

**K123703 HEALGEN HCG ONE STEP PREGNANCY TEST  
(STRIP), HEALGEN HCG ONE STEP PREGNANCY TEST  
(CASSETTE)**Apr 10, 2013  
128 days to decisionK123703 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k123703/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Dec 3, 2012
Decision date	Apr 10, 2013
Days to decision	128 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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