

ADVISORY NOTE

Date of issue	22.02.2022						
Note number	ND_2202_01_ERRATUM						
Product name and catalogue numer	CORMAY CK-MB CALIBRATOR Cat. No: 5-182						
Lot number	XXX-21, XXX-22, XXX-23						
Expiry date	<table border="0"> <tr> <td><b>XXX-21</b></td> <td><b>2023-07</b></td> </tr> <tr> <td><b>XXX-22</b></td> <td><b>2023-06</b></td> </tr> <tr> <td><b>XXX-23</b></td> <td><b>2023-06</b></td> </tr> </table>	<b>XXX-21</b>	<b>2023-07</b>	<b>XXX-22</b>	<b>2023-06</b>	<b>XXX-23</b>	<b>2023-06</b>
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<b>XXX-23</b>	<b>2023-06</b>						
Issue description	<p>The information on the expiry dates of the CK-MB CALIBRATOR in the Advisory Note ND_2202_01 was incorrect. In the Erratum ND_2202_01_ERRATUM the correct information on the expiry dates of the calibrator is given above.</p> <p>Results obtained during routine calibrator quality control exceeded the internal acceptance criteria. To correct the problem, the value of the <b>CORMAY CK-MB CALIBRATOR</b> (Cat. No: 5-182) with the batch numbers: XXX-21, XXX-22, XXX-23 was redetermined. New calibrator value is <b>206 U/L</b>.</p>						
Necessary actions	<ol style="list-style-type: none"> <li>1. Read the Advisory Note and <b>use the re-determined values</b> of calibrators during determinations of CK-MB.</li> <li>2. Enter a new calibrator value to the analyzer.</li> <li>3. Perform <b>calibration and a quality control</b> prior to ordering patient samples.</li> </ol> <p>Please, complete and return the verification form. The note is only for reference. <b>Do not dispose the product!</b></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*

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Anna Smolira  
Quality Assurance  
Podpisany przez: Anna Smolira