YALE-NEW HAVEN HOSPITAL	TITLE: **BNII Operation Procedure (Siemens)**		**DEPT OF LAB MEDICINE CLINICAL IMMUNOLOGY Policy and Procedure Manual**
			DOCUMENT # IMM 183
			Page 1 of 16
WRITTEN BY: Kathy Radziunas Penny Smith	**EFFECTIVE DATE:** October 8, 2012	**REVISION:** NEW	**SUPERCEDES:** **IMM 43 - Immage 800 Quantitation of proteins by Nephlometry**

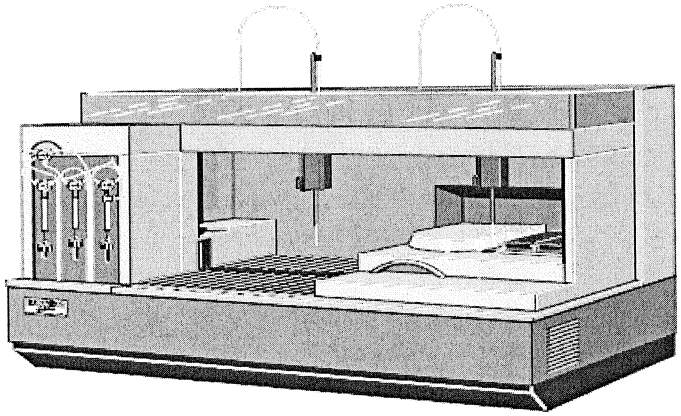
I. PRINCIPLE:

The BN II System *allows a fully automatic*, quantitative determination of proteins by means of nephelometry in various body fluids such as serum, urine and CSF. The most frequently used measuring principle in immunochemical protein determination in serum, urine and other body fluids are nephelometry. In this method, the light scattered onto the antigen-antibody complexes is measured. The intensity of the measured scattered light is proportional to the amount of antigen-antibody complexes in the sample under certain conditions. If the antibody volume is kept constant, the signal behaves proportionally to the antigen volume. A reference curve is generated by a standard with a known antigen content on which the scattered light signals of the samples can be evaluated and calculated as an antigen concentration.

II. INSTRUMENTATION:

The BN II System comprises the following parts:

A. **Analyzer** The analyzer
– pipettes the samples,
– prepares dilutions,
– incubates and measures the assay preparations.



B. **Computer** The computer
– enables patient data to be entered and the program menus to be selected
– calculates reference curves and assay results
– saves and prints assay results and
– communicates with the lab LIS.

The Analyzer Function Units are the rack unit, dispensing unit, transfer arm unit, reaction section unit and wet section unit:

A. The **Rack Unit** holds samples, standard serums, controls, reagents and supplemental reagents. The rack unit contains 15 lanes. Reagents and supplemental reagents are placed in lanes 1 to 5. Lanes 6 to15 are designed for samples, control serums and standard serums and are narrower than lanes 1 to 5. The racks for samples, standards and controls are narrower than the reagent racks and can therefore only be inserted in lanes 6 to 15.
When a rack is pushed into a lane, the switch of the appropriate lane flips and the LED starts flashing. The flipped switch prevents another rack from being pushed into this lane. This prevents double occupation of a lane.
A rack transport device with scanner transports the racks into their processing position identifies them and reads in the barcodes from the tubes. Samples without barcodes are detected and must either be identified manually or positioned prior to loading by the user with the help of the BN™ II.

B. The **Dispensing Unit** consists of the **reagent dilutor** and the **sample dilutor**.
The reagent dilutor consists of a 1000 µl syringe and two valves. It can pipette reagent and supplemental reagent and rinses with diluent, buffer or washing solution.

The sample dilutor has two syringes with two valves:
– a 250 µl syringe which mainly transfers the samples and draws up supplemental reagent.
– a 2500 µl syringe which rinses with diluent, buffer or washng solution and then draws up the volume for dispensing the probe and rinsing in the washing unit.

C. **Two Transfer arms:**

The **right transfer arm** picks up the sample from the sample tube with the dispensing probe,
– transfers the sample to the dilution well,
– performs the dilutions necessary for this assay,
– mixes the pre-diluted sample by vibrating the probe,
– draws up supplemental reagent if necessary and
– pipettes the diluted sample into the reaction cuvettes of the rotor.

