

F02-QAD-04\_02 /20.07.2021

## **ADVISORY NOTE**

Date of issue	29 <sup>th</sup> March 2023	
Note number	ND_2303_03	
Product name and catalogue numer	Name	Cat. No
ŭ	Liquick Cor-GLUCOSE 30	2-219
	Liquick Cor-GLUCOSE 60	2-201
	Liquick Cor-GLUCOSE 120	2-202
Lot number	all lots	
Expiry date	n/a	

## Issue description

Results obtained during routine reagents quality control exceeded the internal acceptance criteria. To solve the problem:

1. The value of the **2-STANDARD**, which is included in Liquick Cor-GLUCOSE 30 (Cat. No. 2-219) and Liquick Cor-GLUCOSE 60 (Nr kat. 2-201) kits, was redetermined, based on the primary standard NIST 965b.

New standard value is:

REAGENT	LOT NUMBER	STANDARD VALUE
2-STANDARD	XXX-XX58	91.5 mg/dl (5.08 mmol/l)
	XXX-XX59	91.1 mg/dl (5.06 mmol/l)
	XXX-XX <b>60</b>	94.3 mg/dl (5.23 mmol/l)

- 2. Due to the changed values of the aqueous standards, values assigned for glucose for manual method in control materials:
  - CORMAY SERUM HN (Cat. No 5-172) lot HN10,
  - CORMAY SERUM HP (Cat. No 5-173) lot HP10,

were also re-determined and reported in the erratum NDE 2303 02 (Attachment 1).

## **Necessary actions**

- Read carefully Advisory Note, Erratum NDE\_2303\_02 (Attachment 1) and use the re-determined values of standard and controls during determinations of glucose.
- Perform calibration and 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,