respons®920

Immunoglobulin E FS*

Order Information

Cat. No.	Kit size
1 7239 99 10 921	Σ 320 (4 x 80)

Intended Use

Diagnostic reagent for quantitative in vitro determination of immunoglobulin E (IgE) in human serum or heparin plasma on automated DiaSys respons®920.

Summary

The human immunoglobulin classes (IgG, IgA, IgM, IgE and IgD) are a group of functionally and structurally closely related glycoproteins. Human IgE has a molecular weight of about 190 000 dalton and consists of two identical heavy chains and two identical light chains which are bound together by disulfide bonds in a characteristic Y-shaped form. The original function of IgE is the specific defense of parasites. In the developed countries, it plays a major role in the mediation of immediate type hypersensitivity reactions (type I according to Coombs and Gell). Harmless, polyvalent antigens (pollen, house dust mites), stimulate B cells at the site of entry to synthesize specific IgE which in part binds to mast cells. The half life of unbound IgE is 2 – 3 days while mast cell-bound IgE has a half-life from months to years. During the next contact of the antigen with the sensitized mast cell, bound IgE are cross-linked. The cell is degranulated and mediators (mainly histamine) are released which cause, for example, symptoms of hay fever, asthma, and atopic eczema. Elevated IgE levels occur in atopic diseases, parasitic infection, diseases with T cell dysfunction (e.g. AIDS), certain malignant tumors (respiratory tract, gastrointestinal tract), hyper-IgE syndrome, graft-versus-host disease, and in severe burns. Measurement of total IgE is mainly conducted to diagnose of atopic diseases where highly increased IgE levels may occur. IgE testing is a good tool especially in differential diagnostic examination of clinical pictures with possible allergic background [1].

Method

Particle enhanced immunoturbidimetric test

Determination of IgE concentration by photometric measurement of antigen antibody reaction of latex particles coated with antibodies to human IgE with IgE present in the sample.

Reagents

Components and Concentrations

R1:	Glycine	pH 8.3	170 mmol/L
	NaCl		100 mmol/L
R2:	Glycine	pH 7.3	170 mmol/L
	NaCl		100 mmol/L
	Latex particles coated with anti-human IgE monoclonal antibody (mouse)		1.3 g/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

Warnings and Precautions

1. The reagents contain sodium azide (< 0.1%) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. Heterophile antibodies in patient samples may cause falsified results.
5. In very rare cases, samples of patients with gammopathy might give falsified results [2].
6. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Stability [3]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
6 months	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal IgE calibrator set is recommended for calibration. Calibrator values have been made traceable to the WHO Reference Material NIBSC 75/502. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal IgE	1 7230 99 10 059	5 x 1 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range from 35 up to 900 IU/mL, depending on the concentration of the highest calibrator. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	10 IU/mL
No prozone effect up to 17000 IU/mL.	
Onboard stability	30 days
Calibration stability	7 days

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [IU/mL]
Bilirubin (conjugated)	60 mg/dL	54.4
	60 mg/dL	197
Bilirubin (unconjugated)	60 mg/dL	56.4
	60 mg/dL	191
Hemoglobin	1000 mg/dL	86.1
	1200 mg/dL	151
Lipemia (triglycerides)	400 mg/dL	50.1
	1600 mg/dL	176
For further information on interfering substances refer to Young DS [4,5],		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [IU/mL]	82.2	119	482
CV [%]	2.34	2.16	1.47
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [IU/mL]	81.3	120	484
CV [%]	3.33	2.41	2.29

Method comparison (n=89)	
Test x	DiaSys Immunoglobulin E FS (Hitachi 917)
Test y	DiaSys Immunoglobulin E FS (respons®920)
Slope	0.972
Intercept	8.68 IU/mL
Coefficient of correlation	0.997

** according to CLSI document EP17-A, Vol. 24, No. 34

Reference Range [6,7]

Age group	Upper limit of the normal range (95th percentile)
Newborns	1.5 IU/mL
1st year	15 IU/mL
1 – 5 years	60 IU/mL
6 – 9 years	90 IU/mL
10 – 15 years	200 IU/mL
Adults	100 IU/mL

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 667-78,774-85.
2. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240-1243.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 34-5.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
5. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in September 2021. Published by AACC Press and John Wiley and Sons, Inc.
6. Ringel KP, Dati F, Buchholz E. IgE-Normalwerte bei Kindern, Laboratoriumsblätter 1982;32:26-34.
7. Dati F, Ringel KP. Reference values for serum IgE in healthy non-atopic children and adults. Clin Chem 1982; 28:1556.

IVD CE

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* Fluid Stable

respons®920

Immunoglobulin E FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	IgE				Auto Rerun	:	☐
Report Name	:	Immunoglobulin E				Total Reagents	:	2
Unit	:	IU/mL	Decimal Places	:	1	Reagent R1	:	IgE R1
Wavelength-Primary	:	578	Secondary	:	0	Reagent R2	:	IgE R2
Assay Type	:	2 – point	Curve Type	:	4P Logit-Log			
M1 Start	:	18	M1 End	:	18	**Consumables/Calibrators:**		
M2 Start	:	28	M2 End	:	28	Blank /Level 0		0
Sample Replicates	:	1	Standard Replicates	:	3	Calibrator 1		**
Control Replicates	:	1	Control Interval	:	0	Calibrator 2		**
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator 3		**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator 4		**
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.0000	Calibrator 5		**
Technical Minimum	:	*	Technical Maximum	:	*			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Technical Limits are automatically defined by software via upper and lower calibrator level.
** Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	IgE		
Sample Type	:	Serum		

Sample Volumes

Normal	:	3.00 µL	Dilution Ratio	:	1	X
Increase	:	6.00 µL	Dilution Ratio	:	1	X
Decrease	:	3.00 µL	Dilution Ratio	:	6	X
Standard Volume	:	3.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160 µL	R1 Stirrer Speed	:	Low
RGT-2 Volume	:	80 µL	R2 Stirrer Speed	:	Low

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	IgE		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (IU/mL)	Upper Limit (IU/mL)
Normal	:	0.00	100.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other