Onsite

Siemens Healthineers

BN™ II System Onsite Training Workbook

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1 Welcome

Welcome to Training

Siemens Healthineers would like to welcome you to the onsite training on the BN™ II System.

This course is designed to teach you the skills needed to operate, calibrate, maintain, and troubleshoot the BN™ II System. Our staff welcomes the opportunity to present this training program to you.

Operator Training Course Goals

The goal of this course is to prepare the customer to operate, maintain, and train others on the BN™ II System.

Course Objectives

Upon completion of this course, you will be able to:

- Identify system components
- Navigate the system software
- Enter Lot Data
- Process calibration and controls
- Evaluate calibrations, controls, and sample results
- Process patient samples including barcoded and non-barcoded
- Edit patient sample requests
- Perform maintenance procedures
- Perform Shutdown and Data Folder Back up
- Perform basic system troubleshooting

Training Agenda

Morning	Afternoon
Day 1 Introduction/Training Expectations • PACE microsoft form • Online Refresher Questions • Review Agenda System Components Overview System Startup – Daily Maintenance System Software Overview Product Inventory • Scan in Lot Data • Manual entry Lot Data Process Calibration (no supplemental reagent) • Load Reagents • Load Protein Standard Process Controls • Load Controls Review calibration and control results • Review calibration curve • Review calibration flags and options • Review QC results • Review QC flags and options Process Barcoded Samples • Discuss manual predilution • Review Lab Journal options • Review results and flags Process Calibration (supplemental reagent) • Manual Reagent ID	Day 1 • Review calibration and control results • Log Book Overview Process Non-barcoded samples • Add Test Requests and Dilutions Discuss: • QC Statistics • External Predilution • Non-specific reaction Batch Programming (optional) Perform BNII Shutdown • Data Folder Backup Note: Prepare the neodisher GK for maintenance on day 2.

Training Agenda

Day 2 Eye Opener Questions System Startup – Daily Maintenance Perform Maintenance • Weekly • Monthly • Half-Yearly • Discuss Yearly Process Barcoded Samples – STAT • Definitions Overview Patient Demographics (optional) Process Short Samples Define Other Vendor's QC (optional) Perform Troubleshooting Perform BNII Shutdown • Data Folder Backup Finale Questions Validation Checklist Microsoft Form Customer Course Evaluation Microsoft Form	

BN™ II System Onsite Training
Course Validation Checklist

The participant places a checkmark beside the competency when it is completed. When all competencies are checked, the instructor and participant will sign and date below as a record of completion.

Topics	Competencies	Completed
System Components and Software Overview	Identify the system hardware components	
	Navigate System Software	
Product Inventory	Perform Lot Data Entry	
	Perform Manual Lot Data Entry	
System Startup - Daily Maintenance	Perform the tasks listed in the Quick Reference Guide - System Startup	
Calibration and Controls - classical & latex	Request calibration and controls - Load standards, controls, and reagents	
	Review calibration curve	
	Review calibration flags and options	
	Review QC results	
	Review QC flags and options	
	Describe QC Statistics	
Samples	Process barcoded samples - manually enter requests	
	Process non-barcoded samples	
	Evaluate sample results	
	Add test requests: repeat measurement, repeat measurement from another dilution, change a dilution, STAT	
	Process a low-volume sample	
	Describe External (manual) Predilution	
	Describe a non-specific reaction	

Definition Overview	Define other vendors' controls	
	Define profiles	
Log Book	Respond to an error	
	Describe Log Book options	
Configuration Overview	Describe options and functions	
Maintenance	Perform Weekly maintenance	
	Perform Monthly maintenance	
	Perform Half-yearly maintenance	
	Discuss Yearly maintenance	
BN II Shutdown	Perform a shutdown	
Data Folder Backup	Perform Data Folder Backup	
Troubleshooting	Manually identify an unreadable barcode	
	Respond to and correct programmed samples	

Instructor:
Participant:
Date:

What was most helpful to you during this program?

How can we improve this program to make it more meaningful to you?

2 System Startup – Daily Maintenance

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Perform Daily Maintenance tasks
- Startup the System
- Update the Dilution Well count

1. Check System Liquids, Waste, and Dilution Strips

   - Replenish the buffer, diluent, and wash solution (1 bottle of BN II Additive to 5 L of distilled water) as needed.
   - Empty the waste if necessary.
   - Replace used dilution strips and carefully place the dilution frames into position.

Note: The system will not initialize if the dilution frames are not placed correctly in the dilution frame holder.

After preparation, how long is the Wash Solution good for?

_____

What is the expiration date for the diluent and buffer when in use? _____

Does the system notify you if the waste is full? _____

2. Initialize the System

   - Turn on the BN II analyzer using the button on the left side.
   - Turn on the computer.
   - Log in to the Operating System.
   - When the desktop appears, double click on the BNII Alias icon.
   - In to the BNII software, enter User & Password in the Login/Logout box.
   - In the Info dialog observe the Information display area beneath System status.
   - During initialization, do not interrupt the movements by performing any hardware function, such as lifting the front panel or loading a rack.
   - Check the tubing and syringes for kinks, leaks, air bubbles and dirt.

     If there are air bubbles or dirt, rinse tubing and syringes several times by selecting System - User Service- Syringe. Select the syringe, washing solution, the number of washing steps and Rinse.

   Note: The Information Display Area will show “analyzer is ready” in the system status field after the completion of initialization.

What are the sizes (uL) of the three syringes?

_____

3. Update the Dilution Well Count

   - When the Dilution strips dialog appears, click Change dilution strips.
   - You have already changed the strips, so click Left new, then Right new and OK.
   - The value for DiIn wells in the Analyzer display area should be 264.

How many cuvettes are available to use? _____

How many cuvettes are on the system? _____

3 Product Inventory – Lot Data Entry

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Identify Siemens lot numbers for reagents, standards, and controls.
- Enter lot data using the barcode scanner.
- View lot data for standards and controls.
- Manual entry of lot data

1. Observe the lot number on the box or bottle for reagents, standards, and controls. The last 2 digits is the lot number sometimes followed with a letter and the first 4 digits is the product identifier.
2. Following the procedure in the QRG, scan the assigned values of standards and controls.
3. To view the assigned values, click Calibration > Control lots or Standard lots.

   When would an assigned value need to be entered manually?

   _____

   What size bottle are reagents packaged in? _____

   What size bottle are standards and controls packaged in? _____ _

4. Using the QRG, manually enter in values for a control or standard that has not been scanned in.

Why would a control or standard require manual entry of values?

___ _____

4 Assay Calibration

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Load reagents
- Program calibration for assays with no supplemental reagent
- Respond to instrument needs.
- Review calibration curves.

1. Load Reagents (assays with no supplemental reagent)
   - Place bottles in a reagent rack with the barcode labels positioned to face the barcode reader.
   - Push the rack into any of the lanes 1 through 5 until you hear a click.
   - Do not load the standard.

2. Program Calibrations
   - Click on the Reference curves icon.
   - Click on the assay. Be sure the BNII icon is displayed next to the reagent lot onboard the system.
   - Click Measure. The color of assay changes from green to blue, indicating that the calibration is in progress.
   - Click Yes to the message if the lot has already been calibrated.
   - Repeat the previous steps for additional assays with no supplemental.
   - Close the Reference curves window.

3. Determine Instrument Needs
   - Note the red background on the Info dialog.
   - Click Missing in the Reagents display area.
   - Standard is listed in red because it is needed.
   - Load the Standard in a control rack. Make sure the barcode label faces the rack opening. Place the rack in any lane, 6 through 15, and listen for the click.
   - Close the window and look at the Validation display area. Note the number in the in process field. This indicates the number of calibration curves are in progress.
   - Observe the movement of the right and left transfer arms.

4. Review Calibration Curves
   - When the curves are completed, click on the Reference curves icon.
   - Highlight an assay and verify that the correct lot number is displayed.
   - Click Show curves.
   - Determine curve validity. Acceptable mean deviation for most assays is ≤ 5.0%.

   Note: Most assays can have 3 reagent lot numbers calibrated and 3 curves per lot.

How many reagent bottles can be placed in a rack? _____

Does the system show a time when the assays are completed? _____

Which transfer arm probe goes into the reagent bottle? _____

Why is it important to review the calibration curve if it has been automatically accepted?

_____

5 Process Controls

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Request controls.
- Determine instrument need.
- Review control results.

1. Request Controls
   - Display the Routine menu and select Request controls.
   - Highlight the Xs for the assays that are calibrating.
   - Click Measure. The Xs change to ?s, indicating that the controls are in process.
   - Close the window.
2. Determine Instrument Needs
   - Click Missing in the Reagents display area.
   - Refer to the displayed list to load the controls that are needed.
   - Close the Reagent list.
3. Review Control Results
   - When results are available, click the Control journal icon.
   - Review the icons in the tool bar.
   - The Control journal displays:
     - Percent deviation from the mean value of the control
     - Results in concentration
     - Expected mean in parentheses
   - For most assays, the controls are acceptable if they are ±15% from the mean value.

How does the system know the mean value of the controls?

_____

How many control bottles can be loaded in one rack?

_____

Why are the bottles tilted in the rack?

_____

If the control result is outside of the ±15% acceptability, will the system allow samples to be processed?

_____

6 Process Barcoded Samples (no interface)

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Enter requests for barcoded sample (no interface) .
- Determine instrument needs.
- Load sample racks in appropriate lanes.
- Review sample results.

1. Processing barcoded samples with no interface

   - Follow the procedure in the BN II Quick Reference Guide.
   - Assign tests

Which transfer arm probe goes into the sample tube? _____

How many samples can be loaded in one rack? _____

How many samples can be loaded on the system at one time?

_____

2. Review Results

   - Click on the Lab journal icon to view the sample results.
   - When all sample results are available, click on the printer icon in the upper left corner of the window to print the results.

In the Lab Journal, click on the light bulb.  (Show legend icon)

Describe the Turbidity Flag. _____

_____

What needs to be done with a sample that has a turbidity flag? _____

_____

Note: See IFU Limitations of the Procedure (Resources - Training Workbook)

7 Assay Calibration (non-kit & kit)

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Enter new reagent lot number automatically.
- Manual identification of a reagent.
- Calibrate non-kit and kit assays.
- Review calibration curves.
- Process and review quality control.

1. Load Reagents (kit)

   - Load a rack with reagent and its supplemental reagent and insert in any lane 3, 4, or 5.
     - Click Reagents in the Reagents display area on the Info dialog. Note that supplemental reagent is marked with a black X in the Lane 3-5 column. This means the reagent must be placed in lanes 3, 4, or 5 so the right transfer arm can reach it.
   - The new lot numbers are entered automatically, and you will see the message New lot number of reagent is on board the analyzer. Please measure a new calibration curve – (lot number). Click OK and the Reference curves dialog opens automatically.
   - Click Yes to the message if the lot has already been calibrated.
   - In the Reference curves dialog, select the assay. Because the reagent and supplemental are from the same box (kit), the lot numbers will be displayed on the right and the BNII icon will be seen next to the lot numbers. If not, click on the triangle and choose the lot number. The reagent and supplemental are from the same kit and should always be used as a pair.
   - Click Measure.
   - Click Missing in the Reagents display area.
   - Standard is listed in red because it is needed.
   - Load the standard in a control rack. Place the rack in any lane, 6 through 15, and listen for the click.

2. Load Reagents (non-kit)

   - Load a rack with reagent and its supplemental reagent. The supplemental reagent is packaged separately (non-kit). Intentionally turn the supplemental reagent barcode label so the scanner cannot read it.
   - Load the rack. The rack is ejected automatically, and the Loading dialog appears. This happens because the barcode scanner cannot read the label for the supplemental reagent.

2. Manual Reagent Identification

   - Check the lot number on the supplemental reagent vial in the rack.
   - Click on the reagent rack position marked with a "?"
   - Scroll down the list on the right and highlight the supplemental reagent with the correct lot number beside it. Click Take at the lower right corner of the dialog.
     - Note if you do not see the correct lot number, in the menu, select Calibration > Reagent lots. Select the reagent and enter the new lot no.
   - When the message All vials/bottles have been identified appears, click OK.
   - Pull the rack halfway out of the lane and reinsert it.

3. Program Calibrations
    - Click on the Reference curves icon.
    - Click on the assay. Be sure the BNII icon is displayed next to the reagent lot onboard the system. The supplemental reagent will not be displayed because it is packaged separately from the reagent and has a different lot number (non-kit).
    - Click Measure. The color of assay changes from green to blue, indicating the calibration is in progress.
    - Click Yes to the message if the lot has already been calibrated.
    - Close the Reference curves window.
4. Process Controls
    - Display the Routine menu and select Request Controls.
    - Highlight the Xs for the controls.
    - Click Measure.
    - Close the Control Request window.
5. Review Calibration Curves
    - Click on the Reference curves icon.
    - Click the assay then Show curves. Click on the printer icon to print the curve (optional).
    - Evaluate the curve(s) acceptability.
6. Determine Control Acceptability
    - For most assays, the controls are acceptable if they are ± 15% from the mean value.

Note: Kit assays can have 1 lot number calibrated and 3 curves per lot.

When will a reagent lot need to be manually entered?

_____

What is the purpose of the supplemental reagent?

_____

Can a control be ordered if there is no acceptable calibration curve?

_____

8 Process Non-Barcoded Samples

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Manually build a job list.
- Assign rack positions for non-barcoded samples using Autoload.

1. Processing non-barcoded samples
   - Follow the procedure in the BN II System Quick Reference Guide.
2. Lab journal Review
   - Review results.

On the toolbar in the Lab journal, what is clicked to display the description of the flags?

_____

What icon in the Lab journal indicates a sample has been processed?

_____

9 Adding Tests and Changing Dilutions

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Add tests to previously processed samples.
- Repeat assays and change dilution factors.
- Change the dilution factor for an assay before the sample is processed.

1. Add a test to a sample
   - Select the Lab journal icon.
   - Double-click the sample ID. The dialog Enter job list is displayed. In the Assays field, click the assay to add.
   - To add an assay for multiple samples, select the samples in the Lab journal. Then, in the toolbar, click ? and add the assay to the selected samples
   - To save the changes, click Save or Save & Close.
2. Repeat Assays and Change the Dilution Factor
   - In the Lab journal click on the assay result.
   - Click Action and select Repeat. The dialog Dilutions is displayed.
   - Click on a dilution.
   - Click Measure.
3. Change the Sample Dilution Factor before Processing
   - Use the Enter job list function to program a new sample.
   - Click on the Dilution button.
   - Click on a dilution field to highlight it.
   - Click on the New dilution (pencil/tablet) icon in the toolbar. The X will move to the field that is highlighted.
   - Click OK.
   - Click Save.
   - Load the sample.

Why would the dilution factor be changed on a sample prior to processing?

10 Batch Programming (Optional)

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Program a batch run.
- Delete the programming.

