

## ADVISORY NOTE

Date of issue	18 <sup>th</sup> May 2021
Note number	ND_2105_01
Product name and catalogue numer	8-875 DILUENT PLUS (20L) 8-877 LYSING REAGENT KX21 CN FREE (0,5L)
Lot number	Not Applicable
Expiry date	Not Applicable
Issue description	
<p>Cormay created NEW generation of Sysmex KX21 line reagents to the greater satisfaction of customers. The second generation of Cormay's Diluent and Lyse demonstrated 99% correlation for main CBC parameters relative to the original Sysmex reagents.</p> <p>NEW - II generation would be manufactured from May 2021.</p> <p>It is forbidden to mix reagents within two generations. The bottles would be labeled as the "II generation" to make possible to distinguish between I and II generation of reagents.</p> <p>For quality control it is recommended to use the control blood CBC-ST PLUS by R&amp;D Systems, Inc. for II generation of Cormay reagents.</p> <p>The set of LYSING REAGENT KX 21 CN FREE (6 x 500 ml) 8-884 it will be is discontinued effective immediately.</p>	
Necessary actions	
<p>The procedure of reagents replacement:</p> <ol style="list-style-type: none"> <li>1. Turn on the analyzer.</li> <li>2. Remove the caps from the first generation reagents (lyse and diluent) bottles and place the cubitainers spouts in dry and clean vessels.</li> <li>3. Select [4: Replace Lyse] from menu screen.</li> <li>4. After the screen displays the error message: "Replenish Diluent Container" place the cubitainers spouts in the second generation reagents (lyse and diluent) bottles and press [1: Reaspiring Diluent] key.</li> <li>5. After completing the procedure reaspiring of reagents perform "Replace Lyse" procedure twice.</li> <li>6. Perform „Shutdown" procedure.</li> <li>7. Turn on the analyzer.</li> <li>8. Perform „QC Analysis" procedure.</li> <li>9. Perform „Calibration" procedure as needed.</li> </ol> <p><b>PLEASE DO NOT MIX REAGENTS FROM I AND II GENERATION.</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.**

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We apologize for any inconvenience caused by the above situation.

Sincerely,

X *Sonia Konicz*

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Sonia Konicz  
Hematology Product Manager