



Shriners Hospitals
for Children®

ABSTRACT

The Shriners Study of the Efficacy
Of Chrisal Probiotics as a
Method of
Decreasing Nosocomial Infections
Reducing Respiratory Reactions
Eliminating Allergic Reactions
Removing of Biofilm
Improving cleaning Effectiveness
Reducing Labor Requirements
Maintaining Environmental Responsibility

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SUMMARY REASONS FOR THIS STUDY

The Shriners Hospitals for Children has always searched for ways to provide better infection control, reduce respiratory problems, increase safety, provide better cleaning, reduce material and labor costs and protect the environment.

As important additional factors affecting the growing problems with infection control and cleaning have come to light, such as the major impact biofilm has in the propagation of a wide variety of pathogens, and the recognition that existing cleaners and disinfectants exacerbate the growing respiratory problems with children as well as engender allergic reactions in both the staff and the patients, created a more urgent search for less toxic alternative solutions.

KEY PROBLEMS

NOSOCOMIAL INFECTIONS Today hospitals have changed from safe havens of healing into facilities to be avoided except only for the shortest possible stays. The CDC has noted that better than 80% of all infections emanate from biofilm. Hospital acquired infections in just the USA now cause as many deaths as from automobile accidents, AIDS, and breast cancer combined, and cost hospitals alone well over \$30 billion annually on a national scale.

“DISINFECTANTS CAUSE INFECTIONS FACTOR” An important consideration is the growing awareness of the negative effects triggered by disinfectants which, paradoxically, are a causative contributory factor to the very problems they and other toxic chemical solutions are designed to prevent.

RESPIRATORY PROBLEMS Another major problem for hospitals, nursing homes and other health care facilities are the respiratory problems triggered by disinfectants and other chemicals used in cleaning our facilities that, ironically, are supposed to prevent the very problems they cause. The growing incidence of asthma in children and the reactions to cleaning chemicals noted is another reason for our interest in studying the non-allergenic probiotic solution.

EFFECTIVENESS & THE DEGREE OF CLEANLINESS Better testing technology has shown that the standards of what was traditionally considered “clean” are now well outdated and we now know that standard products regardless of brand do not deconstruct biofilm.

EFFICIENCY & THE LABOR FACTOR One of the criteria in the study is: How to reduce the labor required to achieve higher degrees of cleanliness and make labor more effective and to compensate for mistakes and lapses of attention by staff.

COSTS A major concern in these times when economic resources are stretched thin are additional ways to reduce costs, but not at the expense of cleaning quality.

ENVIRONMENTAL IMPACT The growing regulatory pressures, mandating what chemicals can be used and where and how they are disposed, has created a prime goal for organizations to pursue “green” paradigms and products wherever practical.

STUDY GOAL SUMMARY

The Shriners hospital study was designed as a comprehensive, in-depth review of a new paradigm in cleaning that met the long term goals of providing a major improvement in efficacy, cost effectiveness, safety, ease of use, reduced environmental impact, and reduced material and labor costs. The study is not designed to consider a substitution of products. It is part of an in-depth strategic effort to consider a method, that would solve a number of today's concerns and meet the requirements of the future for all of our facilities.

PROJECT EVALUATION

This study is based upon a large number of factors and criteria. A considerable body of additional medical and scientific data, derived from a number of university and hospital studies of the efficacy of Chrisal, were included. These studies utilized the evaluation of other on-site and laboratory studies comprised of over 22,000 laboratory tests, spanning the past five years, as comparative and corroborating information in forming our conclusions.

TEST AREAS 25 locations within the hospital were selected including public and patient treatment areas.

TESTING PROCEDURES Each area to be tested was first cleaned with the hospital's normal cleaning products. At each location: (1) ATP (Adenosine Triphosphate) testing was done using Hygeina ATP test swabs for the sampling and which then were read using a Hygeina ATP Meter. Simultaneously (2) Cultures were taken of the same area using 3-M culture swabs then delivered to the lab and poured onto 3-M culture media, incubated for 24 hours before being checked and then frozen for photographs. The same procedures were used for the ongoing testing thereafter.

