

F02-QAD-04_06 /20.07.2021

ADVISORY NOTE

Date of issue	05.10.2023
Note number	ND_2310_01
Product name and catalogue numer	Myt-5D (Cat. No MYT502)
Lot number	MYT2310
Expiry date	2023-12-05
Issue description	

APPLIES TO USERS OF MYTHIC 70 ANALYZER!!!

The expected range of HGB value for control blood low level provided in assay value sheet was incorrect. To solve the problem, the range was redetermined. The new range is \pm 0.5 g/dL instead of \pm 0.3 g/dL and it is reported in revised assay value sheet (Attachment 1).

Necessary actions

Read carefully the attachment and use the re-determined range of HGB parameter for control blood low level.

Please 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 Coordinator