



CIDEX™ OPA SOLUTION

EFFECTIVENESS AGAINST
DISEASE-CAUSING
MICROBES

MAIN POINTS

- Five studies have evaluated the effectiveness of CIDEX™ OPA Solution against:
 - ✓ More than 200 strains of bacteria, including antibiotic-resistant strains
 - ✓ Mycobacteria
 - ✓ Spore-forming bacteria
 - ✓ Viruses (CIDEX™ OPA has been directly tested against HUMAN CORONAVIRUS, and has been demonstrated to be effective)
 - ✓ Fungi¹⁻⁵
- CIDEX™ OPA Solution kills everything tested except spores very quickly, even under rigorous testing.¹⁻⁵
- CIDEX™ OPA Solution remains effective in the presence of blood and organic matter.^{2,3}

PURPOSE

The purpose of this document is to provide a review of scientific findings on the killing efficacy of CIDEX™ ortho-phthalaldehyde (OPA) Solution. Five research studies have been reviewed and summarized. Several additional sources were used to provide background information.

Introduction and Background

Healthcare-Associated Infections

In 2015, 687,000 healthcare-associated infections occurred in the U.S.⁶ These infections resulted in approximately 72,000 deaths, and are one of the most frequent “adverse medical events” in the U.S.⁶

“

A comprehensive review of the medical literature suggests that transmission of infection resulting from gastrointestinal endoscopy is an extremely rare event, and has invariably been associated with a breach in cleaning protocols or defective equipment.”⁸



CIDEX™ OPA SOLUTION

CIDEX™ OPA Solution is a high-level disinfectant (HLD) with low odor and is highly compatible with medical materials.^{1, 2, 8} It was developed by Johnson & Johnson Medical Inc. and cleared for use in the U.S. in 1999.⁹ Scientists have studied the effectiveness of CIDEX™ OPA Solution and have found it to be effective at killing a broad spectrum of bacteria and other disease-causing organisms.^{1-5, 8-9}

STUDY METHODS

While the exact testing methods varied between studies, the same general steps were taken in all five research studies.

1. Disease-causing microorganisms (microbes) were obtained either from stock laboratory supplies or from hospitalized patients.
2. Microbes were grown.
3. Microbes on inoculated carriers or in suspension were exposed to CIDEX™ OPA Solution for a set amount of time.
4. Tests were performed to measure microbe survival after exposure to CIDEX™ OPA Solution.¹⁻⁵

LOG₁₀ REDUCTIONS

The effectiveness of HLD is often measured in log₁₀ reduction factors.^{1, 3-5}

To illustrate the concept of log₁₀ reduction factors, imagine that there are 5 million bacteria contaminating a medical instrument.

- If disinfected with an HLD with a log₁₀ reduction factor of 5.0, 50 bacteria will remain
- If disinfected with an HLD with a log₁₀ reduction factor of 4.0, 500 bacteria will remain
- If disinfected with an HLD with a log₁₀ reduction factor of 3.0, 5,000 bacteria will remain

In other words, a one-unit increase on the log₁₀ scale indicates an increase in killing effectiveness of 10 times.

CIDEX™ OPA SOLUTION

EFFECTIVENESS AGAINST VEGETATIVE BACTERIA

The effectiveness of CIDEX™ OPA Solution has been tested against many vegetative bacteria. See Table 1.

Table 1.
Vegetative Bacteria Killed by CIDEX™ OPA Solution

<i>Acinetobacter baumannii</i>
<i>Acinetobacter</i> species unspecified
<i>Enterobacter cloacae</i> isolated from a patient
<i>Enterobacteriaceae</i> isolated from a patient
<i>Enterococcus faecalis</i>
– Laboratory strain
– Isolates from patients
<i>Escherichia coli</i>
– 2 laboratory strains
– Isolates from patients
<i>Helicobacter pylori</i>
– 2 laboratory strains
<i>Klebsiella pneumoniae</i>
<i>Proteus mirabilis</i>
<i>Pseudomonas aeruginosa</i>
– 2 laboratory strains
– Isolates from patients
<i>Serratia marcescens</i>
<i>Staphylococcus</i> species unspecified
<i>Staphylococcus aureus</i>
– 2 laboratory strains
– Isolates from patients
<i>Stenotrophomonas maltophilia</i>
<i>Streptococcus</i> species unspecified
<i>Staphylococcus epidermidis</i>
<i>Xanthomonas maltophilia</i>