INFECTION CONTROL FINDINGS

This was the crux of the study. Even the best run hospital will be influenced by bacteria that are either brought in from outside; as in the case of those brought in by patients and staff, from the public areas, and visitors, or by those that manage to gain a foothold in areas that are difficult to clean on a consistent basis.

The new scientific data generated over the last few years pinpoints the degree of culpability of biofilm in the propagation of infection. There is also new information of how much larger and more pivotal the role of the microscopic environment is on health. Compounding the problem is the rapidly growing resistance of pathogens to antibiotics and the realization that the problems are being caused by the very chemicals created as a means to combat them. Chrisal's probiotic products were chosen because no other products claiming to have probiotic activity have been found to meet all of the criteria required and to have sustainable non-toxic probiotic constituents and prolonged shelf life. In addition, there is a very large body of scientific and medical testing that has been conducted over the past five years on the Chrisal products that are extremely positive. Therefore the following factors of prime importance were met:

- 1) **CHRISAL HAS PROVEN TO BE THE ONLY PRODUCT THAT ACTUALLY SAFELY AND EASILY DECONSTRUCTS AND REMOVES BIOFILM.** The need to focus on cleaning and reducing or eliminating biofilm as a way of reducing bacteria load rather than trying to just kill bacteria with disinfectants was clearly demonstrated.

Biofilm is built by bacteria as a “protective housing” – it is an aggregate of microorganisms in which cells adhere to each other on a surface. These adherent cells are

frequently embedded within a self-produced matrix of extracellular polymeric substance (EPS), which is also referred to as a hydrated slime. Biofilms will form on both living and on non-living surfaces and is prevalent in natural, industrial and hospital settings, as well as homes and all other surfaces. (It cannot be removed by conventional products or methods)

- 2) **UNDERSTANDING THE DANGERS OF BIOFILM:** Biofilms have been found to be involved in a wide variety of microbial infections in the body. By one estimate **80% of all infections emanated from, or are caused by biofilm.** Infectious processes in which biofilms have been implicated include common problems such as urinary tract and catheter infections to middle-ear infections, gingivitis and many others including more lethal processes such as endocarditis, infections in joint prostheses and heart valves.
- 3) **THE “DISINFECTANTS CAUSE INFECTIONS” FACTOR:** This counter intuitive statement is the quandary posed by disinfectants and an extremely important factor that has only recently come to be recognized about the disinfectant process. The key to understanding the reasons that the disinfecting process causes infections is simple. **Many of the organisms killed by disinfectants cannot be mechanically removed.** The normal method and mechanics of wiping with paper towels or cloths to pick up all the “bodies”, even on the smoothest of surfaces fails to remove all the microbial carcasses – the problem is that most surfaces that appear smooth to the naked eye, may be compared to the fractured, uneven and pitted surface of the moon scaled at a microscopic level. This is a major problem in that many of these microbial bodies are physically unreachable in cracks, holes, pits, depressions and other geographic features of the surfaces of most objects on a microscopic level. This provides “free food” to the first opportunistic organism that lands on the surface.
- 4) A major factor in infection control is that all **disinfectants and cleaners stop working as soon as they are dry or shortly thereafter.** The Chrisal products continue to clean for a minimum of 72 hours after they dry.
- 5) **WHY CONVENTIONAL CLEANING AND DISINFECTANTS CAUSE INCREASE RISK OF INFECTION:** After being disinfected, the treated surfaces retain billions of dead organisms that are food available to the first opportunistic organisms that land on that surface or that come up from the biofilm below. This surface then provides pathogens, which are more aggressive, with a massive source of carbohydrates and proteins, while eliminating the competing benign bacteria that normally keep dangerous organisms in check.
- 6) **RE-GROWTH ELIMINATED:** Once the biofilm has been eliminated, it has been found that as long as the Chrisal Probiotic Products are used to clean at least once every three days, biofilm will not grow back. In other studies we noted that even when live MRSA was applied to a surface where biofilm has been remove using Chrisal probiotics, MRSA failed to become viable.
- 7) **SOLUTION CRITICAL AREAS - THE COMBINATION OF CHRISAL AND DISINFECTANTS:** Recognizing the downside of disinfectants only raises the additional issue of the regulatory requirement to disinfect to 99.9%. Because it is therefore currently impossible for Hospital and medical facilities to stop using disinfectants in the foreseeable future, as such changes require overcoming conventional thinking and acceptance of the new paradigm, we have noted that there is a way to gain the advantage the new paradigm provides, while adhering to the regulatory requirements. It is to utilize both methods as noted below.

