Công ty TNHH Trung Nhân

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

HƯỚNG DẪN SỬ DỤNG
HÓA CHẤT XÉT NGHIỆM
DÙNG CHO MÁY PHÂN TÍCH SINH HÓA

Hãng sản xuất: GOLDSITE DIAGNOSTIC INC. – CHINA

Người đại diện hợp pháp của cơ sở
Ký tên (Ghi họ tên đầy đủ, chức danh)

GIÁM ĐỐC

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NEPHSTAR™
Transferrin（TRF）Kit

Catalog No. DK015

1. Intended Use

This product is used on NEPHSTAR™ protein analysis system for quantitative determination of human Transferrin (TRF) in serum as an aid in diagnosis of abnormal TRF metabolism.

2. Summary

Transferrin is an iron binding protein. Its main function is the transport of iron to proliferating cells and it is an important growth factor. Increased levels are found in iron deficiency, pregnancy, oestrogen administration and lipoidal nephrosis. Decreased levels may be encountered in hereditary deficiencies, testosterone administration, infection, acute inflammation, some forms of nephrosis, tumors, haemochromatosis, acute malaria and malnutrition.

3. Test Principle

Immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antiserum, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antiserum is in excess. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA015	TRF Antiserum	1×2.0 ml
DB015	TRF Reaction buffer	1×25.0 mL
DC015	TRF Magnetic card	1
DM015	TRF Control	1×0.3mL
	Manual	1

5. Materials required but not supplied

5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 100-1000uL(YB302)
5.6 Equipment for collection of Samples

6. Storage and Stability

The unopened reagent kit should be stored under 2-8°C and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8°C and the buffer at **18-25℃ and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation

Use serum samples. Collect blood samples by venepuncture and let them clot naturally and separate the sera as soon as possible to prevent haemolysis. Sera may be stored at 2-8°C for 48 hours, otherwise freeze at –20°C or below; do not freeze and thaw sera more than once. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of sera may result in misleading values:

7.1 Highly lipemic, turbid and haemolysed samples are not suitable for nephelometric assays and should not be used unless centrifuged or prepared using other methods. If the background is too turbid and can not be removed, please think of other measuring method.

7.2 Testing of samples containing rheumatoid factors, paraproteins or circulating immunocomplexes can result in misleading values due to non-specific scattering light possibly generated by these articles.

8. Test Procedure

Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（1/11）	20ul
TRF Reaction Buffer	400ul
TRF Antiserum	40ul

8.1 Switch NEPHSTAR on.

8.2 Enter chemistry number. Enter chemistry number of TRF kit (TRF=15). If TRF assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.

8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.

8.4 Dilute samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110）. The default dilution scheme for TRF assay is 1/11 (e.g. 400uL sample diluent + 40uL sample）.

8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 20uL of diluted sample carefully to the bottom of the cuvette.

8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.

8.7 Enter sample dilution: 11. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.

8.8 Place cuvette in chamber. Place the cuevette containing a stirring bar and 20uL of diluted sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.

8.9 Add reagent. Add 400 uL TRF reaction buffer and 40 uL TRF antiserum simultaneously into the cuvette using the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.

8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will

increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

8.11 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/121（400μL sample diluent + 40μL 1/11 diluted sample）. Accordingly the sample dilution should be altered to 1/121（press BACK and then the number keys to alter the sample dilution）。

8.12 If NEPHSTAR indicates result is lower than measurement range, reassay the sample at a lower dilution of e.g. 1/5（160μL sample diluent + 40μL sample）. Accordingly the sample dilution should be altered to 1/5（press BACK and then the number keys to alter the sample dilution）。

8.13 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is 0.3 g/L and the upper limit is 6 g/L when the default dilution scheme is applied. The sensitivity limit is 0.14 g/L when samples are diluted at 1/5.

11. Antigen Excess

Sample concentration of less than 14.3 g/L will not result in antigen excess, when the results will be misleadingly low. On suspicion of antigen excess please reassay the sample at dilution of 1/121 (400uL sample diluent + 40uL 1/11 diluted sample).

12. Reference Range

12.1 According to CRM470，normal range of TRF concentration of healthy adult is：2.0 – 3.6 g/L. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of TRF. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

13. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

TRF（g/l）	CV（%）
1.1	2.25
5.2	2.61

14. Correlation Study

A correlation study is performed on 20 clinical serum samples using this kit on NEPHSTAR and Behring TRF reagent on BNII. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=1.09X-0.05

(Y= NEPHSTAR™ TRF，X=BNA TRF)

Correlation coefficient r=0.982

15. Caution And Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR™ specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

16. Referrences

Deutsch E, Geyer G, Wenger R, Laboratoriumsmedizin. Normalbereich der Ergebnisse und Interpretation abnormer Befunde, 3rd ed. Basel/Munich: Karger 1992.

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NEPHSTAR™
Anti-Streptolysin O (ASO) Kit

Code No. DK021

1. Intended Use

This product is used on NEPHSTAR™ protein analysis system for quantitative determination of human Anti-Streptolysin O (ASO) in serum as an aid in determination of levels of streptococcal infection.

2. Summary

The group A β-haemolytic streptococci produces various toxins that can act as antigens, one of these exotoxins is streptolysin O. The affected organism produces specific antibodies against streptolysin O. The concentration of ASL (O) in the patient's serum will enable to establish the degree of infection due to β-haemolytic streptococci.

Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis and streptococcal infections. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as skin, heart, joints etc… and acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

3. Test Principle

Particle-enhanced immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antibody covalently coupled to latex particles, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antibody is in excess. The latex particles increase the size of complexes formed and thus the amount of light as well as the test sensitivity. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA021	ASO Antiserum	2×0.9 ml
DB021	ASO Reaction buffer	1×25.0 mL
DC021	ASO Magnetic card	1
DM021	ASO Control	1×0.3mL
	Manual	1

5. Materials required but not supplied

5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 100-1000uL(YB302)
5.6 Equipment for collection of samples

6. Storage and Stability

The unopened reagent kit should be stored under 2-8°C and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8°C and the buffer at **18-25℃ and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation

Use serum samples. Collect blood samples by venepuncture and let them clot naturally and separate the sera as soon as possible to prevent haemolysis. Sera may be stored at 2-8°C for 48 hours, otherwise freeze at –20°C or below; do not freeze and thaw sera more than once. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of sera may result in misleading values:

7.1 Highly lipemic, turbid and haemolysed samples are not suitable for nephelometric assays and should not be used unless centrifuged or prepared using other methods. If the background is too turbid and can not be removed, please think of other measuring method.

7.2 Testing of samples containing rheumatoid factors, paraproteins or circulating immunocomplexes can result in misleading values due to non-specific scattering light possibly generated by these articles.

8. Test Procedure

Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（1/11）	20ul
ASO Reaction Buffer	400ul
ASO Antiserum	30ul

8.1 Switch NEPHSTAR on.

8.2 Enter chemistry number. Enter chemistry number of ASO kit (ASO=21). If ASO assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.

8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.

8.4 Dilute samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110). The default dilution scheme for ASO assay is 1/11 (e.g. 200uL sample diluent + 20uL sample）。

8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 20uL of diluted sample carefully to the bottom of the cuvette.

8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.

8.7 Enter sample dilution: 11. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.

8.8 Place cuvette in chamber. Place the cuevette containing a stirring bar and 20uL of diluted sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.

8.9 Add reagent. Add 400 uL ASO reaction buffer and 30 uL ASO antiserum simultaneously into the cuvette using

the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.

8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

8.11 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/121（200μL sample diluent + 20μL 1/11 diluted sample）. Accordingly the sample dilution should be altered to 1/121（press BACK and then the number keys to alter the sample dilution）。

8.12 If NEPHSTAR indicates result is lower than measurement range, reassay the sample at a lower dilution of e.g. 1/5（160μL sample diluent + 40μL sample）. Accordingly the sample dilution should be altered to 1/5（press BACK and then the number keys to alter the sample dilution）。

8.13 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is 50 IU/mL and the upper limit is 600 IU/mL when the default dilution scheme is applied. The sensitivity limit is 25 IU/mL when samples are diluted at 1/5.

11. Antigen Excess

Sample concentration of less than 3000 IU/mL will not result in antigen excess, when the results will be misleadingly low. On suspicion of antigen excess please reassay the sample at dilution of 1/440 (780uL sample diluent + 20uL 1/11 diluted sample).

12. Reference Range

12.1 According to WHO，normal range of ASO concentration of healthy adult is：<200 IU/mL. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of ASO. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

13. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

ASO（IU/mL）	CV（%）
168	2.37
465	2.29

14. Correlation Study

A correlation study is performed on 20 clinical serum samples using this kit on NEPHSTAR and Beckman Array ASO reagent on Array 360. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=0.975X - 8.32

(Y= NEPHSTAR™ ASO，X=Array ASO)

Correlation coefficient r=0.968

15. Caution And Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR™ specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

16. Referrences

16.1 Dillon, H. C. jr., Reeves M. A., Am. J. Med., 56, 333-346 (1974).

16.2 Klein, G. C., Baker, C. N., Jones, W. L., 21, 999-1001 (1971)

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NEPHSTAR™
C-Reactive Protein （CRP）Kit

Catalog No.	DK022

1. Intended Use

This product is used on NEPHSTAR™ protein analysis system for quantitative determination of human C-Reactive Protein (CRP) in serum as an aid in diagnosis and treatment of inflammatory conditions, bacterial infection as well as cardiac diseases.

2. Summary

CRP is synthesized in liver and consists of five identical polypeptide chains forming a five-membered ring of molecular weight of 120 kD. CRP is one of the most characteristic acute-phase proteins and is considered as a reliable indicator of disease activity in various clinical conditions. Its concentration in blood increases rapidly by
as much as 1000-fold upon exposure to various inflammatory stimuli. CRP has been used successfully for clinical diagnosis and monitoring of a variety of infections and diseases, including infections caused by bacteria, fungi, and viruses ; intercurrent infections in leukemia and systemic lupus erythematosus; noninfectious inflammatory diseases such as rheumatoid arthritis; and diseases with cellular necrosis such as myocardial infarction. Measurements of CRP are especially useful in distinguishing viral from bacterial infections.
Among the methods used to measure CRP in serum are radial immunodiffusion, turbidimetry, nephelometry, enzyme immunoassays, etc.. The acute nature of many diseases in which CRP is relevant for diagnosis and monitoring requires a rapid, easily interpreted, quantitative test, which comes true with this kit.

3. Test Principle

Particle-enhanced immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antibody covalently coupled to latex particles, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antiserum is in excess. The latex particles increase the size of complexes formed and thus the amount of light as well as the test sensitivity. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA022	CRP Antiserum	1×2.0 ml
DB022	CRP Reaction buffer	1×25.0 mL
DC022	CRP Magnetic card	1
DM022	CRP Control	1×0.3mL
	Manual	1

5. Materials required but not supplied

5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 100-1000uL(YB302)
5.6 Equipment for collection of Samples

6. Storage and Stability

The unopened reagent kit should be stored under 2-8°C and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8°C and the buffer at **18-25℃ and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation

Use serum samples. Collect blood samples by venepuncture and let them clot naturally and separate the sera as soon as possible to prevent haemolysis. Sera may be stored at 2-8°C for 48 hours, otherwise freeze at –20°C or below; do not freeze and thaw sera more than once. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of sera may result in misleading values:

7.1 Highly lipemic, turbid and haemolysed samples are not suitable for nephelometric assays and should not be used unless centrifuged or prepared using other methods. If the background is too turbid and can not be removed, please think of other measuring method.
7.2 Testing of samples containing rheumatoid factors, paraproteins or circulating immunocomplexes can result in misleading values due to non-specific scattering light possibly generated by these articles.

