



Urgent Field Safety Notice

BR-04011

April 2011

N Latex Free Light Chain lambda (OPJB 03) on BN™ II with Assay Protocol Update 4.7 (OUS) or BN ProSpec® System with Assay Protocol Update 2.7 (OUS) or Update 1.2 (EA).

Potential for erroneous FLC lambda results when running in combination with other methods.

Dear valued Customer:

Our records indicate that you have received the N Latex FLC lambda product (OPJB03).

Siemens Healthcare Diagnostics has confirmed that the **N Latex FLC Lambda (assay no. 81) in rare cases may show falsely elevated results when running in random access together with other methods on the BN™ II or BN ProSpec® System. N Latex FLC Kappa determinations are not affected.**

Siemens Healthcare Diagnostics is conducting a voluntary field corrective action and will install a revised assay protocol to solve this restriction. Until availability of the new protocol, it is required to **run at least the FLC Lambda determinations in batch mode** either before or after your daily routine (for more details please refer to the attached instructions). For your convenience we recommend to run both N Latex FLC Lambda and N Latex FLC Kappa together in batch mode.

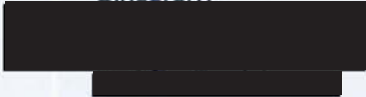
Please consult with your laboratory director regarding re-evaluation of previous test results.


Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files and forward this information to all parties that may use this product.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) has been notified of this action.

Please be assured that all efforts are taken to solve the issue as soon as possible. In the meantime we sincerely apologize for the inconvenience this action is causing in your lab and thank you for your close cooperation.

Sincerely,


Director
Quality Systems & Compliance


Senior Product Manager
Global Marketing Plasma Proteins

Attachment: Instructions for batch mode on BN II and BN ProSpec

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Instructions for batch mode on BN™ II System

FLC kappa and lambda need to be run in batch either before or after the routine

The following steps need to be performed before starting the measurement of the FLC kappa and lambda patient samples:

1. Cleaning of reagent and sample probe

- Load reagent “Cleaner SCS” (product no. OQUB) and a ‘dummy sample’
- Request one sample measurement for service assay “CleanR_S” (assay no. 997)

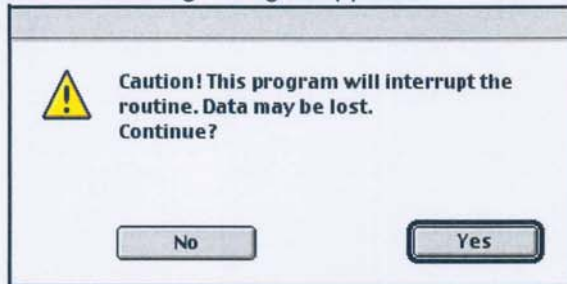
The screenshot shows the 'Enter job list' dialog box. It contains several input fields and a table of assays. The 'Sample' field is circled in red. The 'Assays' table has '997 CleanR_S' circled in red. The 'Save & Close' button is also circled in red.

Assays						
40 FIB	41 AT3	42 CRP2	43 FLS	44 FNC	45 A_II	46 ApoE
50 FRT	54 RF	55 ASL	56 CRPj	58 ADN _s	60 MYD	61 IgGC
62 IgAC	63 IgMC	64 IgG3	65 IgG4	66 CysC	67 ALBC	68 a2MC
69 TPC	70 C1I	71 CRR1	72 SAA	73 b2MU	74 IgE2	75 HCY
77 CDT	85 ASLn	997 CleanR_S				

- Enter a sample name, choose the CleanR_S assay (no. 997) and save & close the dialogue
- Wait until ‘assay’ is finished before you proceed (takes approx. 3 minutes) with the cuvette washing procedure
- Alternatively a separate rotor with fresh cuvettes exclusively for the determination of FLC kappa and FLC lambda can be used - then you can skip the cuvette washing procedure and continue with either step 3a or 3b dependent on availability of reference curve

2. Cuvette washing procedure

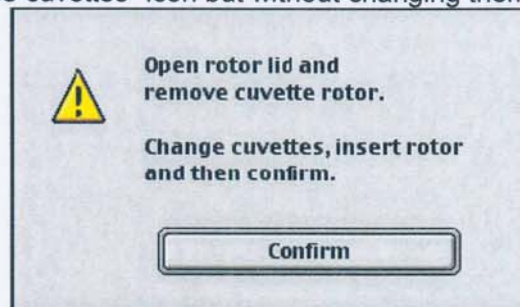
- In the BNII menu bar choose the 'Cuvette function' which is situated above the 'User Service' and the following dialogue appears:



- Apply "Yes" button and the cuvette dialogue opens:

No. of cuvette	Blank value	No. of cuvette	Blank value	No. of cuvette	Blank value	Max. blank value:
1	152	21	143	41	136	500
2	141	22	133	42	122	Accept new threshold
3	144	23	319	43	304	
4	154	24	230	44	175	
5	141	25	212	45	160	
6	149	26	234	46	160	
7	240	27	181	47	136	Number of cuvettes above the blank value: 4
8	343	28	132	48	243	Mean value: 193
9	524	29	624	49	131	Status
10	242	30	132	50	1109	Measure cuvette blanks
11	271	31	298	51	129	Replace cuvettes
12	336	32	203	52	127	Cancel
13	214	33	158	53	132	OK
14	493	34	144	54	133	
15	419	35	150	55	133	
16	175	36	185	56	233	
17	218	37	189	57	221	
18	150	38	178	58	505	
19	129	39	150	59	215	
20	206	40	138	60	136	

