National Patient Safety Alert

Department of Health & Social Care

SUPPLY DISRUPTION FOR NOVA BIOMEDICAL STATSTRIP BLOOD KETONE TEST STRIPS

Date of issue:	13-Oct-26	Reference no:	NatPSA/2026/007/NSDR

This alert is for action by: all organisations that use Nova Biomedical StatStrip blood ketone test strips in critical or routine patient care.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards). This lead should be supported by clinical leaders in local pathology and point-of-care testing teams and clinical leaders in all services which use Nova Biomedical (Nova) StatStrip blood ketone test strips. Affected providers may include acute, primary and community care, mental health and ambulance services.

Explanation of identified safety issue:

Nova 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 has initiated a recall, advising that these lots should not be used. Lot numbers can be found on Nova's Field Safety Notice. Nova has paused distribution of affected lots and advised that any further lots found to fail QC testing should also be withdrawn from use. This may result in further disruption to blood ketone point-of-care testing. Nova currently expects new product to be available for shipment to the UK during the week of 26 October 2026.

Blood ketone testing is an important diagnostic and monitoring method used in patients at risk of, or with suspected or established, diabetic ketoacidosis (DKA), euglycaemic DKA and other clinically significant ketonaemia. 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, mental health services, primary care and district/community nursing.

Without blood ketone tests patients may come to harm or be exposed to potential harm. 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 for clinically appropriate ketone testing 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.

Interim clinical prioritisation guidance has been published by NHS England to support clinical decision-making regarding use of available blood ketone test strips whilst maintaining rapid recognition and safe management of diabetic ketoacidosis (DKA), euglycaemic DKA and other clinically significant ketonaemia.

Actions required

Actions to be completed by 20/10/2026

Organisations should identify a clinical lead and form a working group to act on the Field Safety Notice issued by Nova and follow the advice issued by MHRA in their Device Safety Notice.

This will include taking action to:

1. Discontinue clinical use and dispose of all lots identified by Nova as subject to recall.
2. 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.
3. Identify and validate alternative ketone testing methods where available, including alternative point-of-care devices and laboratory testing.
4. Prioritise available blood ketone testing for patients at greatest clinical risk where supply is constrained.

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Notes

The priority categories provided in the interim clinical prioritisation guidance published by NHS England are intended as short-term clinical guidance during the supply disruption and are not a nationally validated triage system. Local decision-making on use of available supply must be clinically led and consider the risks to each patient. Any alternative supplier of ketone blood testing should be assessed and approved by the local pathology service prior to use.

Nova have indicated that newly manufactured stock is expected to arrive in the UK for onward distribution during the week commencing 26 October 2026. They have committed to ensuring a fair allocation of this stock across all four nations and working with national partners to achieve this.

References

1. MHRA. Device Safety Information Notice. Nova Biomedical StatStrip ketone test strips: risk of disruption to blood ketone testing due to quality-control failures and supply interruption DSI/2026/013 - GOV.UK. 9 October 2026.
2. MHRA. Field Safety Notice Nova Biomedical Ref. 41092838. Medicines and Healthcare products Regulatory Agency. 9 October 2026.
3. NHS England. Interim clinical prioritisation guidance. NHS England » Interim clinical prioritisation guidance for blood ketone testing during supply disruption. 9 October 2026.
4. NHS Supply Chain. Important Customer Notice. Supply Issues Nova StatStrip® Ketone Test Strips » NHS Supply Chain. 13 October 2026.

Stakeholder engagement

- Joint British Diabetes Societies for Inpatient Care Group

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.