8. Test Procedure

Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（1/40）	40ul
CRP Reaction Buffer	400ul
CRP Antiserum	40ul

8.1 Switch NEPHSTAR on.
8.2 Enter chemistry number. Enter chemistry number of CRP kit (CRP=22). If CRP assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.
8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is

identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.

8.4 Dilute samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110). The default dilution scheme for CRP assay is 1/40 (e.g. 780uL sample diluent + 20uL sample)。

8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 40uL of diluted sample carefully to the bottom of the cuvette.

8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.

8.7 Enter sample dilution: 40. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.

8.8 Place cuvette in chamber. Place the cuevette containing a stirring bar and 40uL of diluted sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.

8.9 Add reagent. Add 400 uL CRP reaction buffer and 40 uL CRP antiserum simultaneously into the cuvette using the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.

8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

8.11 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/440（400μL sample diluent + 40μL 1/40 diluted sample）. Accordingly the sample dilution should be altered to 1/440（press BACK and then the number keys to alter the sample dilution）。

8.12 If NEPHSTAR indicates result is lower than measurement range, reassay the sample at a lower dilution of e.g. 1/11（400μL sample diluent + 40μL sample）. Accordingly the sample dilution should be altered to 1/11（press BACK and then the number keys to alter the sample dilution）。

8.13 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is 2.0mg/L and the upper limit is 150mg/L when the default dilution scheme is applied. The sensitivity limit is 0.25mg/L when samples are diluted at 1/5.

11. Antigen Excess

Sample concentration of less than 6000mg/L will not result in antigen excess, when the results will be misleadingly low. On suspicion of antigen excess please reassay the sample at dilution of 1/1600 (400uL sample diluent + 40uL 1/40 diluted sample).

12. Reference Range

12.1 According to CRM470，normal range of CRP concentration of healthy adult is：<5mg/L. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of CRP. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

13. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

CRP（mg/L）	CV（%）
8.0	3.05
98.2	2.78

14. Correlation Study

A correlation study is performed on 20 clinical serum samples using this kit on NEPHSTAR and Behring CRP reagent on BNII. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=0.985X-1.29

(Y= NEPHSTARTM CRP，X=BNIITM CRP)

Correlation coefficient r=0.976

15. Caution And Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR™ specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

16. Referrences

16.1. Urdal P, Borch SM, Landaas S, Krutnes MB, Gogstad GO, Hjortdahl P. Rapid immunometric measurement of C-reactive protein in whole blood. Clin Chem 1992;38:580-584.

16.2 Chambers RE, Whicker JT, Dieppe PA. Acute phase proteins in inflammatory disease. Clin Diagnosis Lab 1988;1:29-37.

16.3 Morley JJ, Kushner I. Serum C-reactive protein levels in disease. Ann N Y Acad Sci 1982;389:406-18.
16.4 Lindback S, Heligren U, Julander I, Hanseon LO. The value of C-reactive protein as a marker of bacterial infection in patients with septicaemia, endocarditis and influenza. Scand J Infect Dis 1989;21:543-.9.

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NEPHSTAR™
Rheumatoid Factor (RF) Kit

Code No. DK023

1. Intended Use

This product is used on NEPHSTAR™ protein analysis system for quantitative determination of human rheumatoid factor (RF) in serum as an aid in diagnosis of rheumatoid arthritis.

2. Summary

Rheumatoid factors are a heterogeneous group of autoantibodies directed against the antigenic determinants on the Fc-region of IgG molecules. They are important in the diagnosis of rheumatoid arthritis, but can also be found in other inflammatory-rheumatic diseases and in various non-rheumatic diseases. They are also found in clinically healthy persons over 60 years of age. Despite these restrictions, the detection of rheumatoid factors is a diagnostic criterion of the American College of Rheumatology for classifying rheumatoid arthritis. These autoantibodies occur in all the immunoglobulin classes, although the usual analytical methods are limited to the detection of rheumatoid factors of the IgM type.

3. Test Principle

Particle-enhanced immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antibody covalently coupled to latex particles, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antibody is in excess. The latex particles increase the size of complexes formed and thus the amount of light as well as the test sensitivity. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA023	RF Antiserum	2×0.45 ml
DB023	RF Reaction buffer	1×25.0 mL
DC023	RF Magnetic card	1
DM023	RF Control	1×0.3mL
	Manual	1

5. Materials required but not supplied

5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 100-1000uL(YB302)
5.6 Equipment for collection of samples

6. Storage and Stability

The unopened reagent kit should be stored under 2-8°C and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8°C and the buffer at **18-25℃ and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation

Use serum samples. Collect blood samples by venepuncture and let them clot naturally and separate the sera as soon as possible to prevent haemolysis. Sera may be stored at 2-8°C for 48 hours, otherwise freeze at –20°C or below; do not freeze and thaw sera more than once. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of sera may result in misleading values:

7.1 Highly lipemic, turbid and haemolysed samples are not suitable for nephelometric assays and should not be used unless centrifuged or prepared using other methods. If the background is too turbid and can not be removed, please think of other measuring method.

7.2 Testing of samples containing rheumatoid factors, paraproteins or circulating immunocomplexes can result in misleading values due to non-specific scattering light possibly generated by these articles.

8. Test Procedure

Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（1/20）	40ul
RF Reaction Buffer	400ul
RF Antiserum	15ul

8.1 Switch NEPHSTAR on.

8.2 Enter chemistry number. Enter chemistry number of RF kit (RF=23). If RF assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.

