

**K111999 HEALGEN 11 REAGENT STRIP FOR URINALYSIS,  
HEALGEN 10 REAGENT STRIP FOR URINALYSIS, AND  
HEALGEN 4 REAGENT STRIP FOR URINAL**Apr 17, 2012  
279 days to decisionK111999 · Product code: **JIO** · Chemistry  
Source: <https://www.510kdatabase.net/k111999/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood, Occult, Colorimetric, In Urine (JIO)
Date received	Jul 13, 2011
Decision date	Apr 17, 2012
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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