

**K260095 Heal-Check Rapid COVID-19 Antigen Self-Test**Apr 13, 2026  
90 days to decisionK260095 · Product code: **QYT** · Microbiology  
Source: <https://www.510kdatabase.net/k260095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	Jan 13, 2026
Decision date	Apr 13, 2026
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Healgen Scientific, LLC</b>
Location	Houston, TX, US
Contact	Bingliang Fang
Website	<a href="https://www.healgen.com">https://www.healgen.com</a>
510(k) history	27 submissions · 27 cleared · 2012-2026

Healgen Scientific, LLC is a leading in-vitro diagnostics (IVD) developer and manufacturer based in Houston, Texas. Established in 2007, the company specializes in high-quality diagnostic testing technologies across multiple therapeutic areas. Healgen has achieved FDA 510(k) clearances from total submissions since 2012, with no denied submissions on record. The company's regulatory portfolio is dominated by toxicology devices, including drug screening and fentanyl detection products, alongside offerings in chemistry, microbiology, and infectious disease diagnostics. The I...