8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.

8.4 Dilute samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110）. The default dilution scheme for RF assay is 1/20 (e.g. 380uL sample diluent + 20uL sample）。

8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 40uL of diluted sample carefully to the bottom of the cuvette.

8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.

8.7 Enter sample dilution: 20. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.

8.8 Place cuvette in chamber. Place the cuevette containing a stirring bar and 40uL of diluted sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.

8.9 Add reagent. Add 400 uL RF reaction buffer and 15 uL RF antiserum simultaneously into the cuvette using the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of

reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.

8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

8.11 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/220（200μL sample diluent + 20μL 1/20 diluted sample）. Accordingly the sample dilution should be altered to 1/220（press BACK and then the number keys to alter the sample dilution）。

8.12 If NEPHSTAR indicates result is lower than measurement range, reassay the sample at a lower dilution of e.g. 1/11（200μL sample diluent + 20μL sample）. Accordingly the sample dilution should be altered to 1/11（press BACK and then the number keys to alter the sample dilution）。

8.13 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is 20 IU/mL and the upper limit is 300 IU/mL when the default dilution scheme is applied. The sensitivity limit is 11 IU/mL when samples are diluted at 1/11.

11. Antigen Excess

Sample concentration of less than 8000 IU/mL will not result in antigen excess. But such high RF concentration of patient sample will not happen.

12. Reference Range

12.1 According to WHO，normal range of RF concentration of healthy adult is：<30 IU/mL. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of RF. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

13. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

RF（IU/mL）	CV（%）
50	1.89
324	2.02

14. Correlation Study

A correlation study is performed on 20 clinical serum samples using this kit on NEPHSTAR and Beckman Array RF reagent on Array 360. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=0.982X - 3.32
(Y= NEPHSTAR™ RF，X=Array RF)
Correlation coefficient r=0.972

15. Caution and Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR™ specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

16. Referrences

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NEPHSTAR™
Ultrasensitive C-Reactive Protein （UsCRP）Kit

Catalog No. **DK025**

1. Intended Use

This product is used on NEPHSTAR™ protein analysis system for quantitative determination of human Ultrasensitive C-Reactive Protein (UsCRP) in serum as an aid in diagnosis and treatment of inflammatory conditions, bacterial infection as well as cardiac diseases.

2. Summary

C-Reactive Protein (CRP) is an acute marker of inflammatory processes. In case of an acute inflammation the concentration of CRP increases and decreases more quickly than the red cell sedimentation rate. The increase of CRP occurs in a non-specific way in different kinds of tissular aggression, as for example in infectious states, rheumatoid arthritis, myocardium infarct, malignant tumour, etc.

Routinely available immunochemical assay methods for CRP have limited sensitivity, and until recently, CRP concentrations below 10 mg/L could not be measured precisely, leading to the wide spread adoption of this value as the upper limit of the health-associated reference range. This is satisfactory for most purposes in general medicine.

However, in neonatal pediatric practice, a high sensitive CRP immunoassay shows that health-associated reference values are below 1 – 2 mg/L and that any rise above such values is associated with serious disease, usually bacterial infection.

More recently, application of sensitive CRP assays to studies of adult cardiovascular disease has revealed important prognostic relationships between modest increase of CRP and the occurrence, progression, and thrombo-occlusive complications of atherosclerosis. We therefore developed an ultra sensitive CRP assay with a detection limit around 1.0 mg/L and a high measuring range (0 – 150 mg/L CRP).

3. Test Principle

Particle-enhanced immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antibody covalently coupled to latex particles, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antiserum is in excess. The latex particles increase the size of complexes formed and thus the amount of light as well as the test sensitivity. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA025	UsCRP Antiserum	1×2.0 ml
DB025	UsCRP Reaction buffer	1×25.0 mL
DC025	UsCRP Magnetic card	1
DM025	UsCRP Control	1×0.3mL
	Manual	1

5. Materials required but not supplied

5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 100-1000uL(YB302)
5.6 Equipment for collection of Samples

6. Storage and Stability

The unopened reagent kit should be stored under 2-8°C and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8°C and the buffer at **18-25℃ and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation

Use serum samples. Collect blood samples by venepuncture and let them clot naturally and separate the sera as soon as possible to prevent haemolysis. Sera may be stored at 2-8°C for 48 hours, otherwise freeze at –20°C or below; do not freeze and thaw sera more than once. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of sera may result in misleading values:

7.1 Highly lipemic, turbid and haemolysed samples are not suitable for nephelometric assays and should not be used unless centrifuged or prepared using other methods. If the background is too turbid and can not be removed, please think of other measuring method.

7.2 Testing of samples containing rheumatoid factors, paraproteins or circulating immunocomplexes can result in misleading values due to non-specific scattering light possibly generated by these articles.

8. Test Procedure

Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（1/5）	40ul
UsCRP Reaction Buffer	400ul
UsCRP Antiserum	40ul

8.1 Switch NEPHSTAR on.

8.2 Enter chemistry number. Enter chemistry number of UsCRP kit (UsCRP=25). If UsCRP assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.

8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to that printed on the card or kit label, otherwise

swipe card to update the curve data stored in NEPHSTAR.

8.4 Dilute samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110）. The default dilution scheme for UsCRP assay is 1/5 (e.g. 160uL sample diluent + 40uL sample）。

8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 40uL of diluted sample carefully to the bottom of the cuvette.

8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.

8.7 Enter sample dilution: 5. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.

8.8 Place cuvette in chamber. Place the cuevette containing a stirring bar and 40uL of diluted sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.

8.9 Add reagent. Add 400 uL UsCRP reaction buffer and 40 uL UsCRP antiserum simultaneously into the cuvette using the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.

