

INTERTEK CRS

Oral Care Product Testing

Unique expertise to support your product development and marketing claims

OUR PURPOSE

Bringing Quality, Safety and Sustainability to Life

OUR VISION

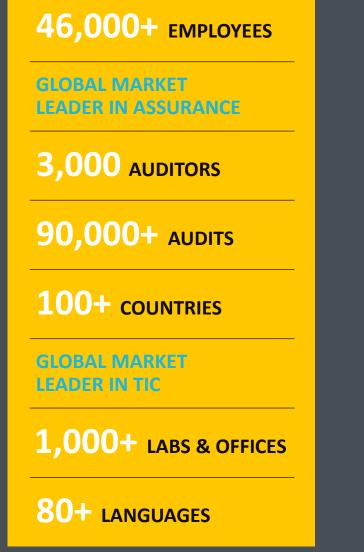
To be the world's most trusted partner for Quality Assurance

OUR VALUES

- We are a global family that values diversity
- We always do the right thing. With precision, pace and passion
- We trust each other and have fun winning together
- We own and shape our future
- We create sustainable growth. For all

INTERTEK IS UNIQUELY POSITIONED TO DELIVER ATIC SOLUTIONS





Systemic approach to Quality and Safety $\overline{\langle}$ intertek TESTING ASSURANCE INSPECTION CERTIFICATION **Our Sectors** Products Trade Resources

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OUR EXPERTISE

We provide two main types of services :



Routine and bespoke *in vitro* testing of oral care products to support product development and generate data for claims support and advertising

Support for oral care clinical studies e.g. salivary clearance studies, oral malodor or *in situ* studies.

INTERTEK CHEMICALS & PHARMACEUTICALS UK









30 years serving global companies

- Bioanalysis & Biomarkers
- Drug development characterisation for advanced pharmaceuticals (gene therapies, vaccines, oligonucleotides, medical devices)

Intertek Melbourn

GMP

- 30 years serving global companies
- Drug formulation and development support
- Specialised experience for OINDP and drug delivery technologies
- Largest ICH Stability storage facility in Europe

Intertek Wilton

ISO 17025

30 years serving global companies

- R&D Support and Problem
 Solving
- Regulatory Compliance testing for medical devices, healthcare, packaging, chemicals
- Chemical/physical mechanical testing of polymers, ceramics, composites, metals, coatings



Intertek CRS

HTA

18 years serving global companies

- Routine & bespoke *in vitro* testing of oral care products to support product development and generate data for claims support and advertising
- Support for oral care clinical studies

OUR EXPERTISE

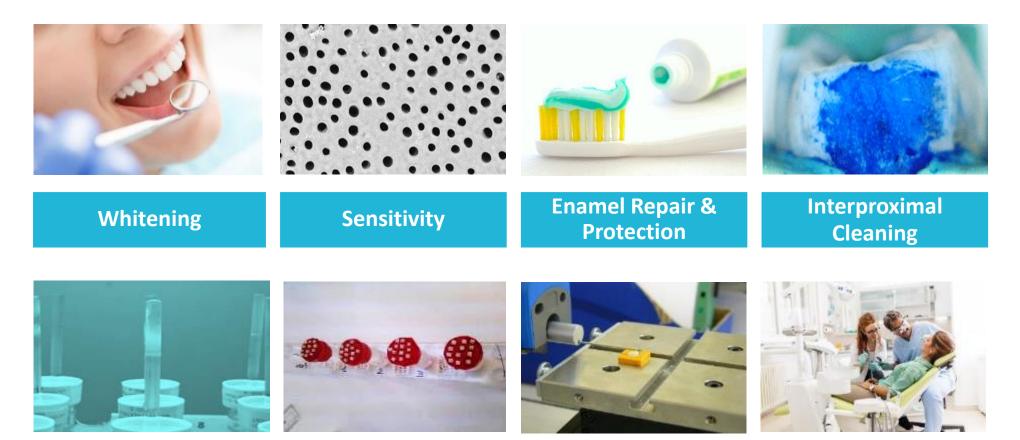
A unique *in vitro* testing expertise applicable to all marketing regions. Our specialised facility is one of only 3 labs in the World focused on safety and efficacy assessment of oral care products

Our team is highly specialized with over 18 years of experience and extensive knowledge of testing oral care products. We design and develop tailored studies & advise on what tests are appropriate to meet your aims We are committed to providing a Total Quality Assured resource that delivers robust results, a responsive throughput and costeffective solutions We are licensed by the Human Tissue Authority to store and use human teeth for research purposes

