

ADVISORY NOTE

Date of issue	20.11.2023
Note number	ND_2311_01
Product name and catalogue numer	PRESTIGE 24i LQ CREATININE; Cat. no: 4-233, 4-433
Lot number	all lots
Expiry date	n/a
Issue description	
<p>APPLIES TO USERS OF <u>Biolis 24i Premium ANALYZER</u> !!!</p> <p>Results obtained during routine reagent quality control exceeded the internal acceptance criteria. To solve the problem the application program for the Biolis 24i Premium analyzer was optimized (Attachment 1). The new application program is also included in the updated instructions for use. The current instructions for use can be found on the website – www.cormaydiagnostics.com.</p>	
Necessary actions	
<ul style="list-style-type: none"> • Read carefully advisory note • Update the application on the analyzer before performing the test (Attachment 1) • Perform calibration and quality control prior to ordering patient samples • Complete and return the Verification Form <p>The note is only for reference. Do not discard the product!</p>	

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