8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

8.11 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/55（400μL sample diluent + 40μL 1/5 diluted sample）. Accordingly the sample dilution should be altered to 1/55（press BACK and then the number keys to alter the sample dilution）。

8.12 If NEPHSTAR indicates result is lower than measurement range, reassay the sample at a lower dilution of e.g. 1/1（undiluted）. Accordingly the sample dilution should be altered to 1（press BACK and then the number keys to alter the sample dilution）。

8.13 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is 0.25 mg/L and the upper limit is 18mg/L when the default dilution scheme is applied. The sensitivity limit is 0.05mg/L when samples are assayed undiluted.

11. Antigen Excess

Sample concentration of less than 750mg/L will not result in antigen excess, when the results will be misleadingly low. On suspicion of antigen excess please reassay the sample at dilution of 1/200 (780uL sample diluent + 20uL 1/5 diluted sample).

12. Reference Range

12.1 According to literature，normal range of UsCRP concentration of healthy adult is：<3mg/L. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of UsCRP. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

13. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

UsCRP（mg/L）	CV（%）
1.8	2.68
12.6	3.12

14. Correlation Study

A correlation study is performed on 20 clinical serum samples using this kit on NEPHSTAR and Behring UsCRP reagent on BNII. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=0.971X-0.09

(Y= NEPHSTAR™ UsCRP，X=BNII CRP)

Correlation coefficient r=0.985

15. Caution And Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR™ specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

16. Referrences

1. Claus DR, Osmand AP, Gewurz H. Radioimmunoassay of human C-reactive protein and levels in normal sera. J Lab Clin Med 1976;
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2. Wasunna A, Whitelaw A, Gallimore R, Hawkins PN, Pepys MB. C-reactive protein and bacterial infection in preterm infants. Eur J Pediatr 1990; 149:424-427

3. Heinrich J, Schulte H, Schönfeld R, Köhler E, Assmann G. Association of variables of coagulation, fibrinolysis and acute-phase with atherosclerosis in coronary and peripheral arteries and those arteries supplying the brain. Thromb Haemostas 1995; 73: 374-379

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NEPHSTAR™
Urine Micro Albumin（mALB）Kit

Catalog No.	DK061

1. Intended Use

This product is used on NEPHSTAR™ protein analysis system for quantitative determination of human Micro Albumin (mALB) in urine as an aid in diagnosis of abnormal mALB metabolism.

2. Summary

Microalbuminuria is defined as a condition characterized by urinary albumin excretion above 19 mg/l, normal urinary excretion for adults, in the absence of clinically detectable nephropathy. A number of investigators using immunoassays for albumin have established a range of 20 or 30 mg/l to 200 mg/l as diagnostic for microalbuminuria. Individuals with an established diagnosis of diabetes or essential hypertension represent the most important groups to be followed for elevations in albumin excretion rates. Microalbuminuria may have causes other than incipient diabetic nephropathy. Subclinical elevations in urinary albumin excretion rates may be caused by urinary tract infections, congestive heart disease, hypertension, exercise, non-diabetic renal disease and poor diabetic control.

3. Test Principle

Immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antiserum, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antiserum is in excess. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA061	mALB Antiserum	1×2.0 ml
DB061	mALB Reaction buffer	1×25.0 mL
DC061	mALB Magnetic card	1
DM061	mALB Control	1×0.5mL
	Manual	1

5. Materials required but not supplied

5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 100-1000uL(YB302)
5.6 Equipment for collection of Samples

6. Storage and Stability

The unopened reagent kit should be stored under 2-8°C and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8°C and the buffer at room temperature(**18-25℃) and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation

Use freshly collected urine samples: these should be centrifuged prior to analysis to remove particulate matter. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of urine sample may result in misleading values:

- Microbially contaminated or turbid samples may not be suitable for nephelometric measurements and should not be used unless they have been centrifuged or prepared in some appropriate manner. An alternative assay method, e.g. radial immunodiffusion, is recommended if background turbidity cannot be removed.

8. Test Procedure

Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（undiluted）	20ul
mALB Reaction Buffer	400ul
mALB Antiserum	40ul

8.1 Switch NEPHSTAR on.
8.2 Enter chemistry number. Enter chemistry number of mALB kit (mALB=61). If mALB assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.
8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.
8.4 Dilute samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110) if necessary. The default dilution scheme for mALB assay is 1/1 (undiluted) .
8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 20uL of undiluted sample carefully to the bottom of the cuvette.
8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.
8.7 Enter sample dilution: 1. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.
8.8 Place cuvette in chamber. Place the cuevette containing a stirring bar and 20uL of sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.
8.9 Add reagent. Add 400 uL mALB reaction buffer and 40 uL mALB antiserum simultaneously into the cuvette using the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.

8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

8.11 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/11（200μL sample diluent + 20μL sample）. Accordingly the sample dilution should be altered to 1/11（press BACK and then the number keys to alter the sample dilution）。

8.12 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is 10.0 mg/L and the upper limit is 220.0 mg/L when the default dilution scheme is applied. The sensitivity limit is 110 mg/L when samples are diluted at 1/11.

11. Antigen Excess

Sample concentration of less than 1900 mg/L will not result in antigen excess, when the results will be misleadingly low. On suspicion of antigen excess please reassay the sample at dilution of 1/40 (780uL sample diluent + 20uL undiluted sample).

12. Reference Range

12.1 According to IFCC，normal range of mALB concentration in random urine of healthy adult is：25.0 mg/L. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of mALB. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

13. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

mALB（mg/L）	CV（%）
19	2.63
188	2.29

14. Correlation Study

A correlation study is performed on 20 clinical serum samples using this kit on NEPHSTAR and Behring mALB reagent on BNII. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=1.12X-2.35

(Y= NEPHSTAR™ mALB，X=BNII mALB)

Correlation coefficient r=0.978

15. Caution And Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR™ specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

16. Referrences

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NEPHSTAR™
Cystatin C （Cys C）Kit

Catalog No.	DK066

1. Intended Use
This product is used on NEPHSTAR™ protein analysis system for quantitative determination of human **Cystatin C （Cys C）** in serum , plasma as an aid in diagnosis and treatment of renal diseases.

