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Use after reading this "Instructions for Use"

FUJI DRI-CHEM CONTROL QP-L

■ Intended use

FUJI DRI-CHEM CONTROL QP-L is a control serum specially designed for FUJI DRI-CHEM system. This product is used to confirm performance using slides for plasma and serum. "Mean values and expected ranges" for the tests are provided to evaluate control status.

For *in vitro* diagnostic use only.

■ Reagents

This product is prepared from pooled human serum and provided in a lyophilized form. Enzymes derived from animals are added for enzyme tests as shown below.

Enzyme	Source
Gamma Glutamyltransferase	Bovine kidney
Glutamic oxalacetic transaminase	Porcine heart
Glutamic pyruvic transaminase	Porcine heart
Creatine phosphokinase	Rabbit muscle
Lactate dehydrogenase	Porcine heart and porcine muscle
Alkaline phosphatase	Bovine kidney
Amylase	Porcine pancreas
Leucine aminopeptidase	Porcine kidney

■ Test object

GLU, BUN, UA, TCHO, HDL-C, TG, CRE, TP, Ca, ALB, TBIL, DBIL, IP, Mg, GGT, GOT/AST, GPT/ALT, CPK, LDH, ALP, AMYL, LAP and CHE

■ System applied

1. Analyzer : FUJI DRI-CHEM ANALYZER
2. Slide : FUJI DRI-CHEM SLIDE for plasma and serum

■ Procedure

1. Wear proper gloves, glasses and other protective gear for your safety.
2. FUJI DRI-CHEM CONTROL QP-L should be stored below -20 °C (-4.0 °F) and warmed up to room temperature for at least 30 minutes prior to reconstitution.
3. Remove the metal seal and a rubber stopper from the vial. Add 3 mL of room-temperature distilled water to the vial. Use of a volumetric pipette is recommended for accurate preparation.
4. After adding the distilled water, replace the rubber stopper immediately to avoid concentration.
5. Let stand for 30 minutes, with stopper firmly in place, then swirl gently several times so as to mix and dissolve completely. Do not shake.
6. Once reconstituted, this product should be used immediately, and sealed up tightly and stored in a refrigerator between 2–8 °C (35.6–46.4 °F) to keep stable after using.

■ Warnings and precautions

1. This product has been found to be non-reactive for HBsAg (hepatitis B surface antigen) by RIA method, and for HCV-Ab (hepatitis-C virus antibody) and HIV-Ab (human immunodeficiency virus antibody) by EIA method. However, as there is no absolute proof of non-infectiousness, this product should be handled with care in the same way as patient specimens.
2. CPK activity could be affected by the temperature of the water added when reconstituting.
3. ALP activity rises gradually after reconstitution.
4. The stability after reconstitution varies with each analyte. Avoid using beyond the time specified in "Stability after reconstitution" as shown below, or when significant change has been observed.
5. TBIL, DBIL and CPK are known to deteriorate by light. Please be careful when QP-L is transferred to a transparent tube.
6. After use, this product is categorized as an infectious waste. Make sure to dispose of it in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal such as incineration, melting, sterilization or disinfection.

■ Stability after reconstitution

Tests	Temp.	Stability
GLU, BUN, UA, TCHO, TG, IP, DBIL, Mg, CRE, TP, Ca, ALB, TBIL, HDL-C	2–8 °C (35.6–46.4 °F)	12 hrs.
GGT, GOT/AST, GPT/ALT, LDH, AMYL, LAP, CHE	18–25 °C (64.4–77.0 °F)	8 hrs.
	2–8 °C (35.6–46.4 °F)	6 hrs.
CPK, ALP	18–25 °C (64.4–77.0 °F)	4 hrs.
	2–8 °C (35.6–46.4 °F)	2 hrs.
	18–25 °C (64.4–77.0 °F)	1 hr.

■ Storage and shelf life

1. Storage condition : Below -20 °C (-4.0 °F)
2. Expiry date is printed on the carton.

■ Contents

1. FUJI DRI-CHEM CONTROL QP-L : 3 mL × 6 bottles
2. "Mean values and expected ranges" : 1 sheet



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Fuji Photo Film (Europe) GmbH
Heesenstr. 31, D-40549 Düsseldorf, GERMANY



Fuji Photo Film Co., Ltd.
3-11-46, Senzui, Asaka-shi, Saitama 351-8585, JAPAN



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