

**K242531 NOVEOS Specific IgE (sIgE) Assay**Apr 23, 2025  
240 days to decisionK242531 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k242531/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Aug 26, 2024
Decision date	Apr 23, 2025
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Capture Reagent G010, Johnson Grass (Sorghum halepense); Capture Reagent T007, Oak (Quercus alba) ; Capture Reagent G002, Bermuda Grass (Cynodon dactylon); Capture Reagent W001, Common Ragweed (Ambrosia artemisiifolia); Capture Reagent E005, Dog Dander (Canis familiaris); Capture Reagent T003, Common Silver Birch (Betula verrucosa); Capture Reagent F001, Egg White (Gallus gallus); Capture Reagent F002, Cow's Milk (Bos taurus); NOVEOS Immunoassay Analyz

**APPLICANT**

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Company	<b>Hycor Biomedical</b>
Location	Garden Grove, CA, US
Contact	Aashrey Kaul
510(k) history	7 submissions · 7 cleared · 2018-2026

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242531/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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