

REF

Level 1		Level 2		Level 3		Mix Pack	
REF	Size	REF	Size	REF	Size	REF	Size
ZKE0101	6*3.0 mL	ZKE0201	6*3.0 mL	ZKE0301	6*3.0 mL	ZKE0403	12*3.0 mL
ZKE0102	12*3.0 mL	ZKE0202	12*3.0 mL	ZKE0302	12*3.0 mL		

Endocrine Control II

This product is intended for use as an assayed quality control to monitor the precision of analytes listed in the package insert.

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Key to Graphical Symbols Used

LOT

batch code



use by



manufacturer



contains sufficient for <n> tests

IVD

in vitro diagnostic medical device



temperature limitation

REF

catalogue number



consult instructions for use

EC REP

authorized representative in the European Community

EC REP

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Email: customerservice@autobio.com.cn

Contact your local dealers for all product-related questions in your local language

Instruction

The Endocrine Control II is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices.

Materials provided

- [Endocrine Control II – Level 1](#)
- [Endocrine Control II – Level 2](#)
- [Endocrine Control II – Level 3](#)

The Endocrine Controls are provided in lyophilized form containing human or animal origin.

Materials Required but not Provided

1. Micropipette
2. Distilled water or deionized water

Warnings and Precautions

1. For professional use only.
2. Follow the instruction for use carefully.
3. Handle the potentially contaminated materials and wastes safely according to local requirement.
4. CAUTION: the controls contain material of human origin, which has been tested and found non-reactive for HBsAg, HIV-1 and HIV-2, HCV and syphilis. It is recommended that all human sourced materials be considered potentially infectious. This assay contains materials of animal origin. Bovine components originate from countries where BSE has not been reported.
5. This product contains chemical reagents which may cause sensitization by skin contact, which must be avoided to contact with skin. This material and its container must be disposed in a safe way. If swallowed, seek medical advice immediately and show this container or label.
6. Do not smoke, drink, eat or use cosmetics in the working area.
7. Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after operations.
8. Use caution when handling patient samples to prevent cross contamination. Use of disposable pipettes or pipette tips is mandatory.
9. Conduct the assay away from bad ambient conditions. e. g. ambient air containing high concentration corrosive gas such as sodium hypochlorite acid, alkaline, acetaldehyde and so on, or containing dust.
10. Do not use controls beyond the labeled expiry date.
11. Do not mix or use controls of one same level from different batch codes.
12. When storing the controls, be certain the vials are securely sealed.
13. Do not substitute any reagent in this kit from other manufacturers or other lots.
14. When any damage to the protective packaging or any change of analytical performance is observed, do not use the kit.
15. When opening the vial, avoid any loss of the materials.

Storage

1. Store the control at 2-8 °C. The unopened Endocrine Controls are stable at 2-8 °C until the expiration date.
2. Once the control is reconstituted, it can be stored at 2-8 °C for 14 days with the following exceptions: ACTH should be tested immediately; C-Peptide is stable for 4 hours; IGF-1 is stable for 3 days; Insulin is stable for 7 days; HGH is stable for 10 days.

3. For storage longer than 7 days, store opened control in aliquots and freeze at -20 °C, it can be stored at -20 °C for 20 days except for ACTH and C-Peptide. Avoid multiple freeze-thaw cycles.

Preparation for use

Prior to use, bring the control to room temperature (18-25°C) for at least 30 minutes.

Reconstitute each vial of the lyophilized Endocrine Control II with 3.0 mL of distilled water carefully. Allow the reconstituted material to stand for at least 30 minutes. Then invert the controls to mix it completely. Avoid foam formation.

The Endocrine Control should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

Assignment of values

Each batch of Endocrine Control II will be tested on different analyzers. The range produced herein should only be considered as a reference and it is recommended that each laboratory establish its own mean and acceptable ranges.

The suitable analytes are listed in the following table:

T3	FSH
T4	PRG
FT3	Testosterone
FT4	E2
TSH	C-Peptide
TG	Insulin
PRL	17 α -OHP
LH	DHEA-S
HGH	IGF-1
ACTH	Aldosterone
Cortisol	β -HCG
Folate	Vitamin B12
25-OH Vitamin D	

Limitations of the Procedure

1. This product can't be used for calibration.
2. This product can't be used as a standard.
3. It is recommended to establish the quality control range suitable for the reagents and instruments of each laboratory.