

Urgent Field Safety Notice

MY-FSN-RDS-NPC-2025-003

RDS / Near Patient Care

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Version 1

28 October 2025

EA 9180 Na discrepant results

Product Name	ELECTROLYTE ANALYZER W/O STARTERKIT 9180
GMMI / Part No	ELECTROLYTE ANALYZER W/O STARTERKIT 9180 / GMMI: 03157334001
Device Identifier (UDI)	Diamond Diagnostics (manufacturer): Reference Electrode 9180 / GMMI: 09969772001 Reference Electrode Housing 9180 / GMMI: 09969764001
Production Identifier (Lot No./Serial No.)	n/a
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)

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⁻, Ca²⁺, 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 Reference Electrode 09969772001 (manufactured by Diamond Diagnostics, hereafter "DD Ref Electrode"), which was introduced to replace Roche Reference Electrode



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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

Please **immediately stop** using sodium (Na+) results from your 9180 analyzers with the DD Ref Electrode and switch back to Roche Reference Electrode (03112306180) and Reference Electrode Housing (03112284180).

Reference Electrode:

Instrument	9180 Electrolyte Analyzer	
Manufacturer	Diamond Diagnostics	Roche Diagnostics
Product Name	Reference Electrode 9180	Reference Electrode ISE 91XX
Product Number	09969772001	03112306180
Pack Size	1's	1's

Reference Electrode Housing:

Instrument	9180 Electrolyte Analyzer	
Manufacturer	Diamond Diagnostics	Roche Diagnostics
Product Name	Reference Electrode Housing 9180	Reference Electrode Housing ISE 91XX
Product Number	09969764001	03112284180
Pack Size	1's	1's

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.



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Communication of this Field Safety Notice

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 and on which this action has an impact.

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

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

Important Information

1. Please immediately stop using sodium (Na+) results from your 9180 analyzers with the DD Ref Electrode.
2. Please switch back to Roche Reference Electrode (03112306180) and Reference Electrode Housing (03112284180) for continued testing.

Actions Required

1. Please complete the Customer Acknowledgment Receipt within **2 business days** via the navify® Portal: Product and Safety Care to confirm that you have read and understood this notice.
2. For future purchases, please take note of the following material numbers: Roche Reference Electrode (03112306180) and Reference Electrode Housing (03112284180).
3. Replacement kit for the recently purchased DD Ref Electrode and its Housing will be provided upon request. Please indicate the number of complimentary replacement kit(s) required based on your instrument via the navify® Portal: Product and Safety Care.

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Contact

If you have any questions, please do not hesitate to contact your sales representative or our Customer Call Centre:
1800 88 8881

Thank you.

Best regards,
ROCHE DIAGNOCTIS (M) SDN. BHD.



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