THE PERFECT “ONE-TWO PUNCH” COMBINATION: When it is understood that one of Chrisal’s key functions is to totally eliminate contaminants and biological matter from any surface, it becomes obvious that Chrisal and a disinfectant now can provide the perfect synergistic process. A One-Two Punch solution to the problem of disinfecting any area. In another study we noted that at the Lokeren Hospital, Chrisal is being applied in every area of the hospital ongoing and for the last four years. In order to adhere to the regulations requiring disinfection in critical areas such as in the operating rooms before operations, the hospital utilizes Chrisal on a normal basis before scheduled operations, disinfects just prior to procedures and then returns to using Chrisal subsequent to the procedure. Since changing all the hospital’s cleaning supplies, with the exception of the required operating room disinfectant, to Chrisal, the Hospital has now risen to being in the top 3% of the all hospitals in the country having the least amount of infections.

Therefore, Chrisal not only makes disinfectants far more effective by eliminating the biofilm that protect pathogens from disinfectants, but Chrisal then also eliminates all the organic matter resulting from the disinfection process. This is a vast improvement in infection control and meets or exceeds all of the criteria of our study.

ADDITIONAL PROTECTION OF INTEREST: It should be noted that in addition to all the studies to date showing **that the use of the Chrisal Probiotic Products tend to lower infection rates by 70% to 80%** in hospitals, there also are studies showing how effective Chrisal can be against spore based organisms, including **C-Diff**, which is now a serious problem. (We referenced the report from the University of Liverpool report on **C-Diff** and Chrisal. Of additional interest are all the reports indicating the elimination of **MRSA** by Chrisal, including one from the University of Ulster and the Burn Center in Kiev. The study relevant to the control of **MRSA** is covered in-depth in the study from the University of Gent, the Lokeren Hospital and in the Italian University Study).

- 8) **NEGATIVE FACTORS IN USING CHRISAL.** None. There were no negative factors experienced in the study in any way with the use of the Chrisal products.

IMPORTANT RESPIRATORY FACTOR

- 9) **RESPIRATORY DYNAMICS:** Another major problem solved with Chrisal Probiotics is the elimination of the respiratory problems triggered by the disinfectants and chemical cleaners currently in use. Hospitals are treating more and more asthmatic and other patients having respiratory problems. Our study has proven that Chrisal Probiotics, do not trigger any respiratory problems, distress or negative responses in patients. We have noted contrary to most other conventional products, that in fact, Chrisal also removes allergens and irritants from the environment so that there is a benefit to both patients and staff.
- 10) **COST FACTORS:** In addition to being more effective, it has been estimated that using the Chrisal Probiotic products should lower the costs of cleaning materials by up to 50% or more. Chrisal products have also been shown to reduce labor costs by up to 50 percent.

In addition there is an extremely large cost benefit to the reduction of infections caused by hospital stays. Preventing just one hospital contracted infection per year yields a cost savings in excess of the yearly cost of using the products. In essence we have determined that changing to Chrisal products reduces the costs of cleaning to the hospital, considering cost avoidance, to Zero! Thus, the use of the Chrisal probiotics changes a cost center, through cost avoidance of other large costs factors, into an indirect profit.

