

Mar-2020

Additional Mouse IgG Test Settings for Cedex Bio HT Analyzers

Product-specific calibration for optimal accuracy

IgG is not an exactly defined compound, there can be relevant differences in structure and molecular weight. Mouse IgG molecules containing the constant Fc part, including the IgG subclasses IgG1, IgG2a and IgG2b, can be detected using the Cedex Mouse IgG assay. Nevertheless, their affinity to the test antibody in the IgG assay can be different compared to the IgG in 'Calibrator F Bio'. Therefore, if CAL F is used for a generic calibration of the assay, the testing inaccuracy can be higher for individual IgG samples, mainly in the upper part of the test range. In worst case, up to 20% underestimation has been observed near the upper limit of the test range.

In order to achieve the optimal accuracy of test results also in case of uncommon IgG molecules, the individual IgG product can be used for a specific calibration. The custom calibrator solution needs a concentration of about 1.5 g/L IgG (in the range of 1.35 - 1.7 g/L) determined with a reference method like HPLC, and it simply can be used instead of CAL F. Use 0.9% sodium chloride solution (can be prepared from NaCl Diluent 9% by 1:10 dilution with water) for the dilution of the specific IgG product to the required concentration.

Controls should also be based on the same IgG molecule.

Additional protocols for the analyzer enable the parallel use of custom calibrations for several different IgG products on the same instrument.

Required reagents on a Cedex Bio HT Analyzer:

- | | |
|------------------------------------|----------------------|
| ▪ Mouse IgG Bio HT, 200 tests, | mat. no. 08377979001 |
| ▪ NaCl Diluent 9%, 6 x 22 mL, | mat. no. 06609406001 |
| ▪ Calibrator F Bio, 6 x 1 mL, | mat. no. 08377987001 |
| ▪ Control F Level 1 Bio, 6 x 1 mL, | mat. no. 08377995001 |
| ▪ Control F Level 2 Bio, 6 x 1 mL, | mat. no. 08378002001 |
| ▪ Control F Level 3 Bio, 6 x 1 mL, | mat. no. 08378029001 |

Recommended:

- custom calibrator solution of 1.5 g/L specific IgG (in range of 1.35 - 1.7 g/L), 550 µL total volume are required for calibration of the three levels (low/high/dil), or 250 µL for one level only
- custom controls of the specific IgG

Mouse IgG test settings for the **Cedex Bio HT** Analyzer

IgG test range	Protocol	Calibrator ID	Controls
Low 10 – 200 mg/L, specific calibration	MIGLB 0-201 v1	CAL F 07-1511-5	Control F Level 1 Bio
	MIGL1 0-362 v1 *	CALF1 07-1554-9	Custom (75 – 150 mg/L)
	MIGL2 0-363 v1 *	CALF2 07-1555-7	Custom (75 – 150 mg/L)
	MIGL3 0-364 v1 *	CALF3 07-1556-8	Custom (75 – 150 mg/L)
	MIGL4 0-365 v1 *	CALF4 07-1546-8	Custom (75 – 150 mg/L)
	MIGL5 0-366 v1 *	CALF5 07-1515-8	Custom (75 – 150 mg/L)
	MIGL6 0-367 v1 *	CALF6 07-1148-9	Custom (75 – 150 mg/L)
	MIGL7 0-368 v1 *	CALF7 07-1146-2	Custom (75 – 150 mg/L)
	MIGL8 0-369 v1 *	CALF8 07-1094-6	Custom (75 – 150 mg/L)
	MIGL9 0-370 v1 *	CALF9 07-1088-1	Custom (75 – 150 mg/L)
High 200 – 1,500 mg/L, specific calibration	MIGHB 0-202 v1	CAL F 07-1511-5	Control F Level 2 Bio Control F Level 3 Bio
	MIGH1 0-371 v1 *	CALF1 07-1554-9	Custom (0.5 – 1.25 g/L)
	MIGH2 0-372 v1 *	CALF2 07-1555-7	Custom (0.5 – 1.25 g/L)
	MIGH3 0-373 v1 *	CALF3 07-1556-8	Custom (0.5 – 1.25 g/L)
	MIGH4 0-374 v1 *	CALF4 07-1546-8	Custom (0.5 – 1.25 g/L)
	MIGH5 0-375 v1 *	CALF5 07-1515-8	Custom (0.5 – 1.25 g/L)
	MIGH6 0-376 v1 *	CALF6 07-1148-9	Custom (0.5 – 1.25 g/L)
	MIGH7 0-377 v1 *	CALF7 07-1146-2	Custom (0.5 – 1.25 g/L)
	MIGH8 0-378 v1 *	CALF8 07-1094-6	Custom (0.5 – 1.25 g/L)
	MIGH9 0-379 v1 *	CALF9 07-1088-1	Custom (0.5 – 1.25 g/L)
High Dilution 1,000 – 7,500 mg/L, specific calibration	MIGHD 0-203 v1	CAL F 07-1511-5	Custom control 1,250 – 6,500 mg/L
	MIGD1 0-380 v1 *	CALF1 07-1554-9	Custom (1.25 – 6.5 g/L)
	MIGD2 0-381 v1 *	CALF2 07-1555-7	Custom (1.25 – 6.5 g/L)
	MIGD3 0-382 v1 *	CALF3 07-1556-8	Custom (1.25 – 6.5 g/L)
	MIGD4 0-383 v1 *	CALF4 07-1546-8	Custom (1.25 – 6.5 g/L)
	MIGD5 0-384 v1 *	CALF5 07-1515-8	Custom (1.25 – 6.5 g/L)
	MIGD6 0-385 v1 *	CALF6 07-1148-9	Custom (1.25 – 6.5 g/L)
	MIGD7 0-386 v1 *	CALF7 07-1146-2	Custom (1.25 – 6.5 g/L)
	MIGD8 0-387 v1 *	CALF8 07-1094-6	Custom (1.25 – 6.5 g/L)
	MIGD9 0-388 v1 *	CALF9 07-1088-1	Custom (1.25 – 6.5 g/L)

* Additional protocols not included in the common TAS file,
and not mentioned in the instructions for use

The protocols can be installed on the Cedex Bio HT Analyzer from the file
'MouseIgG_CedexBioHT_AdditionalProtocols_Mar2020.zip'