

1. IDENTIFICATIONS

Parameter	Level 1	Level 2	Level 3
Product Name	Thyroid Hormone Control	Thyroid Hormone Control	Thyroid Hormone Control
Matrix	Stab. Human Serum	Stab. Human Serum	Stab. Human Serum
ID. No	HS201-023-1	HS201-023-2	HS201-023-3
Lot No	Refer to CoA	Refer to CoA	Refer to CoA
Expiry Date	Refer to CoA	Refer to CoA	Refer to CoA
Manufacturing Date	Refer to CoA	Refer to CoA	Refer to CoA
Form	Lyophilized	Lyophilized	Lyophilized
Volume	3,0 mL	3,0 mL	3,0 mL
Tube	8,0-10 mL Amber Glass (GL18)	8,0-10 mL Amber Glass (GL18)	8,0-10 mL Amber Glass (GL18)
Stopper	Lyo-Rubber, red (GL 18)	Lyo-Rubber, red (GL 18)	Lyo-Rubber, red (GL 18)
Cap	White	Yellow	Red

2. CHEM./BIOL. CHARACTERISTICS

Test	Method	Specification
pH	pH-Meter	7.0 – 7.4
Bioburden	CASO Agar	< 10 ² cfu/mL
Reconstitution	Rolling System	< 20 min.
Residual Moisture	Thermogravimetry	< 2%
O.D. (546 nm., undil.)	UV/VIS	< 0,500
Preservative:	-	Anti-microbial agent <0,01%

3. ANALYTES (Prod. Ranges)

Analyte	Level 1	Level 2	Level 3
FT3 pmol/L	< 5,0	10 (7,0-13,0)	> 15
TT3 µg/L	< 0,8	1,5 (1,0-2,0)	> 3,0
FT4 pmol/L	< 10	20 (15-25)	> 30
TT4 µg/L	< 50	70 (50-100)	200 (150-250)
TSH U/L	0,1-2,0	3,0 (2,0-5,0)	10 (7,0-13)

4. HOMOGENITY

Test parameter: TSH

Per batch ≥ 10 vials according to ISO 13528:2015

Release Criteria for TSH: $S_s\% \leq 4,05\%$

$S_s\%$: Rilibak Acceptable $RMSD * 0,3$

5. STABILITY

Closed Dropper: 12 months (+2/8°C)

Open Dropper: 1 days (+18/25°C)

5 days (+2/8°C)

6. BIOHAZARD / HEALTH AND SAFETY INFORMATION

The used H. Plasma units of European origin have been tested by CE-marked test kits and found to be non-reactive for HBsAg, anti-HIV 1+2, anti-HCV, and Syphilis. In addition, HAV, HBV, HCV, HIV-1, and Parvo B19 have been tested by PCR. The above referenced

lot was only formed with these donors. However, all human material should be considered potentially infectious. Since no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen.

7. IMPORTANT NOTE

For Research and Manufacturing Only. Not for Injection. This material is used for IQC/EQA of POC Measuring Systems.

8. WASTE MANAGEMENT

Observe local environmental regulations.

9. Country of Origin

Germany

10. FINAL STATEMENT

This batch has been manufactured, tested, released, and packed in accordance with JTC Diagnostics' Quality System.