In three studies, CIDEX™ OPA Solution was highly bactericidal against all vegetative, non-spore forming microbes.^{1, 2, 4}

In two studies by Herruzo-Cabrera, both laboratory stock strains and patient-isolated strains of bacteria were utilized, and CIDEX™ OPA Solution was able to reduce the bacterial load by greater than 10,000 times (log10 reduction factors of 4.63 and 4.7) within 10 minutes.^{1, 4}

According to Akamatsu, CIDEX™ OPA Solution eliminated all viable cells for 11 different strains of bacteria in 15 seconds or less.² In addition, CIDEX™ OPA Solution remained bactericidal and fast-acting in the presence of human serum for all of the 11 organisms tested.²

Another study was designed to represent a “worst case scenario” by using:

- Rough-surfaced instruments.
- Inoculating the instrument with both lab and freshly isolated strains of bacteria and fungi from ICU patients.
 - Over 200 strains were tested, including 66 strains of *P. aeruginosa*, some of which were resistant or multiple drug-resistant
 - *P. aeruginosa* can cause respiratory infections in patients who have endoscopy procedures, and it can often survive high-level disinfection.¹

CIDEX™ OPA Solution easily killed all of the microbes tested with the exception of *P. aeruginosa*. While OPA was not able to kill all of the *P. aeruginosa* strains, it was still able to effectively kill 77% of 44 clinical isolates after 10 minutes of exposure.¹

When CIDEX™ OPA Solution was compared to other HLDs, CIDEX™ OPA Solution was often faster and more effective.

- In one study, CIDEX™ OPA Solution was twice as fast as glutaraldehyde (GTA) at eliminating 11 strains of bacteria.²
- In another study, CIDEX™ OPA Solution killed a higher percentage of microbes than Perasafe (92% vs. 74%).⁴ (see Figure 1)

Percent of 54 Microbial Species Completely Killed by HLD Sorce: Herruzo-Cabrera et al. (2006)

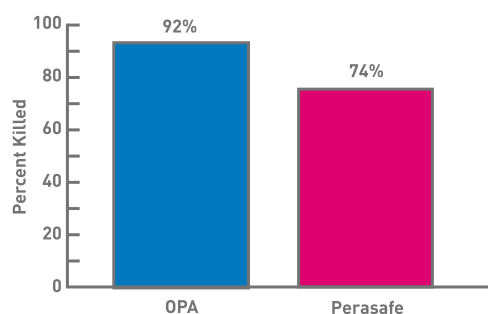


Figure 1. Percent of species killed by CIDEX™ OPA Solution and Perasafe

CIDEX™ OPA SOLUTION

EFFECTIVENESS AGAINST MYCOBACTERIA

“CIDEX™ OPA, at a concentration of 0.55%, shows excellent mycobactericidal activity within 10 min... In comparison, 2% GTA requires at least 20 min to be effective (this time period is even longer for some mycobacteria, e.g. *M. avium* intracellulare). These findings would vindicate substitution of 2% GTA with 0.55%”¹

CIDEX™ OPA SOLUTION EFFECTIVENESS AGAINST MYCOBACTERIA



Figure 2. Close-up of a Mycobacterium tuberculosis growth

Image Source: Public Health Image Library

Mycobacteria cause healthcare-related infections.³ *M. tuberculosis* infections can occur from improperly disinfected endoscopes and bronchoscopes. In addition, *M. chelonae* has been implicated in hospital-acquired infections.³

CIDEX™ OPA Solution has been shown to kill mycobacteria in multiple studies.^{1,3,4}

→ In one study:

- CIDEX™ OPA Solution reduced the number of mycobacteria by a factor greater than 10,000 (log10 reduction factor of 4.3) after 10 minutes of exposure.⁴
- CIDEX™ OPA Solution was more effective at killing mycobacteria than Perasafe.⁴

