Helix® COVID-19 Test System

*An end-to-end, highly scalable solution to detect active COVID-19 infections and enable safe return to the workplace*

Fully staffed, centrally located clinical testing site in San Diego

Easy, self-collected lower nasal swab with healthcare professional (HCP) supervision

Results available next day (after sample collection)

Results directly to ordering HCP and employee; summary report to employer

How it works

**Program set-up**
- Define testing plan (frequency, eligibility)
- Share list of employees with Helix
- Send Helix program overview and FAQs to all eligible employees

**Sample collection**
- At designated time, employee goes to Helix San Diego drive-thru site
- Helix coordinates HCP test order
- HCP supervises self-collection via lower nasal swab

**Clinical testing**
- Samples are transferred to Helix’s CLIA / CAP laboratory
- Processed on the Helix® COVID-19 test
- Results available by end of the next day after the sample is collected

**Return of results**
- Results returned directly to HCP and employee
- Employer receives summary results, including positives
- Reporting to public health agencies as required

Testing plan: Key factors to consider

- Impact of an undetected COVID-19 infection on employee health and business operations
- Level of transmission among employees and in the local community
- Occupational risk, including need to interact in person with the public, ability to maintain physical distancing, work with vulnerable populations
- Risk profile of employee population relative to general population

When deciding who to test, employers should consult with a healthcare professional and monitor guidance from the CDC and state and local public health officials

Interested in learning more? Visit helix.com/covid or get in touch at covid@helix.com
Bringing our extensive experience in high volume genomic testing to expand access to sensitive and scalable tests for COVID-19

The Helix® COVID-19 Test

Clinical Performance Studies

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<tbody>
<tr>
<td>Sensitivity (PPA)</td>
<td>100% (92.9 - 100%)</td>
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<tr>
<td>Specificity (NPA)</td>
<td>100% (89.8 - 100%)</td>
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- The SARS-CoV-2 assay is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory nasopharyngeal (NP), anterior nares (AN) and oropharyngeal (OP) swab specimens from individuals suspected of COVID-19 by their healthcare provider
- Visit helix.com/covid for more information

The Helix Laboratory

- High-complexity, CLIA-certified, CAP-accredited facility with a demonstrated track record of powering high-volume clinical projects
- Helix's barcoded collection system allows for rapid and error free accessioning
- Highly automated and capable of accessioning up to 10,000 samples per day; able to scale beyond as needed

CLIA #05D2117342, CAP #9382893

Pricing

- Prices include:
  - Fully kitted collection system
  - HCP ordering and supervision of sample collection
  - Processing in the Helix Laboratory, with next day turnaround time
  - Return of results to the ordering HCP and employee, and summary results to the employer
- Volume-based pricing requires three month commitment

<table>
<thead>
<tr>
<th># of samples / week</th>
<th>Price / sample</th>
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<tbody>
<tr>
<td>Ad hoc</td>
<td>$125</td>
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<tr>
<td>&lt;100</td>
<td>$100</td>
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<tr>
<td>100 – 499</td>
<td>$95</td>
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<tr>
<td>500+</td>
<td>$90</td>
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Limitations of the Helix COVID-19 Test

- This test has not been FDA cleared or approved
- This test has been validated in accordance with the FDA's Guidance Document (Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency). FDA independent review of this validation and issuance of an Emergency Use Authorization (EUA) is pending.

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