The right transfer arm also performs the complete standard dilutions and pipettes the diluted standard serums into the rotor. The volumes to be transferred are between 5 µl and 150 µl.

The **left transfer arm** picks up the reagent from the reagent supply and transports it to the reaction cuvettes of the rotor where the reagent is mixed with the existing sample by vibrating the probe. The fluid in the dispensing probe is heated up to 37 ™C during the transfer process so that there is a constant temperature of 37 ™C in the reaction cuvette immediately after pipetting. The temperature is kept constant for the duration of the reaction by the heated rotor.

Each transfer arm has a washing unit. The dispensing probe moves to this washing unit between the individual pipettings and is cleaned inside and outside by rinsing. This avoids contamination and blockage of the dispensing probe as well as contamination of sample material and reagents. After every cleaning, the rinsing solution in the washing unit is automatically aspirated into an internal tank. As soon as this container becomes full, the system empties it automatically.

D. **Reaction Section Unit** consists of the dilution unit, the rotor, the optic and cuvette washing units.
The dilution unit contains two frames with 22 strips each. Each strip consists of 6 dilution wells. The analyzer checks whether the frame is inserted in the dilution unit with magnetic contacts. When both frames are filled up with new dilution wells, the system uses the left frame first and changes to the right frame as soon as the capacity is exhausted. Samples, controls and standards are diluted in the dilution wells according to the assay protocol.
The cuvette rotor is fitted with 60 cuvettes, which are divided into segments of five. The individual cuvettes are arranged at a radius of 6™.
The reaction preparations to be analyzed are pipetted into the rotor's reaction cuvettes. The temperature in the rotor compartment is 37 ™C.
Measurements are made with the rotor turning, one measurement per rotation. A measuring curve is determined and a value measures at a specific time.
Optic unit operates using the scattered light principle.
Cuvettes are cleaned after measuring through aspiration, rinsing and aspirating with rinsing solution again in the Cuvette Washing Unit.
Cuvettes are re-used.

E. **Wet Section Unit** which consists of the vacuum container, waste container and supply bottles.
The vacuum is generated by the vacuum pump in a vacuum container with a capacity of 2.5 L. It is used to aspirate the fluid from the cuvette washing unit and the washing units for the dispensing probe into the waste water

The waste water container is drained by a pump into a suitable container. The waste water container holds 2.5 L. Draining takes place automatically

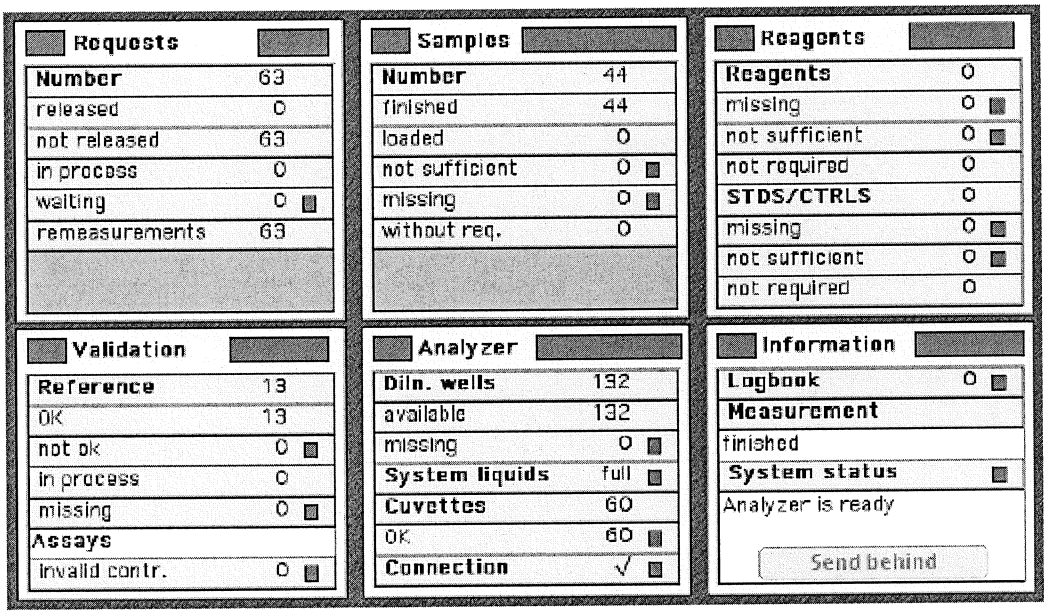
– when the instrument is switched on
– every 20 minutes
– when the instrument is shut down or

The BN™ II is equipped with 5-liter supply bottles. Intake nozzles are inserted in the supply containers, which also contain intake tubes and fill level detectors. Three supply bottles, with the following contents, are arranged on the left hand side behind the front panel of the system: the diluent supply bottle, buffer supply bottle and rinsing solution bottle.

