

 analyticon	Product / Process Change Notification	File No.	ExCC26-016_A
		Rev. No.	1
	Analyticon Biotechnologies GmbH Am Muehlenberg 10 35104 Lichtenfels, Germany	Date	17.08.2026
		Page	1 of 2

Dear Sir or Madam,

hereby we want to inform about changed concentration data of reactive ingredients.

A description of our change control process is given in the following table:

Short description:	Changed concentration data of reactive ingredients
Product / Process:	All CombiScreen® urine test strips (Legacy Devices)
Ref.-No.:	As usual known
Effectiveness of change:	Smooth roll-out in production during the fourth quarter of 2026 Applies to products using the Instruction For Use (IFU) with the following imprints: PBA9342_21_001_00_07.01_20260611 (revision 07) PBA9343_21_001_00_03.01_20260618 (revision 03) PBA9357_21_001_00_03.01_20260615 (revision 03)

Root cause and impact of change process:

Chapter REAGENTS / TEST PAD

A new reference system was established to determine the concentration values of reactive ingredients of the urine test strips:

From now onwards, the test pad will be used as the reference when specifying the concentration, and the concentration per test pad will be stated.

The introduction of the reference system has changed the calculation of the percentage shares. The test strip formulation did not change.

As this is only a theoretical calculation and the formulation did not change, any impact on the function, performance, usability, safety or applicable regulatory requirements of the test strips or on its intended use can be excluded.

Stock of all products with the previous instructions for use will be sold off as normal.

All changes are highlighted in grey for comparison with the previous version. The instructions for use are available to view and download on the homepage via the following link:

https://www.analyticon-diagnostics.com/de/service_und_support/downloads.html

(Please enter the item number and select the IFU!).

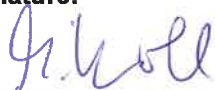
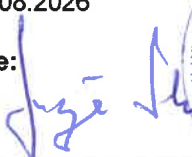
Required Measures by the Customer:

Please take note of the change and pass on this information to all relevant parties within and outside your organization.

Please check whether the change affects any existing registrations. If we can assist you with further information or documents in this regard, please contact registration@analyticon-diagnostics.com.

External Notification!	ExCC26-016_A_Changes_IFU_CombiScreen_IVDD_Products_1.docx
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Productmanagement Name: Michaela Kroll Date: 17.08.2026 Signature: 	Person responsible for regulatory compliance: Name: Dr. Jürgen Schmich Date: 17.08.2026 Signature:  
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