HOTLINE: Effective February 16, 2021

New Test **2011967** **Allergens, Pediatric, Common Profile IgE** **COMPEDPRO**

Methodology: Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay
Performed: Sun-Sat
Reported: 1-2 days

Specimen Required: Patient Prep: Multiple patient encounters should be avoided.
Collect: Serum separator tube. Multiple specimen tubes should be avoided.
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1.35 mL serum to an ARUP Standard Transport Tube. (Min: 0.69 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year

Reference Interval:

Reporting Range (reported in kU/L)	Probability of IgE Mediated Clinical Reaction	Class Scoring
Less than 0.10	No significant level detected	0
0.10 - 0.34	Clinical relevance undetermined	0/1
0.35 - 0.70	Low	1
0.71 - 3.50	Moderate	2
3.51 - 17.50	High	3
17.51 - 50.00	Very high	4
50.01 - 100.00	Very high	5
Greater than 100.00	Very high	6

Test Number	Components	Reference Interval	
0050345	Immunoglobulin E	Effective November 17, 2014	
		Age	**Reference Interval**
		0-5 months	13 kU/L or less
		6-12 months	34 kU/L or less
		1-2 years	97 kU/L or less
		3 years	199 kU/L or less
		4-6 years	307 kU/L or less
		7-8 years	403 kU/L or less
		9-12 years	696 kU/L or less
		13-15 years	629 kU/L or less
		16-17 years	537 kU/L or less
		18 years and older	214 kU/L or less

Interpretive Data:
Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis**.**

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: Allergens included: Cat Dander, American Cockroach, Codfish, Dog Dander, Egg White, D. farinae, Alternaria alternata (tenuis), Milk (Cow), Peanut, Soybean, Wheat, and IgE Serum Total.

CPT Code(s): 86003 x11; 82785

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.