III. INFO SYSTEM OVERVIEW:

The Info System provides comprehensive information on the state of the system.

The individual display areas of the **Info dialog** are linked to dialogs with more detailed information relevant to the condition.

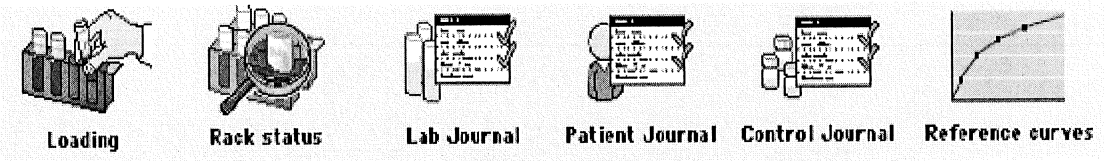


The six displays are:

1. Requests- current jobs, results released, results not released, requests in progress, requests to be loaded, and re-measurement requests.
2. Samples- number of samples in job list, samples finished, samples on the analyzer, insufficient samples, samples programmed and not on analyzer, and samples without requests.
3. Reagents- all requires reagents, standards and controls placed on analyzer are on list. Missing reagents, standards and controls are shown in red.
4. Validation- indicates number of reference curves measured, valid reference curves, invalid reference curve, reference curves being recorded, reference curves to be determined and number of invalid controls.

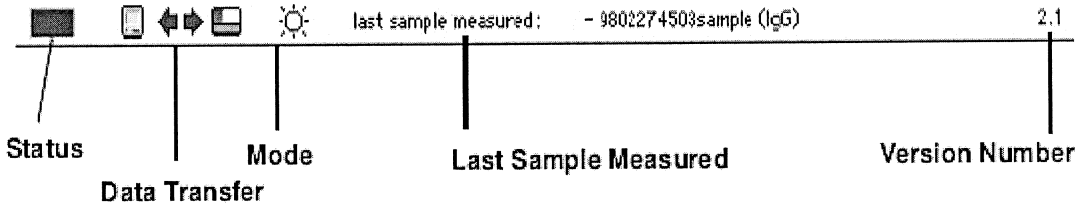
5. Analyzer- indicates available and/or missing dilution wells, status of system liquids, number of measuring cuvettes, and computer connection status.
6. Information-displays logbooks messages, time necessary to complete job list, and system status.

The **TOOL BAR** options include;



1. Loading- preload non-barcoded samples
2. Rack status- overview of racks and rack lanes
3. Lab journal- change requests
4. Patient journal- view patient results
5. Control journal- view control results
6. Reference curves- view reference curves. Three curves are stored for a maximum of three reagent lots per test

The **STATUS DISPLAY** is at the bottom of the Info dialog and shows the current status of the system.



IV. MATERIALS:

1. N Reaction Buffer- REF# OUMS 65

Intended Use
Reaction medium for immunochemical determinations.
Composition
Polyethylene glycol and sodium chloride (11.6 g/L) in phosphate buffer (0.05 mol/L). Preservative – sodium azide (<1 g/L)
Preparation of Reagent
The N Reaction Buffer is ready-for-use as supplied and requires no additional preparation
Storage and Stability
Store at +15 to +25 C: The expiry date is given on the label
Stability once opened: 6 weeks

2. N Diluent- REF# OUMT 65

Intended Use
Solution for preparing dilutions for immunochemical determinations.
Composition
Phosphate buffered saline in sodium aside (<1 g/L0
Preparation of Reagent
The N diluents is ready-for-use as supplied and requires no additional preparation
Storage and Stability
Store at +15 to +25 C: The expiry date is given on the label
Stability once opened: 3 weeks

3. BNII Additive- REF# OQKY 61

Intended use
Washing Solution (concentrate) for cleaning BNII System cuvettes
Composition
Detergent Solution, with Preservative: Mergal K9N (85 g/L)
Preparation of Reagent
Dissolve the content of a 100 ml vial in 5 liters distilled water to prepare the Washing Solution
Storage and Stability
Storage at +2 to +8 C
Stability of Washing Solution: 1 week