- Click on "Replace cuvettes" icon but without changing them! Following dialogue appears:



- Apply the "Confirm" button and wait until system has finished the cuvette washing procedure and measurement of the blank values

Attachment

- This procedure needs to be performed a second time
- Continue with the calibration of FLC lambda (assay no. 81) in case no valid reference curve is available (see point 3a).
- If valid curve is available, please continue as described under point 3b.

3a. Calibration of FLC lambda (assay no. 81)

- Load all required assay components on board
- Establish calibration curve of FLC lambda (assay no. 81)
- Continue with point 3b

3b. Measurement of N FLC Control SL1 and SL2 and patient samples

- Request FLC controls SL1/SL2 and patient samples for FLC kappa (assay no. 80) and FLC lambda (assay no. 81) and start your measurements.

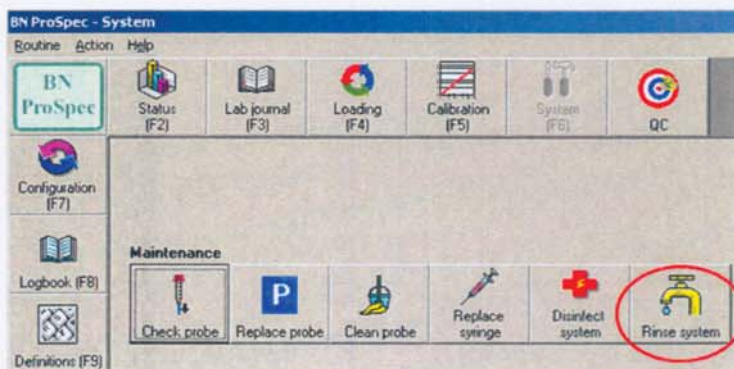
Instructions for batch mode on BN ProSpec® System

FLC kappa and lambda need to be run in batch either before or after the daily routine

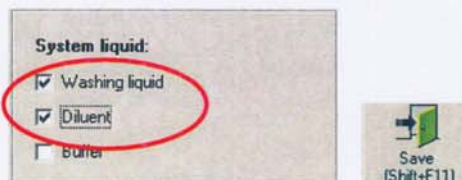
The following steps need to be performed before starting the measurement of the FLC kappa and FLC lambda patient samples:

1. Rinse the System

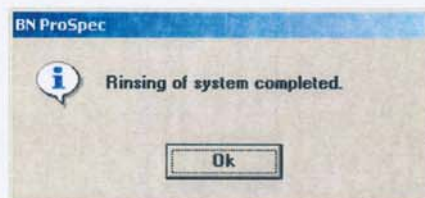
- Go to system menu
- Click icon "Rinse system"



- Choose "Washing liquid" and "Diluent" and save changes



- Once the rinse of the system is completed (takes approx. 3 minutes) following message box appears which needs to be confirmed:



Attachment

- Continue with the calibration of FLC kappa (assay no. 80) and FLC lambda (assay no. 81) in case no valid reference curves are available (see point 2a).
- If valid curves are available, please continue with the FLC control measurements as described under point 2b.

2a. Calibration of FLC kappa (assay no. 80) and FLC lambda (assay no. 81)

- Load all required assay components on board
- Establish calibration curves of FLC kappa (assay no. 80) and FLC lambda (assay no. 81) assay
- If the reference curves are valid, measure at least one control level of control and proceed with step 3

2b. Measurement of N FLC Control SL1 and SL2

- Request N FLC Control SL1 (product no. OPJE03) and SL2 (product no. OPJF03) for FLC kappa (assay no. 80) and FLC lambda (assay no. 81)
- All control values must be within confidence range of $\pm 20\%$. If single control values are out of range, please repeat control measurements until the values are within range and continue with step 3

3. Measurement of patient samples

- Start measurement of patient samples for FLC kappa and FLC lambda

FIELD CORRECTION EFFECTIVENESS CHECK

(N Latex FLC lambda on BN™ II with Assay Protocol 4.7 or BN ProSpec System with Assay Protocol Update 2.7 or 1.2)

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice and instructions for batch mode dated April 2011 regarding N Latex FLC lambda. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

- | | | |
|--|-----|----|
| 1. Did your facility receive a field correction letter from Siemens Healthcare Diagnostics regarding _____ | Yes | No |
| [This question is necessary only if the Effectiveness Check Letter is mailed separately from the FCA Letter] | | |
| 2. Did we effectively communicate all necessary information? | Yes | No |
| 3. Do you now have any of the noted product on hand? (Please check inventories before answering.) | Yes | No |
| 4. If the answer to the question above is Yes, do you intend to take the recommended action as requested? | Yes | No |

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT
(###) ###-####

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