1. Programming
    - Select Routine, Enter job list.
    - Click on the Batch Input box.
    - Enter Number of samples - 10.
    - Enter the Start Number - 125.
    - You may put a precursor name or number in the Sample ID field, eg, Health Fair.
    - Click on the assay(s).
    - Click Save and Close.
    - Open the Lab journal to view the sample IDs and requests.
2. Deleting
    - In the Info dialog click Missing in the Samples display area.
    - Click Edit, Select all to highlight the samples.
    - Click on the Delete icon and choose Complete Selection.

What is an advantage of batching samples for processing? _____

_____

11 BNII Shutdown and Data Folder Backup

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Shut down the analyzer
- Delete the Runtime Folder
- Back up the Data Folder

Note: The Data Folder stores important information relating to calibrations, assays, standards, and controls. A backup copy of the Data Folder can be used to restore this information on your system.

Each time the BNII program is launched, it automatically makes a copy of the Data Folder. The system stores a total of 4 copies. When the analyzer initializes, if you see no assays listed or valid reference curves stored, the Data Folder could be empty or corrupted. Each time the BNII program is launched, it will make a copy of the empty or corrupted Data Folder. It is recommended that you call the Siemens Healthineers Technical Solutions Center immediately to assist you with restoring the Data Folder.

Additionally, you should backup the Data Folder to a USB when new calibrations have been run, new information has been entered for assays, standards, and control, and for Weekly Maintenance.

1. Shut Down the BNII Application
    - Print the Lab journal: Lab journal icon, Printer icon.
    - Release results if interfaced: Lab journal icon, Release to Host icon.
    - Delete the Lab journal:
        - Click the Lab journal icon.
        - Click the Edit menu and choose Select All to highlight the results.
        - Click the Trash Can icon.
        - Click Complete Selection.
        - Close the Lab journal window.
    - From the menu bar select BNII and select Quit BNII.
    - Click Perform.
    - Click Close.
    - DO NOT click Cancel prematurely. Wait until the desktop appears.
2. Using the BNII Quick Reference Guide perform the Data Folder Backup
    - Delete the Runtime folder.
    - Copy Data Folder to the USB.
    - Empty Trash.
    - Shutdown BNII and turn off.

12 Maintenance

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Perform weekly maintenance
- Perform monthly maintenance
- Perform half-yearly maintenance
- Discuss yearly maintenance

12.1 Weekly Maintenance

1. Clean the Surface of the system
   - Clean the surface of the system with a link-free cloth moistened with cleaning solution (rotor cover, the trough for the dilution frames and the rack unit).

     NOTE: Do not use alcohol to clean the Plexiglas.

2. Check the syringes and valves for leaks
   - Check the syringes and valves for leaks.
   - Check for crystallization of buffer at the transition from syringe to valve.
   - If valves are leaking contact a service representative.

   When do you check the tubing and syringes for kinks, leaks, air bubbles, leaking and microbial contamination?

   _____

3. Check the reagent and sample probes for damage and blockage
   - Select System > User service > Clean dispensing probe.
   - Select Yes.
   - Select Clean now.
   - Lift the Plexiglas and clean the tip of both probes with a lint free cloth moistened with cleaning solution.
   - Select Cleaning done

   NOTE: The sample transfer arm and then the reagent transfer arm will move one after the other to an adjustment point in lane 15. (approximately 20 second intervals)

   - Check the probe is directly above the notch on lane 15. If it does not align contact Siemens Healthineers service.
   - While the reagent transfer arm moves to the adjustment point, the sample probe moves to the washing station. The probe moves over the washing station and dispenses liquid.
     - Evaluate the liquid must dip straight into the washing station and be cylindrical and transparent. It must not be fanned and must not splash.
   - Then the reagent transfer arm moves over the left washing station and dispenses liquid.
   - Select Done.

   What needs to be done if the liquid dispensed does not meet the criteria mentioned above?

   _____

   How do you clear a clogged sample dispensing probe?

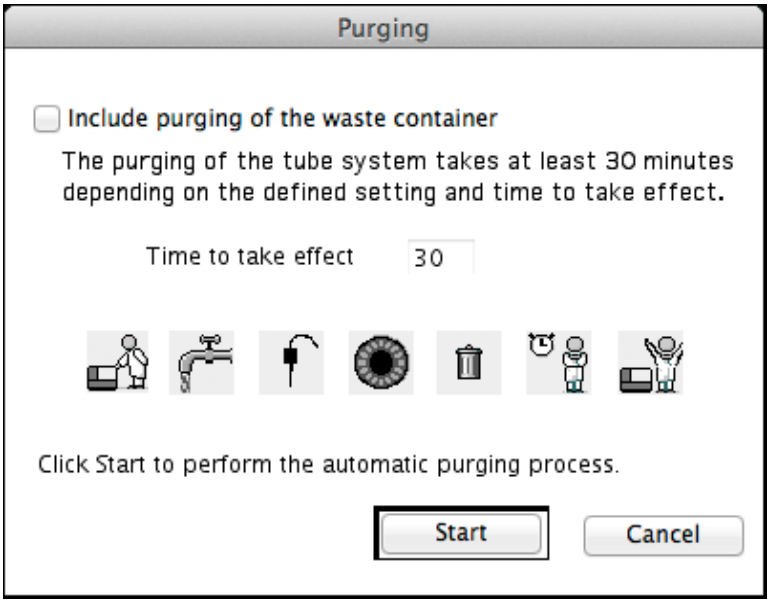
   _____

12.2 Monthly Maintenance

1. Replace the washing solution container
   - Replace the washing solution container with a used and clean diluent container. This helps to prevent contamination buildup.

2. Purge the tubing and waste container (recommended)
   - Prepare the neodisher GK the DAY BEFORE this procedure, if undissolved it can obstruct the tubing.
     - Fill a container with 4L of distilled water. For each L add 10g of the neodisher GK (approx. 1 cap full).

   - Fill another container with 1L of the prepared purging solution.
   - Empty the external waste container.
   - Select System > User service > Purging.
   - Select OK.
   - Select check box Include purging of the waste container.
   - Time to take effect: 30.

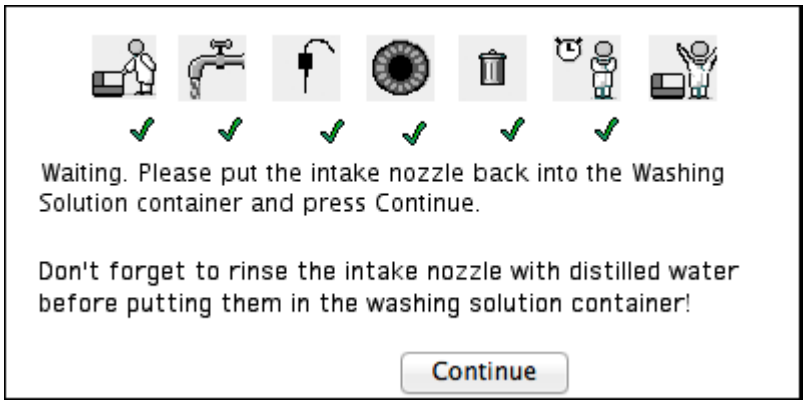


   - Select Start.
     - The dialog states that the routine has been interrupted.
   - Select Start.
   - Place all three container level sensors into the 1L purging solution container.
   - Select Continue.

   Note: Completed steps are marked with a green check mark under the icons.

   - When the dialog box below appears, place the drain tube of the external waste into the remaining 3L purging solution.

- Select Continue.
- When the dialog box below appears, take the drain tubing out of the purging solution and place it back into the external waste container.

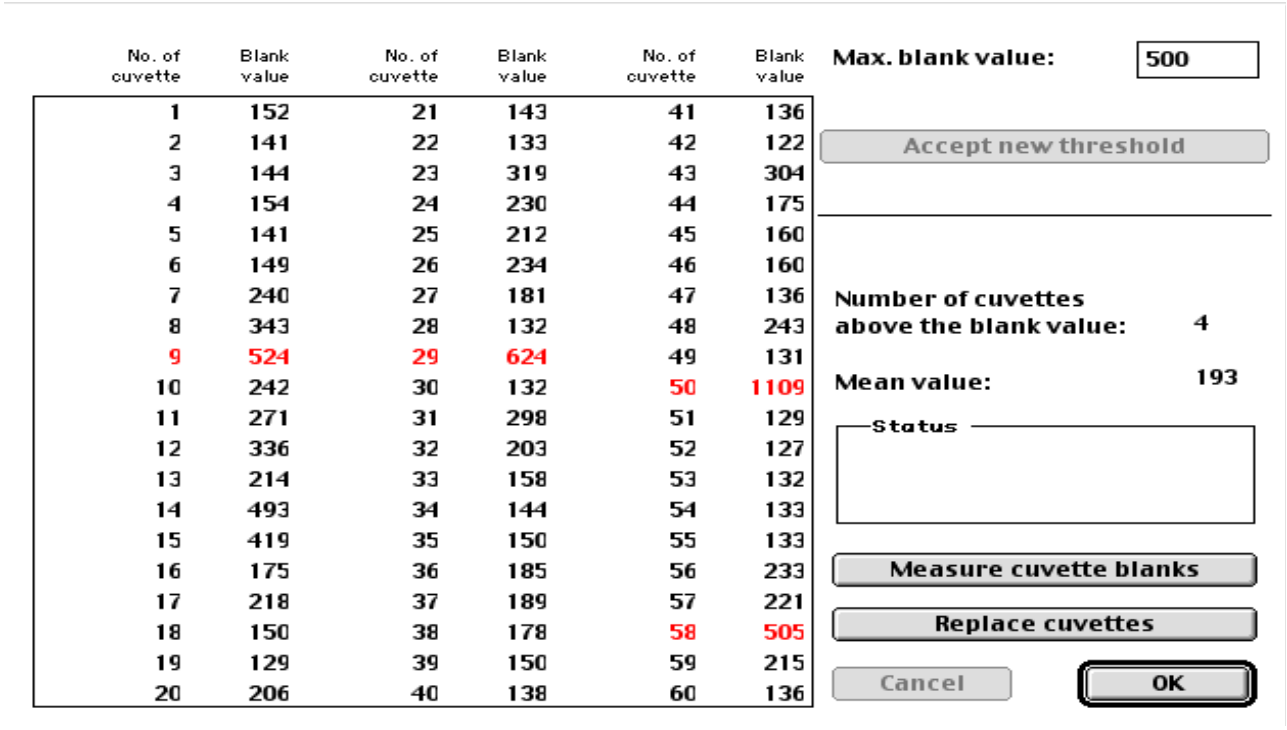


- Take all the intake nozzles out of the purging solution, rinse with distilled water, clean with a damp lint-free cloth and place back into the appropriate containers.
- To start the rinsing process, select Continue.
- When all purging solution has been rinsed out of the system, the dialog states Analyzer in Routinemode. To confirm this message, select Continue.
- Select Quit when the dialog states Purging of the tubing is finished.
- The dialog is closed.

3. Replace the wash solution filter
   - On the left side of the system, loosen the Luer lock connections of the old washing solution filter.
   - Insert the new filter. Close the Luer lock connections.

NOTE: Wash filter is changed before replacing cuvettes to avoid getting residual neodisher into the cuvettes.

4. Replace cuvettes
   - In the software select System > User service > Cuvette.
   - Select Yes when the dialog is displayed.
   - The dialog Cuvette is displayed.

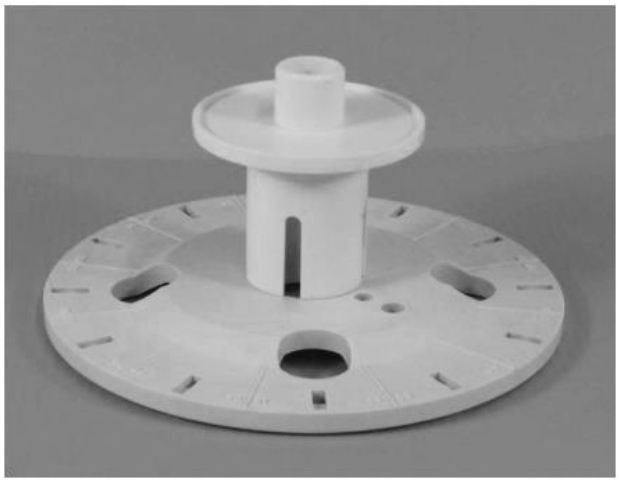


No. of cuvette	Blank value	No. of cuvette	Blank value	No. of cuvette	Blank value
1	152	21	143	41	136
2	141	22	133	42	122
3	144	23	319	43	304
4	154	24	230	44	175
5	141	25	212	45	160
6	149	26	234	46	160
7	240	27	181	47	136
8	343	28	132	48	243
9	524	29	624	49	131
10	242	30	132	50	1109
11	271	31	298	51	129
12	336	32	203	52	127
13	214	33	158	53	132
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

   - Select Replace cuvettes shown in the dialog box above.
     - The right transfer arm is moved to another position so the rotor cover can be removed.
   - The dialog below is displayed.

Do not select Confirm until after the cuvettes have been replaced.

- Lift the Plexiglas cover.
- Remove the rotor cover.
- Hold the rotor in position with hand while unscrewing the knurled nut with the other hand. Unscrew counterclockwise.
- Remove the rotor assembly by lifting up on the second knurled nut.
- Place the rotor assembly on the 3rd hand shown below.



- While holding the rotor assembly, remove the second knurled nut by unscrewing it counterclockwise.
- Carefully remove the top plate or upper part of the rotor assembly.
- Remove and discard the old segments.
- Load the new segments onto the rotor between the lines on the rotor plate.

NOTE: Handle the cuvette segments by the top tab only. Do not touch the cuvette body.

- Place the upper rotor plate onto the rotor plate where the cuvettes are seated. Make sure that the locator pin on the lower plate is seated in the hole on the upper plate.
- Hold the assembly and screw the second knurled nut back on tightly.
- Seat the assembly back into its original positioning. Spin the rotor until the locator pin in the rotor station fits through the hole in the rotor plate assembly.

NOTE: The top of the cuvettes should be even with the rotor station platform when seated properly.

- Hold the rotor assembly in place while screwing the knurled nut onto the assembly.
- In the dialog box, select Confirm.
  - The analyzer drives the cuvette washing units back into position.
- Put the rotor cover back in position
- Close the Plexiglas.

NOTE: The instrument will automatically measure the cuvette blanks.

5. Clean the Mouse
   - Wipe the surface with a soft, lint-free cloth moistened with cleaning solution.

12.3 Half-yearly Maintenance

Reference the BNII System Instruction Manual to perform the following:

1. Replace the syringes with the white piston heads.
2. Maintain the syringes with silicon oil.

12.4 Yearly Maintenance

1. Replace the syringes with the black piston heads or contact Siemens Healthineers service to have them replaced.

13 Process Barcoded Samples (no interface)

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Process barcoded samples
- Program a STAT sample
- Filter results in the Lab journal

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1. Enter the Job list and Process the Samples
   - Load all sample rack(s). For this exercise, it is recommended that you put the samples in numerical order and load the rack(s) in order so that the sample numbers will be in numerical order in the Lab journal.
   - In the Samples display area on the Info dialog click without req.
   - Click Edit in the menu bar and Select all
   - Click the Details icon at the top of the window.
   - The first sample number read by the barcode scanner appears in the Sample ID box. Select the assay(s) and then click Save. Continue assigning assay(s) to sample numbers.
2. Program a STAT sample
   - Mark the last sample STAT.
   - In the Lab journal find the indicator for a STAT sample.
3. Filter Results in the Lab journal
   - When results are available:
     - Click View in the tool bar and select Assay selection.
     - Click an assay to see a list of all results.
   - To return to the default view, click on the Deselect filter icon (eyeball).