4. BNII Dilution Wells-REF# OVIC 11

5. BNII Cuvette Sements-REF# OVIB 31

6. Neodisher GK– REF# OQRK 51

Intended use
Decontamination of system tubing
Composition
Sodiumphosphateribasi,dodecahydrate/Trinatriumphosphat/phosphate trisodique >30%
Preparation of Reagent
Dissolve 10 g of Neodisher GK in 1 liter warm water. Allow to sit overnight.
Storage and Stability
Storage at +2 to +25 C. The expiry date is given on the label

IV. ASSAY REAGENT LOT NUMBER INPUT:

Two options are available for reagent lot input:

1. Automatic Reagent Lot Entry (For Siemens reagents only)
   - Load the reagent in an available rack.
   - Allow instrument to pull rack in.
   - Software will prompt user "A new lot number has been loaded on the analyzer. Calibration is required "123456".
   - Click **OK**. The number at the end of the message refers to the lot number that the instrument has recognized for the reagent loaded.
2. Manual input of reagent lot numbers.
   - Select **Calibration – Reagent Lots**
   - Click on the reagent for which you wish to enter the lot number.
   - In "Enter new lot no.", enter the last two digits of the six-digit reagent product code located on the reagent bottle.
   - Click on **Add** to add reagent to current list or click on **Replace** if you wish to replace the current lot.

V. STANDARD LOT NUMBER AND ASSIGNED VALUES INPUT:

Two options are available for standard lot input:

1. Automatic entry using barcode sheets.
   - Remove barcode sheet from packaging
   - Place sheet on a flat surface.
   - Using scanner, scan the first barcode line. The program will open a dialog with a string of digits and a chime will sound to verify the line was read.
   - Scan remaining lines until dialog box closes on the program screen.
   - Verify the values in the **Calibration-Standard Lots** screen.

2. Manual input of Standard Lot Numbers and Assigned Values Entry.
   - Click on **Calibration Standard Lots**.
   - Click on the appropriate standard.
   - Click on the **Standard Lot Details** icon
   - Enter the 5^{th} and 6^{th} digit of the product code.
   - Click on assay
   - Select units
   - Enter "**nominal**" value
   - Click **Save**.
   - Verify the values have been input properly in the **Calibration-Standard Lots** screen.

VI. CONTROL LOT NUMBER AND ASSIGNED VALUES INPUT:

Two options are available for control lot input:

1. Automatic entry using Siemens barcode sheets.
   - Remove barcode sheet from packaging
   - Place sheet on a flat surface.
   - Using scanner, scan the first barcode line. The program will open a dialog with a string of digits and a chime will sound to verify the line was read.
   - Scan remaining lines until the dialog box closes on the program screen.
   - Verify the values in the **Control Lot** screen.

2. Manual input of control lot numbers and values.
   - Click on **Calibration-Control Lots**
   - Click on the appropriate control.
   - Enter the 5^{th} and 6^{th} digit of the product code.
   - Click on assay
   - Select units
   - Enter **"nominal"** value
   - Click **Save**
   - Verify the values have been input properly in the **Control Lot** screen.

VII. OPERATION:

1. Power on the Analyzer/Computer:

- Verify that diluetnt, reaction buffer and wash solution containers have sufficient volume.
- Turn on the BNII system
- Turn on the computer
- Fill the dilution frame with dilution wells.

2. Starting the BN™ II program (via the Apple Macintosh computer)

- Double-click the BN™ II logo
- The following appear in sequence:
  - The BN™ II logo
  - The BN™ II program's menu bar and the **Info** dialog
- During initialization the following occurs;
  System performs self check
  Tubing, syringes, pipettors are rinsed
  Reaction cuvettes are cleaned and blanked
  Transfer arms move to home position
  Vacuum is generated
  Barcode scanner initializes and clears lanes

  The initialization process is complete after around 10 -15 minutes.

