



**CHANGE NOTIFICATION**

Notification number	PZ_2310_01	Date	30.10.2023
Change number	098		
Subject of the change	Classification and labelling change.		
Affected products	Cat no	Product name	
	See: Attachment 1		
Change category	<input type="checkbox"/> raw materials <input type="checkbox"/> quality control <input type="checkbox"/> packages <input checked="" type="checkbox"/> informations provided with the product <input type="checkbox"/> manufacturing <input type="checkbox"/> final product <input type="checkbox"/> other		
Change description	<p>The classification and labelling of reagents:</p> <ul style="list-style-type: none"> <li>• <b>UREA (2-REAGENT),</b></li> <li>• <b>BIL DIRECT (1-REAGENT),</b></li> <li>• <b>BIL TOTAL (1-REAGENT),</b></li> <li>• <b>AMYLASE,</b></li> <li>• <b>ALP (1-REAGENT i 2-REAGENT),</b></li> <li>• <b>RF (1-REAGENT),</b></li> <li>• <b>CHOLINESTERASE (1-REAGENT)</b></li> </ul> <p>and labelling of <b>UIBC</b> reagent (1-REAGENT) has been changed.</p> <p>The current labelling below:</p> <ul style="list-style-type: none"> <li>• UREA REAGENT             <div data-bbox="571 1256 1369 1509" style="border: 1px solid black; padding: 5px;">  <p><b>Warning</b> H319 Causes serious eye irritation. P280 Wear protective gloves, protective clothing, eye protection or face protection . P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> </div> </li> <li>• BIL DIRECT REAGENT             <div data-bbox="571 1563 1369 1921" style="border: 1px solid black; padding: 5px;">  <p><b>Warning</b> H319 Causes serious eye irritation . EUH208 Contains hydroxylammonium chloride. May produce an allergic reaction. P280 Wear protective gloves, protective clothing, eye protection or face protection . P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> </div> </li> </ul>		

- BIL TOTAL REAGENT



**Warning**

H319 Causes serious eye irritation .  
H410 Very toxic to aquatic life with long lasting effects.



P280 Wear protective gloves, protective clothing, eye protection or face protection .

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P273 Avoid release to the environment.

P391 Collect spillage.

- AMYLASE REAGENT



**Warning**

H319 Causes serious eye irritation.

P280 Wear protective gloves, protective clothing, eye protection or face protection .

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- ALP REAGENT



**Warning**

H317 May cause an allergic skin reaction.

P280 Wear protective gloves, protective clothing, eye protection or face protection.

P302 + P352 IF ON SKIN: Wash with plenty of soap and water .

- RF REAGENT



**Warning**

H317 May cause an allergic skin reaction.

P280 Wear protective gloves, protective clothing, eye protection or face protection.

P302 + P352 IF ON SKIN: Wash with plenty of soap and water .

- CHOLINESTERASE REAGENT



**Danger**

H318 Causes serious eye damage.

P280 Wear protective gloves, protective clothing, eye protection or face protection.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- UIBC REAGENT

EUH210 Safety data sheet available on request.

Reason for change	Fulfilling the requirements of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 taking into account Adaptation to Technical Progress (ATP) to the CLP Regulation.
Implementation	November 2023
Additional information	<p>Reagents with the new labelling will be available for sale beginning from November 2023. Products with the old labelling may also be available – while stocks last.</p> <p>Once you receive the notification, follow the new classification of the reagents and the aqueous standard. Use personal protective equipment when working.</p> <p>Updated material safety data sheet (MSDS) is available at: <a href="https://cormaydiagnostics.com/">https://cormaydiagnostics.com/</a></p>
Attachments	Attachment 1 - List of kit affected by the change

If there are any questions or concerns with respect to this change, please feel to contact your Area Sales Managers

Quality Assurance Manager