14 Patient Demographics (optional)

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Enter patient demographics
- Enter laboratory name and address
- Print single patient report

1. Enter Patient Demographics
   - Open the Lab journal and double-click on a processed barcoded sample to open the Enter job list dialog.
   - Click Patient and enter:
     - Last Name: Doubtfire
     - First Name: Irma
     - Date of Birth: 12/29/1953
     - Sex: Female
     - Click Save.
   - Enter some patient information for two processed barcoded samples.
   - Click on the Patient Journal icon to view the entries.
2. Enter Laboratory Information
   - Select System, Configuration and Journal. Type in your laboratory's information.
   - Click Save.
3. Printing Patient Reports
   - Click on the Patient Journal icon and then click on the Print icon to print the entire Patient Journal.
   - To print a single patient report, highlight a patient name and click View and Own Selection.
   - Click on the Print icon.
   - To return to the normal display, click View and All Patients.

15 Defining Other Vendor's QC (Optional)

References

- BN™II System Instruction Manual

Objectives

Upon completion of this exercise, you will be able to:

- Define controls
- Enter control lot numbers and nominal values
- Process control as a sample and change to a control

1. Define Controls
   - Select Definition, Controls.
   - Click on the New (pencil/tablet) icon.
   - Enter Name of control: Biorad 1.
   - Enter Identification: 9901. You must use a unique 4-digit identifier for each control.
   - Enter Expiration: 240 min.

   What is the expiration used for?

   _____

   - Leave bottle size default at 2 mL and click Save.
   - If defining more controls, you can use 9902 as identification for Biorad 2 and 9903 as identification for Biorad 3.
   - In the Control Definition dialog, highlight the cell at the intersection of the assay and the new control and click on the New assignment (pencil/tablet) icon to bring up the Control Details window. For this exercise, click IgG for Biorad 1.
   - Enter 15% or 20% permitted deviation. When unassayed controls are used, 20% is recommended as the starting permitted deviation. You can change this later, if desired.
   - Change the default dilution level, if necessary, to accommodate the analyte concentration in the control.
   - Leave the other defaults for running controls unchanged and click Save.
   - Close the Control Definitions window.

2. Enter Lot Numbers and Values
   - Select Calibration and Control Lots.
   - Double-click on the control name and enter the lot number of the control. You can use 01 for Biorad 1, 02 for Biorad 2, and 03 for Biorad 3.
   - Enter a nominal value for IgG for Biorad 1. Click Save.
   - To view the upper and lower limit based on a 20% deviation, double-click on the nominal value in the IgG cell for Biorad 1.

3. To Process Other Vendor's QC (Optional)
   - Pour control into a sample tube and either manually identify it using the 6-digit number or print a barcode label for the control.
   - Change the sample to control. Select Action pop-up menu and Change sample to control...

Are the controls entered in the monthly QC statistics?

_____

16 Processing Short Samples

References

- BN™II System Quick Reference Guide
- BN™II System Instruction Manual

Objectives

Upon completion of this exercise, you will be able to:

- Customize System Configuration
- Process a sample in a pediatric rack

1. Customize System Configuration

   - Click System, Configuration, and Measurement. Verify that the box "Use same ID several times" is NOT marked. If this box is marked, the system will not allow samples to be assigned to a pediatric rack. However, if you are running 2 sample types with the same ID number (eg, CSF and urine from the same patient), this box must be marked. If you are changing this option, the Lab journal must be empty. Click Save.

     Note: If the system is connected to a LAS, do not activate the check box Use sample ID several times.

2. Process a Sample with Insufficient Volume

   - Using the BN II System Quick Reference Guide for assistance, program assays on a non-barcoded insufficient sample.

   Watch the transfer arm as it goes into the sample. What does the probe do?

   _____

   What display area on the Info dialog changes to yellow?

   _____

   - When you see the indicator for "insufficient sample" on the Info dialog, eject the rack.
   - To delete the rack position for the sample, click on the Loading icon. Select the sample rack number in the Rack ID list. Highlight the sample ID and click Delete.
   - To assign the sample to a pediatric rack, choose your pediatric rack and select that number in the Rack ID list. Click Autoload and Ignore all empty positions. Close the Loading dialog.
   - Transfer the sample to a microcentrifuge tube and place in the pediatric rack. Load the rack on the BN II system.

3. Follow-up (optional)

   - When results are complete, delete the Lab journal.
   - Click System, Configuration, and Measurement. Mark the box "Use same ID several times" and click Save.

17 Troubleshooting

References

- BN™II System Instruction Manual
- BN™II System Quick Reference Guide

Objectives

Upon completion of this exercise, you will be able to:

- Troubleshoot basic hardware and software issues.
- Use **Logbook** messages to resolve issues

Your goal is to print your Lab journal with sample results. Your BN II has been programmed for samples to be run.

Before you insert the sample and reagent racks, resolve any issues in red noted on the Info dialog screen. Check the Logbook message for help. Record your observations and resolutions on the form below.

As samples are running, resolve errors and or issues that may appear.

Tip: Be sure to investigate the Logbook errors. Click on the error text and read in the Event and What to Do areas.

Problem:
Resolution:
Problem:
Resolution:
Problem:
Resolution:
Problem:
Resolution:

18 Resources

SIEMENS Healthineers

BN II System

Assay Protocols

Update 4.6, Date of Issue: 2022-05

siemens-healthineers.com

Version			Date	Changes
Manual	**Software**	**Assay Protocol Update**		
2.9	2.5/2.6	4.6	2019-09	Footnote 4: Cover Ring EVAP. STOPPERS added.
3.0	2.5, 2.6	4.6	2022-05	Reference Range: CRP

Disclaimer

Siemens Healthineers has validated the provided instructions, reagents, instrument, software and customizable features for this system to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens Healthineers as they may affect performance of the system and test results.

Product availability may vary from country to country and is subject to varying regulatory requirements.

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Changes are highlighted in blue, which may also include editorial corrections without content changes.

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☐	HPT	Haptoglobin / N Antiserum to Human Haptoglobin	8
☐	AAG	α_1-acid Glycoprotein / N Antiserum to Human α_1-acid Glycoprotein	8
☐	PRE	Prealbumin / N Antiserum to Human Prealbumin	8
☐	sTfR	soluble Transferrin Receptor / N Latex sTfR	8
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☐	CER	Ceruloplasmin / N Antiserum to Human Ceruloplasmin	8
☐	RbP	Retinol-binding-Protein / N Antiserum to Human RbP	8
☐	kap	Ig/L-chain, type kappa / N Antiserum to Human Ig/L-chain, κ-type	8
☐	FLC_K	free Ig/L-chain, type kappa / N Latex FLC kappa	8
☐	lam	Ig/L-chain, type lambda / N Antiserum to Human Ig/L-chain, λ-type	8
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☐	C1I	C1-Inhibitor / N Antiserum to Human C1-Inhibitor	10
☐	FIB	Fibrinogen / N Antiserum to Human Fibrinogen	10
☐	AT3	Antithrombin III / N Antiserum to Human Antithrombin III	10
☐	PLS	Plasminogen / N Antiserum to Human Plasminogen	10
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Table of Assay Protocols

SAN[a]	Abbr.	Protein	Specimen	Reagent					Supplements		Recommended Controls		Measuring Range[c]				Reference Range[d]			Standards	APV[e]	Eval. Mode
				Package	Quantity			On-board Stability[b] [days at 8 hours each]		On-board Stability[b] [days at 8 hours each]		On-board Stability[b] [h]	Condition	Initial Measuring Range	Minimum Measuring Range	Unit	Condition		Unit			
1	IgG	IgG	serum; EDTA plasma; heparin plasma	N Antiserum to Human IgG NAS IGG							N/T PROT CONTROL SL/L	n/a		1.4 – 46	0.07 – 2.3	g/L		7.0 – 16.0[g]	g/L	N PROT STANDARD SL	1.2	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OSAS19 SMN 10446299	1 ×	5 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAS11 SMN 10446297	1 ×	2 mL		3/6[f]														
51	IgG1	IgG Subclass 1	serum; EDTA plasma; heparin plasma	N AS IgG1 N AS IGG1							N/T PROT CONTROL SL/L	n/a		0.85 – 27	0.04 – 1.4	g/L		4.05 – 10.11[g]	g/L	N PROT STANDARD SL	3.0	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OQXI09 SMN 10446168	1 ×	1.5 mL		3/6[f]			N/T PROT CONTROL SL/H	n/a										
52	IgG2	IgG Subclass 2	serum; EDTA plasma; heparin plasma	N AS IgG2 N AS IGG2					N SUPPLEMENT P	[b]	N/T PROT CONTROL SL/L	n/a		0.35 – 11	0.09 – 2.8	g/L		1.69 – 7.86[g]	g/L	N PROT STANDARD SL	3.0	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OQXK09 SMN 10446169	1 ×	1.5 mL		3/6[f]			N/T PROT CONTROL SL/H	n/a										
78	IgG3n	IgG Subclass 3	serum; EDTA plasma; heparin plasma	N Latex IgG3 N IGG3					N SUPPLEMENT P	[b]	N/T PROT CONTROL SL/L	n/a		0.033 – 2.1	0.0017 – 0.11	g/L		0.11 – 0.85[g]	g/L	N PROT STANDARD SL	1.0	Fixed Time with Pre-reaction
									Cleaner SCS	5	N/T PROT CONTROL SL/M	n/a										
				REF OPAV03 SMN 10445972	1 ×	2 mL	N IGG3 REAGENT	5/10[f]			N/T PROT CONTROL SL/H	n/a										
79	IgG4n	IgG Subclass 4	serum; EDTA plasma; heparin plasma	N Latex IgG4 N IGG4					N SUPPLEMENT P	[b]	N/T PROT CONTROL SL/L	n/a		0.052 – 3.3	0.0026 – 0.17	g/L		0.03 – 2.01[g]	g/L	N PROT STANDARD SL	1.0	Fixed Time with Pre-reaction
									Cleaner SCS	5	N/T PROT CONTROL SL/M	n/a										
				REF OPAU03 SMN 10445971	1 ×	2 mL	N IGG4 REAGENT	5/10[f]			N/T PROT CONTROL SL/H	n/a										
2	IgA	IgA	serum; EDTA plasma; heparin plasma	N Antiserum to Human IgA NAS IGA							N/T PROT CONTROL SL/L	n/a		0.25 – 8.0	0.25 – 8.0	g/L		0.7 – 4.0[g]	g/L	N PROT STANDARD SL	1.2	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OSAR19 SMN 10446295	1 ×	5 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAR11 SMN 10446293	1 ×	2 mL		3/6[f]														
22	IgAs	IgA[h]	serum; EDTA plasma; heparin plasma	N Antiserum to Human IgA NAS IGA					N SUPPLEMENT P	[b]	N/T PROT CONTROL SL/L	n/a		0.06 – 2.0	0.06 – 2.0	g/L		–[g]		N PROT STANDARD SL	1.3	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OSAR19 SMN 10446295	1 ×	5 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAR11 SMN 10446293	1 ×	2 mL		3/6[f]														
3	IgM	IgM	serum; EDTA plasma; heparin plasma	N Antiserum to Human IgM NAS IGM							N/T PROT CONTROL SL/L	n/a		0.2 – 6.4	0.2 – 6.4	g/L		0.4 – 2.3[g]	g/L	N PROT STANDARD SL	1.2	Fixed Time with Pre-reaction
											N/T PROT CONTROL SL/M	n/a										
				REF OSAT19 SMN 10446303	1 ×	5 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAT11 SMN 10446301	1 ×	2 mL		3/6[f]														
23	IgMs	IgM[h]	serum; EDTA plasma; heparin plasma	N Antiserum to Human IgM NAS IGM					N SUPPLEMENT P	[b]	N/T PROT CONTROL SL/L	n/a		0.05 – 1.6	0.05 – 1.6	g/L		–[g]		N PROT STANDARD SL	1.3	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OSAT19 SMN 10446303	1 ×	5 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAT11 SMN 10446301	1 ×	2 mL		3/6[f]														
4	C3	C3c	serum; EDTA plasma; heparin plasma	N Antiserum to Human C3c N AS C3							N/T PROT CONTROL SL/L	n/a		0.12 – 4.1	0.03 – 1.0	g/L		0.9 – 1.8[i]	g/L	N PROT STANDARD SL	1.2	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OSAP15 SMN 10446291	1 ×	5 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAP09 SMN 10446290	1 ×	2 mL		3/6[f]														
5	C4	C4	serum; EDTA plasma; heparin plasma	N Antiserum to Human C4 N AS C4							N/T PROT CONTROL SL/L	n/a		0.06 – 1.9	0.02 – 0.48	g/L		0.1 – 0.4	g/L	N PROT STANDARD SL	1.2	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OSAO15 SMN 10446289	1 ×	5 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAO09 SMN 10446288	1 ×	2 mL		3/6[f]														
6	TRF	Transferrin	serum; EDTA plasma; heparin plasma	N Antiserum to Human Transferrin N AS TRF							N/T PROT CONTROL SL/L	n/a		0.35 – 5.6	0.09 – 1.4	g/L		2.0 – 3.6	g/L	N PROT STANDARD SL	1.2	Fixed Time
											N/T PROT CONTROL SL/M	n/a										
				REF OSAX15 SMN 10446309	1 ×	5 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAX09 SMN 10446308	1 ×	2 mL		3/6[f]														

