

**FDA website: Healgen is FDA authorized**

Device Name	Authorization Status	Clearance Type
Hangzhou Realy Tech Co Ltd. 2019-nCoV IgG/IgM Rapid Test	Not FDA Authorized	H
Hangzhou Sejoy Electronics & Instrument Co., Ltd. COVID-19 IgG/IgM Rapid Test Cassette	Not FDA Authorized	H
Healgen Scientific, LLC. COVID-19 IgG/IgM Rapid Test Cassette(Whole Blood/Serum/Plasma)	FDA Authorized	H, M
HUMASIS Co., Ltd. Humasis COVID-19 IgG/IgM Test	Not FDA Authorized	H
INNOVITA (Tangshan) Biological Technology Co., Ltd. 2019-nCoV Ab Test (Colloidal Gold)	Not FDA Authorized	H

**FDA website: Healgen is Zhejiang Orientgene US Affiliate**

# Product Registration & Device Listing

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**Establishment:**  
ZHEJIANG ORIENT GENE BIOTECH

**Business Trade Name:**  
Healgen

3787 East Yangguang Avenue  
Dipu Street, Anji  
Huzhou Zhejiang, CN 313300  
**Registration Number:** 3008517993  
**FEI Number\*:** 3008517993  
**Status:** Active  
**Date Of Registration Status:** 2020

**Owner/Operator:**  
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\* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set