



Turbodyne™ RF

Quantitative turbidimetric immunoassay for determination of Rheumatoid Factors on Turbodyne SC™

Intended Use:

Turbodyne™ RF is used for the detection of Rheumatoid Arthritis (RA), Differential diagnosis of RA from Rheumatic fever and other rheumatic disorders.

Turbodyne™ RF Kit components:

| | |
|---|--|
| Turbodyne™ RF Activation Buffer (R1) | Ready to Use |
| Turbodyne™ RF Latex Reagent (R2) | Ready to use uniform suspension of polystyrene latex particles coated with suitably modified Fc fraction of human IgG |
| Turbodyne™ RF Smart Card | Smart card with RF Calibration curve calibrated with a standard traceable to International Reference Preparation of Rheumatoid Arthritis serum |
| Other Accessories | Package Insert & Cuvettes |

Performance Characteristics:

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|--|
| Measuring range: 15 - 120 IU/ml |
| Specificity: Suitably modified Fc fraction of human IgG specific for IgM rheumatoid factors |

| FEATURES | BENEFITS |
|---|--|
| Latex based Fc fraction of aggregated human IgG reagent (R2) | High Specificity to heterospecific IgM - RF |
| Lot Specific Smart card | Secures master calibration, optimized mixing and accurate reading of reaction |
| Calibration traceable to WHO International reference preparation of Rheumatoid arthritis serum | Results aligned to International standards Good inter - method agreement in results |
| Convenient pack size of 20 tests | Facilitates complete utilization of reagent within stability period |
| Unique cuvette design | Secures optimized onboard mixing |
| Disposable Cuvettes | Secures no carryover effects, reduces labour and minimizes biohazard |

| Storage / Stability | Temperature | Duration |
|-------------------------|-------------|-----------|
| Unopened kit | 2-8°C | 12 months |
| In Use Stability | 2-8°C | 75 days |

| Available Pack Sizes |
|----------------------|
| 20 Tests |

| | |
|--------------------------|-----------------------|
| Suggested control | Turbodyne™ RF control |
|--------------------------|-----------------------|



TurbodyneTM CRP

Quantitative turbidimetric immunoassay for determination of C-Reactive Protein on Turbodyne SCTM

Intended Use:

TurbodyneTM CRP is used for the detection of inflammatory conditions, measuring the severity of conditions, differential diagnosis of bacterial and viral infections, also used for monitoring response to therapy.

TurbodyneTM CRP Kit components:

| | |
|--|--|
| TurbodyneTM CRP Activation Buffer (R1) | Ready to Use |
| TurbodyneTM CRP Latex Reagent (R2) | Ready to use uniform suspension of polystyrene latex particles coated with anti-CRP antibody. |
| TurbodyneTM CRP Smart Card | Smart card Calibration curve calibrated with a standard traceable to W.H.O. International Reference Standard (85/506) for Human C-reactive protein |
| Other Accessories | Package Insert & Cuvettes |

Performance Characteristics:

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|--|
| Measuring range: 0.6-10 mg/dl |
| Specificity: Anti-CRP antibodies of IgG class specific to CRP |

| FEATURES | BENEFITS |
|---|--|
| Ready to use uniform suspension of polystyrene latex particles coated with anti-CRP antibody (R2) | High Specificity to C - reactive protein |
| Lot Specific Smart card | Secures master calibration, optimized mixing and accurate reading of reaction |
| Calibrator traceable to International reference standard (85/506) for C - reactive protein | Results aligned to International standards Good inter - method agreement in results |
| Convenient pack size of 20 tests | Facilitates complete utilization of reagent within stability period |
| Unique cuvette design | Secures optimized onboard mixing |
| Disposable Cuvettes | Secures no carryover effects, reduces labour and minimizes biohazard |

| Storage / Stability | Temperature | Duration |
|---------------------|-------------|-----------|
| Unopened kit | 2-8°C | 12 months |
| In Use Stability | 2-8°C | 75 days |

| Available Pack Sizes |
|----------------------|
| 20 Tests |

| | |
|--------------------------|-------------------------------------|
| Suggested control | Turbodyne TM CRP control |
|--------------------------|-------------------------------------|



Turbodyne™ ASO

Quantitative turbidimetric immunoassay for determination of Antistreptolysin O on Turbodyne SC™

Intended Use: _____

Turbodyne™ ASO is used for detection of Group A streptococcal infection such as sore throat, rheumatic fever and rheumatic heart disease.