→ In another study, CIDEX™ OPA Solution was shown to be faster acting against mycobacteria than GTA.³ (See Figure 3)

Time to Kill Mycobacteria Species by HLD under “Clean” Conditions (without serum)

(Source: Fraud et al. (2001))

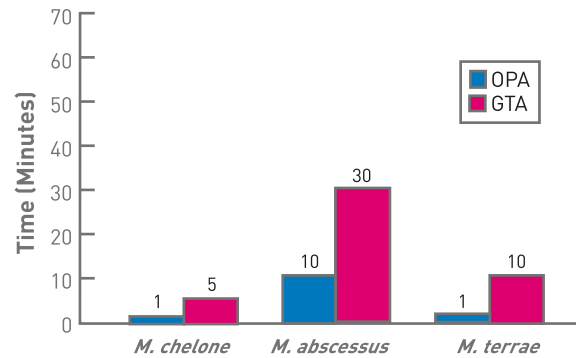


Figure 3. Killing time of Mycobacteria by CIDEX™ OPA Solution and GTA in “clean” conditions

The addition of serum did not affect the efficacy of CIDEX™ OPA Solution against the tested mycobacteria.^{2,3} It did, however, increase the amount of time required for GTA disinfection, doubling the required time for two of the species.³ (See Figure 4).

Time to Kill Mycobacteria Species by HLD under “Dirty” Conditions (without serum)

(Source: Fraud et al. (2001))

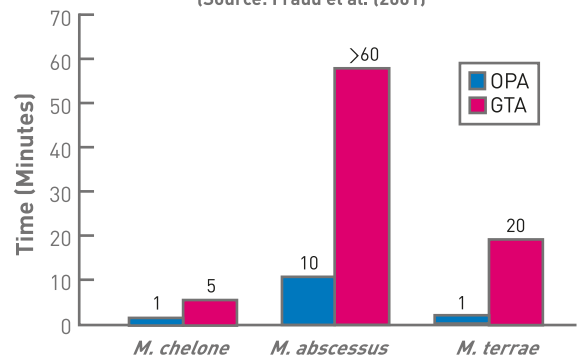


Figure 4. Killing time of Mycobacteria by CIDEX™ OPA Solution and GTA in “dirty” conditions

“Results showed that 0.5% acidic and alkaline CIDEX™ OPA were rapidly mycobactericidal, under both ‘clean’ and ‘dirty’ conditions, and more importantly were active against GTA-resistant strains.”³

CIDEX™ OPA SOLUTION

EFFECTIVENESS AGAINST SPORES AND VIRUSES

The effectiveness of CIDEX™ OPA Solution has been tested against several mycobacteria. See Table 2.

Table 2
Mycoacteria Killed by CIDEX™ OPA Solution

<i>Mycobacterium abscessus</i>
<i>M. avium</i>
– 2 laboratory strains
– a patient isolate
<i>M. chelonae</i>
– Laboratory strain
– a patient isolate
– 2 Laboratory strains resistant to GTA
<i>M. fortuitum</i>
– 2 laboratory strains
<i>M. kansasii</i>
<i>M. smegmatis</i>
<i>M. terrae</i>
<i>M. tuberculosis</i>
– 2 laboratory strains

CIDEX™ OPA Solution can also kill GTA-resistant mycobacteria, such as *M. chelonae* (Epping) and *M. chelonae* (Harefield).³ These organisms were eliminated by CIDEX™ OPA Solution within two minutes or less in both clean and dirty conditions.³

CIDEX™ OPA SOLUTION EFFECTIVENESS AGAINST SPORES AND SPORE-FORMING BACTERIA

Because HLDs are not required to eliminate spores (only sterilization completely eliminates spores⁹), there are limited data about the efficacy of CIDEX™ OPA Solution against them. The effectiveness of CIDEX™ OPA Solution has been tested against the two spore-forming bacteria.

