CE

Turbodyne™ Control

CONTROLS FOR QUALITY CONTROL PROCEDURES

SUMMARY

Clinical laboratory performs qualitative, semi-quantitative and quantitative tests on various biological specimens.
Quantitative tests determine the amount of a particular substance with the help of some instrument and express the results numerically. Most quantitative procedures involve several operations, or steps and each operation is subject to some degree of inaccuracy or imprecision. Monitoring and assessing the reliability and precision of methods and techniques form the fundamentals of good laboratory practices.
Turbodyne™ range of controls is assayed controls useful for monitoring the precision of laboratory testing procedures.
Turbodyne™ controls are also useful for validating the calibration and performance of the respective **Turbodyne™** reagents using **Turbodyne™ SC** analyzer.

REAGENT

Turbodyne™ range of controls are prepared from human serum/plasma/whole blood and fortified with suitable constituents of animal origin, preservatives and stabilizers that are usually not known to interfere in the test results. The **Turbodyne™** range of controls is available as mentioned below:

PRODUCT ANALYTE CONTENT

PRODUCT	ANALYTE CONTENT	ANALYTE SYMBOL	REF
Turbodyne™ RF Control	Rheumatoid factor	RF	108540005
Turbodyne™ CRP Control	C-reactive protein	CRP	108550005
Turbodyne™ CRP UV Control	C-reactive protein	CRP UV	108670005
Turbodyne™ ASO Control	Antistreptolysin O	ASO	108560005
Turbodyne™ MA Control	Micro Albumin	MA	108570005
Turbodyne™ D-Dimer Control	D-Dimer	D-Dimer	108580005
Turbodyne™ C3 Control	C3	C3	108640005
Turbodyne™ C4 Control	C4	C4	108650005
Turbodyne™ Cystatin C Control	Cystatin C	Cystatin C	108590002
Turbodyne™ HbA1c Control	HbA1c	HbA1c	108600002
Turbodyne™ IgE Control	Immunoglobulin E	IgE	108610002
Turbodyne™ Ferritin Control	Ferritin	Ferritin	108710002

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its performance.

REAGENT STORAGE AND STABILITY

Controls	Form	Stability
Turbodyne™ RF, **Turbodyne™** CRP UV, **Turbodyne™** C3, **Turbodyne™** C4, **Turbodyne™** CRP, **Turbodyne™** HbA1c	Lyophilized	7 days at 2-8 °C once reconstituted and handled without contamination
Turbodyne™ ASO	Lyophilized	1 day at 2-8 °C once reconstituted and handled without contamination
Turbodyne™ D-Dimer	Lyophilized	5 hours at 2-8 °C once reconstituted and handled without contamination
Turbodyne™ IgE, **Turbodyne™** MA, **Turbodyne™** Cystatin C, **Turbodyne™** Ferritin	Liquid Stable	7 days at 2-8 °C once opened and handled without contamination

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.

3. Reagents contain 0.09% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagents can be damaged due to microbial contamination or on exposure to extreme temperatures.
5. The mean values and acceptable range printed on the assay value sheet are specific for this lot of the product. The values are obtained by testing each lot **Turbodyne™** controls with various lots of the respective **Turbodyne™** immunoturbidimetry reagents on **Turbodyne™ SC** analyzer.

TEST PROCEDURE

1. Bring reagents to room temperature before use.
2. If the **Turbodyne™** control is in the lyophilized form then the **Turbodyne™** control must be reconstituted exactly with the stated amount (mentioned on vial label) of distilled water/Hemolysing solution (as mentioned on vial), wait for 10 minutes, gently swirl the vial till the solution attains homogeneity and is at RT (25^0C - 30^0C). Once reconstituted it is ready to use.
3. If the **Turbodyne™** control is in ready to use (liquid) form it can be used immediately after it has been brought to room temperature.
4. **Turbodyne™** control must be treated as a specimen and run strictly adhering to the instructions described by the manufacturer of reagents used for analysis.

REMARKS

Usage of well calibrated pipettes and correct procedure is critical for achieving correct results.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Clinical diagnosis and management by laboratory methods, 17th Edition, edited by John Bernand Henry, pgs 74-93.
2. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

	Temperature limitation		Manufacturer	CONTROL	Control
	Use by		Consult Instructions for use		This way up
	Date of Manufacture	REF	Catalogue Number	EC REP	Authorised Representative in the European Community
LOT	Batch Number/ Lot Number	IVD	*In vitro* Diagnostic Medical Device		

TULIP DIAGNOSTICS (P) LTD.

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EC REP

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