

June-2023

## **Additional IgG Test Settings for Cedex Bio HT Analyzers**

### **IgG-specific calibration for optimal accuracy:**

IgG is not an exactly defined compound, there can be relevant differences in structure and molecular weight. Recombinant antibodies, especially the artificially designed molecules, often have structures different from native IgG. All products containing the constant Fc part of human immunoglobulins can be detected by the Cedex IgG assay. Nevertheless, their affinity to the test antibody in the IgG assay can be slightly different compared to the IgG in 'Calibrator A Bio'. Therefore, when CAL A is used for 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 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.

Controls should also be based on the same IgG product.

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

### **Higher IgG concentration ranges:**

For determination of IgG concentrations > 8 g/L, there are test settings available with automated sample predilution. The correct function of these settings has been verified, nevertheless, with very high IgG concentrations, especially if > 32 g/L, there can be sample inhomogeneity effects in dependence on the specific sample matrix (by aggregation, exsolution, absorption). Therefore, for such high concentrations, the testing accuracy should be verified for the individual sample type.

### **Required reagents on a Cedex Bio HT Analyzer:**

- |                                       |                      |
|---------------------------------------|----------------------|
| ▪ IgG Bio HT, 100 tests,              | mat. no. 06608540001 |
| ▪ NaCl Diluent 9%, 6 x 22 mL,         | mat. no. 06609406001 |
| ▪ Cleaner Alkaline Bio HT, 200 tests, | mat. no. 06612369001 |
| ▪ Accelerator, 100 mL,                | mat. no. 06609333001 |

optional:

- |                                    |                      |
|------------------------------------|----------------------|
| ▪ Calibrator A Bio, 6 x 1 mL,      | mat. no. 06682189001 |
| ▪ Control A Level 1 Bio, 6 x 1 mL, | mat. no. 06682197001 |
| ▪ Control A Level 2 Bio, 6 x 1 mL, | mat. no. 06682227001 |
| ▪ Control A Level 3 Bio, 6 x 1 mL, | mat. no. 06682545001 |

or ▪ custom calibrator solution of 1.5 g/L IgG (in range of 1.35 – 1.7 g/L)

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

| IgG test range                                                          | Protocol              | Calibrator ID      | Controls                                                  |
|-------------------------------------------------------------------------|-----------------------|--------------------|-----------------------------------------------------------|
| <b>Low</b><br><br>10 – 80 mg/L<br><br>(0.067 – 0.533<br>$\mu$ mol/L)    | <b>IGGLB</b> 0-919 v5 | CAL A 07-1100-4    | Dilution 1:10 of<br>Control A Level 2 Bio<br>in 0.9% NaCl |
|                                                                         | IGGL1 0-570 v1 *      | Custom-1 07-1131-4 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGGL2 0-571 v1 *      | Custom-2 07-1132-2 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGGL3 0-572 v1 *      | Custom-3 07-1134-9 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGGL4 0-573 v1 *      | Custom-4 07-1135-7 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGGL5 0-574 v1 *      | Custom-5 07-1161-6 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGGL6 0-575 v1 *      | Custom-6 07-1162-4 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGGL7 0-576 v1 *      | Custom-7 07-1163-2 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGGL8 0-577 v1 *      | Custom-8 07-9160-1 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGGL9 0-578 v1 *      | Custom-9 07-9161-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL10 0-579 v1 *      | Custom10 07-9164-4 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL11 0-580 v1 *      | Custom11 07-9170-9 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL12 0-581 v1 *      | Custom12 07-9175-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL13 0-582 v1 *      | Custom13 07-9189-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL14 0-583 v1 *      | Custom14 07-9192-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL15 0-584 v1 *      | Custom15 07-9595-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL16 0-585 v1 *      | Custom16 07-9600-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL17 0-586 v1 *      | Custom17 07-9614-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL18 0-587 v1 *      | Custom18 07-9628-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL19 0-588 v1 *      | Custom19 07-9631-0 | Custom (20 – 70 mg/L)                                     |
|                                                                         | IGL20 0-589 v1 *      | Custom20 07-9645-0 | Custom (20 – 70 mg/L)                                     |
| <b>High</b><br><br>80 – 1600 mg/L<br><br>(0.533 – 10.67<br>$\mu$ mol/L) | <b>IGGHB</b> 0-926 v4 | CAL A 07-1100-4    | Control A Level 2 Bio<br>Control A Level 3 Bio            |
|                                                                         | IGGH1 0-749 v3 *      | Custom-1 07-1131-4 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGGH2 0-158 v3 *      | Custom-2 07-1132-2 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGGH3 0-159 v3 *      | Custom-3 07-1134-9 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGGH4 0-160 v3 *      | Custom-4 07-1135-7 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGGH5 0-157 v3 *      | Custom-5 07-1161-6 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGGH6 0-165 v3 *      | Custom-6 07-1162-4 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGGH7 0-173 v3 *      | Custom-7 07-1163-2 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGGH8 0-166 v1 *      | Custom-8 07-9160-1 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGGH9 0-167 v1 *      | Custom-9 07-9161-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH10 0-168 v1 *      | Custom10 07-9164-4 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH11 0-169 v1 *      | Custom11 07-9170-9 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH12 0-170 v1 *      | Custom12 07-9175-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH13 0-171 v1 *      | Custom13 07-9189-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH14 0-172 v1 *      | Custom14 07-9192-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH15 0-174 v1 *      | Custom15 07-9595-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH16 0-175 v1 *      | Custom16 07-9600-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH17 0-177 v1 *      | Custom17 07-9614-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH18 0-178 v1 *      | Custom18 07-9628-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH19 0-179 v1 *      | Custom19 07-9631-0 | Custom (0.15 – 1.5 g/L)                                   |
|                                                                         | IGH20 0-180 v1 *      | Custom20 07-9645-0 | Custom (0.15 – 1.5 g/L)                                   |