Turbodyne™ ASO Kit components:

| | |
|--|---|
| Turbodyne™ ASO Activation Buffer (R1) | Ready to Use |
| Turbodyne™ ASO Latex Reagent (R2) | Ready to use uniform suspension of polystyrene latex particles coated with stabilized Streptolysin 'O' |
| Turbodyne™ ASO Smart Card | Smart card Calibration curve that is traceable to the International standard for Anti-Streptolysin 'O' (97/662) |
| Other Accessories | Package Insert & Cuvettes |

Performance Characteristics:

| |
|---|
| Measuring range: 75-600 IU/ml |
| Specificity: Purified Streptolysin 'O' specific for Anti-Streptolysin 'O' antibodies |

| FEATURES | BENEFITS |
|---|--|
| Latex conjugated with Stabilized Streptolysin 'O' reagent (R2) | High Specificity to Antistreptolysin 'O' |
| Lot Specific Smart card | Secures master calibration, optimized mixing and accurate reading of reaction |
| Calibrator traceable to International reference standard for Antistreptolysin 'O' (97/662) | Results aligned to International standards Good inter - method agreement in results |
| Convenient pack size of 20 tests | Facilitates utilization of reagent within stability period |
| Unique cuvette design | Secures optimized onboard mixing |
| Disposable Cuvettes | Secures no carryover effects, reduces labour and minimizes biohazard |

| Storage / Stability | Temperature | Duration |
|-------------------------|-------------|-----------|
| Unopened kit | 2-8°C | 12 months |
| In Use Stability | 2-8°C | 75 days |

| Available Pack Sizes |
|----------------------|
| 20 Tests |

| | |
|--------------------------|------------------------|
| Suggested control | Turbodyne™ ASO control |
|--------------------------|------------------------|



Turbodyne™ MA

Quantitative turbidimetric immunoassay for determination of Microalbuminuria on Turbodyne SC™

Intended Use: _____

Turbodyne™ MA is used for the detection of Microalbuminuria.

Turbodyne™ MA Kit components:

| | |
|--|---|
| Turbodyne™ MA Activation Buffer (R1) | Ready to Use |
| Turbodyne™ MA Anti-Human Albumin Reagent (R2) | Ready to use solution of anti-human albumin antibody |
| Turbodyne™ MA Smart Card | Smart card with MA master calibration curve calibrated with a standard traceable to the IFCC reference material CRM 470 |
| Other Accessories | Package Insert & Cuvettes |

Performance Characteristics:

| |
|---|
| Measuring range: 25-400 mg/L |
| Specificity: Anti-human albumin antibody specific to human albumin |

| FEATURES | BENEFITS |
|---|--|
| Anti-human albumin reagent (R2) | High Specificity to human albumin |
| Lot Specific Smart card | Secures master calibration, optimized mixing and accurate reading of reaction |
| Calibrator traceable to IFCC reference preparation 'CRM 470' | Results aligned to International standards Good inter - method agreement in results |
| Convenient pack size of 20 tests | Facilitates utilization of reagent within stability period |
| Unique cuvette design | Secures optimized onboard mixing |
| Disposable Cuvettes | Secures no carryover effects, reduces labour and minimizes biohazard |

| Storage / Stability | Temperature | Duration |
|-------------------------|-------------|-----------|
| Unopened kit | 2-8°C | 12 months |
| In Use Stability | 2-8°C | 75 days |

| Available Pack Sizes |
|----------------------|
| 20 Tests |

| | |
|--------------------------|-----------------------|
| Suggested control | Turbodyne™ MA control |
|--------------------------|-----------------------|



Turbodyne™ IgE

Quantitative turbidimetric immunoassay for the estimation of Immunoglobulin E (IgE) in human serum on Turbodyne SC™

Intended Use: _____

Turbodyne™ IgE is used to determine if an allergic reaction is IgE mediated or non IgE mediated. IgE levels can increase in atopic diseases, neoplasm, immunodeficiencies and parasitic infections.

Turbodyne™ IgE Kit components:

| | |
|--|--|
| Turbodyne™ IgE Activation Buffer (R1) | Ready to Use |
| Turbodyne™ IgE Latex Reagent (R2) | Ready to use polystyrene latex particles coated with antihuman IgE |
| Turbodyne™ IgE Smart Card | Smart Card with IgE master calibration curve calibrated with a standard traceable to the Standard International Preparation of IgE 75/502 from WHO |
| Other Accessories | Package Insert & Cuvettes |

Performance Characteristics:

| |
|--|
| Measuring range: 30-600 IU/ml |
| Specificity: Anti-human IgE antibody specific to IgE in human serum |

| FEATURES | BENEFITS |
|---|--|
| Ready to use polystyrene latex particles coated with antihuman IgE (R2) | High Specificity to Immunoglobulin class IgE |
| Lot Specific Smart card | Secures master calibration, optimized mixing and accurate reading of reaction |
| Calibrator traceable to International reference preparation (WHO) of IgE 75/502 | Results aligned to International standards Good inter - method agreement in results |
| Convenient pack size of 20 tests | Facilitates utilization of reagent within stability period |
| Unique cuvette design | Secures optimized onboard mixing |
| Disposable Cuvettes | Secures no carryover effects, reduces labour and minimizes biohazard |

| Storage / Stability | Temperature | Duration |
|---------------------|-------------|-----------|
| Unopened kit | 2-8°C | 12 months |
| In Use Stability | 2-8°C | 75 days |

| Available Pack Sizes |
|----------------------|
| 20 Tests |

| | |
|--------------------------|------------------------|
| Suggested control | Turbodyne™ IgE control |
|--------------------------|------------------------|



