NEXT control solutions (not provided).**
These control solutions are designed specifically for use with the CONTOUR®NEXT systems. The control results should fall within the control range(s) printed on each test strip bottle. If they don't, do not use your meter for blood glucose testing until you resolve the issue.

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WARNING

- **Choking:** Keep out of reach of children. This product contains small parts that could cause suffocation if accidentally swallowed.
- **Potential Biohazard:** Health care professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting infectious diseases. The user should follow the recommendations for the prevention of blood-borne transmissible diseases in health care settings as recommended for potentially infectious human specimens.[1]
- **Potential Biohazard:** Dispose of the test strips as medical waste or as advised by your health care professional.
- **Potential Biohazard:** Always wash your hands with soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

Chemical Composition: FAD glucose dehydrogenase (*Aspergillus* sp., 4.0 U/test strip) 21%; Mediator 54%; Non-reactive ingredients 25%.

Comparison Options: All CONTOUR NEXT systems are designed for use with venous and capillary whole blood. Comparison to a laboratory method must be done simultaneously with aliquots of the same sample.

NOTE: Glucose concentrations drop rapidly due to glycolysis (approximately 5%–7% per hour).[2]

Limitations:

1. **Preservatives:** Blood may be collected by health care professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.
2. **Altitude:** Up to 6301 meters does not significantly affect results.
3. **Peritoneal Dialysis Solutions:** Icodextrin does not interfere with CONTOUR NEXT test strips.
4. **Contraindications:** Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension, hyperosmolar hyperglycemia and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.[3]
5. **Interference:** The CONTOUR NEXT test strips were tested against the following potentially interfering substances occurring naturally in the blood: bilirubin, cholesterol, creatinine, galactose, glutathione, hemoglobin, triglycerides, and uric acid. No interfering effect was observed for any substance at the highest concentration[4] of either the common pathological level or three times the upper reference value.[5]
6. **Interference:** The CONTOUR NEXT test strips were tested against the following potentially interfering substances occurring from therapeutic treatments: ascorbic acid, paracetamol (acetaminophen), dopamine, sodium gentisate, ibuprofen, icodextrin, L-dopa, maltose, methyl dopa, pralidoxime iodide, sodium salicylate, tolazamide, tolbutamide. No interfering effect was observed for any substance at the highest concentration[4] of either the toxic concentration or three times the maximum therapeutic concentration.[5]
7. **Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.**
8. **Hematocrit:** CONTOUR NEXT test strip results are not significantly affected by hematocrit levels in the range of 0% to 70%.[5]

References:

1. Sewell DL. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline, 3rd Edition*. Clinical and Laboratory Standards Institute. CLSI document M29-A3; ISBN 156238-567-4. March 2005.
2. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th Edition. Philadelphia, PA: WB Saunders Co; 2001;444.
3. Atkin SH, et al. Fingerstick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12):1020-1024.
4. McEnroe RJ, et al. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. EP7-A2, vol 25, no 27. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.
5. Bernstein R, Parkes JL, Goldy A, et al. A new test strip technology platform for self-monitoring of blood glucose. *Journal of Diabetes Science and Technology*. 2013;7(5):1386-1399.

Ascensia Diabetes Care Australia Pty Ltd
Suite 416, 33 Lexington Drive
Bella Vista, NSW, 2153, Australia
Ph: 1-800-289-312
www.diabetes.ascensia.com.au
For enquiries, technical support, and information on ordering test strips, contact Customer Service: 1-800-289-312

ASCENSIA Diabetes Care

Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel, Switzerland

www.diabetes.ascensia.com

If a serious incident has occurred during the use of this device or as a result of its use, please report it to the manufacturer and/or its authorized representative and to your national authority.