Customer Advisory Notice

PRODUCT: Nova StatStrip® Glucose / β-Ketone Hospital Meter

Customer Advisory Notice: 02-26SS-IE ***DATE: 14 October 2026***

URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

Nova StatStrip® Ketone Test Strips: Increased Quality Control (QC) test failures for certain lots of Ketone Test Strips

WHAT YOU NEED TO KNOW

- Specific lots of StatStrip Ketone Test Strips have demonstrated a higher-than-expected rate of failure during quality control testing.
- Discontinue use of affected lots and dispose of them according to your institution's established procedures and requirements.
- Nova's investigation shows that the issue affects QC testing only. To date, no performance issues have been identified when testing with whole blood. No issues have been attributed to the StatStrip Glucose and β-Ketone Hospital Meter to date.

Dear Nova StatStrip® Customer,

As part of Nova Biomedical's ongoing commitment to product quality and customer support, Nova Biomedical is initiating an urgent medical device field safety corrective action due to increased QC test failures associated with the StatStrip Ketone Test Strip lots listed below.

Affected Product and Lots

Part Number	Product Name	UDI-DI	Affected Lot Number(s)
46951	TEST STRIP 50CT KET STRIP DUAL PACK	10385480469514	2224344249, 2225013249 2225079249, 2225111249, 2225167249, 2226068249, 2226070249, 2226110249 2226173249, 2226175249

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This issue does not impact the StatStrip meter or testing patient samples following successful QC testing using unaffected lots. Nova is actively working to ensure supply of unaffected lots to our customers while we implement corrective actions.

To date, Nova has received several reports from customers indicating that certain lots of StatStrip Ketone Test Strips, when used to perform Quality Control (QC) testing, may demonstrate higher-than-expected rates of QC failure. Following investigation, Nova has identified the potential for increased QC failures which may contribute to a delay in obtaining patient ketone results and delays in the subsequent clinical assessment or treatment of patients.

Our investigation has verified that failures are limited to use of StatStrip Ketone Test strips when used to perform quality control tests only. This is due to fundamental differences between the composition of QC material and patient blood samples. Whole blood contains red blood cells, proteins, electrolytes, buffers, and other endogenous components and has different viscosity, surface tension, diffusion, wetting, and reagent-solubilization characteristics compared with an aqueous QC material. These matrix differences can affect reagent dissolution, mass transport to the electrode, and the resulting electrochemical signal. Consequently, a change in strip chemistry or reagent stability may produce a measurable bias in QC material without producing an equivalent bias in whole-blood samples.

Clinical Impact

The primary risk is a delay in obtaining ketone results, which may delay clinical assessment or treatment. Nova's investigation has not identified performance failures when testing blood samples with affected lots. The observed issue is related to QC testing and does not indicate a malfunction of the meter.

Nova Biomedical has received no reports of patient injury, death, or serious adverse health consequences associated with this issue.

Customer Actions

End users should take the following actions for those lots identified in the table above:

- Immediately stop use and quarantine affected lots.
  - Identify and record affected inventory based on the table provided above, including the lot number and vial information.
  - Dispose of all affected lots according to your institution's established procedures for disposal and safety requirements.
  - Complete and return the acknowledgement form to the e-mail address provided below so Nova Biomedical can confirm receipt of this notice. Return this acknowledgement even in the absence of affected stock.
    - Please contact: Nova Biomedical
      - Email: EU-QA@novabio.com
      - Phone Number: +44 1928 704047

If you have lots that **are not** listed in the table above, they may continue to be used for QC and patient testing. If doing so, Nova reiterates the instructions for use for QC testing and

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troubleshooting must be followed according to the StatStrip Glucose and β-Ketone Hospital Meter Instructions for Use (IFU) manual. Do not test patient samples until all QC requirements have been met as outlined in the IFU and according to your institution's established procedures and requirements for quality control.

If affected lots were previously used

If required QC results were acceptable before patient testing, no additional action is recommended at this time. If QC failures occurred, follow your institution's established investigation procedures.

Supply and Replacement

Nova is manufacturing and releasing new lots of StatStrip Ketone Test Strip and will coordinate replacement of affected inventory when product becomes available. Nova currently expects new product to be available for shipment during the week of October 26, 2026. **Availability may vary by customer and region as supply recovery progresses.**

If StatStrip Ketone Test Strips are unavailable, customers should follow their institution's established clinical protocols and approved alternative testing procedures. For patients with suspected diabetic ketoacidosis (DKA), laboratory blood ketone testing (β-hydroxybutyrate) is the preferred alternative to point-of-care ketone testing. If laboratory blood ketone testing is not available, urine ketone testing for acetoacetate may be used in accordance with institutional protocols. For patients being monitored during treatment of DKA, laboratory blood ketone testing remains the preferred method for assessing response to therapy and resolution of ketoacidosis. When laboratory blood ketone testing is unavailable, clinicians may use institution-approved assessments such as anion gap, pH, and bicarbonate measurements as part of the overall clinical evaluation.

Questions and Support

Ireland Customers:
Nova Biomedical
Email: EU-QA@novabio.com
Phone Number : +44 1928 704047

Please have the affected lot number and vial information available when contacting Nova Biomedical for support.

Nova Biomedical appreciates your prompt attention to this notice and your continued partnership. We apologize for the inconvenience and are available to support you through the replacement process.

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CUSTOMER ACKNOWLEDGEMENT FORM

URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

02-26SS-IE Nova StatStrip® Ketone Strips

Response is Required

Customer / Facility Name:	
Customer Account Number, if applicable:	
Address:	
Contact Name / Title:	
Phone / Email:	
Signature / Date:	

Inventory Review and Replacement Information

Part Number	Affected Lot Number	Quantity on Hand	Quantity Discarded	Comments
46951	2224344249			
46951	2225013249			
46951	2225079249			
46951	2225111249			
46951	2225167249			
46951	2226070249			
46951	2226068249			
46951	2226110249			
46951	2226173249			
46951	2226175249			
Have any complaints been reported for the affected product?				Yes / No
Have any adverse events been associated with the affected product?				Yes / No

If yes, please explain:

_____

_____

_____

Questions:

☐ Please have Customer Service contact me (if applicable).

Nova Biomedical, 200 Prospect Street, Waltham, MA 02454

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Facilities, Sites, or Locations Covered by Submission of this Form

In the Section below, please list the names and addresses of all facilities, sites, or locations that are covered by the submission of this Acknowledgment Form (if applicable).

Facility/Site Name & Address	
Facility/Site Name & Address	
Facility/Site Name & Address	
Facility/Site Name & Address	
Facility/Site Name & Address	
Facility/Site Name & Address	

Please return the completed form to:

Nova Biomedical at: EU-QA@novabio.com

If you have questions regarding this form, please contact Nova Biomedical Technical Support at 1 (800) 545-6682 (USA) or at (800) 263-5999 (Canada). For customers outside of the USA or Canada, please contact your local Nova Biomedical Subsidiary or authorized Nova Biomedical distributor.

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