Notification Number:	5/2019
Date:	07 June 2019

Product Notification

FOR THE ATTENTION OF THE LABORATORY MANAGER / DIRECTOR

Product: **Aldosterone** **Code:** DKO053

Notification: Release of updated assay

Dear Valued Customer,

Further to the previous communication on this topic (Ref: PN-4 2019) where we informed you of the change to the key antibody used within the Aldosterone assay (product code: DKO053), we are delighted to announce that the first lot of this will be available from the 7th June 2019.

The kits containing the new antibody reagent will commence from lot number: #5118 which will have an expiry of 2020-06 and all subsequent lots produced will contain this new antibody reagent.

As anticipated in the previous communication, the

overall performance of the assay kit containing the current and new antibodies will be comparable. However, we have made some small improvements to the assay protocol and IFU between the previous and new kit versions. These include:

Section 3 – Reagents, Materials and Instrumentation: Conjugate has changed to ready to use

Section 3 – Reagents, Materials and Instrumentation: Wash solution has an updated formulation and will require a different dilution – and will be supplied as a 10x solution

Section 3 – Reagents, Materials and Instrumentation: the assay will contain an additional control sample as opposed to the single control currently supplied

Section 4 – Warnings: the measuring range of the assay has been changed to 41.5 – 2000 pg/mL (the lower end of the measuring range being set by the LoD of the assay)

Section 6.2 – Procedure / Preparation of wash buffer: the wash solution should be prepared by diluting 1:10

Section 6.3 – Procedure / Preparation of diluted conjugate: section no longer required as conjugate will be supplied ready to use

Section 6.4 – Procedure / Preparation of sample / Annex A: organic solvent has been removed from the procedure to prepare urine samples within the assay and the protocol has been simplified. Procedure for handling urine samples is now included in the IFU and not as part of Annex A.

Section 8.3 – Results / Calculation of results: information on how to calculate results for urine samples is now included

Sections 9 & 10 – Reference values* / Performance characteristics: these sections have been updated following the validation of the new reagent

*** Please note**: previous reference ranges were taken from publications whereas the new reference values have been generated from the kit from in house testing.

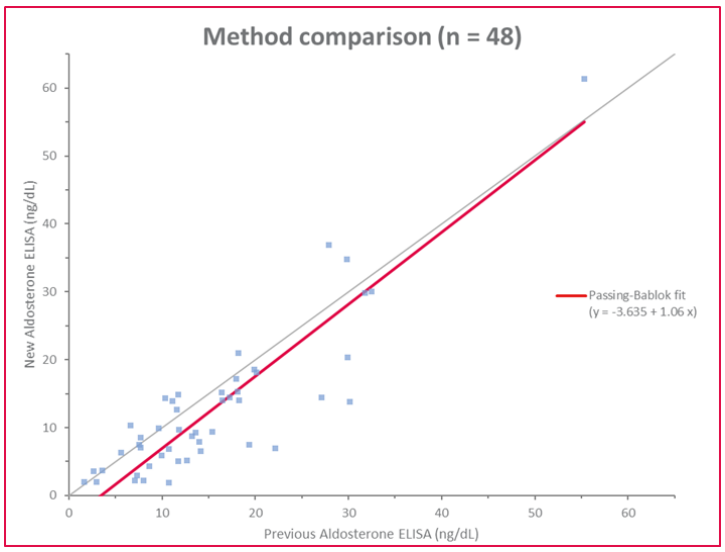
These changes are summarised in the table below and will be highlighted in the product insert and are applicable starting from lot number 5118 and will be applicable to all subsequent lots. We would suggest that you review the new IFU prior to running the assay to ensure compliance with the updated protocol.

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 IDS representative at your earliest convenience.

Summary of differences Section No. (new IFU)	Current kit	New kit (5118 onwards)
Section 3 – Reagents, Materials and Instrumentation:	Conjugate to be diluted 1/50	Conjugate has changed to ready to use
Section 3 – Reagents, Materials and Instrumentation	Wash solution to be diluted 1/50	Wash solution has an updated formulation and will require a different dilution – and will be supplied as a 10x solution
Section 3 – Reagents, Materials and Instrumentation	1 internal control	2 internal controls
Section 4 – Measuring range	20.0 – 2000 pg/mL	41.5 – 2000 pg/mL
Section 6.2 – Procedure / Preparation of wash buffer:	the wash solution should be prepared by diluting 1:50	the wash solution should be prepared by diluting 1:10
Section 6.3 – Procedure / Preparation of diluted conjugate	the conjugate should be prepared by diluting 1:50	section no longer required as conjugate will be supplied ready to use
Section 6.4 – Procedure / Preparation of sample / Annex A:	Organic Solvent required Urine procedure included in the Annex A	organic solvent has been removed from the procedure to prepare urine samples within the assay and the protocol has been simplified. Procedure for handling urine samples is now included in the IFU and not as part of Annex A.
Section 8.3 – Results / Calculation of results:	information on how to calculate results for urine samples is included in Annex A	information on how to calculate results for urine samples is now included
Sections 9 & 10 – Reference values* / Performance characteristics		these sections have been updated following the validation of the new reagent

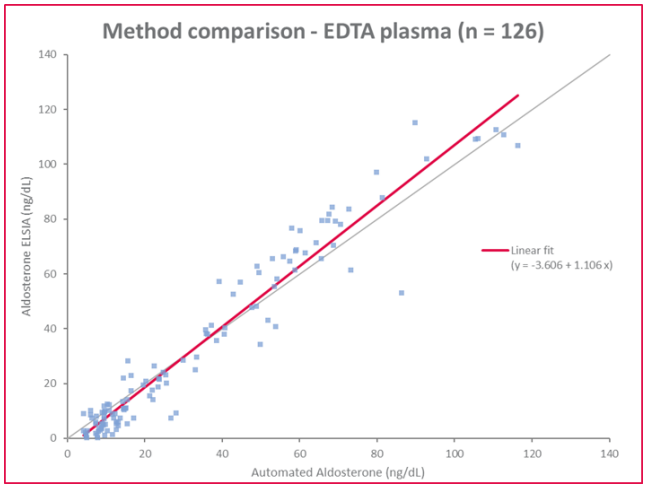
Method Comparison:

a) Previous vs New



- y = -3.606 + 1.106x
- r = 0.9 the previous and new formulations are well correlated
- Some differences observed in detection of low samples

b) New vs CLIA ISYS



- y = -3.606 + 1.106x
- r = 0.97
- The 2 assays are well correlated, but with some differences in low sample detection

Reference Ranges

Previous vs New

Old Range	New Range

Serum:		**pg/mL**	
Healthy Adult		Mean	Range
Early Morning, Supine		68.9	20-180
Upright, 2 Hours		109.2	30-400
24-Hour Urine:		**µg/day**	
Healthy Adult	Volume	Mean	Range
Urine	1650 mL	11.83	2-22

Serum/plasma:
<14.6 – 174 pg/mL
Urine:
2 – 23 µg/24hr

We are in process of assessing new reference ranges split for both standing and supine. Once these updated ranges are assigned we will communicate these and update the IFU accordingly.