NOTIFICATION: URINARY CORTISOL - NEW RELEASE

Product: Urinary Cortisol
Code: DKO018

As part of the continuous improvement programme at DiaMetra Srl we are pleased to announce the release of an improved version of the **Urinary Cortisol assay (DKO018).** This will be available from April 2019 and will commence with lot number #5016. Benefits to this improved assay include:

- Excellent correlation against existing LC-MS/MS
- Improved sensitivity and specificity
- Updated normal range values
- Updated measuring range

The key change we have made to the assay is to standardise against an LCMS/MS method. This change ensures our assay provides more accurate assessment of reported result which supports improved patient management.

As a result of this re-standardisation, we have performed a new reference range study. Details of this are included in the IFU and highlighted in the table below. As with all immunoassays, it is advisable for a laboratory to establish its own range of normal and pathological values, particularly following any changes to an assay. Internal assessment of reference range has been performed and it is important that patient samples are assessed using updated reference values assigned using this kit.

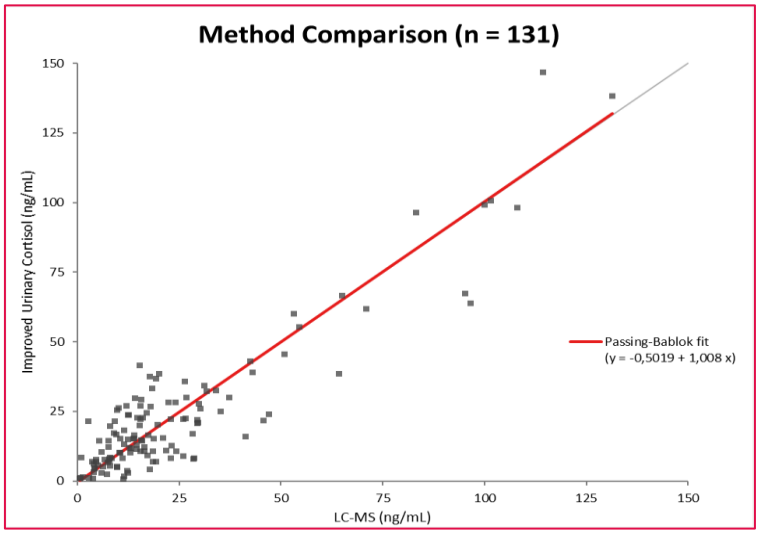
DiaMetra Srl. strives to provide you with products of the highest quality; we value your business and thank you for your continued support. If you have any questions concerning this notification or require further details on the information contained within this notification, please contact your local DiaMetra representative at your earliest convenience.

Parameter	Current	From April 2019 (commencing with #5016)
Correlation vs LC-MS/MS	*N/A*	*Y = -0.50 + 1.01x*
Sensitivity (analytical)	*2.95 ng/mL*	*0.22 ng/mL*
Normal range	***50 – 190 µg / 24 hr***	***1.5 – 63 µg / 24 hr***
Measuring range	*10 – 500 ng/mL*	*1 – 200 ng/mL*
Summarised protocol – basic *(please refer to kit IFU for detailed assay protocol to run the assay)*	- Allow calibrators to mix for 5 mins prior to use - Prepare the Wash Solution by diluting the 10x Conc. Wash solution 1:10 in distilled water - Add 10 µL calibrators / controls / samples to the microplate followed by 300 µL of conjugate - Incubate at 37°C for 1 hour - Remove contents of the wells and wash 3 times with 350 µL of diluted wash solution - Add 100 µL of TMB Substrate to all wells - Incubate at RT (22 - 28°C) for 15 mins – in the dark - Add 100 µL of Stop Solution to all wells and shake gently - Read absorbance at 450 nm with reference 620 – 630 nm or blank within 5 minutes	

Method Comparison

Re-standardised Urinary Cortisol vs LC-MS/MS

The re-standardised Diametra Urinary Cortisol assay was compared with an existing LC-MS/MS assay, following CLSI EP-9A2, “Method Comparison and Bias Estimation Using Patient Samples”.

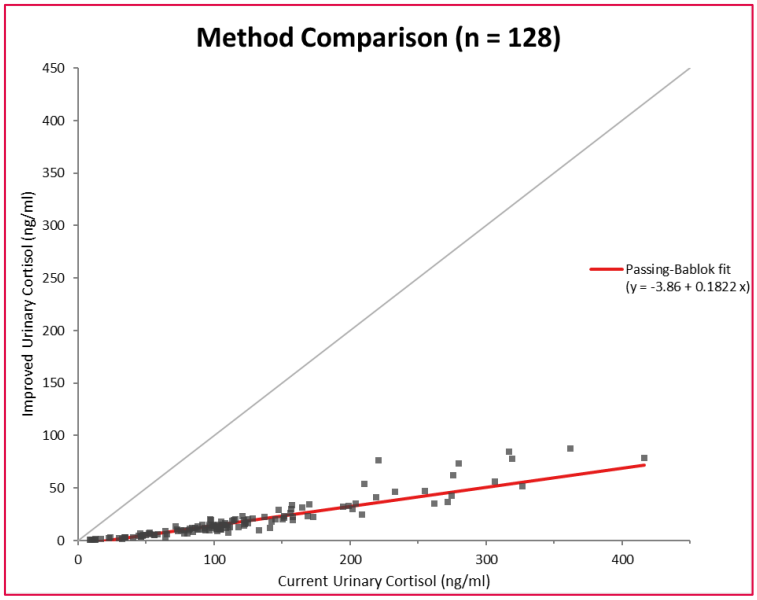


A total of 131 human urine samples, selected to represent a wide range of cortisol concentrations (0.6 to 131.35 ng/mL), were tested with the DiaMetra Urinary Cortisol. Passing-Bablok regression analysis was performed on the comparative data.

Unit	n	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation coefficient (r)
ng/mL	131	1.01	0.91 to 1.1	-0.50	-2.11 to 0.64	0.91

Re-standardised Urinary Cortisol vs current Urinary Cortisol assay

The re-standardised Diametra Urinary Cortisol assay was compared with the current assay formulation, following CLSI EP-9A2, “Method Comparison and Bias Estimation Using Patient Samples”.



A total of 128 human urine samples, selected to represent a wide range of cortisol concentrations (8.98 to 416. ng/mL), were tested with the improved DiaMetra Urinary Cortisol. Passing-Bablok regression analysis was performed on the comparative data.

Unit	n	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation coefficient (r)
ng/mL	128	0.18	0.17 to 0.20	-3.86	-5.16 to -2.87	0.93