2. Summary
Cystatin C is a small, 13kDa, non-glycosylated basic protein belonging to the cystain super-family of cysteine protease inhibitors. Cystatin C is produced by virtually all nucleated cells, and is present in all investigated body fluids. The production is constant and is unaffected by inflammatory processes, gender, age and muscle mass. It is freely filtered through a normal Glomerular membrane, but is then reabsorbed and almost entirely catabolized in the proximal tubules, no Cystatin C returns to the blood. So, the Cystatin C concentration in human blood is closely related to GFR. Therefore, Cystatin C is considered a useful endogenous marker for the detection of renal impairment, numerous studies have shown that serum Cystatin C is superior to serum creatinine as a marker for GFR.

3. Test Principle
Particle-enhanced immunonephelometry is applied. This method involves measuring the light scattered by insoluble complexes formed by reaction between specific protein in samples and its respective antibody covalently coupled to latex particles, and the amount of scattered light is directly proportional to the concentration of the protein under condition that antiserum is in excess. The latex particles increase the size of complexes formed and thus the amount of light as well as the test sensitivity. Concentrations are automatically calculated by reference to a calibration curve stored in the instrument.

4. Kit Components

Code	Name	Volume/Quantity
DA022	**Cys C** Antiserum	2×1.0 ml
DB022	**Cys C** Reaction buffer	1×25.0 mL
DC022	**Cys C** Magnetic card	1
DM022	**Cys C** Control	1×0.3mL
	Manual	1

5. Materials required but not supplied
5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Electronic pipette（YB201）
5.4 Pipette 5-50uL (YB301)
5.5 Pipette 100-1000uL(YB302)
5.6 Equipment for collection of Samples

6. Storage and Stability
The unopened reagent kit should be stored under 2-8°C and can be used until the expiry date labeled on the kit. Do not freeze! The buffer should be equilibrated to room temperature before use. Once opened store the antisera and control at 2-8°C and the buffer at **18-25℃ and be sure to screw on the cap tightly.** Under these conditions the buffer is stable for 3 months, antisera and control for 1 month.

7. Sample Collection And Preparation
Use serum, heparinized plasma and EDTA plasma samples. samples may be stored at 2-8°C for 48 hours, otherwise freeze at –20°C or below; do not freeze and thaw sera more than once. Sample dilutions should be freshly prepared on the day of assay. Testing of the following types of samples may result in misleading values:

7.1 Highly lipemic, turbid and haemolysed samples are not suitable for nephelometric assays and should not be used unless centrifuged or prepared using other methods. If the background is too turbid and can not be removed, please think of other measuring method.

7.2 Testing of samples containing rheumatoid factors, paraproteins or circulating immunocomplexes can result in misleading values due to non-specific scattering light possibly generated by these articles.

8. Test Procedure
Summary: Reagent volumes added to the cuvette

Reagent	Volume
Sample（1/5）	30ul
Cys C Reaction Buffer	400ul
Cys C Antiserum	40ul

8.1 Switch NEPHSTAR on.

8.2 Enter chemistry number. Enter chemistry number of Cys C kit (Cys C=66). If Cys C assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.

8.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to that printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.

8.4 Dilute samples or controls using NEPHSTAR Sample Diluent supplied in NEPHSTAR Accessory pack (Cat. No: DK110）. The default dilution scheme for Cys C assay is 1/5 (e.g. 200uL sample diluent + 50uL sample）。

8.5 Prepare one cuvette for each sample to be assayed. Place a stirring bar to the cuvette using the forceps supplied with NEPHSTAR, then add 30uL of diluted sample carefully to the bottom of the cuvette.

8.6 Enter sample ID. Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.

8.7 Enter sample dilution: 5. Accept the default sample dilution by pressing ENTER, otherwise press number keys to alter the dilution scheme.

8.8 Place cuvette in chamber. Place the cuevette containing a stirring bar and 30uL of diluted sample in the chamber and press it down slightly until it reaches the bottom of the chamber. The cuvette will be detected automatically.

8.9 Add reagent. Add 400 uL Cys C reaction buffer and 40 uL Cys C antiserum simultaneously into the cuvette

using the electronic pipette （Cat. No.: YB201）supplied with NEPHSTAR. NEPHSTAR will sense the addition of reagents. With movement of the stirring bar, the assay begins after blanking and result will be printed automatically at the end of the assay.

8.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

8.11 If NEPHSTAR indicates result is higher than measurement range, reassay the sample at a higher dilution of e.g. 1/40（210μL sample diluent + 30μL 1/5diluted sample）. Accordingly the sample dilution should be altered to 1/40（press BACK and then the number keys to alter the sample dilution）。

8.12 If NEPHSTAR indicates result is lower than measurement range, reassay the sample at a lower dilution of e.g. 1/1. Accordingly the sample dilution should be altered to 1/1（press BACK and then the number keys to alter the sample dilution）。

8.13 On completion of all assays of the same chemistry press ESC and return to step 8.2. Enter new chemistry number and begin another assay.

9. Quality Control

In accord with good laboratory practice, users should run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.

10. Sensitivity and measuring range

The sensitivity limit is 0.4mg/L and the upper limit is 7.5mg/L when the default dilution scheme is applied. The sensitivity limit is 0.08mg/L when samples are diluted at 1/1.

11. Antigen Excess

Sample concentration of less than 35mg/L will not result in antigen excess, when the results will be misleadingly low.

