

**Product Change Notification Letter**  
**Uric acid and Uric Acid Plus parameters**

Dear Valuable Customers,

As we informed, the REACH regulation prohibits to use Tritons in amount equal or higher than 0.1% of chemical mixture from the 4<sup>th</sup> January 2021. Due to this requirement, we had to modify some of our reagents. Today, we would like to inform about change of **URIC ACID** and **URIC ACID PLUS FORMULATION**. Please, see below details.

1. **Introduce for selling the new II-nd Generation of Uric Acid with ascorbate oxidase** - beginning of May 2021. The new generation will bring additional benefits:
  - More eco-friendly - new formulations **without Triton**;
  - Increased specimen range - dedicated for serum, plasma and **urine**;
  - More **resistant for interfering** substances
    - ascorbate does not interfere with the test up to 30 mg/dl in case of serum/plasma, and up to 50 mg/dl in case of urine;
    - haemoglobin does not interfere with the test up to 5 g/dl.

Additional information:

- Available indexes for second generation are listed in the table A.
- New generation kits will be marked with additional label "II GENERATION".
- The volume and number of tests possible to perform from one kit are not changed.
- There may be correction in case of limit of quantitation (LoQ), linearity, calibration rule (Multi-point Linear, instead of Two Point Linear), incubation time and reaction time.
- Instruction for use (IFU) will be updated and completed with urine results.
- Please, use the correct assigned value for the UA II-nd generation in Cormay Serum HN & HP, Cormay Urine Control Level 1 & 2 and Cormay Multicalibrator Level 1 & 2 – values dedicated for method - Enzymatic with uricase peroxidase **and ascorbate oxidase**, colorimetric.

**Tab. A.** Available kits of Uric Acid II-nd Generation

Cat. No	Description	R1 [ml]	R2 [ml]	STANDARD [ml]
2-235	Liquick Cor-UA 30	5 x 24	1 x 30	STANDARD (1 x 2 ml)
2-208	Liquick Cor-UA 60	5 x 48	1 x 60	-
2-209	Liquick Cor-UA 120	5 x 96	1 x 120	-
7-208	ACCENT-200 UA	2 x 30	1 x 15	-
7-308	ACCENT-300 UA	2 x 48	1 x 25,5	-
7-408	A-400 UA	2 x 38	1 x 19,5	-
7-813	A-800 UA	2 x 55	2 x 17	-
4-208	PRESTIGE 24i LQ UA	6 x 40	6 x 12,5	-
4-408	PRESTIGE 24i LQ UA	8 x 23	8 x 7,5	-
4-508	HC-UA	6 x 78,5	6 x 20	-
9-409	OS-UA	2 x 56	2 x 18,5	-
4-711	BIOLIS 15i UA*	4 x 9,6	4 x 3,3	-
5-515	BIOLIS 50i UA	3 x 58,5	3 x 17,5	-

\*Kit available up to the end of 2021.

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2. **URIC ACID PLUS WITHDRAWAL** – production of kits listed in the table B will be discontinued. The kits of UA PLUS with tritons formulation under current catalogue numbers, will be available for sales for customers outside EU, until stocks last. Instead of URIC ACID PLUS, we recommend using the URIC ACID II-nd Generation which can be treat as an equivalent (the same range of specimen).

**Tab. B.** UA PLUS withdrawn kits

Cat. No	Description	R1 [ml]	R2 [ml]	STANDARD [ml]
2-260	Liquick Cor-UA 30 PLUS	5 x 24	1 x 30	STANDARD (1 x 2 ml)
2-258	Liquick Cor-UA 60 PLUS	5 x 48	1 x 60	-
2-259	Liquick Cor-UA 120 PLUS	5 x 96	1 x 120	-
2-309	Liquick Cor-UA 500 PLUS	3 x 400	1 x 300	-
7-263	ACCENT-200 UA PLUS	2 x 31	1 x 16	-
7-363	ACCENT-300 UA PLUS	2 x 47,5	1 x 24,5	-
7-463	A-400 UA PLUS	2 x 38	1 x 19,5	-
7-881	A-800 UA PLUS	2 x 55	2 x 17	-
4-209	PRESTIGE 24i LQ UA PLUS	6 x 40	6 x 12,5	-
4-409	PRESTIGE 24i LQ UA PLUS	8 x 23	8 x 7,5	-

Following actions are required before the first use of the new reagent:

- Read carefully instruction for use, pay special attention to performance characteristics and check application on analyser.
- Update application, if it has been changed and assigned values for calibrators and controls.
- Perform calibration and quality control procedure.

For any further information, please contact our Sales Representatives.

Yours sincerely,

*Pawel Pastor*

Clinical Chemistry Product Manager

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