|                                                                              |                         |                    |                                                |
|------------------------------------------------------------------------------|-------------------------|--------------------|------------------------------------------------|
| <b>Pre-Dilution 1:5</b><br><br>0.4 – 8.0 g/L<br><br>(2.67 – 53.35<br>µmol/L) | <b>IGGHD</b> 0-722 v4   | CAL A 07-1100-4    | Control A Level 2 Bio<br>Control A Level 3 Bio |
|                                                                              | IGGD1 0-305 v2 *        | Custom-1 07-1131-4 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGGD2 0-306 v2 *        | Custom-2 07-1132-2 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGGD3 0-311 v2 *        | Custom-3 07-1134-9 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGGD4 0-314 v2 *        | Custom-4 07-1135-7 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGGD5 0-315 v1 *        | Custom-5 07-1161-6 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGGD6 0-316 v1 *        | Custom-6 07-1162-4 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGGD7 0-317 v1 *        | Custom-7 07-1163-2 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGGD8 0-307 v1 *        | Custom-8 07-9160-1 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGGD9 0-308 v1 *        | Custom-9 07-9161-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD10 0-309 v1 *        | Custom10 07-9164-4 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD11 0-310 v1 *        | Custom11 07-9170-9 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD12 0-313 v1 *        | Custom12 07-9175-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD13 0-303 v1 *        | Custom13 07-9189-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD14 0-304 v1 *        | Custom14 07-9192-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD15 0-320 v1 *        | Custom15 07-9595-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD16 0-323 v1 *        | Custom16 07-9600-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD17 0-324 v1 *        | Custom17 07-9614-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD18 0-325 v1 *        | Custom18 07-9628-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD19 0-326 v1 *        | Custom19 07-9631-0 | Custom (0.7 – 7 g/L)                           |
|                                                                              | IGD20 0-327 v1 *        | Custom20 07-9645-0 | Custom (0.7 – 7 g/L)                           |
| <b>Extended 1:20</b><br><br>1.6 – 32 g/L<br><br>(10.7 – 213<br>µmol/L)       | <b>IGGHE</b> 0-740 v3 * | CAL A 07-1100-4    | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE1 0-312 v1 *        | Custom-1 07-1131-4 | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE2 0-298 v1 *        | Custom-2 07-1132-2 | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE3 0-299 v1 *        | Custom-3 07-1134-9 | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE4 0-300 v1 *        | Custom-4 07-1135-7 | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE5 0-301 v1 *        | Custom-5 07-1161-6 | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE6 0-302 v1 *        | Custom-6 07-1162-4 | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE7 0-328 v1 *        | Custom-7 07-1163-2 | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE8 0-346 v1 *        | Custom-8 07-9160-1 | Custom (3 – 30 g/L)                            |
|                                                                              | IGGE9 0-347 v1 *        | Custom-9 07-9161-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE10 0-348 v1 *        | Custom10 07-9164-4 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE11 0-351 v1 *        | Custom11 07-9170-9 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE12 0-352 v1 *        | Custom12 07-9175-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE13 0-353 v1 *        | Custom13 07-9189-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE14 0-354 v1 *        | Custom14 07-9192-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE15 0-355 v1 *        | Custom15 07-9595-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE16 0-356 v1 *        | Custom16 07-9600-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE17 0-357 v1 *        | Custom17 07-9614-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE18 0-359 v1 *        | Custom18 07-9628-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE19 0-360 v1 *        | Custom19 07-9631-0 | Custom (3 – 30 g/L)                            |
|                                                                              | IGE20 0-389 v1 *        | Custom20 07-9645-0 | Custom (3 – 30 g/L)                            |
| <b>Pre-Dilution 1:100</b><br>8 – <b>160</b> g/L                              | <b>IG160</b> 0-318 v1 * | CAL A 07-1100-4    | Custom (15 – 150 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  
*IGG\_CedexBioHT\_AdditionalProtocols\_Jun2023.zip*

Changes to previous version from Feb-2022:

- Additional protocols: IGGE2 – IGGE9, IGE10 – IGE20