SAN[a]	Abbr.	Protein	Specimen	Reagent				Supplements		Recommended Controls		Measuring Range[c]				Reference Range[d]			Standards	APV[e]	Eval. Mode
				Package	Quantity		On-board Stability[b] [days at 8 hours each]		On-board Stability[b] [days at 8 hours each]		On-board Stability[b] [h]	Condition	Initial Measuring Range	Minimum Measuring Range	Unit	Condition		Unit			
7	ALB	Albumin	serum; EDTA plasma; heparin plasma	N Antiserum to Human Albumin N AS ALB						N/T PROT CONTROL SL/L	n/a		6.9 – 110	0.35 – 5.5	g/L		35.0 – 52.0	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OSAL23 SMN 10714508	1 ×	2 mL	3/6[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAL25 SMN 10714509	1 ×	5 mL	5/10[f]														
8	AAT	α_1-Antitrypsin	serum; EDTA plasma; heparin plasma	N Antiserum to Human α_1-Antitrypsin N AS AAT						N/T PROT CONTROL SL/L	n/a		0.16 – 5.2	0.04 – 1.3	g/L		0.9 – 2.0	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OSAZ15 SMN 10446312	1 ×	5 mL	5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAZ09 SMN 10446311	1 ×	2 mL	3/6[f]														
9	a2M	α_2-Macroglobulin	serum; heparin plasma	N Antiserum to Human α_2 Macroglobulin N AS A2M						N/T PROT CONTROL SL/L	n/a		0.2 – 6.4	0.05 – 1.6	g/L		1.3 – 3.0	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OSAM21 SMN 10469773	1 ×	5 mL	5/10[f]			N/T PROT CONTROL SL/H	n/a										
10	HPT	Haptoglobin	serum; EDTA plasma; heparin plasma	N Antiserum to Human Haptoglobin N AS HAPT						N/T PROT CONTROL SL/L	n/a		0.26 – 8.3	0.07 – 2.1	g/L		0.3 – 2.0	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OSAV15 SMN 10446305	1 ×	5 mL	5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAV09 SMN 10446304	1 ×	2 mL	3/6[f]														
11	AAG	α_1-acid Glycoprotein	serum; heparin plasma	N Antiserum to Human α_1-acid Glycoprotein N AS AAG						N/T PROT CONTROL SL/L	n/a		0.19 – 6.0	0.05 – 1.5	g/L		0.5 – 1.2	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OSAW15 SMN 10446307	1 ×	5 mL	5/10[f]			N/T PROT CONTROL SL/H	n/a										
				REF OSAW09 SMN 10446306	1 ×	2 mL	3/6[f]														
12	PRE	Prealbumin	serum; heparin plasma	N Antiserum to Human Prealbumin N AS PRE				N SUPPLEMENT P	[b]	N/T PROT CONTROL SL/L	n/a		0.02 – 0.6	0.02 – 0.6	g/L		0.2 – 0.4	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OUIF09 SMN 10446452	1 ×	2 mL	3/6[f]			N/T PROT CONTROL SL/H	n/a										
13	sTfR	soluble Transferrin Receptor	serum; heparin plasma	N Latex sTfR N STFR				N SUPPLEMENT L	[b]	N/T PROT CONTROL SL/L	n/a		0.14 – 4.4	0.14 – 4.4	mg/L		0.76 – 1.76	mg/L	N PROT STANDARD SL	1.0	VLinIntegral
										N/T PROT CONTROL SL/M	n/a	sTfR/Ferritin-Index	0.38 – 1.54	[k]							
				REF OQTC11 SMN 10446127	3 ×	2 mL	5/10[f]			N/T PROT CONTROL SL/H	n/a										
14	HPX	Hemopexin	serum; heparin plasma	N Antiserum to Human Hemopexin N AS HPX						N/T PROT CONTROL SL/L	n/a		0.2 – 6.4	0.05 – 1.6	g/L		0.5 – 1.15	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OUVN09 SMN 10446493	1 ×	2 mL	3/6[f]			N/T PROT CONTROL SL/H	n/a										
15	CER	Ceruloplasmin	serum; heparin plasma	N Antiserum to Human Ceruloplasmin N AS CER						N/T PROT CONTROL SL/L	n/a		0.07 – 2.2	0.02 – 0.55	g/L		0.2 – 0.6	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OUIE09 SMN 10446451	1 ×	2 mL	3/6[f]			N/T PROT CONTROL SL/H	n/a										
16	RbP	Retinol-binding-Protein	serum; heparin plasma	N Antiserum to Human RbP N AS RBP				N SUPPLEMENT P	[b]	N/T PROT CONTROL SL/L	n/a		0.01 – 0.2	0.01 – 0.2	g/L		0.03 – 0.06	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a										
				REF OUVO09 SMN 10446494	1 ×	2 mL	3/6[f]			N/T PROT CONTROL SL/H	n/a										
17	kap	Ig/L-chain, type kappa	serum	N Antiserum to Human Ig/L-chain, κ-type N AS KAPPA						N/T PROT CONTROL SL/L	n/a		0.28 – 9.1	0.07 – 2.3	g/L		1.7 – 3.7[g]	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a	Adults' Ig/L-chains quotient κ/λ (Human serum)	1.35 – 2.65	[k]							
				REF OWHG13 SMN 10446595	1 ×	2 mL	3/6[f]			N/T PROT CONTROL SL/H	n/a										
80	FLC_K	free Ig/L-chain, type kappa	serum; EDTA plasma; heparin plasma	N Latex FLC kappa N FLC KAPPA				N FLC SUPPLEMENT	[b]	N FLC CONTROL SL1	n/a		3.4 – 110	0.17 – 5.5	mg/L		8.24 – 28.9[g]	mg/L	N FLC STANDARD SL	2.0	Fixed Time with Pre-reaction
										N FLC CONTROL SL2	n/a	Adults' free Ig/L-chains quotient κ/λ (Human serum), 1[th]–99[th] percentile	0.53 – 1.51	[k]							
				REF OPJA07 SMN 10873629	3 ×	1.7 mL	5/10[f]														
18	lam	Ig/L-chain, type lambda	serum	N Antiserum to Human Ig/L-chain, λ-type N AS LAMBDA						N/T PROT CONTROL SL/L	n/a		0.16 – 5.0	0.04 – 1.3	g/L		0.9 – 2.1[g]	g/L	N PROT STANDARD SL	1.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a	Adults' Ig/L-chains quotient κ/λ (Human serum)	1.35 – 2.65	[k]							
				REF OWHH13 SMN 10446597	1 ×	2 mL	3/6[f]			N/T PROT CONTROL SL/H	n/a										
81	FLC_L	free Ig/L-chain, type lambda	serum; EDTA plasma; heparin plasma	N Latex FLC lambda N FLC LAMBDA				N FLC SUPPLEMENT Cleaner SCS	[b] 5	N FLC CONTROL SL1	n/a		1.9 – 60	0.48 – 15	mg/L		9.10 – 32.6[g]	mg/L	N FLC STANDARD SL	4.0	Fixed Time with Pre-reaction
										N FLC CONTROL SL2	n/a	Adults' free Ig/L-chains quotient κ/λ (Human serum), 1[th]–99[th] percentile	0.53 – 1.51	[k]							
				REF OPJB07 SMN 10873630	3 ×	2.1 mL	5/6[f]														

SAN[a]	Abbr.	Protein	Specimen	Reagent				On-board Stability[b] [days at 8 hours each]	Supplements	On-board Stability[b] [days at 8 hours each]	Recommended Controls	On-board Stability[b] [h]	Measuring Range[c] Condition	Initial Measuring Range	Minimum Measuring Range	Unit	Reference Range[d] Condition		Unit	Standards	APV[e]	Eval. Mode
30	A-I	Apolipoprotein A-I	serum; heparin plasma	N Antiserum to Human Apolipoprotein A-I N AS APOAI					N SUPPLEMENT P	[b]	APO CONTROL CHD	n/a		0.19 – 6.0	0.05 – 1.5	g/L		1.15 – 2.1[l]	g/L	N APO STANDARD	1.1	Fixed Time
																	men	1.10 – 2.05	g/L			
				REF OUED15 SMN 10446438	1 ×	5 mL		5/10[f]									women	1.25 – 2.15	g/L			
																	men (Apo B/ Apo A-I quotient)	0.35 – 1.0	[k]			
				REF OUED09 SMN 10446437	1 ×	2 mL		3/6[f]									women (Apo B/ Apo A-I quotient)	0.3 – 0.9	[k]			
31	ApoB	Apolipoprotein B	serum; heparin plasma	N Antiserum to Human Apolipoprotein B N AS APOB					N SUPPLEMENT P	[b]	APO CONTROL CHD	n/a		0.25 – 4.0	0.25 – 4.0	g/L		0.55 – 1.35[l]	g/L	N APO STANDARD	1.2	Fixed Time
																	men	0.55 – 1.40	g/L			
				REF OSAN15 SMN 10446287	1 ×	5 mL		5/10[f]									women	0.55 – 1.25	g/L			
																	men (Apo B/ Apo A-I quotient)	0.35 – 1.0	[k]			
				REF OSAN09 SMN 10446286	1 ×	2 mL		3/6[f]									women (Apo B/ Apo A-I quotient)	0.3 – 0.9	[k]			
39	Lpa	Lipoprotein(a)	serum; heparin plasma	N Latex Lp(a) Reagent N LP(A) REAGENT							N LP(A) CONTROL SY	n/a		0.1 – 1.6	0.03 – 0.4	g/L		< 0.3[l]	g/L	N LP(A) STANDARD SY	4.0	Fixed Time
																	caucasian, men	< 0.02 – 0.74	g/L			
				REF OQHL11 SMN 10446069	3 × →	2 mL		5/10[f]									caucasian, women	< 0.02 – 0.72	g/L			
																	african-american, men	0.04 – 1.14	g/L			
																	african-american, women	0.02 – 1.08	g/L			
																	hispanic-american, men	0.02 – 0.53	g/L			
																	hispanic-american, women	0.02 – 0.46	g/L			
50	FRT	Ferritin	serum; heparin plasma	N Latex Ferritin N FRT							N/T PROT CONTROL SL/L	n/a		10 – 640	2.5 – 160	µg/L		10 – 250[l]	µg/L	N PROT STANDARD SL	8.0	VLinIntegral
											N/T PROT CONTROL SL/M	n/a					men	20 – 290	µg/L			
				REF OQTH11 SMN 10446130	3 ×	3 mL	N FRT REAGENT	5/10[f]			N/T PROT CONTROL SL/H	n/a					women, premenopausal	4.5 – 170	µg/L			
					3 ×	1 mL	N FRT SUPPLEMENT A	[b]									women, postmenopausal	24 – 260	µg/L			
					1 ×	3 mL	N FRT SUPPLEMENT B										sTfR/Ferritin-Index	0.38 – 1.54	[k]			
84	RFn	RF	serum; EDTA plasma; heparin plasma	N Latex RF Kit N RF							N/T RHEUMA CONTROL SL/1	n/a		10 – 640	10 – 640	IU/mL		< 15.9	IU/mL	N RHEUMA STANDARD SL	1.0	VLinIntegral
											N/T RHEUMA CONTROL SL/2	n/a										
				REF OPCE03 SMN 10445991	3 ×	2 mL	N RF REAGENT	nr[m]/5[f]														
					3 ×	2.4 mL	N RF SUPPLEMENT	[b]														
				REF OPCE05 SMN 10445992	4 ×	4 mL	N RF REAGENT	nr[m]/5[f]														
					4 ×	4.8 mL	N RF SUPPLEMENT	[b]														
85	ASLn	ASL	serum; EDTA plasma; heparin plasma	N Latex ASL N ASL					N SUPPLEMENT P	[b]	N/T RHEUMA CONTROL SL/1	n/a		50 – 1 600	13 – 400	IU/mL	caucasian	< 408	IU/mL	N RHEUMA STANDARD SL	1.1	Fixed Time
											N/T RHEUMA CONTROL SL/2	n/a										
				REF OPBU03 SMN 10445983	3 ×	2 mL		7/10[f]														
				REF OPBU05 SMN 10445984	4 ×	3.5 mL		7/10[f]														
42	CRP2	CRP sensitive	serum; EDTA plasma; heparin plasma	CardioPhase® hsCRP					N SUPPLEMENT P	[b]	APO CONTROL CHD	n/a		0.16 – 10	0.16 – 10	mg/L		< 5	mg/L	N RHEUMA STANDARD SL	5.0	VLinIntegral
				REF OQIY13 SMN 10446090	3 ×	2 mL	CardioPhase hsCRP REAGENT	5/10[f]														
				REF OQIY21 SMN 10446091	5 ×	5 mL	CardioPhase hsCRP REAGENT	5/10[f]														
71	CRP1	CRP	serum; EDTA plasma; heparin plasma	CardioPhase® hsCRP					N SUPPLEMENT P	[b]	N/T RHEUMA CONTROL SL/1	n/a		3.1 – 200	0.16 – 10	mg/L		< 5	mg/L	N RHEUMA STANDARD SL	5.0	VLinIntegral
											N/T RHEUMA CONTROL SL/2	n/a										
				REF OQIY13 SMN 10446090	3 ×	2 mL	CardioPhase hsCRP REAGENT	5/10[f]														
				REF OQIY21 SMN 10446091	5 ×	5 mL	CardioPhase hsCRP REAGENT	5/10[f]														
57	IgE1	IgE	serum; EDTA plasma; heparin plasma	N Latex IgE mono N IGE					N SUPPLEMENT L	[b]	N/T PROT CONTROL SL/L	n/a		18 – 1 150	4.5 – 290	IU/mL		< 100[g]	IU/mL	N PROT STANDARD SL	3.1	VLinIntegral
											N/T PROT CONTROL SL/M	n/a										
				REF OQTG15 SMN 10446129	3 ×	3 mL		5/10[f]			N/T PROT CONTROL SL/H	n/a										
58	ADNs	ADNase B	serum	N Latex ADNase B N ADNS							N ADNS CONTROL[h]	n/a		75 – 3 000	75 – 3 000	U/mL		< 200	IU/mL	N ADNS STANDARD[h]	1.1	Fixed Time
				REF 10873691 (OWTI15)	3 × →	2 mL	N ADNS REAGENT	nr/nr[f]														
					3 ×	1 mL	N ADNS STANDARD															
					3 ×	2 mL	N ADNS CONTROL															
					3 ×	2.8 mL	N ADNS SUPPLEMENT	[b]														
59	b2M	β_2-Microglobulin	serum; EDTA plasma; heparin plasma	N Latex β_2-Microglobulin N B2M					N SUPPLEMENT L	[b]	N/T PROT CONTROL SL/M	n/a		0.7 – 23	0.18 – 5.8	mg/L		1.09 – 2.53	mg/L	N PROT STANDARD SL	3.0	VLinIntegral
											N/T PROT CONTROL SL/H	n/a										
				REF OQWU21 SMN 10446162	3 ×	3 mL	N B2M REAGENT	5/10[f]														
					1 ×	2 mL	N B2M U STAB															

