

CUSTOMER INFORMATION

Changes on Documents for BioMajesty July 2015

Dear BioMajesty users,

We would like to inform you about current changes on DiaSys products and documents for use on BioMajesty.

All modifications are highlighted in Grey by DiaSys. Edition numbers increase with every change. Please note following changes:

Drug interferences in tests based on trinder reactions (Modification D):

According to the Urgent Field Safety Notice from 6th of July, DiaSys inserted a note on interferences by N-acetylcysteine (NAC), acetaminophen and metamizole in the section "Warnings and Precautions". These drugs cause falsely low results in patient samples.

General changes in all instructions for use and technical data for: *BioMajesty*

We corrected typing/rounding errors and harmonized technical data and instructions for use.

Product specific changes in instructions for use for: *BioMajesty*

Product	Cat. No.	Updated Edition No.	Modification
α -Amylase CC FS	1 0501	May 2015/4	In compliance with the technical data the hemoglobin interference of 500 mg/dL was transferred into the instructions for use.
Alkaline phosphatase FS DGKC	1 0401	June 2015/1	A proved application can be provided on request even though no kit is available further on
Cholesterol FS	1 1300	May 2015/6	The measuring range was corrected from 20 mmol/L into 19.4 mmol/L. The technical data were updated accordingly.
		July 2015/7	Modification D
CK-NAC FS	1 1601	June 2015/8	Notes for hazardous and precautionary sentences were updated according to current safety data sheet
Creatinine PAP FS	1 1759	July 2015/8	Modification D
Cystatin C FS	1 7158	April 2015/1	Since April 2015 DiaSys offers a BioMajesty kit for Cystatin C FS (Cat. No. 1 7158 99 10 966)
HDL-C Immuno FS	1 3521	July 2015/7	Modification D
LDL-C Select FS	1 4121	July 2015/6	Modification D
Lipase DC FS	1 4321	June 2015/4	Notes for hazardous and precautionary sentences were updated according to current safety data sheet

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Product	Cat. No.	Updated Edition No.	Modification
NEFA FS	1 5781	July 2015/7	Modification D
Pancreatic amylase CC FS	1 0551	May 2015/4	In compliance with the technical data the hemoglobin interference of 100 mg/dL was transferred into the instructions for use.
Phospholipids FS	1 5741	July 2015/5	Modification D
Triglycerides FS	1 5710	July 2015/7	Modification D
Total protein FS	1 2311	July 2015/5	Notes for hazardous and precautionary sentences were updated according to current safety data sheet
Uric acid FS TOOS	1 3001	July 2015/5	Modification D

Please note that we have already exchanged the documents on the internal part of the DiaSys website.

Please, do not hesitate to ask for further information.

Best regards,

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Technical Product Management