Our data is robust and accepted by global Standards authorities We regularly publish peer reviewed studies at the International Association for Dental Research (IADR)

SUPPORTING YOUR PRODUCT DEVELOPMENT GENERATING DATA FOR YOUR CLAIMS SUPPORT





Plaque Prevention Ha





Clinical Support

SUPPORTING YOUR PRODUCT DEVELOPMENT GENERATING DATA FOR YOUR CLAIMS SUPPORT

Our experts can develop bespoke studies & advise on what tests are appropriate to meet your claims







- Defined test protocols
- Comprehensive reports
- Statistically evaluated data

Our data is robust and can withstand scientific scrutiny



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WHITENING

Intertek CRS In Vitro Oral Care Product Services

WHITENING

We offer a portfolio of tests designed to assess the whitening efficacy of oral products:

- PCR
- X Shades Whiter
- Stain Prevention
- Chemical Stain Removal
- Denture Stain Removal
- Mouthwash Stain Removal
- Propensity to Stain
- Enamel Gloss

4% Forecast CAGR Growth¹ The global teeth whitening market is poised to grow by US\$840m during 2020-2024

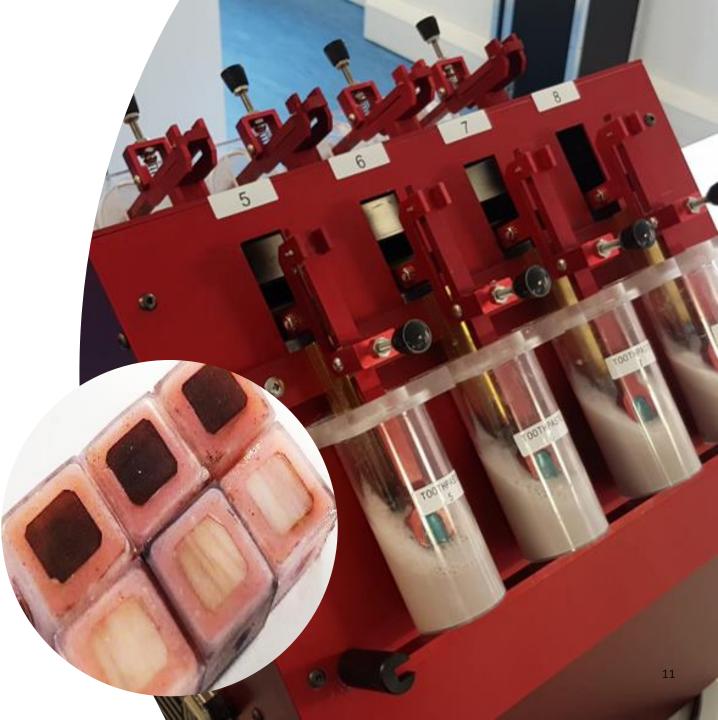
Growth driven by:

- Emerging consumerism through digital & social media
- Rising awareness about oral hygiene
- Availability of teeth whitening OTC products
- Stigma associated with discoloration of teeth

PELLICLE CLEANING RATIO TEST (PCR)

Key information

- Industry standard test to compare the ability of toothpaste formulations to remove stained pellicle, relative to an ADA reference abrasive
- A robust stain is applied to bovine enamel
- A precision spectrophotometer is used to measure colour pre and post brushing
- A V8 brushing machine is used to standardise brushing conditions
- PCR values are calculated relative to an ADA reference abrasive



X SHADES WHITER

- Modified PCR test to converts stain removal into x tooth shades whiter
- Human or bovine enamel samples are stained to the darker end of an internationally shade guide
- A precision spectrophotometer is used to measure colour pre and post brushing
- A V8 brushing machine is used to standardize brushing conditions
- Number of shades whiter is calculated after brushing





CHEMICAL STAIN REMOVAL

Measuring the ability of oral care products to chemically whiten teeth

- Compares the ability of whitening gels or strips to remove stains from extracted human molars with natural intrinsic & extrinsic stain
- A precision spectrophotometer is used to measure colour pre and post treatment
- Ability to remove natural intrinsic & extrinsic stain is assessed



DENTURE CLEANING

- Compares the ability of oral care products to remove stains from denture materials
- Denture materials are stained with an inhouse staining protocol
- A precision spectrophotometer is used to measure colour pre and post brushing
- Ability to remove stains from denture materials is calculated

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MOUTHWASH WHITENING

- Compares the ability of mouthwashes to remove stains
- Human or bovine enamel are stained with a robust stain
- A precision spectrophotometer is used to measure colour pre and post treatment
- Ability of mouthwashes to remove stain is assessed
- The test can be modified to support "removes the stains brushing leaves behind" claim.