3. Loading the dilution wells

After initialization is complete, the **Dilution strips** dialog appears.
- Click the **Change dilution strips** field.
- The fields marked **Left new**, **Right new** and **OK** automatically become active.
-Fully load both frames.
-Click the **Left new / Right new** field.
-Click on the **OK** button and the **Info Dialog** will appear
-Check the available cuvettes. In **Analyzer/ Cuvette**, there should be >54 **OK**

4. **Loading reagents, standards and controls**
   - Place reagents, standards and controls into respective racks.
   - Verify barcode position
   - Remove lids
   - Place standard and control racks in lanes 6-15
   - Place reagent racks in lanes 1-5. Reagents utilizing supplementary reagent requires lanes 3-5.
   - Slide racks into vacant lane until you hear a click. LED light will begin to blink.
5. **Request calibration** – if necessary
   – Click on **Reference curves**.
   - The Reference curves dialog appears.
   - Select assay to be calibrated
   - In the reagent lots menu select the lot positioned in the analyzer.
   - Click on **Measure**
   - To view calibration curve, select the **Reference Curve** icon.
   - Select assay
   - Click on the **Show Curves** button.

6. **Request controls**
   - Select **Routine- Request Controls** from the menu bar.
   - Select the controls to be run by clicking on the box that intersects the assay and control. Only boxes with an X may be selected.
   - Click the Measure button. The X's will change to ?'s.
   - Click on the Close box to close the dialog.
   - Review control results by selecting **Control Journal** icon. The Control Journal will open. Results expressed in % deviation and mean. Controls must be reviewed in **Soft Total QC**.

7. **Loading Barcoded Samples on the Analyzer**
   - Slide the loaded sample rack with barcoded tubes into vacant lane until you hear a click. LED light will begin to blink. After scanning samples, LED will remain on until rack is complete.

8. **Loading Non-barcoded Samples on the Analyzer**
   - Select **Routine- Enter Joblist**

- Type in sample identification number in the Sample ID field
- Click on the profile box or individual assay requested.
- Click on **Save and Close**
- Select **Routine- Loading**
- In the rack identification scroll box, highlight the rack you wish to load samples in.
- In the Identifier scroll box a list of programmed samples will appear. Click on **Autoload** button. If rack is not full, click on **Ignore all empty positions**.
- Click on **Take**
- Load rack in open lane.

9. **Repeat measurement, changing dilutions**
   - Select the **Lab Journal** icon
   - Locate sample and highlight.
   - Click on **Action** and **Repeat**. If repeat is from same dilution click **Measure**. If repeat is from a new dilution or new dilution factor select new sample dilution then click on **From New Dilution** and then **Measure**.
   - Repeat result will appear above first result in Lab Journal
10. **Reloading Diluent, Reaction Buffer of Wash**

    - When analyzer is in standby, select **System Liquids**
    - The System Liquids dialog opens and displays the current liquid levels.
    - Select **Reload Liquids**
    - Select **Yes**
    - Remove the level sensor from the system liquid bottle and replace with a new bottle
    - Click on **System Liquid Reloaded**

11. **Daily Shutdown Procedure**
    - Verify that all results are complete
    - Eject any racks still loaded on instrument.
    - Click on **Rack status**
    - Click on **Eject all racks** button
    - Click on **File – Quit – Perform**. Allow instrument to go through the automatic shutdown process.
    - When desktop is displayed, select **Special –Shutdown** from menu bar then click the blue apple and select Shut down.
    - Cap all reagents, standards and controls and store at 2-8 C.
    - Empty waste container.
    - Reload dilution wells.

VIII. REFERENCE CURVE VALIDATION/ACCEPTANCE CRITERIA:

Calibration of all test methods on the BNII System is performed to ensure quality and accuracy of results. The BNII System performs a multi-point calibration for