SAN[a]	Abbr.	Protein	Specimen	Reagent			On-board Stability[b] [days at 8 hours each]	Supplements	On-board Stability[b] [days at 8 hours each]	Recommended Controls	On-board Stability[b] [h]	Measuring Range[c] Condition	Initial Measuring Range	Minimum Measuring Range	Unit	Reference Range[d] Condition			Unit	Standards	APV[e]	Eval. Mode
				Package	Quantity																	
60	MYO	Myoglobin	serum; EDTA plasma; heparin plasma	N Latex Myoglobin N MYO						N MYO CONTROL[h]	n/a		25 – 400	6.3 – 100	µg/L			< 70	µg/L	N MYO STANDARD[h]	1.1	Fixed Time
				REF 10873690 (OWIA17)	3 × →	2 mL	N MYO REAGENT	3/5[f]														
					3 × →	1 mL	N MYO STANDARD															
					3 × →	0.5 mL	N MYO CONTROL															
					3 ×	0.5 mL	N MYO SUPPLEMENT A	[b]														
					3 ×	1.6 mL	N MYO SUPPLEMENT B															
66	CysC	Cystatin C	serum; heparin plasma	N Latex Cystatin C N CYSC				Cleaner SCS	5	N CYSC CONTROL 1[h]	n/a		0.27 – 9.4	0.27 – 9.4	mg/L			0.49 – 1.19	mg/L	N PROT STANDARD UY	3.0	Fixed Time
										N CYSC CONTROL 2[h]	n/a											
				REF OQNM19 SMN 10873631	3 ×	2 mL	N CYSC REAGENT	5/10[f]														
					3 × →	1 mL	N CYSC CONTROL 1															
					3 × →	1 mL	N CYSC CONTROL 2															
					3 ×	0.5 mL	N CYSC SUPPLEMENT A	[b]														
					1 ×	1.6 mL	N CYSC SUPPLEMENT B															
75	HCY	Homocysteine	serum; EDTA plasma; heparin plasma	N Latex HCY N HCY						N/T PROT CONTROL SL/L	n/a		2 – 64	2 – 64	µmol/L	EDTA plasma		4.9 – 15.0	µmol/L	N PROT STANDARD SL	2.2	Fixed Time
										N/T PROT CONTROL SL/M	n/a											
				REF OPAX03 SMN 10445973	3 ×	1.7 mL	N HCY REAGENT	3/6[f]		N/T PROT CONTROL SL/H	n/a											
					3 ×	2.2 mL	N HCY RA	3/6[f]														
					3 ×	0.6 mL	N HCY SR A	[b]														
					3 ×	1.1 mL	N HCY SR B															
77	CDT	Carbohydrate-deficient Transferrin	serum	N Latex CDT Kit N CDT						N CDT CONTROL 1[h]	n/a		20 – 660[o]	20 – 660	mg/L	1th–99th percentile		28.1 – 76.0[p]	mg/L	N CDT STANDARD[h]	1.0	Fixed Time
										N CDT CONTROL 2[h]	n/a											
				REF OPCS05 SMN 10445997	3 ×	0.9 mL	N CDT REAGENT 1	3/6[f]														
					3 ×	0.9 mL	N CDT REAGENT 2	3/6[f]														
					3 ×	2 mL	N CDT SUPPLEMENT	[b]														
					3 ×	1 mL	N CDT STANDARD															
					3 ×	1 mL	N CDT CONTROL 1	n/a														
					3 ×	1 mL	N CDT CONTROL 2	7 days														
70	C1I	C1-Inhibitor	serum; citrated plasma	N Antiserum to Human C1-Inhibitor N AS C1IN				N SUPPLEMENT P	[b]	N/T PROT CONTROL PY	n/a		0.03 – 0.4	0.03 – 0.4	g/L	serum citrated plasma		0.21 – 0.39[i] 0.18 – 0.32	g/L g/L	N PROT STANDARD PY	1.2	Fixed Time
				REF OQEY09 SMN 10446049	1 ×	2 mL		3/6[f]														
40	FIB	Fibrinogen	EDTA plasma; citrated plasma	N Antiserum to Human Fibrinogen N AS FIB				N SUPPLEMENT P	[b]	N/T PROT CONTROL PY	n/a		0.59 – 9.4	0.15 – 2.4	g/L	citrated plasma		1.8 – 3.50	g/L	N PROT STANDARD PY	1.1	Fixed Time
				REF OSCA09 SMN 10446313	1 ×	2 mL		3/6[f]														
41	AT3	Antithrombin III	EDTA plasma; citrated plasma	N Antiserum to Human Antithrombin III N AS ATIII				N SUPPLEMENT P	[b]	N/T PROT CONTROL PY	n/a		0.03 – 0.54	0.03 – 0.54	g/L	citrated plasma		0.19 – 0.31	g/L	N PROT STANDARD PY	1.2	Fixed Time
				REF OSAY09 SMN 10446310	1 ×	2 mL		3/6[f]														
43	PLS	Plasminogen	EDTA plasma; citrated plasma	N Antiserum to Human Plasminogen N AS PLS				N SUPPLEMENT P	[b]	N/T PROT CONTROL PY	n/a		0.01 – 0.2	0.01 – 0.2	g/L	citrated plasma		0.06 – 0.25	g/L	N PROT STANDARD PY	1.2	Fixed Time
				REF OSCB09 SMN 10446314	1 ×	2 mL		3/6[f]														
21	IgGU	IgG	urine	N Antiserum to Human IgG NAS IGG						N/T PROT CONTROL LC	n/a		3.6 – 58	3.6 – 58	mg/L	second morning urine		< 9.6	mg/L	N PROT STANDARD SL	1.2	Fixed Time
				REF OSAS19 SMN 10446299	1 ×	5 mL		5/10[f]														
				REF OSAS11 SMN 10446297	1 ×	2 mL		3/6[f]														
26	TRFU	Transferrin	urine	N Antiserum to Human Transferrin N AS TRF						N/T PROT CONTROL LC	n/a		2.2 – 35	2.2 – 35	mg/L			–[q]		N PROT STANDARD SL	1.2	Fixed Time
				REF OSAX15 SMN 10446309	1 ×	5 mL		5/10[f]														
				REF OSAX09 SMN 10446308	1 ×	2 mL		3/6[f]														
27	ALBU	Albumin	urine	N Antiserum to Human Albumin N AS ALB						N/T PROT CONTROL LC	n/a		11 – 340	2.2 – 68	mg/L			< 30	mg/L	N PROT STANDARD SL	1.1	Fixed Time with Pre-reaction
				REF OSAL23 SMN 10714508	1 ×	2 mL		3/6[f]														
				REF OSAL25 SMN 10714509	1 ×	5 mL		5/10[f]														
29	a1MU	α_1-Microglobulin	urine	N α_1-Microglobulin Kit N A1M						N/T PROT CONTROL LC	n/a		5.6 – 180	5.6 – 180	mg/L	second morning urine		< 12	mg/L	N PROT STANDARD UY	1.2	Fixed Time
				REF OWLA11 SMN 10446619	1 ×	2 mL	N AS A1M	3/6[f]														
					1 ×	2 mL	N SUPPLEMENT A	[b]														

SAN[a]	Abbr.	Protein	Specimen	Reagent Package	Quantity		On-board Stability[b] [days at 8 hours each]	Supplements On-board Stability[b] [days at 8 hours each]	Recommended Controls On-board Stability[b] [h]	Measuring Range[c] Condition	Initial Measuring Range	Minimum Measuring Range	Unit	Reference Range[d] Condition	Unit	Standards	APV[e]	Eval. Mode
73	b2MU	β_2-Microglobulin	urine	N Latex β_2-Microglobulin N B2M				N SUPPLEMENT L[j] [b]	N/T PROT CONTROL SL/L n/a N/T PROT CONTROL SL/M n/a		0.2 – 5.8	0.2 – 5.8	mg/L	–[q]		N PROT STANDARD SL	3.0	VLinIntegral with Pre-reaction
				REF OQWU21 SMN 10446162	3 × 1 ×	3 mL N B2M REAGENT 2 mL N B2M U STAB	5/10[f]											
61	IgGC	IgG	CSF[r]	N Antiserum to Human IgG NAS IGG					N/T PROT CONTROL LC n/a		3.6 – 115	3.6 – 115	mg/L	< 34	mg/L	N PROT STANDARD SL	1.4	Fixed Time
				REF OSAS19 SMN 10446299	1 ×	5 mL	5/10[f]											
				REF OSAS11 SMN 10446297	1 ×	2 mL	3/6[f]											
62	IgAC	IgA	CSF serum	N Latex IgA N IGA					N/T PROT CONTROL LC n/a N IGA CONTROL[h] n/a	CSF serum	1.25 – 41.5 500 – 16 600	0.25 – 8.3 100 – 3 300	mg/L mg/L	CSF	< 5	mg/L	N IGA STANDARD[h]	1.1	Fixed Time
				REF OQAI15 SMN 10873689	3 × → 3 × → 3 × → 3 × 1 ×	2 mL N IGA REAGENT 1 mL N IGA STANDARD 1 mL N IGA CONTROL 1 mL N IGA SUPPLEMENT A 0.4 mL N IGA SUPPLEMENT B	3/6[f] [b]											
63	IgMC	IgM	CSF	N Latex IgM N IGM					N/T PROT CONTROL LC n/a N IGM CONTROL[h] n/a	CSF	0.13 – 4.2	0.13 – 4.2	mg/L	CSF	< 1.3	mg/L	N IGM STANDARD[h]	1.0	Fixed Time
				REF OQAC15 SMN 10873688	3 × → 3 × → 3 × → 3 × 1 ×	2 mL N IGM REAGENT 1 mL N IGM STANDARD 1 mL N IGM CONTROL 1 mL N IGM SUPPLEMENT A 0.4 mL N IGM SUPPLEMENT B	nr/5[f] n/a [b]											
67	ALBC	Albumin	CSF[r]	N Antiserum to Human Albumin N AS ALB					N/T PROT CONTROL LC n/a		86 – 1 375	17 – 275	mg/L	< 350	mg/L	N PROT STANDARD SL	1.4	Fixed Time
				REF OSAL23 SMN 10714508	1 ×	2 mL	3/6[f]											
				REF OSAL25 SMN 10714509	1 ×	5 mL	5/10[f]											

[a] Siemens Assay No.
[b] On-board stability depends on environmental conditions and fill volume. These are typical figures derived from internal studies but no product specifications. It is recommended to monitor reagent stability by running controls according to the Instruction for Use. For assays employing a supplementary reagent the figures apply to reagent and the respective supplementary reagent.
[c] The exact measuring range depends on the assigned value of the relevant standard lot. Results which are outside the measuring range can be analyzed using a different sample dilution (integrated in the software).
[d] Literature references are given in the Instructions for Use of the relevant reagent.
[e] Assay Protocol Version
[f] Extended reagent on-board stability can be achieved by using BN II Evaporation Stoppers, REF OVLE21, which must be used in combination with COVER RING EVAP. STOPPERS, SMN 11255073.
[g] Pediatric reference ranges for IgG, IgG subclasses, IgA, IgM, IgE, Ig/L-chains and free Ig/L-chains in serum are dependent on age and can vary over a wide range.
[h] Assay protocols are for low protein concentrations in patient samples which require a lower measuring range.
[i] A lower reference range applies to fresh samples.
[j] A new reference curve must be generated for the relevant tests if the lot of the N Supplementary Reagent L is changed.
[k] no unit
[l] Reference range specification in the BN II Software.
[m] not recommended
[n] Component is part of the Reagent Kit.
[o] The manual selection of another sample dilution than 1:5 is not permissible.
[p] The % CDT values in this population, with reference to the results obtained with the N Antiserum to Human Transferrin, ranged from 1.19 to 2.47 % CDT (1^{th} to 99^{th} percentile).
[q] Concentration of the analyte in the urine of healthy individuals is below the detection limit of this method.
[r] IgG and Albumin in serum and CSF can also be analyzed using a single reference curve, provided that the appropriate serum sample dilution is selected manually.

