

FDA website: Healgen is FDA authorized

Device Name	Authorization Status	Device Class
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

Device 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