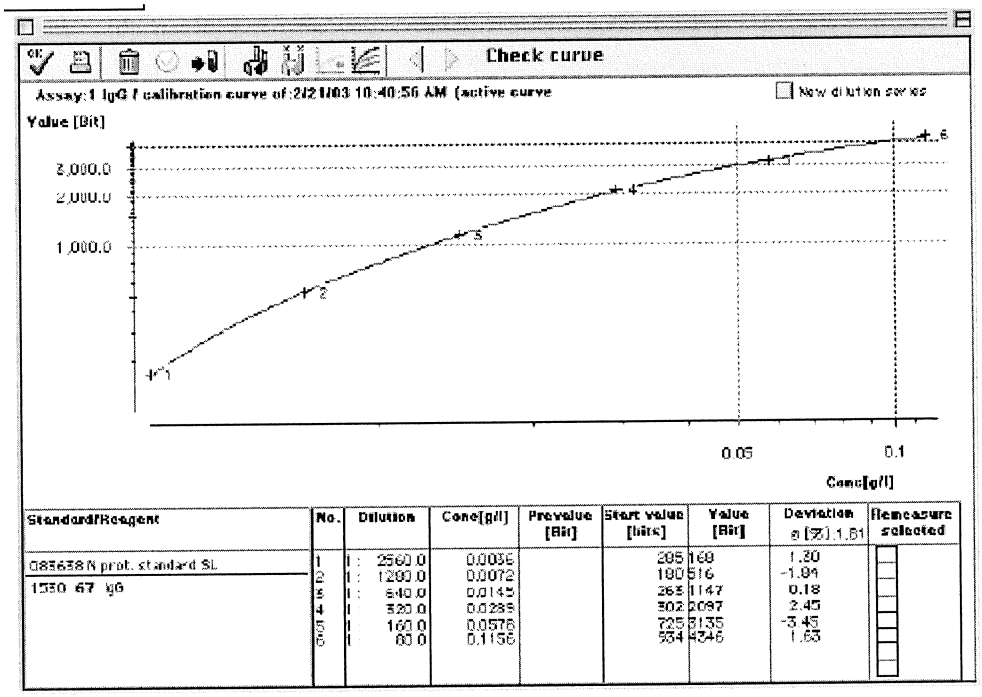
all methods to ensure accuracy across the range of analysis. The BNII System will allow three calibration curves to be stored for up to three lots of reagents. Kit assays will only allow for one lot to be stored.

Two conditions must be met in order to accept reference curve:

1. Deviation of the curve is within range.

Assay	Mean Deviation %
RF	7%
IgG1 & IgG2	10%
Kappa & Lambda	7%
All Other Assays	5%

2. Quality control values are within range.



Calibration curve data is automatically accepted if the mean deviation does not exceed the acceptable criteria for the deviation.

If reference curve does not meet approval, click on **Remeasure All** icon. Click on **New Dilution Series** box to ensure that analyzer will make new dilutions and process the curve.

IX. INTERPRETATION OF RESULTS:

The host computer passes on all the information necessary for processing the sample to the BN™ II System, i.e. the host transfers the job list independently with information about:

- the patient
- the sample ID and
- the assay requests.

The operator needs only to place the samples in the individual racks and push these into the rack unit. Add to or change the host entries with the keyboard and mouse in the **Results – Lab journal** menu.
When you place samples in the analyzer without the host having provided a job list, these samples are ejected again as unknown. The job list must be transferred completely from the host before sample racks are inserted.
With the **Auto-Host** installed, the BN™ II System requests the job list from the host and later sends the results automatically back to the host.

Refer to Soft System Manual.

X. LIMITATIONS:

1. Antigen excess reliability-

By means of pre-reaction, it can be determined whether the result of a sample lies within the antibody excess range or not.
The steps of pre-reaction are as follow:

a. A small percentage of diluted sample is adder with the complete amount of reagent.
b. The signal of this preparation is read for a fixed amount of time
c. If the signal exceeds the threshold preset in the software, a dilution of higher magnitude is necessary for the sample and is automatically performed.
d. If the signal does not exceed the threshold preset in the software, the rest of the sample is added to the reaction and measurement proceeds.

Pre-reaction protocols are performed for the following assays: IgM serum, Albumin Urine and Ig / L-chain type lambda in urine

3. Pre-incubation

To suppress non-specific reactions, pre-incubations can be carried out where required. Supplemental reagents are added to the sample during pre-incubation to bond any disturbance factors in the sample and thus largely rule out nonspecific reactions. The pre-incubation steps are integrated in the assay protocols (software).

Pre-incubation protocols are available for IGM.

4. Turbidity Check

Parameters for the turbidity check are on the fifth page **Dil. & Turb.** of the assay protocols, excluding those using latex reagents. If the turbidity of a sample exceeds the preset limits, samples in the **Lab Journal** will be flagged with an **"X"** turbidity mark in the **Result** field. The turbidity check is performed based on two criteria:

a. The difference of the start value (first measured value after 7.5 seconds) minus the cuvette blank value is greater than 1800 bits. The 1800 bit value is referred to as the **general turbidity threshold**. With these criteria samples are measured with a very high intrinsic turbidity (e.g. lipemic samples) or a fast reaction (e.g. monoclonal immunoglobulins).

b. The difference of the start value (first measured value after 7.5 seconds) minus cuvette blank value is greater than 800 bits plus 15% of the difference of the second measured value and the start value. This criterion was developed to rule out non-specific turbidity or untypical reactions with a small measurement signal difference between the second measured value and the start value. The 800 bit value is referred to as the **turbidity threshold**, the 15% as **turbidity factor**. The general turbidity threshold and factor were determined as standard values by Dade Behring Marburg GmbH.