Volumes and Dilutions

SAN[s]	Abbr.	Protein	Standard Dilutions[t]			Sample Dilution[t]			Sample	Reagent		Supplements		Buffer for Sample		Buffer for Reagent		Reaction
				Count	Range	Specimen	Initial	Minimal	Volume [µL]		Volume [µL]		Volume [µL]		Volume [µL]		Volume [µL]	Time [min]
1	IgG	IgG	N PROT STANDARD SL	6	1:80–1:2 560	serum; EDTA plasma; heparin plasma	1:400	1:20	100	NAS IGG	40				100		60	6
51	IgG1	IgG Subclass 1	N PROT STANDARD SL	6	1:20–1:640	serum; EDTA plasma; heparin plasma	1:100	1:5	25	N AS IGG1	40				70		70	6
52	IgG2	IgG Subclass 2	N PROT STANDARD SL	6	1:5–1:160	serum; EDTA plasma; heparin plasma	1:20	1:5	25	N AS IGG2	40	N SUPPLEMENT P	10		70		70	12
78	IgG3n	IgG Subclass 3	N PROT STANDARD SL	7	1:320–1:20 480	serum; EDTA plasma; heparin plasma	1:2 000	1:100	5 + 35	N IGG3 REAGENT	55	N SUPPLEMENT P	25	N DILUENT	55 + 15	N DILUENT	70	2 + 6
79	IgG4n	IgG Subclass 4	N PROT STANDARD SL	7	1:320–1:20 480	serum; EDTA plasma; heparin plasma	1:2 000	1:100	5 + 50	N IGG4 REAGENT	50	N SUPPLEMENT P	25	N DILUENT	55 + 10	N DILUENT	75	2 + 6
2	IgA	IgA	N PROT STANDARD SL	6	1:5–1:160	serum; EDTA plasma; heparin plasma	1:20	1:20	20	NAS IGA	40				80		80	6
22	IgAs	IgA[u]	N PROT STANDARD SL	6	1:5–1:160	serum; EDTA plasma; heparin plasma	1:5	1:5	20	NAS IGA	40	N SUPPLEMENT P	30		80		50	6
3	IgM	IgM	N PROT STANDARD SL	6	1:2.5–1:80	serum; EDTA plasma; heparin plasma	1:20	1:20	5 + 45	NAS IGM	40				55 + 30		100	2 + 4
23	IgMs	IgM[u]	N PROT STANDARD SL	6	1:2.5–1:80	serum; EDTA plasma; heparin plasma	1:5	1:5	50	NAS IGM	40	N SUPPLEMENT P	30		80		50	6
4	C3	C3c	N PROT STANDARD SL	6	1:5–1:160	serum; EDTA plasma; heparin plasma	1:20	1:5	20	N AS C3	40				80		80	6
5	C4	C4	N PROT STANDARD SL	6	1:2.5–1:80	serum; EDTA plasma; heparin plasma	1:20	1:5	100	N AS C4	40				100		60	6
6	TRF	Transferrin	N PROT STANDARD SL	5	1:10–1:160	serum; EDTA plasma; heparin plasma	1:20	1:5	10	N AS TRF	40				80		80	6
7	ALB	Albumin	N PROT STANDARD SL	5	1:160–1:2 560	serum; EDTA plasma; heparin plasma	1:400	1:20	15	N AS ALB	30				100		130	6
8	AAT	α_1-Antitrypsin	N PROT STANDARD SL	6	1:5–1:160	serum; EDTA plasma; heparin plasma	1:20	1:5	20	N AS AAT	40				80		80	6
9	a2M	α_2-Macroglobulin	N PROT STANDARD SL	6	1:5–1:160	serum; heparin plasma	1:20	1:5	20	N AS A2M	40				80		80	6
10	HPT	Haptoglobin	N PROT STANDARD SL	6	1:2.5–1:80	serum; EDTA plasma; heparin plasma	1:20	1:5	10	N AS HAPT	40				80		80	6
11	AAG	α_1-acid Glycoprotein	N PROT STANDARD SL	6	1:2.5–1:80	serum; heparin plasma	1:20	1:5	15	N AS AAG	30				125		125	6
12	PRE	Prealbumin	N PROT STANDARD SL	6	1:2.5–1:80	serum; heparin plasma	1:5	1:5	50	N AS PRE	40	N SUPPLEMENT P	30		100		60	6
13	sTfR	soluble Transferrin Receptor	N PROT STANDARD SL	6	1:5–1:160	serum; heparin plasma	1:20	1:20	70	N STFR	60	N SUPPLEMENT L	30	N DILUENT	40	N DILUENT	30	6
14	HPX	Hemopexin	N PROT STANDARD SL	6	1:2.5–1:80	serum; heparin plasma	1:20	1:5	20	N AS HPX	40				80		80	6
15	CER	Ceruloplasmin	N PROT STANDARD SL	6	1:2.5–1:80	serum; heparin plasma	1:20	1:5	100	N AS CER	40				100		60	6
16	RbP	Retinol-binding-Protein	N PROT STANDARD SL	5	1:1–1:20	serum; heparin plasma	1:5	1:5	50	N AS RBP	40	N SUPPLEMENT P	10		100		60	6
17	kap	Ig/L-chain, type kappa	N PROT STANDARD SL	6	1:5–1:160	serum	1:20	1:5	10	N AS KAPPA	30				80		80	6
80	FLC_K	free Ig/L-chain, type kappa	N FLC STANDARD SL	6	1:20–1:640	serum; EDTA plasma; heparin plasma	1:100	1:5	8 + 75	N FLC KAPPA	45	N FLC SUPPLEMENT	15	N DILUENT	55 + 5	N DILUENT	90	2 + 10
18	lam	Ig/L-chain, type lambda	N PROT STANDARD SL	6	1:5–1:160	serum	1:20	1:5	10	N AS LAMBDA	40				80		80	6
81	FLC_L	free Ig/L-chain, type lambda	N FLC STANDARD SL	6	1:10–1:320	serum; EDTA plasma; heparin plasma	1:20	1:5	7 + 55	N FLC LAMBDA	55	N FLC SUPPLEMENT	15	N DILUENT	50 + 5	N DILUENT	95	3 + 10
30	A-I	Apolipoprotein A-I	N APO STANDARD	6	1:5–1:160	serum; heparin plasma	1:20	1:5	10	N AS APOAI	40	N SUPPLEMENT P	10		80		80	6
31	ApoB	Apolipoprotein B	N APO STANDARD	5	1:5–1:80	serum; heparin plasma	1:20	1:20	30	N AS APOB	40	N SUPPLEMENT P	10		80		70	6
39	Lpa	Lipoprotein(a)	N LP(A) STANDARD SY	5	1:40–1:640	serum; heparin plasma	1:400	1:100	30	N LP(A) REAGENT	50			N DILUENT	60	N DILUENT	60	6
50	FRT	Ferritin	N PROT STANDARD SL	7	1:10–1:640	serum; heparin plasma	1:20	1:5	120	N FRT REAGENT	40	N FRT SUPPLEMENT A + N FRT SUPPLEMENT B	25	N DILUENT	85	N DILUENT	40	6
84	RFn	RF	N RHEUMA STANDARD SL	7	1:5–1:320	serum; EDTA plasma; heparin plasma	1:20	1:20	20	N RF REAGENT	50	N RF SUPPLEMENT	60	N DILUENT	60	N DILUENT	40	6
85	ASLn	ASL	N RHEUMA STANDARD SL	6	1:40–1:1 280	serum; EDTA plasma; heparin plasma	1:400	1:100	70	N ASL	40	N SUPPLEMENT P	50	N DILUENT	40	N DILUENT	50	6
42	CRP2	CRP sensitive	N RHEUMA STANDARD SL	7	1:40–1:2 560	serum; EDTA plasma; heparin plasma	1:20	1:20	40	CardioPhase hsCRP REAGENT	40	N SUPPLEMENT P	5	N DILUENT	70	N DILUENT	60	6
71	CRP1	CRP	N RHEUMA STANDARD SL	7	1:40–1:2 560	serum; EDTA plasma; heparin plasma	1:400	1:20	40	CardioPhase hsCRP REAGENT	40	N SUPPLEMENT P	5	N DILUENT	70	N DILUENT	60	6
57	IgE1	IgE	N PROT STANDARD SL	7	1:10–1:640	serum; EDTA plasma; heparin plasma	1:20	1:5	80	N IGE	60	N SUPPLEMENT L	20	N DILUENT	30	N DILUENT	40	6
58	ADNs	ADNase B	N ADNS STANDARD[y]	6	1:1–1:40	serum	1:5	1:5	20	N ADNS REAGENT	50	N ADNS SUPPLEMENT	70	N DILUENT	50	N DILUENT	50	12
59	b2M	β_2-Microglobulin	N PROT STANDARD SL	6	1:20–1:640	serum; EDTA plasma; heparin plasma	1:400	1:100	50	N B2M REAGENT	70	N SUPPLEMENT L	15	N DILUENT	55	N DILUENT	70	6
60	MYO	Myoglobin	N MYO STANDARD[y]	5	1:40–1:640	serum; EDTA plasma; heparin plasma	1:20	1:5	80	N MYO REAGENT	75	N MYO SUPPLEMENT A + N MYO SUPPLEMENT B	20		75		75	12
66	CysC	Cystatin C	N PROT STANDARD UY	6	1:20–1:640	serum; heparin plasma	1:100	1:100	30	N CYSC REAGENT	40	N CYSC SUPPLEMENT A + N CYSC SUPPLEMENT B	10	N DILUENT	60	N DILUENT N DILUENT	20 80	6
75	HCY	Homocysteine	N PROT STANDARD SL	6	1:5–1:160	serum; EDTA plasma; heparin plasma	1:5	1:5	14	N HCY REAGENT N HCY RA	42 56	N HCY SR A + N HCY SR B	42	N DILUENT	42	N DILUENT N DILUENT	84 42	12
77	CDT	Carbohydrate-deficient Transferrin	N CDT STANDARD[y]	6	1:2.5–1:80	serum	1:5[w]	1:5	24	N CDT REAGENT 1 N CDT REAGENT 2	30 30	N CDT SUPPLEMENT	65	N SUPPLEMENT L N DILUENT	20 10	N DILUENT N DILUENT	50 60	18
70	C1I	C1-Inhibitor	N PROT STANDARD PY	5	1:2.5–1:40	serum; citrated plasma	1:5	1:5	100	N AS C1IN	40	N SUPPLEMENT P	30		100		60	6
40	FIB	Fibrinogen	N PROT STANDARD PY	5	1:5–1:80	EDTA plasma; citrated plasma	1:20	1:5	20	N AS FIB	40	N SUPPLEMENT P	30		80		80	6
41	AT3	Antithrombin III	N PROT STANDARD PY	5	1:2.5–1:40	EDTA plasma; citrated plasma	1:5	1:5	100	N AS ATIII	40	N SUPPLEMENT P	30		100		60	6
43	PLS	Plasminogen	N PROT STANDARD PY	5	1:2.5–1:40	EDTA plasma; citrated plasma	1:5	1:5	100	N AS PLS	40	N SUPPLEMENT P	30		100		60	6
21	IgGU	IgG	N PROT STANDARD SL	5	1:160–1:2 560	urine	1:1	1:1	100	NAS IGG	40				100		60	6

SAN[s]	Abbr.	Protein	Standard Dilutions[t]			Sample Dilution[t]			Sample		Reagent		Supplements		Buffer for Sample		Buffer for Reagent		Reaction
				Count	Range	Specimen	Initial	Minimal		Volume [µL]		Volume [µL]		Volume [µL]		Volume [µL]		Volume [µL]	Time [min]
26	TRFU	Transferrin	N PROT STANDARD SL	5	1:80–1:1 280	urine	1:1	1:1		100	N AS TRF	40			100		60	6
27	ALBU	Albumin	N PROT STANDARD SL	6	1:640–1:20 480	urine	1:5	1:1		5 + 95	N AS ALB	40			55 + 30		100	2 + 4
29	a1MU	α_1-Microglobulin	N PROT STANDARD UY	6	1:2.5–1:80	urine	1:1	1:1		20	N AS A1M	40	N SUPPLEMENT A	10	90		70	6
73	b2MU	β_2-Microglobulin	N PROT STANDARD SL	6	1:20–1:640	urine	1:100	1:100		2 + 50	N B2M REAGENT	70	N SUPPLEMENT L	15	N DILUENT 55		N DILUENT 70	3 + 6
61	IgGC	IgG	N PROT STANDARD SL	6	1:80–1:2 560	CSF	1:1	1:1		100	NAS IGG	40			100		60	6
62	IgAC	IgA	N IGA STANDARD[y]	6	1:10–1:320	CSF	1:5	1:1	CSF	20	N IGA REAGENT	50	N IGA SUPPLEMENT A + N IGA SUPPLEMENT B	10	N DILUENT	60	N DILUENT	60	6
						serum	1:2 000[x]	1:400[x]	serum	20									
63	IgMC	IgM	N IGM STANDARD[y]	6	1:10–1:320	CSF	1:1[y]	1:1		20	N IGM REAGENT	50	N IGM SUPPLEMENT A + N IGM SUPPLEMENT B	10	N DILUENT	60	N DILUENT	60	6
67	ALBC	Albumin	N PROT STANDARD SL	5	1:160–1:2 560	CSF	1:5	1:1		15	N AS ALB	30			100		130	6

[s] Siemens Assay No.
[t] Automatic dilution with Default Diluent (see System Manual).
[u] Assay protocols are for low protein concentrations in patient samples which require a lower measuring range.
[v] Component is part of the Reagent Kit.
[w] The manual selection of another sample dilution than 1:5 is not permissible.
[x] Serum sample dilution needs to be selected manually.
[y] The "sample" dilution for N CON LC2 is 1:5.

Addendum I Symbol Names of Required Materials, REF and SMN for all products

Symbol names are depicted onto the reagent labels and are not translatable. In the following table symbol names and corresponding product names in the language of these Assay Protocols are listed.

Symbol Name	Product Name	REF	SMN
APO CONTROL CHD	Apolipoprotein Control Serum CHD	OUPH09	10446469
CardioPhase® hsCRP	CardioPhase® hsCRP	OQIY13 OQIY21	10446090 10446091
• CardioPhase hsCRP REAGENT	• CardioPhase® hsCRP Reagent		
Cleaner SCS	Cleaner SCS	OQUB21	10446436
N ADNS	N Latex ADNase B	OWTI15	10873691
• N ADNS REAGENT	• N ADNase B Reagent		
• N ADNS STANDARD	• N ADNase B Standard Serum (human)		
• N ADNS CONTROL	• N ADNase B Control Serum (human)		
• N ADNS SUPPLEMENT	• N ADNase B Supplementary Reagent		
N APO STANDARD	N Apolipoprotein Standard Serum	OUPG09	10446466
N AS A2M	N Antiserum to Human α_2 Macroglobulin	OSAM21	10469773
N AS AAG	N Antiserum to Human α_1-acid Glycoprotein	OSAW15 OSAW09	10446307 10446306
N AS AAT	N Antiserum to Human α_1-Antitrypsin	OSAZ15 OSAZ09	10446312 10446311
N AS ALB	N Antiserum to Human Albumin	OSAL23 OSAL25	10714508 10714509
N AS APOAI	N Antiserum to Human Apolipoprotein A-I	OUED15 OUED09	10446438 10446437
N AS APOB	N Antiserum to Human Apolipoprotein B	OSAN15 OSAN09	10446287 10446286
N AS ATIII	N Antiserum to Human Antithrombin III	OSAY09	10446310
N AS C1IN	N Antiserum to Human C1-Inhibitor	OQEY09	10446049
N AS C3	N Antiserum to Human C3c	OSAP15 OSAP09	10446291 10446290
N AS C4	N Antiserum to Human C4	OSAO15 OSAO09	10446289 10446288
N AS CER	N Antiserum to Human Ceruloplasmin	OUIE09	10446451
N AS FIB	N Antiserum to Human Fibrinogen	OSCA09	10446313
N AS HAPT	N Antiserum to Human Haptoglobin	OSAV15 OSAV09	10446305 10446304
N AS HPX	N Antiserum to Human Hemopexin	OUVN09	10446493
N AS IGG1	N AS IgG1	OQXI09	10446168
N AS IGG2	N AS IgG2	OQXK09	10446169
N AS KAPPA	N Antiserum to Human Ig/L-chain, κ-type	OWHG13	10446595
N AS LAMBDA	N Antiserum to Human Ig/L-chain, λ-type	OWHH13	10446597
N ASL	N Latex ASL	OPBU03 OPBU05	10445983 10445984
N AS PLS	N Antiserum to Human Plasminogen	OSCB09	10446314
N AS PRE	N Antiserum to Human Prealbumin	OUIF09	10446452
N AS RBP	N Antiserum to Human RbP	OUVO09	10446494
N AS TRF	N Antiserum to Human Transferrin	OSAX15 OSAX09	10446309 10446308

Symbol Name	Product Name	REF	SMN
N B2M	N Latex β_2-Microglobulin	OQWU21	10446162
• N B2M REAGENT	• N Latex β_2-Microglobulin Reagent		
• N B2M U STAB	• Urine Stabilizer		
N CDT	N Latex CDT Kit	OPCS05	10445997
• N CDT REAGENT 1	• N CDT Reagent 1		
• N CDT REAGENT 2	• N CDT Reagent 2		
• N CDT SUPPLEMENT	• N CDT Supplementary Reagent		
• N CDT STANDARD	• N CDT Standard SL		
• N CDT CONTROL 1	• N CDT Control SL/1		
• N CDT CONTROL 2	• N CDT Control SL/2		
N CYSC	N Latex Cystatin C	OQNM19	10873631
• N CYSC REAGENT	• N Cystatin C Reagent		
• N CYSC CONTROL 1	• N Cystatin C Control Level 1		
• N CYSC CONTROL 2	• N Cystatin C Control Level 2		
• N CYSC SUPPLEMENT A	• N Cystatin C Supplementary Reagent A		
• N CYSC SUPPLEMENT B	• N Cystatin C Supplementary Reagent B		
N DILUENT	N Diluent	OUMT65	10446457
N FLC CONTROL SL1	N FLC Control SL1	OPJE05	10873661
N FLC CONTROL SL2	N FLC Control SL2	OPJF05	10873663
N FLC STANDARD SL	N FLC Standard SL	OPJD05	10873662
N FLC SUPPLEMENT	N FLC Supplementary Reagent	OPJC05	10873660
• N FLC SUPPLEMENT A	• N FLC Supplementary Reagent A		
• N FLC SUPPLEMENT B	• N FLC Supplementary Reagent B		
N FLC KAPPA	N Latex FLC kappa	OPJA07	10873629
N FLC LAMBDA	N Latex FLC lambda	OPJB07	10873630
N FRT	N Latex Ferritin	OQTH11	10446130
• N FRT REAGENT	• N Latex Ferritin Reagent		
• N FRT SUPPLEMENT A	• N Ferritin Supplementary Reagent A		
• N FRT SUPPLEMENT B	• N Ferritin Supplementary Reagent B		
N HCY	N Latex HCY	OPAX03	10445973
• N HCY REAGENT	• N HCY Reagent		
• N HCY RA	• N HCY RA		
• N HCY SR A	• N HCY SR A		
• N HCY SR B	• N HCY SR B		
N IGA	N Latex IgA	OQAI15	10873689
• N IGA REAGENT	• N IgA Reagent		
• N IGA STANDARD	• N IgA Standard (human)		
• N IGA CONTROL	• N IgA Control (human)		
• N IGA SUPPLEMENT A	• N IgA Supplementary Reagent A		
• N IGA SUPPLEMENT B	• N IgA Supplementary Reagent B		
N IGE	N Latex IgE mono	OQTG15	10446129
N IGG3	N Latex IgG3	OPAV03	10445972
• N IGG3 REAGENT	• N Latex IgG3		
N IGG4	N Latex IgG4	OPAU03	10445971
• N IGG4 REAGENT	• N Latex IgG4		

