AutⓄPure®

Sphera System Packs
CRP TURBILATEX IFCC

Introduction

1. Autopure Turbilatex CRP is a reagent set for quantitative determination of C-Reactive Protein in human serum based on Turbidimetric method.
2. Autopure Turbilatex CRP is a two liquid reagent system using one step procedure.
3. Fresh serum sample is preferred. Samples with presence of fibrin should be centrifuged before testing.
4. Autopure Turbilatex CRP can be determined in just 2 minutes. CRP in serum is stable for 7 days at 2 -8° C and for 3 months at -20° C. Sample should be brought to room temperature before use.
5. Autopure Turbilatex CRP is linear upto 150 mg/L. Do not use highly haemolyzed or lipemic samples.

Principle

Autopure Turbilatex CRP contain latex particles coated with specific anti human CRP which reacts with CRP in the sample resulting in agglutination. Agglutination causes change in absorbance, measured at 600 nm & is proportional to the concentration of CRP in the sample.

Onboard Reagent Stability, Storage & Handling

On-Board Reagent Stability is 2-8°C at 60 Days. The kit components should be stored at 2-8°C and is stable till the expiry date indicated on the label. It is recommended to store the reagents at 2-8°C, tightly closed after use.

DO NOT FREEZE THE REAGENTS. Frozen Latex or Diluent could change the functionality of the test. Contamination of the reagents should be strictly avoided.

Components of Reagents

R1: Tris buffer
R2: Latex particles coated with anti - CRP antibody
CRP Calibrator (Value mentioned on vial label)

Specimen Collection & Preservation

Fresh serum sample is preferred, sample with fibrin should be centrifuge before test.
CRP in serum is stable for 7 days at 2-8°C and 3 months at -20°C
Sample should be brought at room temperature before use.
Do not use highly heamolyzed and lipemic sample

Procedure

Autopure CRP can be used in many other auto analyzer also.
The procedure describe below is for sphere analyzer.

Calculation

Fully automatic analyzer automatically calculate the result on the basis of calibrator value.

Application

Refer the application sheet for details. For other system application contact to local accurex representative.

Calibration

It's recommended to use Accurex kit provided calibrator only.

Calibration frequency
Recalibration is recommended when
1. Kit/reagent lot has changed.
2. Controls value are not is specification.

Quality Control

Each batch of AutoPure CRP is assayed with multiple quality control sera prior to release.

To ensure adequate quality control, it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.

It should be realized that the use of quality control material checks both the reagent and instrument functions together.
If the control values fall outside the specified limits, each of the below criteria should be cross-checked and corrected:

• Proper instrument function - Wavelength setting, light source and temperature control.
• Cleanliness of probes and cuvettes.
• Bacterial contamination of wash water used by the instrument.
• Expiry date of the reagent kit.

Expected Value

Normal: Upto 6 mg/L

Performance Characteristics

1. **Detection limit**: Values less than 2 mg/L give non-reproducible results.

2. **Prozone effect**: No prozone effect was detected up to 400 mg/L.

3. **Interferences**: Bilirubin (20 mg/dl), lipemia (10 g/L) and rheumatoid factors (300 IU/ml) do not interfere. Hemoglobin (>5g/L) interferes.

4. **Precision**: Reproducibility was determined using 2 levels of pooled human serum. The within run and between run reproducibility was determined as shown below:

Pooled Serum	Mean mg/L	% CV within run	% CV between run	N=30
Normal	4.54	3.54	4.53	
Abnormal	43.5	2.51	2.98	

5. **Linearity**: 150 mg/L

Correlation Studies

A comparison of CRP determined using Autopure CRP kit vs AGAPPE MISPA i-2 System and system give following correlation:

y = 1.098x - 0.3308
R² = 0.9998

References

1. Lars-Olof Hanson et al. Current Opinion In Infectious Diseases 1997; 10:196-201.
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6:139-144.
3. Young DS. Effects of drugs on clinical laboratory test, 4th ed.AACC Press, 1995.
4. Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987; 1:15-27.
5. Kari Pulki et al. Scand J Clin Lab Invest 1986; 46:606-607.
6. Werner Muller et al. Journal of Immunological Methods 1985; 80:77-90.
7. Shogo Otsuji et al. Clin Chem 1982; 28/10:2121-2124. Clinical Chemistry

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ISO 13485 CERTIFIED COMPANY C E

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Code:	ACRP	Category:	Open	Group:	ACCUREX 2
Name:	ACRP	Type:	Fixed time		

Calibration	Reagent blank	Correlation	Settings		Edit

General   Number of standards: 1
Validity (hours): 360

Reagent blank   Validity 360 hours
Blank correction [1]

Standards	Single	Calibrator	Dilution rate	Lot	Primary concent	Final concent	Reps.
1	CRPCAL		1	20200930	60.0000	60.0000	2

ACRP

Category: Open
Double click category to edit
Version date: 4/3/2023 3:26:01 PM
Type: Fixed time
Name: ACRP
Version: 1
Group: ACCUREX 2

REAGENTS

Reagent 1 ID: CRP1
Reag 1 bottle: Large
Reagent 2 ID: CRP2
Reag 2 bottle: Small

PIPETTING

Type: R1 + R2 / S
Sample vol: 2 µL
Reagent 1 vol: 240 µL
Reagent 2 vol: 60 µL

TIME

Incubation 1: 145 sec
Incubation 2: 29 sec
Reading: 116 sec

DILUTION

Serum
☑ 1:1 ☐ 1:2 ☐ 1:4
☐ 1:10 ☐ 1:100 ☐ 1:40
Custom rate: 40
QC dilution: 1

Urine
☐ 1:1 ☐ 1:2 ☐ 1:4
☐ 1:10 ☐ 1:100 ☐ 1:40
Custom rate: 40
QC dilution: 1
Diluent vol: 5 µl

WAVELENGTHS

Wavelength 1: 600 nm

WASHING

Needle: 3
Cuvette: 3
Use cleaning solution [1]
Needle post-wash: 0

LIMITS

Blank OD min: 0.4 Abs
Blank OD max: 0.9 Abs
Reaction slope: Positive
Calibration slope: Positive
OD Range min: 0 Abs
OD Range max: 2.5 Abs
Blank OD Δ max: 0 Abs
Min conc: 0 mg / L
Max conc: 150 mg / L

UNITS

Units 1: mg / L
Units 2:
Units 3:
Decimal digits: 2
Target molecule:
Display as inhibition: 0

AUTODILUTION

Enable autodilution [1]
Rate: 4
Max OD: 0 Abs
Max Conc: 150 mg / L
Min Conc: 0 mg / L

REFLEX

Enable reflex: 0
Method:
Limit type: Deactivated
Conc. limit: 0 mg / L

OUTLIERS

Max. curve deviation: 5 %

PATHOLOGICAL RANGES

Mini...	Sample type	Maximu...
0 mg / L		6 mg / L

| Add | Remove | Edit |