

N SUPPLEMENT L

Revision bar indicates update to previous version.

BN II System / BN ProSpec® System

Intended Use

Supplementary reagent for the immunonephelometric determination of Immunoglobulin E (IgE), β_2 -microglobulin (β_2 M), carbohydrate-deficient transferrin (CDT) and soluble transferrin receptor (sTfR) using N Latex IgE mono, N Latex β_2 -Microglobulin, N Latex CDT Kit and N Latex sTfR on the BN II and BN ProSpec[®] System.

A mixture of both supplementary reagents is used to suppress interference by rheumatoid factors and human anti-mouse antibodies (HAMA).

Reagents

Reagent	Description	Storage	Stability
N Supplementary Reagent L N SUPPLEMENT L			
N SUPPLEMENT L/A	 Ready to use liquid containing: mouse immunoglobulin in buffered solution (~0.6 g/L) Preservative: Sodium azide (< 1 g/L) 	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	Do not freeze!
N SUPPLEMENT L/B	 Ready to use liquid containing: buffered salt solution Detergent Preservative: Sodium azide (< 1 g/L) 	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	2–8 °C: once opened, 12 weeks ^{a,b} Do not freeze!

^a if securely capped immediately after use

if contamination (e.g. by microorganisms) is precluded

The mixture of the two supplementary reagents can be used within 4 weeks if the solution is stored tightly closed at 2 to 8 °C after use.

On-board stability

At least 5 days (at 8 hours per day), or a comparable period of time.

On-board stability depends on the system used as well as the laboratory conditions. More detailed information for the respective combination of reagent and supplementary reagent may be found in the respective Assay Protocols document.

Warnings and Precautions

For *in-vitro* diagnostic use only.

For laboratory professional use.

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com/sds.

CAUTION!

Federal (USA) law restricts this device to sale by or on the order of licensed healthcare professionals.

Caution

N SUPPLEMENT L/A

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all government requirements.

Preparing Reagents

Pipette 2.0 mL of **N SUPPLEMENT L/B** into a vial of **N SUPPLEMENT L/A** and shake gently to mix. Reagents stored at 2 to 8 °C can be used immediately.

Procedure

Materials Provided

REF	Contents		
OQTD11	N Supplementary Reagent L N SUPPLEMENT L		
	N Supplementary Reagent L/A N SUPPLEMENT L/A	6 ×	0.5 mL
	N Supplementary Reagent L/B N SUPPLEMENT L/B	2 ×	6 mL

Materials Required but not Provided

ltem	Description	
REF OVLE21	BN II Evaporation Stoppers (optional)	
Instruments, such as:	 BN II System BN ProSpec[®] System 	

Additional materials and supplies as described in the respective System's Instruction Manual.

N SUPPLEMENT Can be used with any reagent and lot on a BN ProSpec[®] System. When the lot of the supplementary reagent is changed, this does not require any renewal of the reference curves for the relevant tests. On a BN II System a new reference curve must be generated for the relevant tests if the lot of the **N SUPPLEMENT** is changed.

All steps necessary for performing the determinations are performed automatically by the BN Systems. For details regarding the principle of the assay method, any additional materials required, calculation of the analytical results, internal quality control and performance characteristics of the tests, please consult the reagent Instructions for Use.

Technical Assistance

For customer support, contact your local technical support provider or distributor. siemens-healthineers.com

Definition of Symbols

The following symbols may appear on the product labeling:

\bigcirc	Do not reuse	22	Use By
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community	Σ	Contains sufficient for <n> tests</n>
\$	Biological Risks	IVD	<i>In Vitro</i> Diagnostic Medical Device
l 🔏	Temperature Limitation		Consult instruction for Use
NON STERILE	Non-sterile	CE	CE marking of conformity
C€0197	CE marking of conformity with notified body ID number. Notified body ID number can vary.	CONTENTS	Contents
→	Reconstitution volume	LEVEL	Level
業	Keep away from sunlight and heat	WARNING	Warning
DANGER	Danger	RxOnly	Prescription device (US only)
UDI	Device Identification (UDI) barcode	REACH xx/xx/xx	REACH Authorization Number

Legal Information

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