- 11) **REDUCTION IN NUMBERS OF DIFFERENT PRODUCTS REQUIRED:** Chrisal can replace the number of normal products used with only four (4) products. This reduces overhead and space costs as well as staff time from both handling and operational costs. There are a number of additional savings as well from important factors like the reduction in air conditioning and maintenance costs by using Chrisal Probiotic Environmental Control.
- 12) **ENVIRONMENTAL IMPACT:** The environmental impact of the disinfectants and chemical products are a growing problem because of the growing local, state and federal regulatory pressures in how these products are to be used, stored and in the methods required for disposal. Chrisal eliminates these problems as the products are non toxic and benign.
- 13) **REACTIONS AND EVALUATIONS FROM STAFF & USERS:** As part of this study, each of the staff members were polled as to their experience during the study. In all, every single staff member using the products have evaluated the Chrisal products as being much better than the old standard chemical products. The staff rated the Chrisal products from “very good” to “We love the products and never want to go back”. Almost every staff member has noted that they can now breathe without worry about respiratory allergic responses or topical allergic reactions.

STUDY CONCLUSION

SUMMATION: The final result of the Shriner’s hospital study revealed that the Chrisal probiotic paradigm exceeds the criteria set forth in our goal to find new methods and solutions that:

- (1) Improves cleaning,
- (2) Reduces infection,
- (3) Eliminates adverse respiratory and allergic response in both patients and staff,
- (4) Reduces both material and labor costs,
- (5) And, also reduces our negative impact on the environment.

Therefore, the results clearly demonstrate the need to change from conventional cleaners to Probiotics, and to use and introduce Chrisal to our organization as a paradigm of choice for the benefit of our patients, staff and management.

**See the summary of test results on following pages - and see full study report for more details*

TESTING RESULTS OVERVIEW

TEST RESULTS – 2011-AUG-24 - PRE-CHRISAL TESTING:

These test results are from areas before the use of probiotic cleaning materials was initiated and the cultures were taken shortly after cleaning by staff using standard hospital cleaning materials.



Seven of the cultures showed no activity due to the cleanliness of the facility. Though, of course, pathogen growth has to be expected in public facilities, especially hospitals, it can be seen that, other than a few locations, the readings are well under what is normally found.

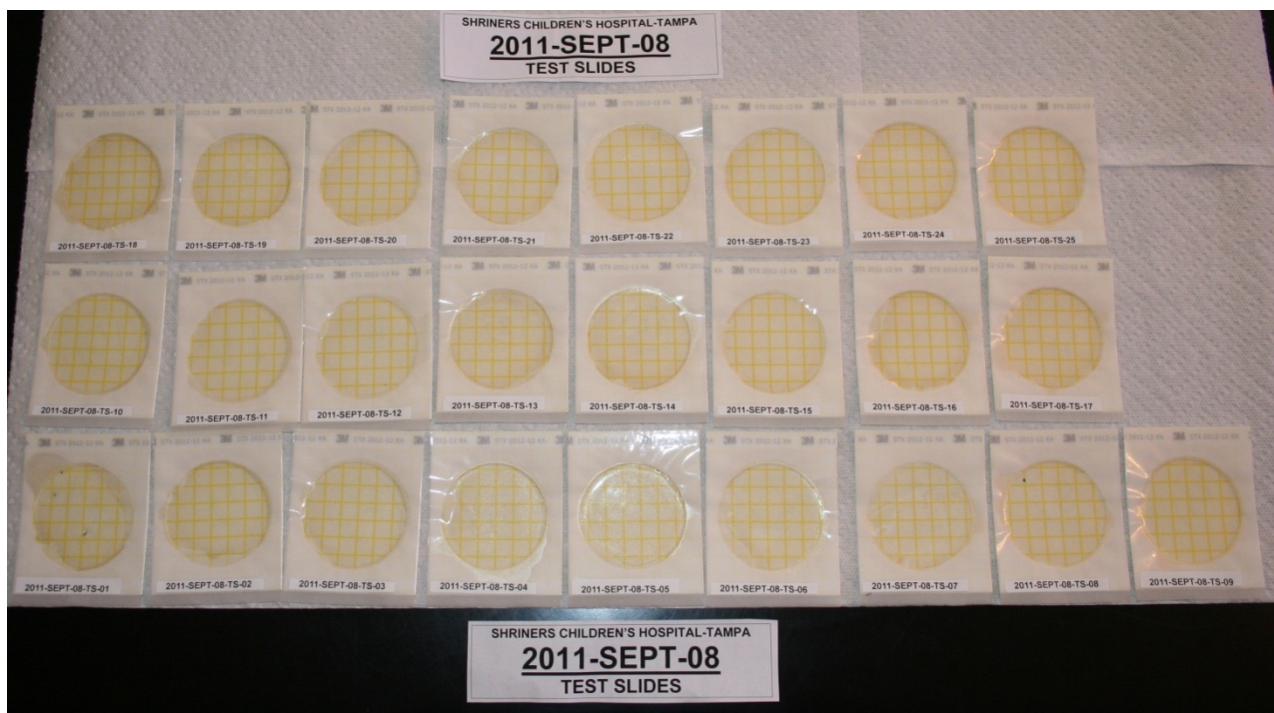
TEST RESULTS – 2011-SEP-01 – START OF THE CHRISAL USE TESTING PERIOD:

