MEDCAPTAIN

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Instructions for Use
Thyroid Autoantibody Controls

[Product Name]

Thyroid Autoantibody Controls

[Packing Size]

L: 3×3.0 mL, H: 3×3.0 mL

[Intended Use]

Thyroid Autoantibody Controls are matched up with Anti-TG/Anti-TPO reagent kits for the quantitative measurement of Anti-TG/Anti-TPO in serum, plasma, or whole blood. The controls are used to monitor the status of instrument system and for quality management of these assays.

[Principle of Control Test]

Thyroid Autoantibody Controls make use of the measurement procedures of Anti-TG/Anti-TPO assay in the test menu. Test results are analyzed statistically, or compared to the reference values (or the target ranges) of the assays to judge whether the specified criteria has been met.

[Main Components]

Component	Main Composition	Content
Thyroid Autoantibody Controls L	Low level Anti-TG/Anti-TPO, MOPS buffer, 50 mmol/L; ProClin 300, 0.5 g/L	3×3.0 mL
Thyroid Autoantibody Controls H	High level Anti-TG/Anti-TPO, MOPS buffer, 50 mmol/L; ProClin 300, 0.5 g/L	3×3.0 mL
Reconstitution Solvent	Deionized water	6×3.0 mL

Note: (1) Components in different lots of controls cannot be mixed or exchanged for use.

(2) Controls are lot-specific. Please refer to the attached package insert for the target ranges of each lot.

Instruments and accessories needed but not supplied (Medcaptain has the supplies)

(1) Medcaptain Immu F6/F6S Automatic Chemiluminescent Immunoassay Analyzers;

(2) 500 μL pipette tips;

(3) Washing solution;

(4) Pre-trigger solution;

(5) Trigger solution;

(6) Anti-TG/Anti-TPO assay kits (CLIA).

[Storage and Shelf-life]

Storage: Sealed and store at 2~8℃. Avoid freezing.

Shelf Life: 16 months.

Opened vial of controls followed by reconstitution can be kept at 10~30℃ for 1 day; at 2~8℃ for 5 days; and at -20℃ or below for 60 days. It can go thorough freeze-thaw cycle only once.

Manufacturing and expiration dates can be found on the labels.

[Matched Instruments]

Medcaptain Immu F6/F6S Automatic Chemiluminescent Immunoassay Analyzers

[Test Procedure]

Reconstitute the controls by following the procedure below:

Pour reconstitution solvent (3.0 mL/vial) completely into each vial of control (Control L or Control H). Cap and seal it, and allow it to stand still for 10 minutes. Shake the vial gently for several times, avoid air bubble formation. Wait until the controls are totally dissolved. Controls can be aliquot into small vials, labeled, and stored at proper condition for future use (See [Storage and Shelf-life]). Each aliquot of controls can be used only once.

Refer to the Chapter of "Operation" in the instruction manual of Chemiluminescent Immunoassay Analyzers for detailed information about control testing. Set up a procedure for control testing, enter the information of controls, and select "Control" in the test menu.

Test the instrument with two levels of Thyroid Autoantibody Controls in accordance with any local applicable regulations. Control testing is highly recommended each time the lot of reagent has been changed, the instrument has been re-calibrated, or after trouble shooting/ maintenance service.

Each laboratory should set up its own control ranges and frequency of control testing, based on its own operation practice.

[Interpretation of Testing Results]

Control test results should fall into the specified ranges. If the results are out of the target ranges, the user should check the system, such as shelf life of the controls, storage condition, instrument performance and status. After root cause analysis and correction, control tests should be repeated. If the same problem exists, please contact customer service of Medcaptain.

[Property and Performance]

1 Appearance and Property

(1) The control pack should contain complete components, with no damage on inner or outer packing. Appearance should be neat and clean, the label is clear and readable, with no liquid leakage;

(2) Controls are white or light yellow dry powder, without any dent or trace of incomplete lyophilization;

(3) Reconstitution solvent is clear liquid. There is no precipitate, no suspension, and no floccule.

2 Fill Volume

Fill volume of the reconstitution solvent should be within ±10.0% of the labeled volume.

3 Accuracy of Control Measurement

Use product calibrators with assigned values from higher level measurement procedure, calibrate the immunoassay analyzer, and use the same lot of reagent to test the controls. Measurement values of the controls should fall into the target ranges.

4 Homogeneity of the Controls

4.1 Within-vial Homogeneity of the Controls

Within-vial homogeneity of the controls is represented with coefficient of variation, and CV≤8.0%.

4.2 Between-vial Homogeneity of the Controls

Between-vial homogeneity of the controls is represented with coefficient of variation, and CV≤5.0%.

[Attention Notes]

1 It is for in-vitro diagnosis only.

2 It can only be used by professionals.

3 Never use expired controls.

4 Avoid violent agitation of the controls, and prevent bubble formation.

5 Strictly follow the protocol in the package insert, and operate according to the lab guidelines.

6 User should wear gloves and lab coat. Rinse with water if skin is in contact with the reagent. Flush eyes with copious of water if eyes are in touch with the reagent. See a doctor immediately.

7 There is no absolute method to ensure the safety of human sourced material or inactivated microorganism currently. Take all samples, reagent, and reaction waste as potential biohazards. All waste must be handled following the local government regulation about biosafety.

[Interpretation of Symbols]

	Temperature limit		Date of manufacturing
	*In vitro* diagnostic medical device		Catalogue number
	Batch Code		Consult instructions for use or consult electronic instructions for use
	Use-by Date		Authorized representative in the European Community /European Union
	This way up		CE marking
	Manufacturer		Unique device identifier

[References]

[1] US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.

[2] World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.

[Basic Information]

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