

PROCALCITONIN CONTROL



For Usage With; Immunoturbidimetric Systems

STORAGE AND STABILITY

1. Beinquality PROCALCITONIN Direct Immunoturbidimetric Controls (2 Level) are stable until the expiration date when stored +2 /+8 °C (Expiry date on the vial).
2. Once opened and diluted controls are stable **2 days** when stored at dark place +2/+8°C.
3. Once opened and diluted controls are stable **8 Hours** when stored at +15/+25°C.
4. Diluted controls are stable **30 days** when stored at (-15)-(-25)°C (when frozen once)
5. Reconstitute and store tightly capped in a dark place, kept free of contamination.
6. Criterion for the stability data stated by Beinquality: Recovery values are within ±10% of initial value.

PREPARATION OF CONTROLS

1. The contents of the vial by swirling gently to avoid the formation of foam.
2. Portioning (allocation) is not allowed. Never divide any PROCALCITONIN into small portioning.
3. **Avoid storage at R.T. at segments inside priority sections** after aspiration!
4. Store controls inside **Sample Cup** and close tightly, store at +2 /+8 °C for 5 days. Don't transfer back to vial.
5. Remix your controls just prior to use. Before sampling, gently invert the vial several times to ensure homogeneity.
6. Do NOT mix by vortex. Don't shake.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

LIMITATIONS & PRECAUTIONS

1. Check expiration date of the product on the vial. Discard outdated products.
2. Repeated thaw process is not allowed.
3. If there is evidence of microbial contamination or excessive turbidity in the reconstituted product, discard the vial.
4. Do not pipette by mouth.
5. Avoid contact with skin and mucous membranes.
6. This product should not be disposed in general waste, but should be disposed with infectious medical waste.
7. SDS can be obtained at www.beinquality.com.tr, by calling +(90)

212 447 00 75 (Turkey), or by calling your local supplier.

ANALYTIC PERFORMANCE

This product is a freeze-dried product. Product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values and optimum uncertainty values the controls requires proper storage and handling as described. The concentrations or % values of the control components are lot-specific. The exact control values are given in the value sheets.

BIBLIOGRAPHY

1. Council Directive (2000/54/EC). Official Journal of the European Communities No. L262 from Oct. 17, 2000.
2. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of Good Laboratory Practice as specified in Council Directive 87/18/EEC
3. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, *Occupational Exposure to Bloodborne Pathogens.*

TRADEMARKS

Beinquality PROCALCITONIN is a trademark of Beinquality A.Ş. In various jurisdictions.

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GLOSSARY OF HARMONIZED SYMBOLS

| | |
|-------------------------------------------------------------------------------------|-------------------------------------------|
| IVD | <i>In Vitro</i> Diagnostic Medical Device |
| LOT | Lot number |
| REF | Reference Number (Catalog No.) |
| GTIN | Global Trade Item Number |
| CON | Control |
| VALUE | Value |
| PRODUCT OF TURKEY | Product of Turkey |
| CONVENTIONAL UNITS | Conventional Units |
|  | Caution |
|  | Manufacturer |
|  | Expiration date |
|  | Temperature limitation |
|  | Consult instructions for use |