Below are the test results after the first week of cleaning with the Chrisal PIP Probiotic Products



TEST RESULTS – 2011-SEP-08 – CHRISAL USE TESTING PERIOD:

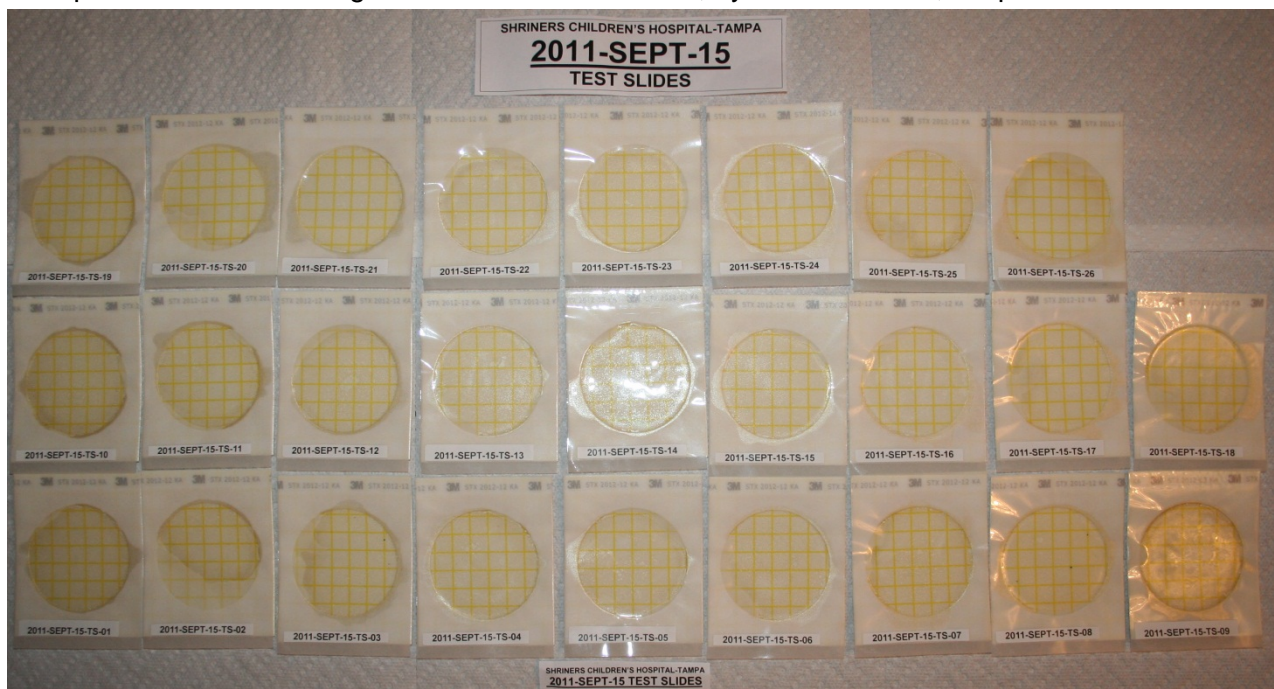
These weekly results when grouped together, better show the progression and advantage of cleaning with probiotics. One of the important advantages provided by the Chrisal PIP probiotic products is the control of biofilm, a characteristic solely available with this new type of cleaning.