Symbol Name	Product Name	REF	SMN
N IGM	N Latex IgM	OQAC15	10873688
• N IGM REAGENT	• N IgM Reagent		
• N IGM STANDARD	• N IgM Standard (human)		
• N IGM CONTROL	• N IgM Control (human)		
• N IGM SUPPLEMENT A	• N IgM Supplementary Reagent A		
• N IGM SUPPLEMENT B	• N IgM Supplementary Reagent B		
N LP(A) REAGENT	N Latex Lp(a) Reagent	OQHL11	10446069
N LP(A) CONTROL SY	N Lp(a) Control SY	OQCW07	10873687
N LP(A) STANDARD SY	N Lp(a) Standard SY	OQCV07	10873686
N MYO	N Latex Myoglobin	OWIA17	10873690
• N MYO REAGENT	• N Myoglobin Reagent		
• N MYO STANDARD	• N Myoglobin Standard (human)		
• N MYO CONTROL	• N Myoglobin Control (human)		
• N MYO SUPPLEMENT A	• N Myoglobin Supplementary Reagent A		
• N MYO SUPPLEMENT B	• N Myoglobin Supplementary Reagent B		
N PROT STANDARD PY	N Protein Standard PY	OUID15	10446450
N PROT STANDARD SL	N Protein Standard SL	OQIM19	10873692
N PROT STANDARD UY	N Protein Standard UY	OQLV11	10873632
N RF	N Latex RF Kit	OPCE03 OPCE05	10445991 10445992
• N RF REAGENT	• N RF Reagent		
• N RF SUPPLEMENT	• N RF Supplement		
N RHEUMA STANDARD SL	N Rheumatology Standard SL	OQKZ15	10873683
N STFR	N Latex sTfR	OQTC11	10446127
N SUPPLEMENT L	N Supplementary Reagent L	OQTD11	10446128
• N SUPPLEMENT L/A	• N Supplementary Reagent L/A		
• N SUPPLEMENT L/B	• N Supplementary Reagent L/B		
N/T PROT CONTROL LC	N/T Protein Control LC	OQLW15	10446105
N/T PROT CONTROL PY	N/T Protein Control PY	OWSY15	10446656
N/T PROT CONTROL SL/H	N/T Protein Control SL/H	OQIP19	10446089
N/T PROT CONTROL SL/L	N/T Protein Control SL/L	OQIN19	10446079
N/T PROT CONTROL SL/M	N/T Protein Control SL/M	OQIO19	10446085
N/T RHEUMA CONTROL SL/1	N/T Rheumatology Control SL/1	OQDB17	10873684
N/T RHEUMA CONTROL SL/2	N/T Rheumatology Control SL/2	OQDC17	10873685
N A1M	N α_1-Microglobulin Kit	OWLA11	10446619
• N AS A1M	• N Antiserum to Human α_1-Microglobulin		
• N SUPPLEMENT A	• N Supplementary Reagent A		
NAS IGA	N Antiserum to Human IgA	OSAR19 OSAR11	10446295 10446293
NAS IGG	N Antiserum to Human IgG	OSAS19 OSAS11	10446299 10446297
NAS IGM	N Antiserum to Human IgM	OSAT19 OSAT11	10446303 10446301
N SUPPLEMENT P	N Supplementary Reagent/Precipitation	OUMU15	10446458

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SIEMENS Healthineers

N Antiserum to Human IgG

NAS IGG

N Antiserum to Human IgA

NAS IGA

N Antiserum to Human IgM

NAS IGM

Revision bar indicates update to previous version.

BN II / BN ProSpec® System

Intended Use

In-vitro diagnostic reagents for the quantitative determination of immunoglobulins (IgG, IgA and IgM) in human serum, heparinized and EDTA plasma, and IgG in human urine and cerebrospinal fluid (CSF) by means of immunonephelometry on the BN II and BN ProSpec® System. Measurements of IgG aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Summary and Explanation

Immunoglobulins are formed by plasma cells as a humoral immune response to contact of the immune system with antigens. The primary reaction after the initial contact is the formation of antibodies of the IgM class followed later by IgG and also IgA antibodies. Quantitative determination of the immunoglobulins can provide important information on the humoral immune status[1].

Decreased serum immunoglobulin concentrations occur in primary immunodeficiency conditions as well as in secondary immune insufficiencies, e.g., in advanced malignant tumours, lymphatic leukemia, multiple myeloma and Waldenstrom's disease. Increased serum immunoglobulin concentrations occur due to polyclonal or oligoclonal Ig proliferation, e.g., in hepatic diseases (hepatitis and liver cirrhosis), acute and chronic infections, autoimmune diseases as well as in the cord blood of neonates with intra-uterine and perinatal infections[2]. Monoclonal immunoglobulin proliferations are observed e.g. in plasmacytomas, Waldenstrom's disease and heavy-chain disease[2]. Monoclonal immunoglobulinemia requires detailed differential diagnostic investigations in addition to the quantitative determination. Local immune reactions with the centralnervous system result in elevated immunoglobulin levels, particularly IgG, in the cerebrospinal fluid[3].

Elevated urinary concentrations of IgG are found in patients with non-selective glomerular proteinuria[4].

Principles of the Method

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity

of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Reagents

Materials provided

N AS IGG, REF OSAS

1 x 5 mL N AS IGG, N Antiserum to Human IgG (γ chain) or

1 x 2 mL N AS IGG, N Antiserum to Human IgG (γ chain) or

N AS IGA, REF OSAR

1 x 5 mL N AS IGA, N Antiserum to Human IgA (α chain) or

1 x 2 mL N AS IGA, N Antiserum to Human IgA (α chain) or

N AS IGM, REF OSAT

1 x 5 mL N AS IGM, N Antiserum to Human IgM (μ chain) or

1 x 2 mL N AS IGM, N Antiserum to Human IgM (μ chain)

Composition

N Antisera are liquid animal sera and are produced by immunization of rabbits with highly purified human immunoglobulin (IgG, IgA or IgM). The concentration of active antibodies is < 3.5 g/L to human IgG, < 4.3 g/L to human IgA and < 32.9 g/L to human IgM.

Preservative

N Antiserum to Human IgG, IgA or IgM: sodium azide < 1 g/L

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
NAS IGG, NAS IGA, NAS IGM
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.

Preparation of Reagents

The N Antisera are ready-for-use as supplied and require no additional preparation.

Storage and Stability

Stability at 2 to 8 °C:

see expiry date on label;

Stability once opened:

four weeks if stored at 2 to 8 °C securely capped immediately after each use and if contamination (e.g., by microorganisms) is precluded;

During storage, N Antisera can develop precipitates or turbidity which are not caused by microbial contamination and which do not affect their activity. In such cases, the antiserum should be filtered prior to use. Disposable filters with a pore size of 0.45 μm are suitable for this purpose.

Do not freeze.

On-board stability:

a minimum of five days at eight hours per day or a comparable period of time.

Note: on-board stability may vary, depending on BN System used and laboratory conditions. For further details, refer to BN II or BN ProSpec® System Instruction Manual.

Materials required but not provided

BN II or BN ProSpec® System

N Protein Standard SL, REF OQIM

N/T Protein Control SL/L, M and H, REF OQIN, OQIO and OQIP

N/T Protein Control LC, REF OQLW

N Reaction Buffer, REF OUMS

N Diluent, REF OUMT

N Supplementary Reagent/Precipitation, REF OUMU (for use with the low-concentration IgA and IgM assay protocols)

BN II Evaporation Stoppers (optional), REF OVLE

Additional materials and supplies as described in your BN System Instruction Manual.

Specimens

Suitable samples are human serum, heparinized or EDTA plasma, either as fresh as possible (stored no more than eight days at 2 to 8 °C) or stored frozen. Fresh human urine stored for no more than three days at 2 to 8 °C and fresh CSF samples stored for no more than seven days at 2 to 8 °C are also suitable for the IgG determination. If paired serum and CSF samples are to be analyzed, they should be drawn simultaneously.

Serum and plasma samples can be stored at below –20 °C for up to three months if they are frozen within 24 hours after collection and if repeated freeze-thaw cycles are avoided. Serum samples must be completely coagulated and, after centrifugation, must not contain any particles or traces of fibrin. Lipemic samples or frozen samples which became turbid after thawing must be clarified by centrifugation (10 minutes at approximately 15,000 x g) prior to testing. Random and timed urine collections are suitable specimens for testing IgG in urine. Urine and CSF samples which have been stored frozen must not be used. Each urine and CSF sample must be centrifuged prior to testing.

Procedure

Notes

1. Consult your BN System Instruction Manual for details regarding operation of the instrument.
2. Reagents and samples stored at 2 to 8 °C can be used immediately.

Assay Protocols for BN Systems

The assay protocols for serum and plasma, as well as for IgG in urine and CSF, respectively, are given in the BN System Instruction Manual and software of the instrument. All steps are performed automatically by the system.

Establishment of the Reference Curve

Reference curves are generated by multi-point calibration. Serial dilutions of N Protein Standard SL are automatically prepared by the instrument using N Diluent. The standard dilutions are to be used within four hours.

The reference curves can be used for as long as controls with corresponding method-dependent target values, e.g. N/T Protein Control SL/L, M and H for the serum/plasma assay and N/T Protein Control LC for the IgG in urine and CSF assay, are reproduced within their respective range. If a different lot of antiserum is used, a new reference curve must be generated.

Assay of Specimens

Serum and plasma samples are automatically diluted 1:400 (IgG), 1:20 (IgA, IgM) or 1:5 in the low-concentration assay protocols (IgAs and IgMs) with N Diluent. The diluted samples must be measured within four hours. IgG in urine or CSF is measured from undiluted samples using a separate assay

protocol. IgG in serum and CSF can also be analyzed using a single reference curve, provided that the appropriate sample dilution is selected manually.

If the results obtained are outside the measuring range, the assay can be repeated using a higher or lower dilution of the sample (IgG in the serum/plasma assay protocol). Urine sample results that are outside the intial measuring range can be repeated using a higher dilution of the sample. Refer to BN System's Instruction Manual for information on repeat measurements using other dilutions.

If the reading in the regular IgA or IgM assay protocol (1:20 sample dilution) is below the measuring range, the sample may be re-tested from the respective low-concentration assay protocol by a new request.

Internal Quality Control

Assay N/T Protein Controls SL/L, M and H after each establishment of a reference curve, the first use of an antiserum vial as well as with each run of serum or plasma samples. For the determination of IgG in urine or CSF samples the N/T Protein Control LC should be used accordingly. The controls are assayed and evaluated as for patient samples. The assigned value and range are listed in the Table of Assigned Values of the respective control.

Follow government regulations or accreditation requirements for quality control frequency.

If the result of a control is outside the range, the determination must be repeated. If the repeated determination confirms the deviation, a new reference curve should be established. Do not release patient results until the cause of deviation has been identified and corrected.

Results

Evaluation is performed automatically in g/L or in a derived unit selected by the user on the BN System.

Limitations of the Procedure

Turbidity and particles in the sample may interfere with the determination. Therefore, samples containing particles must be centrifuged prior to testing. Lipemic or turbid samples which cannot be clarified by centrifugation (10 minutes at approximately 15,000 x g) must not be used. The immunoglobulin assays have been designed to minimize antigen excess in the initial sample dilutions. However, it cannot be completely eliminated and in rare cases very high immunoglobulin concentrations may produce falsely-low results. Especially monoclonal immunoglobulins may show reactivity different from the polyclonal standard, which in isolated cases may lead to artificially decreased or non-linear results. In case of serum or plasma determinations, the constellation of IgG, IgA and IgM should be assessed. A check of IgG results in CSF should be performed by means of ratio diagrams[3]. In case of questionable results, the determinations should be repeated using the next higher sample dilution. For patient monitoring, consecutive immunoglobulin determinations should be performed from the same sample dilution, as far as possible.

Siemens Healthineers has validated use of these reagents on various analyzers to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens Healthineers as they may affect performance of the system and assay results. It is the responsibility of the user to validate modifications to these instructions or use of the reagents on analyzers other than those included in Siemens Healthineers Reference Guides (Application Sheets) or these Instructions for Use.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Due to matrix effects, inter-laboratory survey samples and control samples may yield results that differ from those obtained with other methods. It may therefore be necessary to assess these results in relation to method-specific target values.

Reference Intervals

The following reference intervals apply for serum and plasma samples from healthy adults[5]:

Protein

IgG	7.0	-	16.0	g/L
IgA	0.7	-	4.0	g/L
IgM	0.4	-	2.3	g/L

During childhood and adolescence reference ranges for IgG, IgA, IgM are dependent on age and can vary over a wide range[6]:

IgG

	males		females	
age (years)	2.5th percentile (g/L)	97.5th percentile (g/L)	2.5th percentile (g/L)	97.5th percentile (g/L)
1	3.5	8.6	4.0	9.8
4	5.1	12.6	5.3	13.0
7	6.0	14.7	5.9	14.6
10	6.6	16.2	6.4	15.9
14	6.6	16.2	6.8	16.7
18	6.5	16.0	6.9	17.0

IgA

	males		females	
age (years)	2.5th percentile (g/L)	97.5th percentile (g/L)	2.5th percentile (g/L)	97.5th percentile (g/L)
1	0.17	0.96	0.17	0.94
4	0.36	1.98	0.33	1.85
7	0.48	2.66	0.44	2.44
10	0.57	3.18	0.52	2.90
14	0.64	3.52	0.62	3.43
18	0.68	3.79	0.69	3.80

IgM

	males		females	
age (years)	2.5th percentile (g/L)	97.5th percentile (g/L)	2.5th percentile (g/L)	97.5th percentile (g/L)
1	0.30	1.83	0.34	2.06
4	0.35	2.13	0.42	2.55
7	0.37	2.26	0.45	2.78
10	0.38	2.35	0.48	2.94
14	0.40	2.44	0.50	3.09
18	0.41	2.51	0.52	3.22

Reference interval for IgG in urine samples:

IgG in second morning urine below 9.6 mg/L[4].