5. Test for non-specific reaction

The BN™ II System offers the possibility of detecting non-specific reactions, for example by sample turbidity. To do this, the change in the measurement signal in the absence of reagent is determined.
When you click the checking field **Test for non-specific reaction** in the **Enter job list** dialog, the sample is transferred with buffer and possibly supplemental reagent to the reaction cuvette and measured.
The dilution of the sample thereby depends on the required assays and is carried out either in a 1:5 or 1:20 dilution.
The BN™ II System only continues processing the requested assay if no non-specific reactions occur, i.e. if the threshold of 80 bits is not exceeded. Other requirements for the sample concerned are only processed if no nonspecific reactions occur in the non-specific reaction test.
If non-specific reactions occur, take the sample from the analyzer and clarify (e.g. for lipemic samples by centrifuging, 10 minutes at 15000 x g). Place this sample back in the instrument.
The sample is then processed without a second assay for non-specific reaction

6. **Plausibility check**

The plausibility check prevents results determined from lower sample dilution (usually 1:1 or 1:5) which could be falsified by matrix effects automatically being output as the final results.
If, for example, a 1:20 measurement is repeated due to a result < Measuring range in lower dilution level (1:5), it is checked automatically whether the result of the re-measurement is greater (see *First case*) or smaller (see *Second case*) than a threshold to be determined. This threshold is calculated from the lower range limit of the first measurement (1:20 dilution) plus 15% of this lower limit. The same must also apply for the combination 1:1 preparation to 1:5 preparation. Matrix effects are not to be expected for preparations in dilution levels from 1:20 upwards.
This check is always carried out when two dilution levels which satisfy the above criteria have been measured in succession.

7. **Result display**

First case if the result is above the threshold it is probably due to matrix effects. It is identified with the "result not plausible" flag. The measured value from the 1:20 measurement (< lower measuring range limit) without non-plausibility flag should be taken as a final result of the request. This result must be selected manually and selected by the function **Accept measurement result** (Lab journal: pop-up menu **Action**) as a final result. Automatic release of results for which a single determination with non-plausibility flag exists can be prevented by the configuration **Do not release result automatically** if result is not plausible (plausibility check) to enable individual assessment by the user.
Second case If the result is below this threshold it is a plausible result. This is not marked by a flag and output as a final result of the request.

8. **Behavior in special cases**

If the 1:5 result is determined as a final result by manual user action (Accept measurement result) in the first case, this is output as a result of the request without a non-plausibility flag. However, it is retained with a non-plausibility flag in the third hierarchy level of the single measurements in the lab journal.

XI. MAINTENANCE:

Daily:

1. Check levels of N Diluent, Wash, and N Reaction Buffer. Do Not Pool containers.
2. Check dilution strips and replace if necessary.

3. Check tubing and syringes for any kinks, leaks, bubbles and microbial contamination.
4. Check the Info dialog that the cuvettes are OK
5. Clean dispense probes.
   - Select **System-User Service-Clean Dispensing Probe**
   - The **Cleaning Dispensing Probe** dialog opens- Select **Clean Now**
   - Clean dispense probes with alcohol wipe
   - Select **Cleaning Done**
   - Observe position of probe (both sample and reagent transfer). Verify that the position of the probe is directly over JP alignment point of small indentation on rack lane 15.
   - Verify that priming fluid is in a straight line.
6. Export sample data files and clear results.
   -Select System-**Data Exchange-Export Results**
   -Select Calibration data and Sample and Control Data in the Export results dialog. Data is saved in ASCII format in the Result folder on hard drive.
   Sample and control data are in a file beginning with **"P"**
   Calibration data is stored in a file beginning with **"K"**

   File names also contain information regarding date of collection and rolling number. Example: PYYMMDDN.BN2
   P=sample and control data
   YY=year
   MM=month
   DD=day
   N=rolling number
   -Insert flashdrive into USB2.0 Hub
   -Open **BNII HD**
   -Open **BNII folder**
   -Open **Result folder**. Click on the **"P"** or **"K"** files
   -Eject the flashdrive by dragging it to the trashcan icon
7. Shutdown instrument.
8. Empty waste container.

