

Mar-2020

Additional Ig Fab Test Settings for Cedex Bio HT Analyzers

Product-specific calibration for optimal accuracy

Ig Fab is not an exactly defined compound, there can be relevant differences in structure and molecular weight. All molecules containing the constant region of the human kappa light chain (including free light chains, Fab fragments, full antibodies) can be detected by the Cedex Ig Fab assay. Nevertheless, their affinity to the test antibody in the Ig Fab assay can be different compared to the immunoglobulin in 'Calibrator A Bio'. Therefore, if CAL A is used for a generic calibration of the assay, the determination may be inaccurate for special molecules.

In order to achieve the optimal accuracy of test results for different immunoglobulin molecules, the individual immunoglobulin can be used for a specific calibration. The custom calibrator solution needs a concentration of about 380 mg/L Ig Fab (in the range of 300 - 400 mg/L) determined with a reference method like HPLC or OD 280 nm, and it simply can be used instead of CAL A. 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. The calibrator concentration [CAL] defines the upper limit of the measuring range.

Ranges	FABLB:	10 mg/L to	[CAL]
	FABHB:	300 mg/L to	[20xCAL]
	FABHD:	6000 mg/L to	[100xCAL]

Controls should also be based on the same immunoglobulin molecule. The buffer matrix should be similar to the typical sample type.

Additional protocol copies for the analyzer enable the parallel use of custom calibrations for several different Ig Fab products on the same instrument.

Required reagents on a Cedex Bio HT Analyzer:

- Ig Fab Bio HT, 200 tests, mat. no. 08881359001
- NaCl Diluent 9%, 6 x 22 mL, mat. no. 06609406001
- Accelerator, 100 mL, mat. no. 06609333001

Recommended:

- custom calibrator solution of about 380 mg/L Ig Fab (in the range of 300 - 400 mg/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 Ig Fab

Optional (only for use of protocol FABLA):

- Calibrator A Bio, 6 x 1 mL, mat. no. 06682189001
- Control A Level 2 Bio, 6 x 1 mL, mat. no. 06682227001

Ig Fab test settings for the **Cedex Bio HT** Analyzer

IgG test range	Protocol	Calibrator ID	Controls
Low, 130 – 350 mg/L, calibration: CAL A	FABLA 0-105 v1	CAL A 07-1100-4	1:2 dilution of Control A Level 2 Bio
Low 10 – 400 mg/L specific calibration	FABLB 0-104 v1	CLFAB 07-9015-0	Custom (50 – 300 mg/L)
	FABL1 0-258 v1 *	CFAB1 07-9256-0	Custom (50 – 300 mg/L)
	FABL2 0-259 v1 *	CFAB2 07-9273-0	Custom (50 – 300 mg/L)
	FABL3 0-260 v1 *	CFAB3 07-9287-0	Custom (50 – 300 mg/L)
	FABL4 0-261 v1 *	CFAB4 07-9290-0	Custom (50 – 300 mg/L)
	FABL5 0-262 v1 *	CFAB5 07-9502-0	Custom (50 – 300 mg/L)
High 300 – 8,000 mg/L specific calibration	FABHB 0-106 v1	CLFAB 07-9015-0	Custom (0.5 – 7.0 g/L)
	FABH1 0-263 v1 *	CFAB1 07-9256-0	Custom (0.5 – 7.0 g/L)
	FABH2 0-264 v1 *	CFAB2 07-9273-0	Custom (0.5 – 7.0 g/L)
	FABH3 0-265 v1 *	CFAB3 07-9287-0	Custom (0.5 – 7.0 g/L)
	FABH4 0-266 v1 *	CFAB4 07-9290-0	Custom (0.5 – 7.0 g/L)
	FABH5 0-267 v1 *	CFAB5 07-9502-0	Custom (0.5 – 7.0 g/L)
High Dilution 6,000 – 40,000 mg/L specific calibration	FABHD 0-107 v1	CLFAB 07-9015-0	Custom (9 – 30 g/L)
	FABD1 0-268 v1 *	CFAB1 07-9256-0	Custom (9 – 30 g/L)
	FABD2 0-269 v1 *	CFAB2 07-9273-0	Custom (9 – 30 g/L)
	FABD3 0-270 v1 *	CFAB3 07-9287-0	Custom (9 – 30 g/L)
	FABD4 0-271 v1 *	CFAB4 07-9290-0	Custom (9 – 30 g/L)
	FABD5 0-272 v1 *	CFAB5 07-9502-0	Custom (9 – 30 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
'*IGFab_CedexBioHT_AdditionalProtocols_Mar2020.zip*'