

F02-QAD-04_02 /20.07.2021

ADVISORY NOTE

Date of issue	28 th February 2024		
Note number	ND_2402_02		
Product name, catalogue number and lot number	Name CORMAY SERUM HN CORMAY SERUM HP	Cat. No 5-172 5-173	Lot number HN10 HP10
Expiry date	2025-07		

Issue description

Results obtained during control materials quality monitoring exceeded the internal acceptance criteria. Due to above, values for phosphorus on analysers:

- ACCENT S120 / BS-230,
- ACCENT MC240 / BS-240Pro,
- ACCENT M320 / BS-360E,

were re-assigned in control materials CORMAY SERUM HN and CORMAY SERUM HP.

The re-determined values are reported in the erratum (Attachment 1).

Necessary actions

- Read carefully Advisory Note, erratum (Attachment 1) and use the re-determined values of controls during determinations of phosphorus.
- Perform quality control prior to ordering patient samples.
- Complete and return the Verification Form.

The note is only for reference. Do not discard the product!

Please provide this information to all Users of the above product and keep the Advisory Note as a quality system documentation.

Please complete and return the attached Verification Form to confirm receipt of the Advisory Note.

We apologize for any inconvenience caused by the above situation.

Sincerely,

Quality Assurance Manager