Reference Range

12.1 Normal range of Cys C concentration of healthy adult is：for individuals 1-50years:0.55-1.15mg/L, for individuals >50years:0.63-1.44mg/L. We recommend local reference ranges are produced.

12.2 Diagnosis and treatment can not only depend on determination of Cys C. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

12. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

Cys C（mg/L）	CV （%）
1.1	1.35
3.2	3.20

13. Correlation Study

A correlation study is performed on 20 clinical serum samples using this kit on NEPHSTAR and Behring Cys C reagent on BNII. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=1.08X-0.23

（Y= NEPHSTARTM Cys C，X=BNIITM Cys C)

Correlation coefficient r=0.998

14. Caution And Warning

15.1 The reagents are only for in vitro diagnostic use。

15.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.

15.3 All sera have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

15.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.

15.5 All components of kit are NEPHSTAR™ specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

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NEPHSTAR™
Haemoglobin A1c (HbA1c) Kit

Catalog No. DK071

1. Intended Use

This product is used on NEPHSTAR™ protein analysis system for quantitative determination of human Haemoglobin A1c (HbA1c) percentage to total Haemoglobin in whole blood as an aid in diagnosis of diabetic mellitus.

2. Summary

Diabetes Mellitus is a chronic disease characterized by a hyperglycemia. The consequences are metabolism disorders of carbohydrates, lipids and proteins. The risk of complications associated with diabetes, including nephropathy, retinopathy and cardiovascular diseases, increases in patients with poor metabolic control. In the diabetic patients, where blood glucose levels are elevated, HbA1c is formed as a consequence of the non-enzymatic glycation of the N-terminus of the β -chain of haemoglobin molecule. The level of HbA1c is proportional to the level of glucose in the blood and has been widely accepted as an indicator of the mean daily blood glucose concentration over the preceding 6-8 weeks. It is therefore, a long-term indicator of diabetic control, whereas, the measurement of blood glucose is only a short-term.

3. Test Principle

The HbA1c kit is a quantitative nephelometric test directly for the percentage of glycated hemoglobin (HbA1c) to total haemoglobin (HbT). Total haemoglobin and HbA1c have the same unspecific absorption rate to latex particles. When mouse anti-human HbA1c monoclonal antibody is added, latex-HbA1c-mouse anti-human HbA1c antibody complex is formed. Agglutination is formed when goat anti-mouse igG polyconal antibody interacts with the monoclonal antibody. The amount of agglutination is measured by nephelometry. The HbA1c percentage value is obtained from a calibration curve.

4. Kit Components

Code	Name	Volume/quantity
DL071	NEPHSTAR HbA1c R1 (Latex)	3×2.5 mL
DA071	NEPHSTAR HbA1c R2a	1×1.0 mL
DB071	NEPHSTAR HbA1c R2b	1×2.5 mL
DH071	NEPHSTAR Haemolysis Solution	1×25 mL
DC071	NEPHSTAR HbA1c Card	1
	Manual	1

5. Materials required but not supplied

5.1 NEPHSTAR Protein analysis system（NS100）
5.2 NEPHSTAR Accessory pack（DK110）
5.3 Pipette 5-50μL
5.4 Electronic pipette (YB201)
5.5 Pipette 100-1000μL
5.6 Equipment for collection of samples

5.7 NEPHSTAR HbA1c Control（Code: DM071，1×1.0mL）

6. Storage and Stability

The unopened reagent kit should be stored under 2-8°C avoiding direct sunlight and can be used until the expiry date labeled on the kit. **Do not freeze!** Once opened the HbA1c latex (R1) is stable for 60 days at 2-8°C, the antibody （R2a and R2b) is stable for 30 days at 2-8°C.

7. Reagent preparation

7.1 HbA1c R1,R2a,R2b：Ready to use.

7.2 HbA1c Control: Open the vial and accurately add 1.0mL distilled water into the vial to dissolve the contents. Gently mix for 10 minutes, or until all material has dissolved. The reconstituted control is ready to use as a haemolysate. The reconstituted control is stable for 7 days if stored tightly closed at 2-8°C. The reconstituted control is stable for 6 months if stored tightly closed at -20°C

8. Sample collection and preparation

Haemolysis of samples: Dispense 1mL haemolysis solution into a test tube, add 10μL of whole blood sample into the tube, then mix. Allow the mixture to stand for 5 minutes or until complete lysis is evident. The blood sample can be fresh EDTA venous blood or freshly collected on finger tip. The haemolysate is stable for 48 hours at 2-8°C.

9. Interferences:

No interferences for ascorbic acid(50mg/dL), Triglyceride (2000mg/dL), Bilirubin (40mg/dL), carbamylated Hb (7.5mmol/L) and acetylated Hb (5 mmol/L).

10. Test Procedure

Summary: Reagent volumes added to the cuvette

Reagent	Volume
Haemolysate	10μL
HbA1c R1	300μL
Addition after 3 minutes	
HbA1c R2b	100μL
HbA1c R2a	**40**μL

All reagents should be equilibrated fully to room temperature before use!

10.1 Switch NEPHSTAR on.

10.2 **Enter chemistry number**. Enter chemistry number of HbA1c kit (HbA1c=71). If HbA1c assay has never been performed on the instrument before, please swipe card when “please swipe card” is displayed.

10.3 The assay name and lot of reagent are displayed. Check carefully, press ENTER if the lot number is identical to the last three or four digits of the number printed on the card or kit label, otherwise swipe card to update the curve data stored in NEPHSTAR.

10.4 **Enter sample ID.** Press number keys to enter the sample ID; or press ENTER to accept the currently displayed sample ID.

10.5 Enter sample dilution: 1. Accept the default sample dilution by pressing ENTER. For HbA1c assay the haemolysate should not be diluted.