RESTORES NATURAL TOOTH BRIGHTNESS

- Compares the ability of oral care products to restore natural brightness
- Human or bovine enamel are stained with a robust stain
- A precision spectrophotometer is used to measure tooth brightness pre and post treatment
- Ability of an oral care product to restore natural tooth brightness is assessed



STAIN PREVENTION

- Compares the ability of oral care products to prevent stains from being deposited onto human or bovine enamel, versus no treatment
- A precision spectrophotometer is used to measure colour pre and post treatment
- Samples are subjected to a cycling protocol incorporating treatment, saliva and stain immersions
- Ability to prevent stain uptake is assessed

PROPENSITY TO STAIN

- Measures the propensity of food, drug or • cosmetic product to stain denture materials, enamel or dentine
- A precision spectrophotometer is used to • measure colour pre and post treatment
- Samples are subjected a defined number of • treatment applications
- Propensity to stain is assessed



ENAMEL GLOSS

- Compares the ability of oral care products to improve enamel gloss
- A precision spectrophotometer is used to measure enamel gloss pre and post treatment



SENSITIVITY

Intertek CRS In Vitro Oral Care Product Services

SENSITIVITY

- Dental sensitivity is linked to the movement of fluid within the dentine tubules
- Intertek CRS offers a range of tests designed to assess the ability of oral care products to reduce dental sensitivity:
 - SEM Dentine Occlusion Studies
 - Hydraulic Conductance Studies

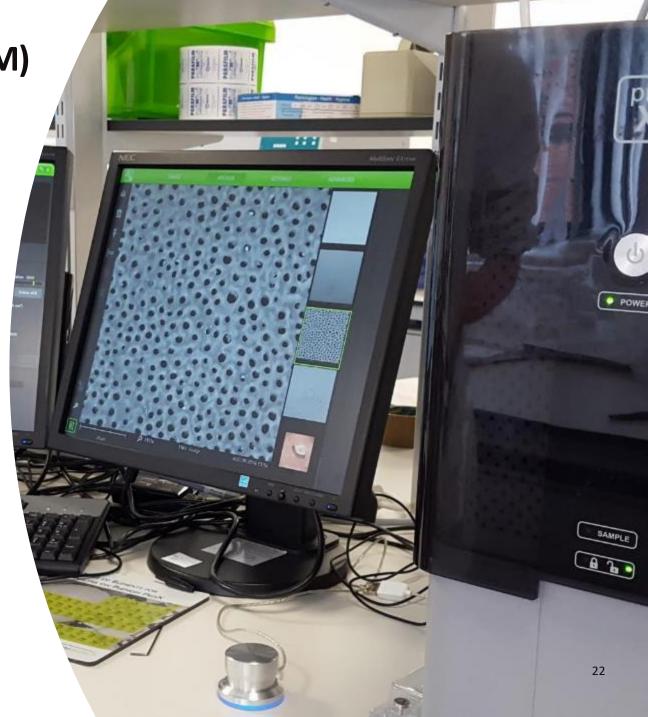
5.4% Forecast CAGR Growth¹ The Global sensitive toothpaste market size is expected to expand at a CAGR of 5.4% from 2020 to 2027

Growth driven by:

- Growing awareness of personal health and dental hygiene
- Rising demand for natural and organic product
- Competitive space products offering multiple benefits such as deep clean, whitening, repair and protection
- Rise of oral diseases and teeth sensitivity problems

SCANNING ELECTRON MICROSCOPE (SEM) DENTINE OCCLUSION

- Compares the ability of oral care products to physically occlude dentine tubules
- Dentine occlusion is assessed by scanning electron microscope
- Post treatment dentine occlusion is assessed on a 5-point occlusion scale by trained assessors
- Ability to physically occlude dentine tubules is assessed



HYDRAULIC CONDUCTANCE

Precision flow controllers, flow sensors and flow cells are used to compare the ability of oral care products to reduce the microfluidic flow of solution through human dentine tubules.