Since an important aspect of cleaning and infection control is to deconstruct biofilm, an important function of these probiotic products are that they work down to the microscopic level and consume the biofilm that is formed by bacteria as its residence and for its protection.

TEST RESULTS – 2011-SEP-15 – CHRISAL USE TESTING PERIOD:

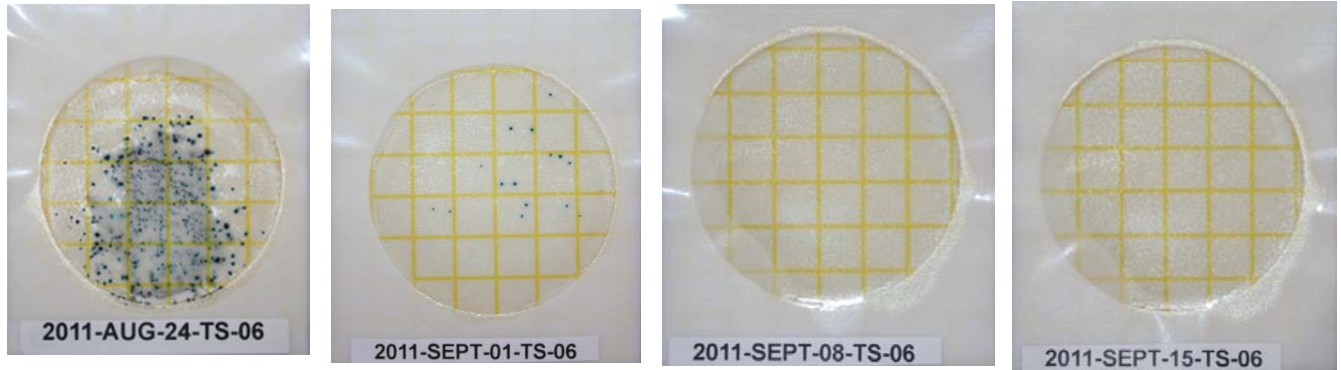
As has been seen in all testing to date both here in the Shriners Children's Hospital in Tampa and from previous corroborating tests from other facilities, by the third week, all probiotic treated



surfaces have had all of the biofilm removed and contingent on cleaning with the probiotics once every three days, they tend to stay free of pathogens and a number of other contaminants and allergens permanently.

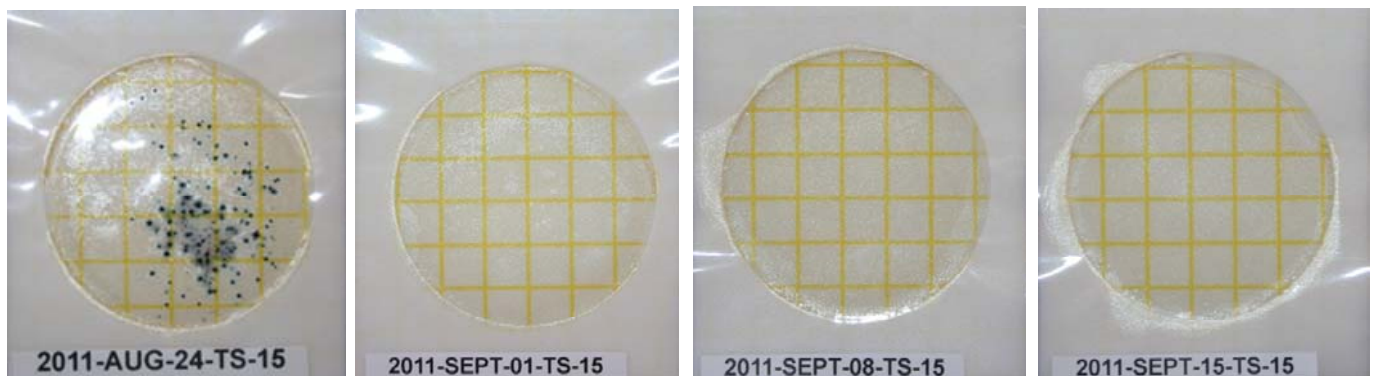
PROGRESSION OVER THE TEST PERIOD

Results Example Test Site-06: The high count plates are a good example of the progression of probiotic cleaning, the following are the progress of each area tested, starting with this test site-06

