Urgent Field Safety Notice

SBN-RDS-NPC-2025-003

RDS / Near Patient Care
Version 2
November 2025

EA 9180 Na discrepant results

Product Name	ELECTROLYTE ANALYZER W/O STARTERKIT 9180
GMMI / Part No **Device Identifier (UDI)**	ELECTROLYTE ANALYZER W/O STARTERKIT 9180 / GMMI: 03157334001 / UDI: 04015630031832 Diamond Diagnostics (manufacturer): Reference Electrode 9180 / GMMI: 09969772001 / UDI: 07613336230893 Reference Electrode Housing 9180 / GMMI: 09969764001 / UDI 00811403010424
Production Identifier (Lot No./Serial No.)	n/a
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)
Document History **Version 1** **Version 2**	 Initial Release Update of recommendation to switch to alternative system

Dear Valued Customer,

Description of Situation

An increasing number of global complaints have been identified related to both falsely high and low sodium (Na+) results from the 9180 Electrolyte Analyzer. These discrepant measurements affect the entire measurement range, with deviations reported between -60 to +40 mmol/L compared to reference values.

Measurement results for other parameters (K+, Cl-, Ca^{2+}, Li+) are not affected.

The detectability and medical risk attributable to incorrect sodium test results depends significantly on the constellation of diagnostic and clinical parameters as erroneous results are not flagged by the instrument and

standard calibration and QC procedures do not reliably identify the issue. Together, in specific clinical scenarios, it is possible that clinical care could be influenced by incorrect (even though still believable) sodium test results, potentially causing adverse health consequences for patients.
The issue is sporadic and is linked to the introduction of the RoHS-compliant, CE-marked Reference Electrode 09969772001 (manufactured by Diamond Diagnostics, hereafter "DD Ref Electrode"), which was introduced to replace the former mercury-based Roche Reference Electrode 03112306180.

There are no reports of patient harm linked to this issue.

Actions taken by Roche

A Corrective and Preventive Action (CAPA) investigation has been initiated, and root cause investigation continues. Once the root cause analysis is complete, appropriate corrective and preventive measures will be defined and communicated, as needed.

Actions to be taken by the customer/user

[For countries that can use the Roche Reference Electrode and the DD Ref Electrode is in use/available:
Please immediately stop using sodium (Na+) results from your 9180 analyzer with the DD Ref Electrode and switch back to the mercury-based Roche Reference Electrode (03112306180) and Reference Electrode Housing (03112284180).
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[For countries that cannot use the Roche Reference Electrode and the DD Ref Electrode is in use:
Please immediately stop using sodium (Na+) results from your 9180 analyzer with the DD Ref Electrode and switch to an alternative testing system (e.g. **cobas** b 221, **cobas** b 123, **cobas** Integra 400 (only in ISE-D mode, and only for Serum and/or Plasma samples)) to obtain sodium (Na+) results. Please ensure that sodium (Na+) results from your 9180 analyzer with the DD Ref Electrode are not used for any clinical decision making.
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In this case, no general recommendations with respect to the review of previous results can be given using the DD Ref Electrode. Please follow your standard laboratory operating procedures. Any specific questions raised should be addressed individually, considering all relevant clinical information.

Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

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This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com

Roche Diagnostics GmbH - SRN: DE-MF-000006260 (legal manufacturer)