Data Sheet
Lipid Calibrator/Controls

1) IDENTIFICATIONS

Parameter	Method	Specification
ID. No	Visual inspection	HS201-025 Calibrator HS201-026-1 Level 1 Control HS201-026-2 Level 2 Control
Trade Name	Lipid Calibrator Lipid Controls	One level Level 1-2
Lot No	Visual inspection	Refer to CoA
Expiry Date	Visual inspection	Refer to CoA
Manufacturing Date	Visual inspection	Refer to CoA
Form	Visual inspection	Lyophilised
Appearance	Visual inspection	Light Yellow lyo cake
Filling Volume	Visual inspection	Calibrator/Controls: 1 mL
Container	Visual inspection	Amber glass vial
Cap	Visual inspection	Calibrator: Blue Level 1 Control: White Level 2 Control: Black

2) CHEM./BIOL. CHARACTERISTICS

Test	Method	Specification
Moisture	Thermal gravimetric*	<2.0 %
pH	pH-Meter*	7.0 – 7.4
Bioburden at bottling	CASO Agar*	< 10^2 cfu/mL
Sterile Filtration	Membrane	0.2 µM sterile filtered
Freeze/thaw turbidity @ 546 nm	Spectrophotometry*	<0.750
Preservative:	N/A	Anti-Microbial Agent <0.01%

*All testing will be checked as three repetitions with different randomized vials.

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3) TARGET VALUES

Test	Unit	Calibrator	Control Level 1	Control Level 2
HDL	mg/dL	55	45 (35-55)	60 (48-72)
LDL	mg/dL	120	95 (75-115)	145 (115-175)

4) VALUE ASSIGNMENT

Value assignment studies and other QC testings are performed utilizing JTC HDL/LDL kits and the URIT analyser at a single center/device. The obtained results are analysed according to CLSI EP05-A.
In the assigned value sheet, the ranges will be defined as ±20% for all parameters.
Release Criteria for target value range: <±20%

5) STABILITY

Parameter	Condition	Specification
Shelf Life	+2-8°C	*Re-testing: 2 years
Accelerated Stability	37°C, 7 days	<±10%
Open Vial Stability	RT, 1 day +2-8°C, 7 days	<±10%

*Following the re-testing of the product, the assigned value sheet will be revised to incorporate the latest findings derived from the latest value assignment study.

6) HOMOGENEITY

Test parameter: HDL
As a release criterion, “Guidelines of the German Medical Association for quality assurance laboratory medical examinations RILIBÄK” rules are applied (edition 13.04.2023).
Per batch ≥ 10 vials according to ISO 13528:2020-09
Release Criteria within vials in same lyophilization cycle: ≤ 3:90 %
Release Criteria within different lyophilization cycle: ≤ 3:90 %
Release Criteria within vials in the same lot < 3.90%.

7) 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.
As no test can completely guarantee this material to be free of pathogens it should be handled as potentially infectious.

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8) STORAGE

For long term stability all levels must be stored at +2-8 °C.

9) IMPORTANT NOTE

For Research and Manufacturing Only. Not for Injection.

10) WASTE MANAGEMENT

Observe local environmental regulations.

11) Country of Origin

Germany

12) FINAL STATEMENT

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

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