

ADVISORY NOTE

Date of issue	16.12.2022
Note number	ND_2212_01
Product name and catalogue numer	MYT-5D Cat. No: MYT502, MYT506N
Lot number	MYT2212
Expiry date	05.02.2023
Issue description	
<p>APPLIES <u>ONLY</u> TO USERS OF MYTHIC 22AL AND MYTHIC 60 ANALYZERS !!!</p> <p>Results obtained during routine quality control of MYT- 5D control blood on MYTHIC 22AL and MYTHIC 60 analyzers, exceeded the internal acceptance criteria. To solve the problem re-metrication of control blood was performed.</p> <ul style="list-style-type: none"> • MYTHIC 22AL USERS: The value of HCT, MCV and MCHC parameters, for <u>high</u> level were re-determined . • MYTHIC 60 USERS: The value of PCT parameter for <u>low, normal and high</u> levels were re-determined . <p>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.</p>	
Necessary actions	
<ul style="list-style-type: none"> • Read carefully the attachment and use the re-determined values of parameters: HCT, MCV, MCHC (MYTHIC 22AL) and PCT (MYTHIC 60). • 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,

X

Anna Smolira
Quality Assurance