

3diag - IgD - 800

IgD Immunoglobulins - for *IMMAGE*[®] 800

REF TD-42641

IVD CE

ANNEX to Instruction for Use:

Application (NIPIA) for *IMMAGE*[®] and *IMMAGE*[®] 800 Immunochemical Systems

PROTOCOL INFORMATION

Reagent Lot Number:	^(*1)	Units:	mg/dL or U/mL
Cartridge Lot Number:	^(*1)	Protocol:	Non-competitive NIPIA
Cartridge Serial Number:	^(*1)	AGXS Limit:	not defined
Reagent Expiry date:	^(*1)		
Sample or Dilution Volume:	8 µL	Diluent:	DIL1 ^(*2)
Reaction Buffer Volume:	195 µL	Buffer:	BUF2 ^(*3)
Calibration Dilution:	1 : 10	Gain:	1
Compartment A Volume:	75 µL	Sample Dilution:	1 : 40 ^(*4)
Compartment B Volume:	30 µL	Reaction Time:	5.0 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.
 For the reanalysis of samples lower than about 10-15 mg/dL, a sample dilution of 1:10 can be programmed, if more accurate and precise results are required for low concentration samples.
 (*5): The use of the calibration update, with only one calibrator level, is discouraged.