

ADVISORY NOTE

Date of issue	15.03.2023	
Note number	ND_2303_01	
Product name and catalogue numer	Name CORMAY URINALYSIS CONTROLS	Cat. No 6-054
Lot number	xxx-1515 xxx-1616	
Expiry date	Lot xxx-1515 xxx-1616	Expiry date 2023-12 2024-06
Issue description		
<p>Results obtained during routine quality control of CORMAY URINALYSIS CONTROLS on URI-TERX and URI-TEX 300 analyzers, exceeded the internal acceptance criteria. To correct the problem, the re-metrication of CORMAY URINALYSIS CONTROLS (Cat. No: 6-054) was performed.</p> <ul style="list-style-type: none"> • URI-TEX USERS: The values of the following parameters were re-determined: - CREATININE parameter for Level 2; - LEUKOCYTES for Level 2. • URI-TEX 300 USERS: The values of the following parameters were re-determined: - CREATININE parameter for Level 1 and Level 2; - LEUKOCYTES for Level 2. • URI-TEX and URI-TEX 300 USERS: The colour chart blocks is determined for patient urine. For internal quality control it is recommended to be read with use of instruments, <u>not visually</u>. The new values are reported in corrected assay value sheet (Attachment 1). The values of the other parameters, not listed in the advisory note, have not changed. 		
Necessary actions		
<ul style="list-style-type: none"> • read carefully Advisory Note, the Attachment and use the re-determined values of parameters: creatinine and leukocytes, • do not perform quality control with use of visual reading, • perform 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,

X

Anna Smolira
Quality Assurance