Figure 5. An electron micrograph of *Bacillus subtilis* cells

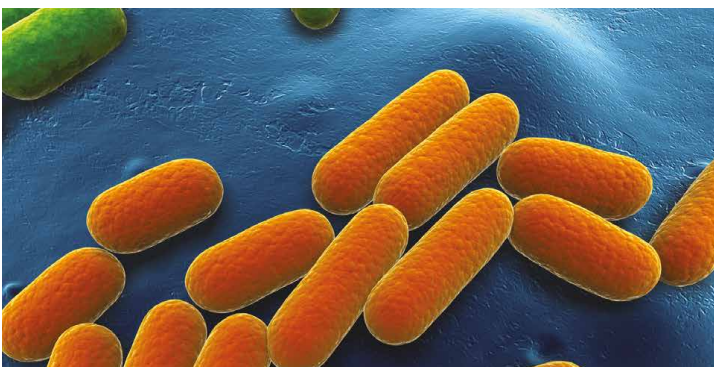


Table 3
Spores Reduced by CIDEX™ OPA Solution

<i>Bacillus subtilis</i>
<i>Bacillus atrophaeus</i>

According to researchers, CIDEX™ OPA Solution has shown effectiveness in reducing the number of *Bacillus atrophaeus* and *B. subtilis* spores.^{4,9}

Currently, there is great concern about hospital-acquired *Clostridium difficile* (or “C. diff” as it is called) infections. *C. difficile* spores are quite sensitive to standard disinfection processes and are eliminated with relatively short times of exposure to HLDs, such as CIDEX™ OPA Solution.⁹

CIDEX™ OPA SOLUTION EFFECTIVENESS AGAINST VIRUSES

Scientists have tested and found CIDEX™ OPA Solution to be virucidal for many viruses. Independent researchers have also tested the effectiveness of CIDEX™ OPA on Hepatitis B and Adenovirus.^{8,2,5}

Table 4
Viruses Destroyed by CIDEX™ OPA Solution

Adenovirus 2
Adenovirus 8
Coxsackie Type B-3
Cytomegalovirus
Hepatitis B (HBV)
Herpes Simplex 1 and 2
HIV-1
Human Coronavirus
Influenza Type A (Hong Kong)
Polio 1
Rhinovirus Type 42
Vaccinia (smallpox)

HEPATITIS B (HBV)

In one study, scientists used radioimmunoassay to determine if the HBV remained infectious after exposure to CIDEX™ OPA Solution.² After 30 seconds, CIDEX™ OPA Solution had reduced the infectivity of HBV below the threshold value for the test.²

CIDEX™ OPA SOLUTION

EFFECTIVENESS AGAINST FUNGI

“The World Health Organization recommends hypochlorous acid and GTA as an effective disinfectant against hepatitis B virus; our results show that OPA is also an effective disinfectant against hepatitis B virus.”²

ADENOVIRUS 8

Adenovirus 8 is a very resilient virus and can persist in the environment on hard surfaces for more than 30 days.⁵ It is a common cause of hospital-acquired eye infections and can be spread by:

- Contact with contaminated medical equipment
- Direct person-to-person contact
- Airborne droplets

CIDEX™ OPA Solution was able to reduce the viral load of Adenovirus 8 to safe levels after one minute of exposure, even in the presence of serum. CIDEX™ OPA Solution was also more effective on Adenovirus 8 after exposure for five minutes than all other germicides tested, including peracetic acid and 70% ethanol.⁵ (See Figure 6).

Effectiveness of HLDs Against Adenovirus 8

Source: Rutala et al. (2006)

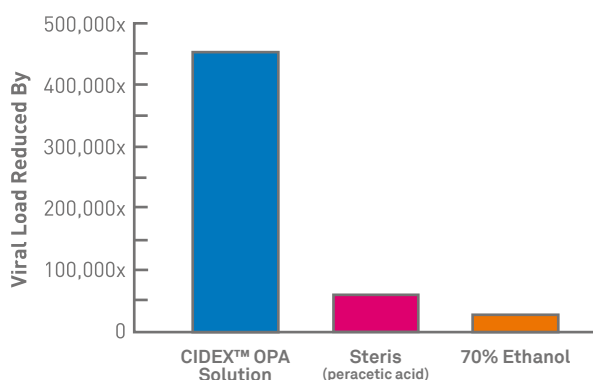


Figure 6. The number of Adenovirus 8 eliminated by three HLDs

CIDEX™ OPA SOLUTION EFFECTIVENESS AGAINST FUNGI



Figure 7. An electron micrograph of Candida albicans
Image Source: Public Health Image Library

The effectiveness of CIDEX™ OPA Solution has been tested against several fungi.

