

Biochemistry Pathological Control



Store at 2-8 °C

Configuration

REF	HBC02
VOL	4 x 5 mL
Biochemistry Pathological Control	4 x Lyoph.-5 mL
Instrument	Universal

Intended use

The Cypress Diagnostics Biochemistry Pathological Control is a human lyophilized serum. Concentrations and their ranges of different analytes are provided in the enclosed table. These ranges are intended for verification of calibration, reagent, analyzer and manipulations in manual techniques and automatic analyzers.

For *in vitro* diagnostic use only. For professional use only.

Reagent composition

Biochemistry Pathological Control	Human lyophilized serum. Additives and bacteriostatic agents.
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The analyte concentrations and their ranges are lot specific and are given in enclosed table.

In order to check the metrological traceability of the specified values, please check the corresponding technical file.

Precautions

- Components of human origin have been tested by CE-marked test kits and found negative for the presence of HBsAg and antibodies to HCV and HIV (1/2). In addition, for HIV and HCV, the negative result has been confirmed by PCR. As the risk of infection cannot be excluded with certainty, however, the product must be handled just as potentially infectious and disposed of accordingly.
- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

Reconstitution: Bring the vial to room temperature for 30 minutes. Gently tap the vial on a table to drop any lyophilized material from the rubber cap in the vial. Open the vial very carefully and, with an accurate volumetric pipette, slowly add exactly 5,0 mL of high-quality distilled water. Take care to avoid any loss of the lyophilized material. Close the vial and allow to stand for 30 minutes. Swirl gently to homogenize. Ensure that all traces of dry material are dissolved. Do not shake, vortex or invert.

Bring to room temperature for about 30 minutes before use and mix carefully before each use. Avoid the formation of foam.

Inaccurate reconstitution, improper storage/handling and errors in assay technique can cause erroneous results.

Storage, stability and disposal

The control is stable at 2-8°C up to the date of expiration as specified on the label. After reconstitution store the vial tightly closed and prevent contaminations during its use. Do not use in case of visible evidence of microbial growth.

The analytes in the reconstituted control serum are stable for:

At 15-25 °C: 8 hours, except for

Bilirubin direct, Alkaline phosphatase: 4 hours

At 2-8 °C: 5 days, except for

Bilirubin total, Bilirubin direct and GPT(ALT): 24 hours

At -25 to -15 °C: 1 month, except for

Bilirubin total, Bilirubin direct and Alkaline phosphatase : 2 weeks

Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Distilled water
- General laboratory equipment

Procedure

The control must be used according to the test instructions of the corresponding assays.

Results of the controls should be within the defined ranges. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Bibliography

1. Council Directive (2000/54EC). Official Journal of the European Communities, No. L262 from Oct, 17th, 2000.
2. International Federation of Clinical Chemistry (IFCC). Education Division, Expert Panel of Quantities and Units: A protocol for the Conversion of Clinical Laboratory data, Journal of Automatic Chemistry Vol. 11, No 5 (Sept-Oct 1986), p. 223-226

2021-09, Rev. 6.0



Biochemistry Pathological Control / Contrôle Biochimie Pathologique (HBC02)