Weekly:

1. Clean instrument surface and rack lanes with 70% ethanol
2. Check syringes, valves and reagent and sample probes.
3. Back up Data Folder to flashdrive
   -hide BNII icon
   -insert flashdrive
   -click on BNII backup
   -open BNII HD
   -open BNII V2.5
   -drag and drop Data folder into Backup window

-highlight folder and rename data folder with date
-close all windows

4. Transfer Sample Data Folders to "O" drive.
   -insert "Sample data folder" flashdrive into laboratory computer.
   -Open Excel program. **Select File-Open-External Flashdrive?**
   -Select **"All files(*.)** from the "Files of type". Open
   -Select **"Delimited", "Macintosh". Next**
   -Set Delimiters to "Tab" and "Semicolon". **Next**
   -Set column data format to "General".
   -Click on "Finish"
   -Data appears in a spreadsheet. Insert a row for column headins.
   -Save file as date.

Monthly:

1. Perform decontamination with NeodisherGK – refer to BNII procedure manual and follow the prompts following selection of **System - User Service - Decontamination** from the BNII software screen.
2. Replace wash filter
3. Replace all cuvette segments
4. Replace Wash solution container with a clean container
5. Clean level sensors in supply bottles with moist lint free cloth
6. Clean barcode scanner with 70% ethanol
7. Clean mouse

XII. Appendix:

183		BNII Instrument Manual
183-A		BNII Instrument Checklist
183-B		BNII Instrument Quiz
183-C		BNII Instrument Test Parameters
183-D		BNII Instrument Quality Control Chart
183-E		BNII Instrument Reference Ranges
183-M1		BNII Instrument Daily Maintenance
183-M2		BNII Instrument Weekly/Monthly Maintenance

Siemens BNII Checklist
Doc# IMM 183-A
Instrument Checklist
Initial ☐ 6 Months ☐

Instrument

YES/NO

1. Performs Daily Start-Up, Shut down of BNII. _____

2. Perform daily, weekly and monthly Maintenance of BNII. _____

3. Can call BNII pending list. _____

4. Able to calibrate and repeat an unacceptable calibration. _____

5. Able to process daily controls.

6. Able to process barcoded and non-barcoded samples _____

7. Able to independently load and run BNII without supervision _____

8. Able to enter new lot of control or standard. _____

9. Able to assess sample requirements for running of all assays. _____

10. Able to add tests and change dilutions. _____

10. Can perform basic troubleshooting of instrument or assay if trouble occurs. _____

11. Understands all reagent stability requirements

11. Aware of inventory/par levels.
    a. Entry of all Lot #s in L Drive _____
    b. Pretesting of all new Lot #s received. _____

Quality Control

1. Able to ascertain QC validation by utilizing the 10X, 2-2S and 1-3S Westgard rules _____

2. Able to ascertain validation of standard curve. _____

3. Proficient using SOFT Total QC _____

Assay Checklist

Test	Read Assay Procedure Yes/No	Performed Assay-Dates Yes/No
IgA,IgAs	_____	_____
IgG	_____	_____
IgM, IgMs	_____	_____
ADNase B	_____	_____
Alpha 1 Antitrypsin	_____	_____
ASL	_____	_____
C3	_____	_____
C4	_____	_____
Ceruloplasmin	_____	_____
CSF Index	_____	_____
Lambda- Serum, Urine	_____	_____
Kappa- Serum, Urine	_____	_____
Haptoglobin	_____	_____
RF	_____	_____
Prealbumin	_____	_____

Training Completed _____

Signature _____ Verified By _____

Learning Technologist Teaching Technologist

Document Author
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October 5, 2012

Signature Approval for Annual Review
Name: BNII Operation Procedure
Siemens Nephlometer

Document #: IMM 183

Name (Print)	Title	Signature	Date of Review	Revision Page and Section # (Use Procedure Review Log to document staff review)	Issue Date for Training if Applicable	Effective Date for Use
TEODORICO LEE	LAB MANAGER	Teodorico Lee	10/5/12	NEW		10/8/12
BRIAN SMITH	LAB DIRECTOR		10/5/2012	NEW		10/8/12