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Urgent Field Safety Notice:

epoc® Blood Analysis System Negative Sodium Bias on Multiple Test Card Lots

To whom it may concern,

Our records indicate that you have received:

Product	Siemens Material Number	GTIN	Lot Number / Expiration
epoc BGEM BUN Test Card [25pk]	10736515	00809708121860	Refer to the Appendix for the complete list of affected lots

The purpose of this communication is to inform you of a potential issue with the product indicated in the table above and provide instructions on actions that your facility must take.

Siemens Healthcare Diagnostics Inc. has confirmed that a negative sodium bias may exist in some epoc test card lots. All other analytes are performing as intended.

The observed average bias for sodium was -4.4 mmol/L. The maximum bias observed was -14 mmol/L, which occurred at a higher sodium concentration around 150 mmol/L. No positive bias has been observed. Quality Control (QC) fluid may or may not detect the issue depending on the bias magnitude and the frequency of QC testing.

Impact to Results

Erroneous sodium test results could lead to a delayed diagnosis of hyponatremia or unnecessary treatment for hyponatremia. An example of the worst-case scenario would be an erroneously depressed sodium level resulting in the incorrect decision to withhold treatment from a patient with hyponatremia leading to worsening electrolyte abnormalities. Mitigations include deviation from historical results, the likelihood of repeat testing prior to initiating treatment, discordance from the clinical presentation of the patient, and the unlikely event the patient is significantly harmed due to a falsely depressed sodium.

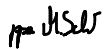
Customer Actions

- Please review this Urgent Field Safety Notice letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- You may discard and request a replacement of any affected lots. Alternatively, if your institution does not need to report sodium, you can turn off sodium following the instruction of the owner's manual and use the cards to test other analytes.
- If you are a distributor, please ensure your customers receive this UFSN letter.
- Complete and return the Field Correction Effectiveness Check Form and if applicable, product replacement form attached to this letter within 30 days.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for any inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



Electronically signed by: Martina
Schreiber
Reason: I am approving this document
Date: Jul 14, 2025 08:57 GMT+2

ppa. Mag. Martina Schreiber



Electronically signed by: Thomas
Hufnagl
Reason: I have reviewed this document
Date: Jul 11, 2025 17:17 GMT+2

i.A. Mag. Thomas Hufnagl

Appendix: *epoc* Test Card Lots Impacted

**All lots pertain to epoc BGEM BUN Test Cards (SMN 10736515) with expiration dates from 20-Sept-2025 to 20-Oct-2025.*

Lots ending-30	Lots ending-40	Lots ending-50	Lots ending-60	Lots ending-70
02-25095-30	02-25096-40	02-25096-50	12-25096-60	02-25099-70
02-25096-30	02-25097-40	02-25098-50	12-25097-60	02-25101-70
02-25098-30	02-25098-40	02-25099-50	12-25098-60	02-25104-70
02-25099-30	02-25099-40	02-25100-50	12-25100-60	02-25105-70
02-25100-30	02-25101-40	02-25102-50	12-25101-60	02-25107-70
02-25101-30	02-25102-40	02-25103-50	12-25102-60	02-25108-70
02-25102-30	02-25105-40	02-25105-50	12-25103-60	02-25110-70
02-25103-30	02-25106-40	02-25107-50	12-25111-60	02-25111-70
02-25105-30	02-25121-40	02-25108-50	02-25112-60	02-25112-70
02-25111-30	02-25122-40	02-25111-50	02-25113-60	02-25113-70
02-25112-30	02-25124-40	02-25112-50	02-25114-60	02-25115-70
02-25114-30	02-25125-40	02-25113-50	02-25115-60	02-25116-70
02-25115-30		02-25114-50	02-25116-60	02-25118-70
02-25116-30		02-25115-50	02-25117-60	02-25120-70
02-25117-30		02-25119-50	02-25118-60	
02-25119-30		02-25120-50	02-25120-60	
02-25121-30			02-25121-60	
02-25122-30			02-25122-60	
02-25124-30			02-25123-60	
			02-25124-60	