Lot: 295300/3 (revision 2022-05-30)		Manual, semi-automate				Automate				
Exp. Date / Date de Pérem.: 2022-12-28										
PRODUCT / PRODUIT	METHOD / METHODE	VALUE (X̄) / VALEUR (X̄)	SD (σ) / SD (σ)	RANGE (X̄±3SD) / PLAGE (X̄±3SD)	UNIT / UNITÉ	VALUE (X̄) / VALEUR (X̄)	SD (σ) / SD (σ)	RANGE (X̄±3SD) / PLAGE (X̄±3SD)	UNIT / UNITÉ	
Albumin	Bromocresol green. Colorimetric	4,64	0,324	3,66 - 5,61	g/dL	4,61	0,277	3,78 - 5,45	g/dL	
Albumine	Vert de Bromocresol. Colorimétrique	46,4	3,24	36,6 - 56,1	g/L	46,1	2,77	37,8 - 54,5	g/L	
Bilirubin total ^(5,6)	DMSO. Colorimetric. With sample blank	3,96	0,277	3,12 - 4,79	mg/dL	3,80	0,228	3,12 - 4,49	mg/dL	
Bilirubine totale ^(5,6)	DMSO. Colorimétrique. Avec blanc d'échantillon	67,6	4,73	53,4 - 81,8	μmol/L	65,0	3,90	53,3 - 76,7	μmol/L	
Bilirubin direct ^(4,5,6)	DMSO. Colorimetric. With sample blank	1,91	0,172	1,40 - 2,43	mg/dL	2,00	0,160	1,52 - 2,48	mg/dL	
Bilirubine directe ^(4,5,6)	DMSO. Colorimétrique. Avec blanc d'échantillon	32,7	2,95	23,9 - 41,6	μmol/L	34,2	2,74	26,0 - 42,4	μmol/L	
Calcium	Arsenazo III. Colorimetric	7,53	0,376	6,40 - 8,66	mEq/L	7,47	0,299	6,58 - 8,37	mEq/L	
Calcium	Arsenazo III. Colorimétrique	3,76	0,188	3,20 - 4,33	mmol/L	3,74	0,149	3,29 - 4,18	mmol/L	
		15,1	0,753	12,8 - 17,3	mg/dL	14,9	0,598	13,2 - 16,7	mg/dL	
Chloride	Thiocyanate. Colorimetric	108,7	4,35	95,6 - 121,7	mEq/L	110	3,31	100 - 120	mEq/L	
Chlore	Thiocyanate. Colorimétrique	385	15,4	339 - 431	mg/dL	391	11,7	356 - 426	mg/dL	
Cholesterol	CHOD - POD. Colorimetric	234	14,0	192 - 276	mg/dL	234	11,7	199 - 270	mg/dL	
Cholestérol	CHOD - POD. Colorimétrique	6,06	0,364	4,97 - 7,16	mmol/L	6,07	0,304	5,16 - 6,98	mmol/L	
Creatinine	Jaffé. Colorimetric-Kinetic	3,89	0,272	3,07 - 4,70	mg/dL	3,97	0,238	3,26 - 4,69	mg/dL	
Créatinine	Jaffé. Colorimétrique-Cinétique	344	24,1	271 - 416	μmol/L	351	21,1	288 - 414	μmol/L	
Glucose	GOD-POD. Colorimetric	223	13,4	183 - 263	mg/dL	225	11,3	191 - 259	mg/dL	
Glucose	GOD-POD. Colorimétrique	12,4	0,743	10,2 - 14,6	mmol/L	12,5	0,625	10,6 - 14,4	mmol/L	
Magnesium	Xylidyl blue. Colorimetric	3,86	0,193	3,28 - 4,44	mg/dL	3,74	0,150	3,29 - 4,19	mg/dL	
Magnésium	Bleu de Xylidyle. Colorimétrique	1,59	0,0794	1,35 - 1,83	mmol/L	1,54	0,0615	1,35 - 1,72	mmol/L	
Total Protein	Biuret. Colorimetric	7,39	0,369	6,28 - 8,50	g/dL	7,47	0,299	6,58 - 8,37	g/dL	
Protéines totales	Biuret. Colorimétrique	73,9	3,69	62,8 - 85,0	g/L	74,7	2,99	65,8 - 83,7	g/L	
Triglycerides	GPO-POD. Colorimetric	204	12,2	167 - 241	mg/dL	204	10,2	174 - 235	mg/dL	
Triglycérides	GPO-POD. Colorimétrique	2,31	0,138	1,89 - 2,72	mmol/L	2,31	0,115	1,96 - 2,65	mmol/L	
Urea	Urease GLDH. UV-Kinetic	89,6	5,37	73,4 - 105,7	mg/dL	88,2	4,41	75,0 - 101,5	mg/dL	
Urée	Uréase GLDH. UV-Cinétique	14,9	0,896	12,3 - 17,6	mmol/L	14,7	0,736	12,5 - 16,9	mmol/L	
Uric acid	Uricase-POD. Colorimetric. Monochromatic	9,67	0,580	7,93 - 11,41	mg/dL	10,30	0,515	8,76 - 11,85	mg/dL	
Acide urique	Uricase-POD. Colorimétrique. Monochromatique	575	34,5	472 - 679	μmol/L	613	30,6	521 - 705	μmol/L	
Uric acid	Uricase-POD. Colorimetric. CYANExpert 130 / Mindray ⁽⁷⁾					9,38	0,469	7,97 - 10,78	mg/dL	
Acide urique	Uricase-POD. Colorimétrique. CYANExpert 130 / Mindray ⁽⁷⁾					558	27,9	474 - 641	μmol/L	
Alkaline Phosphatase (ALP) ^(4,6)	IFCC. Colorimetric. Kinetic.									
Phosphatase Alcaline (PAL) ^(4,6)	IFCC. Colorimétrique. Cinétique.	37°C	342	24,0	270 - 414	U/L	358	21,5	293 - 422	U/L
a-Amylase	CNPG3. Kinetic									
a-Amylase	CNPG3. Cinétique	37°C	260	18,2	206 - 315	U/L	266	16,0	219 - 314	U/L
g-GT	Carboxy substrate. Colorimetric-Kinetic									
g-GT	Carboxy substrate. Colorimétrique-Cinétique	37°C	116,4	8,15	92,0 - 140,8	U/L	117,2	7,03	96,1 - 138,3	U/L
AST- GOT	NADH IFCC. UV-Kinetic									
AST- GOT	NADH IFCC. UV-Cinétique	37°C	184	12,9	145 - 223	U/L	197	11,8	161 - 232	U/L
ALT-GPT ⁽⁵⁾	NADH IFCC. UV-Kinetic									
ALT-GPT ⁽⁵⁾	NADH IFCC. UV-Cinétique	37°C	155	10,8	122 - 187	U/L	145	8,71	119 - 171	U/L
Lactatedehydrogenase (LDH)	Pyruvate DGKC. UV-Kinetic									
Lactatedéshydrogénase (LDH)	Pyruvate DGKC. UV-Cinétique	37°C	530	37,1	418 - 641	U/L	517	31,0	424 - 611	U/L

1. stable up to 8 hours at 15-25°C / Stable jusqu'à 8 heures à 15-25°C

2. stable up to 5 days at 2-8°C / Stable jusqu'à 5 jours à 2-8°C

3. stable up to 4 weeks at -15 to -25°C / Stable jusqu'à 4 semaines de -15 à -25°C

4. stable up to 4 hours at 15-25°C / Stable jusqu'à 4 heures à 15-25°C

5. stable up to 24 hours at 2-8°C / Stable jusqu'à 24 heures à 2-8°C

6. stable up to 2 weeks at -15° to -25°C / Stable jusqu'à 2 semaines de -15 à -25°C

7. Mindray BS-120, BS-200, BS-200E

Note: all the products fulfill points 1, 2 and 3, with the exception of the products with points 4, 5 and 6

Remarque: tous les produits accomplissent les points 1, 2 et 3, à l'exception des produits avec les points 4, 5 et 6



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