Turbodyne™ Cystatin C

Quantitative turbidimetric immunoassay for Cystatin C on Turbodyne SC™

Intended Use: _____

Turbodyne™ Cystatin C is used for detection of Cystatin C. Serum Cystatin C is proposed to be an ideal endogenous marker for glomerular filtration rate (GFR) especially in patients with moderate to severe impaired renal impairment.

Turbodyne™ Cystatin C Kit components:

| | |
|---|---|
| Turbodyne™ Cystatin C Activation Buffer (R1) | Ready to Use |
| Turbodyne™ Cystatin C Latex Reagent (R2) | Ready to use uniform suspension of polystyrene latex particles coated with purified immunoglobulin fraction that is directed against Cystatin C |
| Turbodyne™ Cystatin C Smart Card | Smart card with Cystatin C calibration curve with a standard that has been validated against IFCC standard |
| Other Accessories | Package Insert & Cuvettes |

Performance Characteristics:

| |
|---|
| Measuring range: 0.5-8.0 mg/L |
| Specificity: Purified immunoglobulin fraction specific to Cystatin C |

| FEATURES | BENEFITS |
|--|---|
| Use of latex coated with purified immunoglobulin fraction directed against Cystatin C (R2) | High Specificity |
| Lot Specific Smart card | Secures master calibration, optimized mixing and accurate reading of reaction |
| Convenient pack size of 20 tests | Facilitates utilization of reagent within stability period |
| Unique cuvette design | Secures optimized onboard mixing |
| Disposable Cuvettes | Secures no carryover effects, reduces labour and minimizes biohazard |

| Storage / Stability | Temperature | Duration |
|---------------------|-------------|-----------|
| Unopened kit | 2-8°C | 12 months |
| In Use Stability | 2-8°C | 75 days |

| Available Pack Sizes |
|----------------------|
| 20 Tests |

| | |
|--------------------------|-------------------------------|
| Suggested control | Turbodyne™ Cystatin C control |
|--------------------------|-------------------------------|



Turbodyne™ HbA1c

Turbidimetric immunoassay for quantitative determination of HbA1c in human blood on Turbodyne SC™

Intended Use:

Turbodyne™ HbA1c is used for long term assessment of glycemic state of patients with diabetes and goals for therapy are set at specific HbA1c values. Turbodyne™ HbA1c is a turbidimetric immunoassay for direct determination of HbA1c in human blood without the need to estimate total hemoglobin.

Turbodyne™ HbA1c Kit components:

| | |
|---|--|
| Turbodyne™ HbA1c Latex Reagent (R1) | Ready to use uniform suspension of latex particles |
| Turbodyne™ HbA1c Antibody Reagent (R2) | Ready to use solution of mouse anti-human HbA1c and goat anti mouse IgG antibody |
| Turbodyne™ HbA1c Hemolysing Reagent | Ready to use solution |
| Turbodyne™ HbA1c Smart Card | Smart card with HbA1c calibration curve calibrated with a standards traceable to a NGSP National Glycohaemoglobin Standardisation Program) certified method that has documented traceability to the Diabetes control and Complications Trial (DCCT) reference method |
| Other Accessories | Package Insert & Cuvettes |

Performance Characteristics:

Measuring range: HbA1c in the concentration 5-15%

| FEATURES | BENEFITS |
|--|---|
| Direct results in % HbA1c | Directly measures % HbA1c without measuring total hemoglobin |
| Uses Monoclonal mouse antihuman HbA1c antibody | Accurate results, reacts only with HbA1c |
| Standardized using calibrators traceable to NGSP/DCCT | Results aligned to Reference Method |
| Lot Specific Smart card | Secures master calibration, optimized mixing and accurate reading of reaction |
| Convenient pack size of 20 tests | Facilitates utilization of reagent within stability period |
| Unique cuvette design | Secures optimized onboard mixing |
| Disposable Cuvettes | Secures no carryover effects, reduces labour and minimizes biohazard |

| Storage / Stability | Temperature | Duration |
|-------------------------|-------------|-----------|
| Unopened kit | 2-8°C | 12 months |
| In Use Stability | 2-8°C | 75 days |

| Available Pack Sizes |
|----------------------|
| 20 Tests |

| | |
|--------------------------|--------------------------|
| Suggested control | Turbodyne™ HbA1c control |
|--------------------------|--------------------------|