

**K252523 Healgen® Accurate Oral Fluid Drug Test COT/THC**Feb 12, 2026  
185 days to decisionK252523 · Product code: **NFW** · Toxicology  
Source: <https://www.510kdatabase.net/k252523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cannabinoid, Over The Counter (NFW)
Date received	Aug 11, 2025
Decision date	Feb 12, 2026
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Healgen® Accurate Oral Fluid Drug Test

**APPLICANT**

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Company	<b>Healgen Scientific, LLC</b>
Location	Houston, TX, US
Contact	Jianqiu 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 l...

**REGULATORY CONSULTANT**

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Consulting firm	<b>LSI International, Inc.</b>
Contact	Jenny Xia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k252523/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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