PRECISE PATH
HUMAN CONTROL SERUM

REF. 6001 **1x5 ml** CE IVD

DNV CERTIFIED COMPANY
UNI EN ISO 9001:2008
UN EN ISO 13485:2012

GIESSE DIAGNOSTICS

PRODUCT CHARACTERISTICS

PRECISE PATH is a lyophilized control serum based on human serum with concentrations / activities found in the pathological range. The values indicated are useful for accuracy and precision control of those obtained by manual and automated analytical procedures.

REAGENTS

Human serum with chemical additives and tissue extract of human and animal origin. The concentrations / activities are lot specific. The exact values and ranges are in the enclosed values sheet.

PRECAUTIONS AND WARNING

The product is not classified as dangerous (Dlg. n.285 art. 28 I.N. 128/ 1988). The total concentration of components is lower than the limits reported by 67/548 and 88/379 CE Regulations (and following modifications) about classification, packaging and labelling of dangerous substances. However the reagent should be handled with caution, according to good laboratory practise.

Human control serum is obtained using only blood of donors tested by an FDA method and found non-reactive for HbsAg and negative for antibodies to HIV 1/2 and HCV. However as no test method can rule out the potential risk of infection with absolute certainty, the material should be handled as potentially infectious, just as carefully as a patient sample.

WASTE DISPOSAL

Please consult local regulations for a correct waste disposal.
S56: Dispose of this material and its container at hazardous or special waste collection point.
S57: Use appropriate container to avoid environmental contamination.
S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.

PREPARATION

Carefully open one bottle of PRECISE PATH, avoiding the loss of lyophilizate, and pipette exactly 5.0 ml of distilled / deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.
Note: with the exception of alkaline phosphatase, all enzymes can be measured immediately. To reactivate the alkaline phosphatase, allow the recconstituted serum to stand for one hour at + 25°C.

STORAGE AND STABILITY

Store at 2 - 8 °C. Lyophilized control serum is stable at 2 - 8 °C until the stated expiration date.

Stability of the components in the reconstituted control serum:

at 15 - 25 °C	12 hours
at 2 - 8 °C	5 days
at -25°/ - 15°C	1 month (when frozen once)

Stability of Total Bilirubin in the reconstituted control serum: (when stored protected from light):

at 15 - 25 °C	8 hours
at 2 - 8 °C	24 hours
at -25°/ - 15°C	2 weeks (when frozen once)

Stability of Direct Bilirubin in the reconstituted control serum: (when stored protected from light):

at 15 - 25 °C	4 hours
at 2 - 8 °C	24 hours
at -25°/ - 15°C	2 weeks (when frozen once)

Stability of acid phosphatase and prostatic acid phosphatase in the reconstituted control serum:

at 15 - 25 °C	4 hours
at 2 - 8 °C	24 hours
at -25°/ - 15°C	2 week (when frozen once)

Stability of UIBC in the reconstituted control serum:

at 15 - 25 °C	4 hours
at 2 - 8 °C	1 day
at -25°/ - 15°C	2 weeks (when frozen once)

Store control tightly capped and protected from light when not in use.

REQUIRED MATERIALS NOT PROVIDED

Automatic micropipette, distilled water, general laboratory equipment.

ASSAY

Dispense the required volume into a sample cup and analyze in the same way as for the samples. The control should be run daily in parallel with the patient samples and after every calibration. The control intervals should be adapted to each laboratory's individual requirements.

REFERENCES

1. Occupational Safety and Health Standards: bloodborne pathogen Federal Register. Juli 1, 1998; 6: 267-280.
2. Council Directive 90/679/EEC. Official journal of the European directives n°. L. 374 from Dec. 31,1990:1-12.

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Ed. 2014/12 rev. 01