Table 5

Fungi Killed by CIDEX™ OPA Solution

Candida albicans
Mucor racemosus
Rhizopus nigricans
Aspergillus niger
A. terreus

The results of two studies show CIDEX™ OPA Solution as an effective and fast-acting fungicide.^{1,2}

Herruzo-Cabrera et al. tested the effect of CIDEX™ OPA Solution on eight different isolates of Candida albicans.¹ After 10 minutes of exposure, CIDEX™ OPA Solution reduced the number of organisms by an average of nearly 20,000 times (log10 reduction factor of 4.3).¹

Akamatsu et al. tested the fungicidal activity of CIDEX™ OPA Solution and GTA against five fungi.² CIDEX™ OPA Solution was at least twice as fast at killing the fungi tested as GTA.² (See Figure 8)

Killing Time of OPA and GTA for Fungi in the Presence of Serum

Source: Akamatsu et al. (2005)

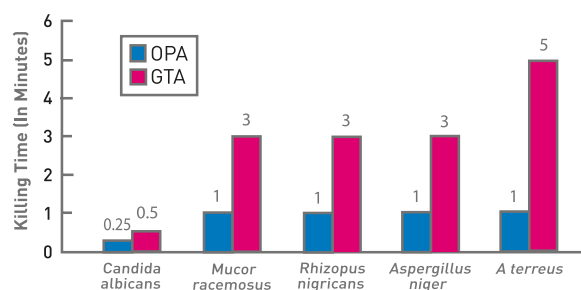


Figure 8. Fungal Killing times by CIDEX™ OPA and GTA in the presence of serum

CIDEX™ OPA SOLUTION

• DISCUSSION AND CONCLUSIONS
• REFERENCES

DISCUSSION AND CONCLUSIONS

CIDEX™ OPA Solution has demonstrated high levels of bactericidal, virucidal, and fungicidal activity in multiple studies against a wide range of organisms.^{1-5,8}

Clinically isolated bacteria should be used when determining the effectiveness of an HLD because of their increased resistance to HLDs.¹ When CIDEX™ OPA Solution was used against the clinically isolated strains, it was effective against the majority of the tested organisms, even under “worst case” conditions.¹

There have been limited published studies of the effectiveness of CIDEX™ OPA Solution against viruses. In some cases, it is impossible to do direct virucidal testing because the viruses currently cannot be grown in a laboratory setting (such as human papillomavirus, and Norwalk and Norwalk-like viruses).⁹ However, some of the most concerning viruses (such as hepatitis B and C and HIV) are very fragile and are easily destroyed by all HLDs.¹¹ CIDEX™ OPA Solution was very effective at eliminating Adenovirus⁹, a very hardy and persistent virus.⁵

CIDEX™ OPA Solution shows fast killing action against microbes that are resistant to GTA, in addition to having other advantages over GTA.³

“CIDEX™ OPA Solution has several potential advantages compared to Glutaraldehyde. It has excellent stability over a wide pH range (pH 3-9), is not a known irritant to the eyes and nasal passages, does not require exposure monitoring, has a barely perceptible odor, and requires no activation.”⁸

Post-gastrointestinal endoscope infection occurs very rarely, and has been highly correlated with a break in disinfection procedures or faulty equipment.⁷ The scientific evidence shows that CIDEX™ OPA Solution is an easy to use HLD and is very effective.^{1,2,9}

Although the data used in these papers suggest that CIDEX™ OPA Solution is effective with exposure conditions different than the cleared claims, CIDEX™ OPA Solution should always be used consistent with its Direction for Use.

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