



Medicines & Healthcare products
Regulatory Agency

DEVICE SAFETY INFORMATION (DSI)

Nova Biomedical StatStrip ketone test strips: risk of disruption to blood ketone testing due to quality-control failures and supply interruption DSI/2026/013

Specialisms: Pathology, Emergency medicine; Diabetes; Paediatrics and neonatology; Critical care; Ambulance services; Community healthcare; Point-of-care testing

DEVICE DETAILS

Nova Biomedical StatStrip Ketone Test Strips

Part Number: **46951**, Product Name: **TEST STRIP 50CT KET STRIP DUAL PACK**

AFFECTED LOT SERIAL NUMBERS

2224295249, 2225013249, 2225072249, 2225079249, 2225111249, 2225118249, 2225167249, 2226068249, 2226070249, 2226110249, 2226173249

MANUFACTURED BY

Nova Biomedical

Summary

Nova Biomedical has identified quality issues affecting specified lots of StatStrip ketone test strips. The affected lots have been associated with quality-control (QC) failures and Nova Biomedical has initiated a recall, advising that these lots should not be used. Nova Biomedical has also paused distribution of the affected lots and advised that any further lots found to fail QC testing should also be withdrawn from use.

The recall, paused distribution and potential withdrawal of additional lots may result in a progressive reduction in the availability of ketone test strips and disruption to blood ketone point-of-care testing. Nova Biomedical has advised that replacement stock is not expected to be available in the UK for approximately 4 weeks, which may increase the risk of supply constraints during this period.

Advice for Healthcare Professionals:

- if your organisation uses Nova Biomedical StatStrips, establish which lots are currently held and available for clinical use
- discontinue clinical use and dispose of all lots identified by Nova Biomedical as subject to recall
- for lots that are not subject to recall, ensure users follow the instructions for use. If a lot fails QC testing on two consecutive occasions, remove the lot from use, dispose of any remaining test strips in accordance with local procedures, and switch to an alternative lot number if available, or use an alternative method for blood ketone testing
- do not assume that the current quantity of strips represents the duration of available supply, as additional lots may become unavailable if there is QC failure
- assess current and anticipated blood ketone testing capacity, including the number and location of ketone testing devices, current usable strip stock and anticipated out-of-stock dates
- identify and validate alternative ketone testing methods where available, including alternative point-of-care devices and laboratory testing
- where supply is constrained, prioritise available blood ketone testing for patients at greatest clinical risk, including patients with suspected or established Diabetic Ketoacidosis (DKA), paediatric patients, acutely unwell patients with type 1 diabetes and patients requiring serial ketone measurements during DKA treatment
- ensure that appropriate escalation arrangements are in place where clinically indicated ketone testing is unavailable
- ensure that relevant clinical, point-of-care testing, procurement and governance teams are aware of the supply disruption and appropriate local contingency arrangements are implemented

Advice for Healthcare Professionals to Provide to Patients:

- the advice in this DSI is aimed at healthcare professionals who are managing your care. You can be reassured that your healthcare professional will take the necessary steps to ensure your care is not impacted. If you have any concerns, contact your healthcare professional

- if you experience vomiting, abdominal pain, deep/rapid breathing, fruity/pear-smelling breath, marked drowsiness or confusion, severe thirst or dehydration, or are becoming progressively unwell, please seek urgent medical care as you may have diabetic ketoacidosis (DKA)
- continue following your prescribed sick-day/insulin plan unless your healthcare professional tells you otherwise. Do not stop using your insulin unless your healthcare professional tells you to
- keep checking blood glucose frequently if you have a meter or continuous glucose monitor (CGM) and report persistent or worsening high blood glucose levels

Advice for Distributors:

- distributors should follow Nova Biomedical's instructions regarding affected lots, including the recall and stop-ship arrangements, and must not supply lots identified as unsuitable for use
- be ready to act on information provided in future safety communications
- please ensure that end users are familiar with this DSI and accompanying [Field Safety Notice](#) (FSN), and any additional FSNs or relevant manufacturer's updates that may be issued

Explanation of identified safety issue

Nova Biomedical has identified quality issues affecting specified lots of StatStrip ketone test strips. The affected lots have been associated with repeated quality-control (QC) failures. Nova Biomedical has initiated a recall of specified lots and has advised that these lots should not be used.

Nova Biomedical has also placed affected lots on stop-ship and advised that additional lots should be withdrawn from use if they subsequently fail QC testing. This creates the potential for a progressive reduction in the quantity of strips available for clinical use.

The resulting supply disruption may significantly reduce the availability of blood ketone point-of-care testing across the NHS. Nova Biomedical has advised that it is unable to replenish UK stock levels for approximately 4 weeks.

Blood ketone testing is an important diagnostic and monitoring method used in patients at risk of, or with suspected or established, diabetic ketoacidosis (DKA). It is used across emergency departments, acute inpatient services, paediatric services, ambulance and paramedic services, community hospitals, urgent community response, virtual wards, hospital-at-home services, primary care and district/community nursing.

The NHS advises that blood ketone concentrations above 3 mmol/L may indicate DKA and require emergency assessment. NICE incorporates blood ketone measurement into the diagnostic and monitoring pathways for DKA.

In children and young people, NICE recommends measurement of blood ketones using a near-patient method when DKA is suspected. Where a near-patient blood ketone method is not available, NICE recommends immediate transfer to a hospital with acute paediatric facilities.

The clinical risk associated with loss of timely blood ketone testing is greatest where a patient is acutely unwell, DKA is suspected or being treated, and an alternative validated method of obtaining a clinically appropriate ketone result is not immediately available.

Loss of testing capacity may result in delayed recognition or assessment of DKA, delayed escalation or hospital transfer, delayed treatment decisions, or impaired monitoring of response to treatment. DKA is a potentially life-threatening condition, and such delays may contribute to severe clinical deterioration, critical illness, permanent harm or death.

The Department of Health and Social Care will be issuing clinical guidance on this.

Additional information

Organisations should consider the impact of reduced blood ketone testing capacity across all services in which rapid ketone testing is clinically required.

Particular consideration should be given to whether the loss of testing could:

- delay recognition or exclusion of DKA;
- delay initiation or modification of treatment;
- delay recognition of failure to respond to DKA treatment;
- result in delayed escalation or hospital admission;
- require transfer of patients solely because appropriate point-of-care testing is unavailable;
- disproportionately affect paediatric, community and pre-hospital services where laboratory testing may not be immediately available; or
- create additional risk if alternative devices are insufficient to meet demand.

Organisations should ensure that local mitigation arrangements do not inadvertently result in patients with suspected DKA being managed in a setting without an appropriate means of assessing or monitoring ketosis.

Organisations should maintain a documented contingency plan until sufficient confirmed, validated and quality-assured ketone-testing capacity is available to meet foreseeable clinical demand.

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the [Yellow Card website](#) or via the Yellow Card app
- in Scotland to [Incident Reporting & Investigation Centre \(IRIC\)](#) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures.

Additional information:

You can [sign up](#) to receive email updates on alerts and device safety information from the MHRA.

You can [sign up](#) to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk