

Certificate of Analysis

1. **Manufacturer**

Mercodia AB, Sylveniusgatan 8A, 754 50 Uppsala, SWEDEN

2. **Description**

Catalog no: 10-1380-01
Product: HNL Homodimer ELISA
Lot no: Lj1380-015
Expiry date: 2027-05-31

<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>Exp. date</i>
Assay Diluent 1X	20-7652	1380-005	2027-07-02
Calibrator Stock, 10 µg/L	20-7653	1380-003	2027-06-26
Coated Plate	20-7650	1380-007	2027-08-18
Transient Plate	20-7651	184647	2029-10-31
Enzyme Conjugate 11X	20-7654	1380-004	2027-06-30
Enzyme Conjugate Buffer	20-7655	1380-006	2027-07-16
Wash Buffer 21X	20-6746	36608	2032-04-07
Stop Solution	20-2693	36554	2032-03-07
Substrate TMB	20-2629	36313	2029-02-28

3. Quality control

Quality control has been performed for lot no Lj1380-015 according to internal procedures at Mercodia AB, and the product is released based on established acceptance criteria.

4. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

5. Intended use

Mercodia HNL Homodimer ELISA provides a method for the quantitative determination of HNL homodimer in human EDTA plasma.

6. Storage and handling

Recommended storage of kit is 2-8°C.

Storage of unused or diluted kit components is stated in the Direction for Use.

7. Hazardous information

Please refer to the Safety Data Sheet for hazard identification.

8. Quality standard documentation

The Mercodia Quality System fulfills the QSR and the requirements for the European CE mark, the Directive 98/79/CE on *in-vitro* diagnostic medical devices. Mercodia is ISO 13485 certified, for compliance with the International Quality Management System for medical devices.

9. Names and signatures of certifying officers

Date of analysis:

2025-10-10

Performed by:

Katerina Zafeiriou

Signature:



Date of approval:

2025-10-15

Approved by:

Giovanni Garcia

Signature:

