

Urgent Field Safety Notice

SBN-CPS-2018-004



CPS / Urinalysis

Version 2

Jun-2019

Limit of detection Urisys 1100

Product Name	Urisys 1100® Combur ¹⁰ Test UX Chemstrip 10 A
Production Description / GMMI	Urisys 1100® Analyzer 03617548001 Combur10Test UX (100 Tests) 11544373049 Combur10Test UX (100 Tests) 11544373173 Combur10Test UX 11544373191 Chemstrip 10 A 11379208119
SW Version	5.61
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche is delighted to inform you of the improvements of the Urisys 1100 Limit of Detection (LoD) gained with Software version 5.71. As soon as Software version 5.71 is installed on your instrument, you are no longer requested to visually verify negative readings from the analyzer of the affected parameters Protein, Nitrite, Ketone, Leukocytes and Blood (intact Erythrocytes).

Actions taken by Roche Diagnostics

Roche will provide you Software version 5.71 free of charge on a new program chip. The Roche material number of the program chip with Software Version 5.71 is 08955433190.

Software version 5.71 improves the limit of detection (LoD) of the Urisys 1100 system for the parameters Protein (PRO), Leukocytes (LEU), Nitrite (NIT), Blood (ERY) and Ketone (KET) as shown in the table below:

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Parameter	Expected values for Urinalysis parameters CE/ international (except US) markets		Limit of Detection of Urisys 1100 international with Combur 10 UX / Chemstrip 10 A	
	Normal Range	Additional Information	Previous Software version 5.61	New Software version 5.71
PRO	≤ 30 mg/dL	> 30 mg/dL proteinuria	38 mg/dL	24 mg/dL
LEU	< 10 WBC/uL	10-100 WBC/uL borderline	55 WBC/μL	35 WBC/μL
NIT	< 1 uM (< 0.005 mg/dL)	A positive result is indicative of urinary tract infection, but a negative result does not rule out UTI.	0.14 mg/dL	0.06 mg/dL
ERY	< 18 ERY/uL	Hematuria ≥ 18 ERY/uL	22 ERY/μL	18 ERY/μL
KET	≤ 2 mg acetoacetic acid per deciliter	Borderline >2 up to 50 mg acetoacetic acid per deciliter	7 mg/dL	5 mg/dL

Please refer to the addendum of this letter regarding scientific literature supporting the values and statements in column “Normal Range” respectively “Additional Information”.

Values for all other parameters stay unchanged. Also, lower detection limit for visual reading stays unchanged for all parameters.

The corresponding Method Sheets have been updated to reflect these obtained performance improvements. First lot with new labeling:

11544373049 Combur10Test UX	Lot. No. not yet available
11544373173 Combur10Test UX	Lot. No. not yet available
11544373191 Combur10Test UX	Lot. No. 41515903
11379208119 Chemstrip 10 A	Lot. No. not yet available

Actions to be taken by the customer/user

Please install the new program chip with Software version 5.71 on your instrument. The installation of this program chip is described in the Operator’s Manual and can be done by the instrument operator without any tools. As soon as Software version 5.71 is installed on your instrument, you are no longer requested to visually verify negative readings from the analyzer of the affected parameters Protein, Nitrite, Ketone, Leukocytes and Blood (intact Erythrocytes).

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization where the devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com

Addendum: Scientific literature references supporting the values and statements in column “Normal Range” respectively “Additional Information”

Parameter	Normal Range	Additional information
KET	Normal ≤ 2 mg acetoacetic acid per deciliter [1]	Borderline >2 up to 50 mg acetoacetic acid per deciliter [1]
PRO	Normal ≤ 30 mg/dL [2]	> 30 mg/dL proteinuria [2]
ERY	Normal < 18 ERY/uL (< 3 ERY/HPF) [1]	Hematuria ≥ 18 ERY/uL (≥ 3 ERY/HPF) [3, 4]
	Conversion factor 5.8 to translate chamber counting HPF into uL [5]	
LEU	Normal < 10 WBC/uL [5]	10-100 WBC/uL borderline [5]
NIT	Normal < 1 uM (< 0.005 mg/dL) [6]	A positive result is indicative of urinary tract infection, but a negative result does not rule out UTI. [7]

1. Richard A. McPherson, M.R.P., *HENRY'S Clinical Diagnosis and Management by Laboratory Methods, 23rd edition*. ISBN 9780323295680, 2017.
2. Johnson, D.W., *Global proteinuria guidelines: are we nearly there yet?* Clin Biochem Rev, 2011. **32**(2): p. 89-95.
3. Wollin, T., B. Laroche, and K. Psooy, *Canadian guidelines for the management of asymptomatic microscopic hematuria in adults*. Can Urol Assoc J, 2009. **3**(1): p. 77-80.
4. Nielsen, M., A. Qaseem, and P. High Value Care Task Force of the American College of, *Hematuria as a Marker of Occult Urinary Tract Cancer: Advice for High-Value Care From the American College of Physicians*. Ann Intern Med, 2016. **164**(7): p. 488-97.

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5. ECLM, *European Urinalysis Guidelines*. Scand J Clin Lab Invest, 2000. **60**: p. 1-96.
6. Pannala, A.S., et al., *The effect of dietary nitrate on salivary, plasma, and urinary nitrate metabolism in humans*. Free Radic Biol Med, 2003. **34**(5): p. 576-84.
7. Simerville, J.A., W.C. Maxted, and J.J. Pahira, *Urinalysis: a comprehensive review*. Am Fam Physician, 2005. **71**(6): p. 1153-62.