Note: Value adapted to IFCC/BCR/CAP reference preparation ERM-DA470 by applying a conversion factor of 0.85.

Reference interval for IgG in CSF samples:

IgG in CSF: below 34 mg/L[3]

Note: Value adapted to IFCC/BCR/CAP reference preparation ERM-DA470 by applying a conversion factor of 0.85.

Reference intervals in the strict sense exist only for CSF/serum ratios[3].

Nevertheless, each facility should determine its own reference intervals since values may vary depending on the individual population studied.

Specific Performance Characteristics

Assay Range

The N Antisera to Human IgG, IgA and IgM are designed to measure immunoglobulin concentrations within a range of approximately:

IgG	1.4	-	46	g/L
IgA	0.25	-	8.0	g/L
IgAs	0.06	-	2.0	g/L
IgM	0.2	-	6.4	g/L
IgMs	0.05	-	1.6	g/L

for a sample dilution of 1:400 (IgG), 1:20 (IgA, IgM) and 1:5 (IgAs, IgMs) in serum or plasma. The N Antiserum to Human IgG is designed to measure IgG concentrations within a range of approximately 3.6 to 58 mg/L for neat urine samples and 3.6 to 115 mg/L for neat CSF samples.

The Limit of Quantitation

The Limit of Quantitation (LoQ) is determined consistent with CLSI/NCCLS Guideline EP17-A and the allowable total error of 30 %. LoQ is the lowest amount of analyte that can be quantitatively determined within a defined total error.

IgG - Serum/Plasma	0.07 g/L
IgG - CSF	3.6 mg/L
IgG - Urine	3.6 mg/L
IgA - Serum/Plasma	0.25 g/L
IgM - Serum/Plasma	0.20 g/L

Specificity

The specificity of N Antiserum to Human IgG, IgA and IgM, respectivly, is tested against human serum and plasma pools and preparations of human IgG, IgA, IgM and Bence-Jones proteins, type Kappa and Lambda in different analytical methods. There are no known cross-reactivities of the antisera used.

No interference with the determinations in serum was detected for concentrations of triglycerides up to 19 g/L (IgG), 5.7 g/L (IgA), 9.9 g/L (IgA low-concentration protocol) and 4.6 g/L (IgM low concentration protocol), bilirubin at 600 mg/L, and free hemoglobin at 10 g/L. No interference from commonly drugs is known.

No interference with the determinations of IgG in urine was detected for concentrations of bilirubin up to 3 mg/dL, and free hemoglobin up to 10 g/L.

Non Interfering Substances

The following substances do not interfere with the IgG assay when present in urine at the concentrations indicated. Inaccuracies (biases) due to these substances are less than 10 % at the urine concentrations listed.

Substance	Substance Test Concentration mg/dL	IgG Concentration mg/L
Acetone	1000	7.70
Ascorbic acid	900	20.9
Ethanol	1000	7.70
Oxalic acid	10	24.9
Riboflavin	6.75	28.5
Sodium chloride	6000	7.37

Substance	Substance Test Concentration mg/dL	IgG Concentration mg/L
Bovine albumin	500	23.6
Boric acid	4500	21.6
Sodium azide	20000	23.6
Sodium fluoride	16000	21.4
Hook Effect: The IgG urine assay shows no hook effect up to 998 mg/L.		

Precision

The following coefficients of variation (CV) were obtained with N Antisera to Human Immunoglobulins (n=40) on a BN System:

IgG / Serum	mean (g/L)	Run-to-Run CV (%)	Within-Run CV (%)	Total CV (%)
N/T Protein Control, SL/L	5.0	2.1	3.0	3.4
N/T Protein Control, SL/M	8.4	1.4	1.8	2.1
N/T Protein Control, SL/H	12.1	1.5	2.6	2.7
Serum Pool (low)	8.8	1.7	1.8	2.3
Serum Pool (high)	12.7	1.5	2.2	2.4

IgG / CSF	mean (mg/L)	Run-to-Run CV (%)	Within-Run CV (%)	Total CV (%)
N/T Protein Control LC	18.7	0.7	1.2	1.3
CSF pool (low)	8.1	0.8	1.3	1.4
CSF pool (high)	42.1	1.0	1.8	1.9

IgG / Urine	mean (mg/L)	Run-to-Run CV (%)	Within-Run CV (%)	Total CV (%)
N/T Protein Control LC	18.8	0.8	1.1	1.3
Urine pool (low)	5.5	3.2	2.9	4.1
Urine pool (high)	19.9	2.5	1.2	2.8

IgA / Serum	mean (g/L)	Run-to-Run CV (%)	Within-Run CV (%)	Total CV (%)
N/T Protein Control, SL/L	1.0	3.7	1.6	4.1
N/T Protein Control, SL/M	1.7	2.7	3.3	4.0
N/T Protein Control, SL/H	2.5	2.1	2.5	3.1
Serum Pool (low)	2.0	2.1	3.2	3.5
Serum Pool (high)	2.5	2.3	2.6	3.3

IgM / Serum	mean (g/L)	Run-to-Run CV (%)	Within-Run CV (%)	Total CV (%)
N/T Protein Control, SL/L	0.47	4.0	3.8	5.3
N/T Protein Control, SL/M	0.69	1.9	3.2	3.4

IgM / Serum	mean (g/L)	Run-to-Run CV (%)	Within-Run CV (%)	Total CV (%)
N/T Protein Control, SL/H	0.90	1.7	2.6	2.8
Serum Pool (low)	0.76	1.9	2.2	2.7
Serum Pool (high)	1.12	1.7	1.7	2.2

The study was performed consistent with CLSI guideline EP5-A on ten days with four replicates per day (n = 40).

The results were generated by analysis of variance.

Method Comparison

One hundred (100) serum samples were assayed with N Antisera to Human Immunoglobulins on a BN System (y) and a radial immunodiffusion (RID) method (x). Correlation of the results yielded the following data:

Protein		Coefficient of Correlation
IgG	y (BN) = 1.09 x (RID) - 0.12 g/L	0.97
IgA	y (BN) = 0.99 x (RID) + 0.06 g/L	0.99
IgM	y (BN) = 1.08 x (RID) - 0.06 g/L	0.99

Seventy-six human urine samples ranging from 3.7 mg/L to 52 mg/L were assayed with N Antisera to Human Immunoglobulins (IgG) on a BN ProSpec® System and on a commercially available immunochemistry system. The method used to fit the linear regression line was Passing Bablok.

Protein		Coefficient of Correlation
IgG	y = 0.926 x - 0.34 mg/L	0.99

Note

The values cited for specific performance characteristics represent typical values and are not to be regarded as specifications for the N Antisera to Human IgG, IgA and IgM.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

Current Version of Assay Protocols

NAS IGA, NAS IGG and NAS IGM can be used in combination with various automated analyzers. Siemens Healthineers provides Assay protocols for instruments under the dedicated link below:

siemens-healthineers.com/ap

As Siemens Healthineers continuously monitors the product performance and safety, the users are required to ensure that they work with the correct revision of the instructions for the product lots in use. Please periodically review the availability of new electronic labeling revisions to ensure safe use of the product.

The IFU version number is visible on each product box label. Siemens Healthineers ensures that all products lots bearing the same IFU version number are compatible with the electronic labeling provided via siemens-healthineers.com/eIFU.

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Definition of Symbols

The following symbols may appear on the product labeling:

	Do not reuse		Use By
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community		Contains sufficient for <n> tests
	Biological Risks	IVD	*In Vitro* Diagnostic Medical Device
	Temperature Limitation		Consult instruction for Use
NON STERILE	Non-sterile	CE	CE marking of conformity
CE 0197	CE marking of conformity with notified body ID number. Notified body ID number can vary.	CONTENTS	Contents
	Reconstitution volume	LEVEL	Level
	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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BN™II Online Refresher

1. The BN™II uses what method of measurement?
    a. Turbidity
    b. Chromogenic
    c. Nephelometry
    d. Immunoassay
2. How do you enter the lot data for standards and controls?
    a. Load the lot data USB
    b. Scan the barcodes on the package insert sheets
    c. Download the lot data from Siemens Document Library
    d. Copy and paste the lot data file
3. How can you trigger the emergency stop on the BN™II?
    a. Lift the front panel / Plexiglas
    b. Click System, Emergency stop
    c. Open the left panel door
    d. Press the toggle switch on the left side of the analyzer
4. What is the name of the dialog where patient results can be reviewed?
    a. Work list
    b. Lab journal
    c. Job list
    d. Sample list
5. What is used to dilute the samples?
    a. Buffer
    b. BN™II Additive
    c. Diluent
    d. Wash solution
6. Samples are diluted with diluent in the
    a. Wash station
    b. Dilution cups
    c. Cuvettes
    d. Sample cups

7. What is loaded in the first five rack lanes?
    a. Patient samples
    b. Controls
    c. Reagents
    d. Standards
8. Which of these is not a function of the probes?
    a. Pipetting
    b. Mixing
    c. Heating
    d. Cap piercing
9. You may pool liquids on the BN™II as long as they have the same lot number.
    a. True
    b. False
10. Level sensor s monitor the liquid level in the system liquid and waste containers.
    a. True
    b. False
11. Samples with low volume should be run in ……
    a. A cup placed in the sample tube
    b. A cup placed in a sample rack
    c. A micro centrifuge tube placed in a pediatric rack
    d. None of the above
12. After initialization of the BN™II is completed, what needs to be done prior to running samples?
    a. Update the number of usable cuvettes
    b. Empty the waste container
    c. Update the number of clean dilution wells
    d. All of the above

Day 2 Eye Opener

1. What lanes should the supplemental reagents be loaded?
    a. Lane 1 or 2 in the rack for 2 ml vials b. Lanes 3 - 5 in the rack for 2 ml vials
    c. Lanes 1 or 2 in the rack for 5 ml vials
    d. Lanes 3 - 5 in the rack for 5 ml vials
2. How long are the reference curves valid?
    a. As long as the controls are valid
    b. 7 days
    c. 1 month
    d. 3 months
3. Which of the following can prevent initialization of the system?
    a. No dilution strips in the dilution frames
    b. Dilution frames not seated properly
    c. Full waste container
    d. Empty buffer container
4. What does it mean if an **H** is displayed next to the result in the Lab journal?
    a. Value is outside of measuring range and must be diluted
    b. Result has been sent to the host
    c. Result is outside if the reference (normal) range
    d. Result is a panic and should be repeated
5. Which options would you use to order controls?
    a. Routine > Request controls
    b. Control journal > Request controls
    c. QC > Request controls
    d. Reference curves > Request controls
6. What is the acceptable mean deviation for most calibrations?
    a. < 5%
    b. < 7%
    c. ± 15%
    d. ±20%

7. How many reagent lot numbers can be calibrated for non-kit assays?
    a. 1
    b. 2
    c. 3
    d. 4
8. How many reagent lots can be calibrated for a kit assay?
    a. 1
    b. 2
    c. 3
    d. 4
9. Which option would you choose to see the contents of each rack?
    a. Lab journal
    b. Rack status
    c. Loading
    d. Configuration
10. How do you eject a USB / memory stick from the Macintosh?
    a. Click System, Eject disk
    b. Click, hold and drag the disk icon to the trash
    c. Click Start, Eject disk
    d. At the bottom right of the screen, click the USB icon and “Safely Remove Hardware and Eject Media”

Finale

1. There is an X flag next to an IgG result in the Lab Journal. What will resolve this?
    a. No resolution needed. Report the result.
    b. Spin the sample at the recommended speed and time, then rerun.
    c. Report as “unable to report due to specimen condition”
    d. Freeze the sample and rerun the next day
2. Your initial IgG results and repeats are out of range for the low, medium and high controls. What would you do?
    a. Open new controls
    b. Recalibrate IgG after troubleshooting
    c. Clean the probe
    d. Request another repeat
3. On the Reagent List what does a black **x** mean?
    a. Reagent is not loaded in Lanes 3-5
    b. Reagent should be loaded in Lanes 3-5
    c. Reagent is empty
    d. Reagent is no longer needed
4. How often should you perform purging?
    a. Weekly
    b. Monthly
    c. Semi-annually
    d. Yearly
5. What are the components of the Wash solution?
    a. Distilled water and neodisher
    b. Distilled water and BN™II Additive
    c. Distilled water and 70% Ethanol
    d. Distilled

6. In the Lab Journal, what is the reason for the blue **x**?
    a. No active reference curve exists
    b. Valid reference curve exists
    c. Active reference curve exists
    d. Invalid curve
7. Which folder contains calibration curves and assigned values for standards and controls?
    a. BN II folder
    b. Macintosh folder
    c. System folder
    d. Data folder
8. When is the wash filter changed?
    a. Weekly
    b. Monthly after Purging, before changing the cuvettes
    c. Monthly after changing the cuvettes
    d. Semi-annually
9. When running samples in the pediatric rack, choose Loading and which option after selecting the rack number:
    a. Autoload
    b. Autoload > Take
    c. Autoload > Ignore all empty positions
    d. Click each sample in the work list to load
10. The system performs a turbidity check on:
    a. All samples
    b. All assays using clear antisera
    c. All latex assays
    d. All non-kit assays

10.8.1 Daily maintenance

Analyzer ID:																															
From (Date):																To (Date):															
Daily maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	15	16	17	18	19	20	21	22	23	24	26	27	28	29	30	31
The system liquid containers have been checked for sufficient contents																															
The dilution frames have been checked for presence, correct positioning, and completeness of the dilution wells																															
The analyzer's right cover has been closed																															
The tubing has been checked for kinks, contamination, leakage, and air bubbles																															
The external waste container has been emptied																															
The preparatory measures for analysis according to (➔ Page 149 *Preparing for the analysis*) have been performed																															
Signature / Initials:																															

10.8.2 Weekly maintenance

Analyzer ID:						
Weekly maintenance		Week 1	Week 2	Week 3	Week 4	Week 5
1.	The surface of the analyzer, the rotor cover, the trough for the dilution frames and the rack lanes have been cleaned					
2.	The syringes and valves have been checked for leakage					
3.	The reagent and sample probes have been checked for damage or blockage					
4.	The reagent and sample probes have been cleaned					
Remark:						
Date:						
Signature:						

10.8.3 Monthly maintenance

Analyzer ID:		
Monthly maintenance		
1.	The system tubing has been purged	
2.	The cuvettes have been replaced	
3.	The level sensors have been cleaned	
4.	The washing solution containers have been replaced	
5.	The washing solution filters have been replaced	
6.	The mouse has been cleaned	
Remark:		
Date:		
Signature:		

10.8.4 Half-yearly maintenance

Analyzer ID:		
Half-yearly maintenance		
1.	The syringes have been maintained with silicon oil	
2.	The syringes with white piston heads have been replaced	
Remark:		
Date:		
Signature:		

10.8.5 Yearly maintenance

Analyzer ID:		
Yearly maintenance		
1.	The syringes with black piston heads have been replaced	
Remark:		
Date:		
Signature:		