MAYO CLINIC LABORATORIES

Test Definition: EDN

Eosinophil Derived Neurotoxin, Serum

Overview

Useful For

Evaluating patients suspected to have a condition associated with eosinophilia or hypereosinophilia

Evaluating patients with elevated peripheral blood eosinophil counts

Managing patients with elevated eosinophil-derived neurotoxin in the context of eosinophil-associated diseases

Method Name

Fluorescence Enzyme Immunoassay (FEIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial within 12 hours of collection. Serum cannot sit on either gel or cells for longer than 12 hours.

Specimen Minimum Volume

0.3 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK
Heat-treated specimen	Reject

If serum is on cell pellet or gel for >12 hours	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	21 days	

Clinical & Interpretive

Clinical Information

Eosinophils are a type of white blood cell (WBC) that derives from myeloid progenitor cells.(1) They are a critical part of the immune response to helminth and other infections and play a significant role in allergic diseases. Eosinophils are characterized by their cytoplasmic granules, which appear dark red when stained with eosin. These cytoplasmic granules contain a number of cytotoxic proteins, including major basic protein, eosinophil cationic protein, and eosinophil-derived neurotoxin (EDN). Upon activation, eosinophils degranulate, with subsequent release of these proteins into the extracellular space. These proteins exhibit a variety of activities, with EDN being a ribonuclease having antiviral activity. Eosinophils generally comprise less than 5% of the total WBC count. Eosinophilia and hypereosinophilia are defined by elevated numbers of eosinophils in the peripheral blood at 500/mcL and above and 1500/mcL and above, respectively. Apart from situations of a normal immune response, elevated eosinophil numbers can be found in allergy, asthma, malignancies, immunodeficiencies, autoimmune diseases, and eosinophilic disorders. In some cases, peripheral blood eosinophil counts may not accurately reflect elevated numbers of eosinophils found in tissues; absolute counts also do not indicate the level of eosinophil activation and degranulation. EDN concentrations have been shown to correlate with peripheral blood eosinophil counts and may provide additional information related to activation status.(2,3)

Reference Values

<70 mcg/L: Normal
70-99 mcg/L: Borderline
> or =100 mcg/L: Elevated
Reference values apply to all ages.

Interpretation

Eosinophil-derived neurotoxin (EDN) concentrations greater than or equal to 100 mcg/L, in the presence of elevated numbers of peripheral blood or tissue-resident eosinophils, may be suggestive of inflammation or increased disease activity in patients with eosinophil-associated diseases.

In the context of normal eosinophil counts, EDN concentrations greater than 70 mcg/L may indicate cellular activation and degranulation.

In the context of elevated eosinophil counts, EDN concentrations less than or equal to 70 mcg/L may indicate limited or

absent cellular activation.

Cautions

Prolonged contact of serum with the cell pellet can lead to increased concentrations of serum eosinophil-derived neurotoxin (EDN). Serum should be aliquoted into a plastic vial immediately (within 12 hours) after centrifugation.

Elevated concentrations of EDN are not diagnostic for any specific condition and should be correlated with other laboratory data and clinical information.

Normal EDN concentrations do not exclude the possibility of eosinophilia or hypereosinophilia.

Supportive Data

An internal study evaluated the correlation between serum eosinophil-derived neurotoxin (EDN) concentrations and peripheral blood eosinophil counts. A cohort of samples that spanned the measurement range for absolute eosinophil counts were collected (n=110). When samples were stratified according to clinical cutoffs for eosinophil counts, a significant difference in EDN concentrations between normal (median: 43.8, 95% CI: 32.8–54.0 mcg/L, n=40) and elevated (median: 120.0, 95% CI: 95.4–149.0 mcg/L, n=70) groups ($p<0.0001$) was observed. Moreover, the three samples that were considered hypereosinophilic (>1.5 x 10(9) cells/L) all had very high concentrations of EDN (median: 200 mcg/L). A receiver operating characteristic (ROC) analysis demonstrated an area under the curve of 0.841 in assessing overall sensitivity and specificity of EDN for eosinophilia. Based on the ROC curve, borderline and abnormal cutoffs were selected at 70 mcg/L and 100 mcg/L, respectively. Both cutoffs demonstrated a specificity of 85% for eosinophilia. However, the cutoff of 70 mcg/L had an improved sensitivity of 74.3% compared to 100 mcg/L with a sensitivity of 57.1%.

Clinical Reference

1. Wechsler ME, Munitz A, Ackerman SJ, et al: Eosinophils in health and disease: A state-of-the-art review. Mayo Clin Proc. 2021 Oct;96(10):2694-2707
2. Rutten B, Young S, Rhedin M, et al: Eosinophil-derived neurotoxin: A biologically and analytically attractive asthma biomarker. PLoS ONE. 2021 Feb 10;16(2):e0246627
3. Rydell N, Nagao M, Ekoff H, et al: Development of an automated ImmunoCAP research assay for eosinophil derived neurotoxin and its use in asthma diagnosis in children. Pract Lab Med. 2019 Sep 19;17:300138

Performance

Method Description

Anti-eosinophil derived neurotoxin (EDN) antibodies, covalently bound to ImmunoCAP, bind to EDN in the patient sample. After washing, enzyme labeled antibodies against EDN are added to form a complex. Following incubation, the unbound enzyme labelled anti-EDN antibodies are washed away, and the bound complex is incubated with a developing agent. After the reaction has been stopped, the fluorescence of the eluate is measured. The response value correlates to the amount of EDN in the sample and a calibration curve is used to transform the response values to concentrations.(Package insert: Phadia ImmunoCAP EDN Assay Kit. Thermo Scientific; Rev 09/2020)

PDF Report

No

Day(s) Performed
Tuesday

Report Available
2 to 8 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
83520

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
EDN	Eosinophil Derived Neurotoxin, S	100976-0

Result ID	Test Result Name	Result LOINC® Value
EDN	Eosinophil Derived Neurotoxin, S	100976-0