10.6 Prepare one cuvette for each sample to be assayed. Place a stirring bar in the cuvette using the forceps supplied with NEPHSTAR. Add 10μL sample haemolysate on the bottom of the cuvette.

10.7 **Place cuvette in chamber.** Place the cuvette in chamber, press it lightly until it contacts the bottom of the chamber. The cuvette will be detected.

10.8 **Add reagent**. Add 300μL HbA1c R1 to the cuvette. NEPHSTAR will sense the addition of R1, the stirring bar will stir and time will be counted down automatically for 3 minutes. You can also count the time with other method and choose to skip this step by pressing SKIP.

10.9 **Add reagent.** When 3-minute time count is finished, NEPHSTAR will beep and indicate addition of reagent. Add 100μL HbA1c R2b and 40μL R2a simultaneously into the cuvette using the electronic pipette (Cat. No: YB201) and **immediately press ENTER** to start the assay. At the end of the assay the result will be displayed and printed automatically.

- **Note: If the assay begins before reagent R2 is added, just pull the cuvette out of the chamber and place it back in the chamber again and turn to step 10.8.**

10.10 On completion of the assay remove the cuvette, press ENTER to perform the next assay. The step will be turned to 10.7. Sample ID will increase sequentially. For alteration of the ID press BACK twice and tip in the right number.

10.11 If NEPHSTAR indicates result is higher or lower than measurement range and exact result is expected, you will have to reassay the sample with other method. Changing the dilution of the sample will result in misleading values.

10.12 On completion of all assays of the same chemistry press ESC and return to step 10.2. Enter new chemistry number and begin another chemistry assay.

11. Quality Control

In accord with good laboratory practice, users are suggested to run control with every batch of samples. Results of control should fall in the validity range labeled on the control vial.
Note: HbA1c control is not standard component of the kit.

12. Sensitivity and measuring range

The sensitivity limit is 3% and the upper limit is 15%.

13. Antigen Excess

Sample HbA1c percentage concentration of less than 40% will not result in antigen excess. But such high HbA1c concentration of patient sample will not happen.

14. Reference Range

14.1 According to WHO，normal range of HbA1c percentage of healthy adult is：3.8 – 5.8%. For diabetic patients, less then 7% of HbA1c percentage is acceptable. We recommend local reference ranges are produced.
14.2 Diagnosis and treatment can not only depend on determination of HbA1c. The clinical symptoms and other laboratory findings of respective patients should be taken into consideration。

15. Precision

Two analyte concentrations are assayed within several days using this kit of the same lot on NEPHSTAR. 20 repeat assays are performed for each concentration. The average coefficient variations (CV) for each concentration are displayed in the following table:

HbA1c（%）	CV（%）
5	4.46
11.8	2.58

16. Correlation Study

A correlation study is performed on 20 clinical samples using this kit on NEPHSTAR and another system using HPLC method. The linear regression equation and correlation equation got as showed below demonstrate a good correlation between the two methods:

Y=0.981X – 0.10
(Y= NEPHSTAR™ HbA1c，X=HPLC HbA1c)
Correlation coefficient r=0.978

17. Caution and Warning

17.1 The reagents are only for in vitro diagnostic use。
17.2 The reagents can be used only by trained personnel and good laboratory practice (GLP) and the stated procedure should be abided strictly.
17.3 All sera or blood have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.
17.4 All reagents of the kit contain sodium azide as preservative. Take caution when handling them. Ingest or contact of the reagents with skin or mucous membranes is forbidden. Wash with large amount of water and seek medical advice if contact does occur. In addition, explosive metal azides may be formed with lead or copper plumbings; when disposing the reagents be sure to flush with large amount of water to avoid buildup of azide.
17.5 All components of kit are NEPHSTAR™ specific. Reagents of different lots are not interchangeable, otherwise the results can be misleading.

18. Referrences

Cohen P.M. Perspective: measurement of Circulating Glycated Protein to Monitor Intermediate – Term Changes in Glycaemic Control Eur J Clin Chem. Clin. Biochem. 1992:30 (12): 851 – 859

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NEPHSTAR
Haemoglobin A1c (HbA1c）Control

Catalog No. **DM071**

Lot: 20100308

1. Intended Use
Accuracy control for quantitative determination of HbA1c in human blood by nephelometric immunoassay.

2. composition
The HbA1c Control is a hemolysate prepared from packed human erythrocytes, lyophilized and stabilised.

3. Package
1*1.0ml code:DM071

4. Reagent Preparation
Open the vial and accurately add 1.0ml distilled water into the vial to dissolve the contents.Gently mix for 10 minutes, or until all material has dissolved .The reconstituted contents should be treated as whole blood sample.

5. Storage and Stability
The reconstituted control is stable for 7 days if stored tightly closed at 2—8℃. The reconstituted control is stable for 6 months if stored tightly closed at -20℃.

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6. Procedure
The reconstituted contents should be treated as a haemolysate regarding the test procedure.

7. Precautions and Warnings
7.1 The reagents are only for in vitro diagnostic use。
7.2 All sera or blood have been tested to be HIV(1&2) antibody negative, HBsAg negative. However, the performed testing method can not assure the absolute absence of infectious agents in blood products, so please be sure to handle the blood products such as controls and antisera as potentially infectious sources.

8. Assigned Values
6.88(5.5-8.26)%

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NEPHSTAR® Accessory Pack
CUVETTE + STIRRER BAR

Catalog No.	DK110

1. Intended Use
For in vitro diagnostic use only especially designed for Nephstar protein analyzer use.

2. Components
2.1 100 pcs of cuvette Composition: PS Specification: 1.2*1.2*4.5cm
2.2 100 pcs of stirring bar Composition: Iron
2.3 1*65ml diluents (option) Composition: pure water 99%

3. Storage
Under room temperature

4. Procedure
As per Nephstar manual

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