

3diag - CysC - 800

Cystatin C - for *IMMAGE*[®] 800

REF TD-42601

IVD CE

IFU Annex: *IMMAGE*[®] and *IMMAGE*[®] 800 Immunochemical Systems Application (Urine)

PROTOCOL INFORMATION

Reagent Lot Number:	(^{*1})	Units:	mg/L
Cartridge Lot Number:	(^{*1})	Protocol:	Non-competitive NIPIA
Cartridge Serial Number:	(^{*1})	AGXS Limit:	not defined
Reagent Expiry date:	(^{*1})		
Sample or Dilution Volume:	20 µL	Diluent:	DIL1 (^{*2})
Reaction Buffer Volume:	195 µL	Buffer:	BUF2 (^{*3})
Calibration Dilution:	1 : 5	Gain:	1
Compartment A Volume:	40 µL	Sample Dilution:	1 : 1 (^{*4})
Compartment B Volume:	10 µL	Reaction Time:	2.5 minutes

CALIBRATION INFORMATION

Levels:	6	Replicates:	2
Update Level:	4 (^{*5})	Replicates:	2 (^{*5})
Model:	Logistic 4 parameters		

NOTES

- (^{*1}): See the labels of the Reagent Cartridge.
- (^{*2}): Beckman Coulter P/N no. 447640. For the *IMMAGE*[®] it has to be defined as DIL10.
- (^{*3}): Beckman Coulter P/N no. 447040. For the *IMMAGE*[®] it has to be defined as BUF10.
- (^{*4}): It has to be programmed after performing the calibration process for the first time.
- (^{*5}): The use of the calibration update, with only one calibrator level, is discouraged.