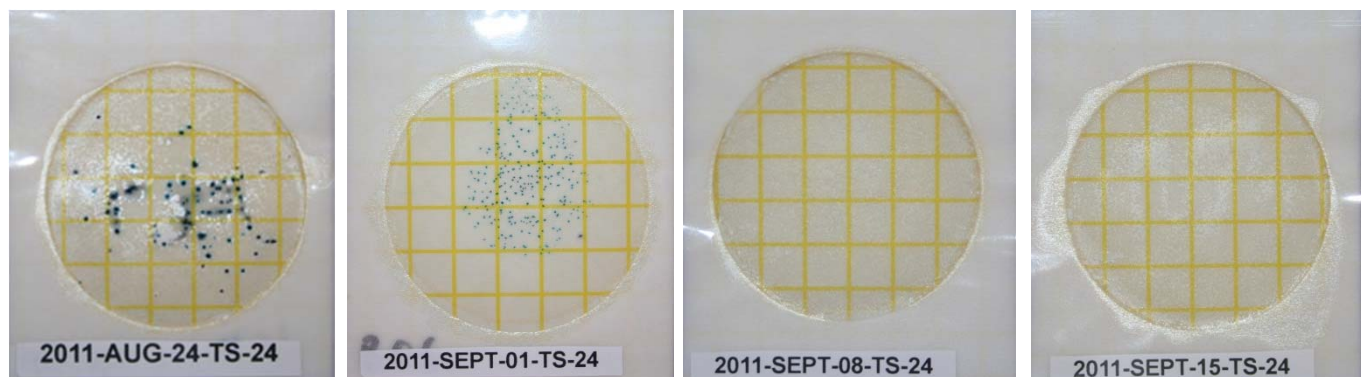


The above is the progression of test location-06 with the first culture on the left being the results of testing the area cleaned with the hospital's normal cleaning and disinfecting products. The second culture is the week after the PIP Probiotic cleaners started to be used. Each slide thereafter is the weekly test results from the PIP Probiotic cleaned area.

Results Example Test Site-15: As is seen, the progression of the probiotic solution each time is dependable in all cases and also matches the dozens of other studies examined.



Results Example Test Site-24: Site-24 is another normal progression of probiotic cleaning.



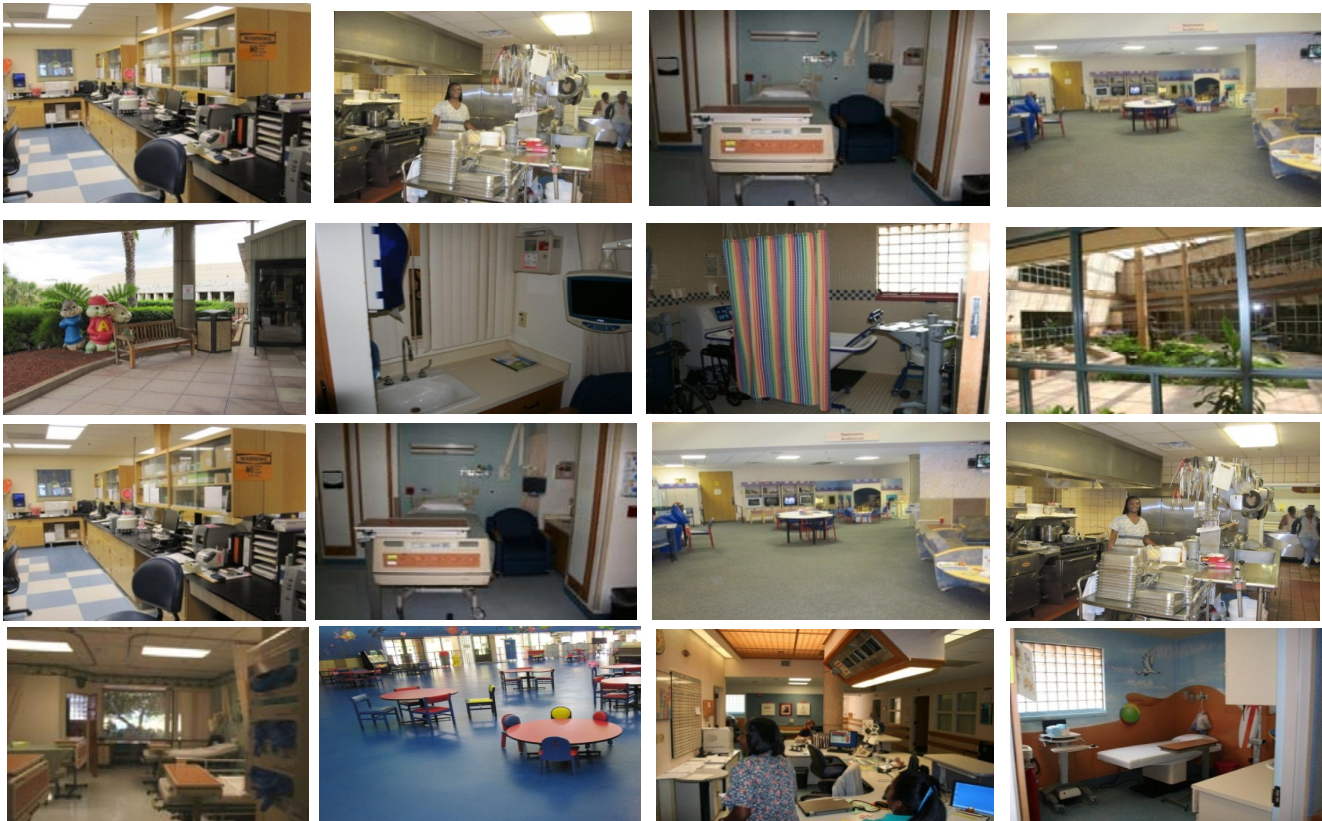
The photos below show ATP testing of several of the Hospital sites that are part of this study



Some of the cleaning staff during training on Chrisal and while using the products:



Photos of Some Of The Testing Locations



STUDY ENTITIES

This study was performed at the Tampa Shriner's Hospital for Children. A multidisciplinary team was assembled to manage this study and evaluate the associated health benefits. The members of the team involved in this study include:

- Gene Bracewell, Chairman Emeritus, Board of Directors, Shriners Hospitals for Children
- Sheryl Chewning, RN, CIC, CPHO, LHRM, Director of Performance Improvement, Risk Management, and Infection Control, Pediatric Specialty Care, Tampa
- Carol Ann Jenkins, Administrative Director of Support Services, Tampa
- Jim Gamez, International Headquarters, Pediatric Specialty Care, Supply Chain Sourcing Specialist, Supply Chain Management Department, Tampa
- Roberta 'Bert' Hardy, Director of Environmental Services, Tampa
- Patty Veasey, Tampa

Shriners Tampa Hospital DAY Cleaning Crew Trained On Products:

*Mary Mcneil, *Carolyn Blackman, *Camil Lancaster, *Tommy Miller, *Kenny Sneed,

Shriners Tampa Hospital NIGHT Cleaning Crew Trained On Products:

*Nilsa Fernandez, *Rebecca Munoz, *Horris Ray

Other Support Entities for the Shriners Tampa Children's Hospital Study:

*Dr. Marina G. Morris, M.D., Medical Sciences Group, *Kim Metzler-Rice, Hygiena USA,
*Robert W. Yates, 3M Microbiology, *Lino G. Morris, CEO, Chrisal, *Howard Zalkin, Chrisal