ENAMEL REPAIR & PROTECTION



Intertek CRS In Vitro Oral Care Product Services

ENAMEL REPAIR & PROTECTION

Strong enamel is key to maintaining healthy teeth

Intertek CRS offers a range of tests deigned to assess the ability of oral care products to repair and protect enamel:

- Enamel Remineralisation / demineralisation studies
- Fluoride uptake studies

2.3 bn

people worldwide are estimates to suffer from dental caries (WHO, Global Burden of Disease Study 2017)

Sensitive Products Market Growth driven

by:

- Growing awareness of personal health and dental hygiene
- High consumption of alcohol and cigarettes
- Ageing population,
- High consumption of acidic drinks and food,
- Rise in prevalence of periodontal disease

ENAMEL REPAIR & PROTECTION

- Compares the ability of oral care products to repair and protect enamel
- Enamel samples are prepared to stringent specifications to enable accurate measurements
- Lesions can be formed in enamel samples to create damaged enamel samples
- Precision surface microhardness machines are used to measure changes in enamel microhardness
- A range of protocols are available to compare the ability of oral care products to repair damaged enamel and to protect enamel from dietary erosive challenges



FLUORIDE UPTAKE



- Compares the ability of oral care products to deliver fluoride into the surface of enamel lesions
- Lesions can be formed in enamel samples
- A vacuum and acid system can be used to extract fluoride from enamel lesions
- Fluoride concentration of the samples is measured with calibrated fluoride ion selective electrodes

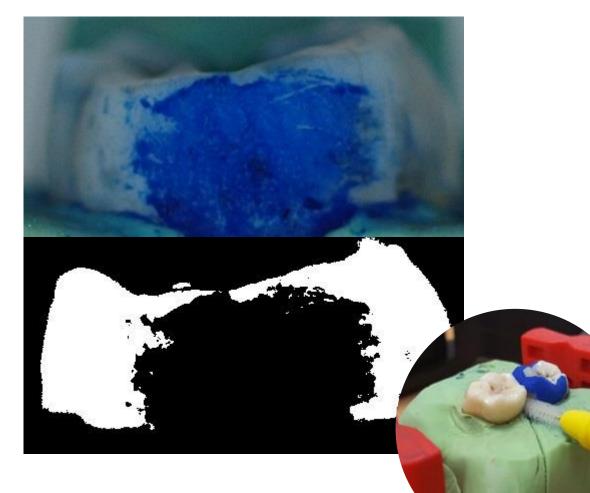


INTERPROXIMAL CLEANING

Intertek CRS In Vitro Oral Care Product Services

INTERPROXIMAL CLEANING





- Interproximal areas of teeth are the most difficult to clean effectively
- Manufacturers have developed a range of oral care products to clean interproximal areas of teeth
- Intertek has developed a range of models to compare the ability of oral care products to clean interproximal areas of teeth
 - Interproximal regions are covered with a plaque substitute
 - Interproximal cleaning is quantified using image analysis software

PLAQUE PREVENTION

Intertek CRS In Vitro Oral Care Product Services

PREVENTS PLAQUE BIOFILM BUILD UP



- Compares the ability of oral care products to prevent plaque biofilm build-up
- Plaque is seeded from pooled human saliva containing sucrose
- A four-day protocol is used involving intermittent exposure to oral care products
- Plaque biofilm is quantified by weight and/or total viable counts



PH BUFFERING CAPACITY OF ORAL CARE PRODUCTS

- Compares the ability of oral care products to buffer plaque and prevent a pH drop to pH levels associated with demineralisation during a sucrose challenge
- Dental plaque is seeded from pooled human saliva and treated with the oral care products
- Dental plaque are exposed to sucrose and the pH measured over 20 minutes
- The pH of the dental plaque is measured with a micro pH electrode
- The ability of an oral care product to buffer plaque and prevent a pH drop is assessed





PLAQUE REMOVAL

- Compares the ability of oral care products to remove dental plaque
- Dental plaque is seeded from pooled human saliva and is grown on the surface of human molars
- A disclosing solution is used to quantity the plaque coverage pre and post treatment
- Image analysis software is used to assess the removal of dental plaque



HARD TISSUE PREPARATION

Intertek CRS In Vitro Oral Care Product Services



PREPARATION OF HARD TISSUE SAMPLES

- Supporting your internal R & D
- Many oral care product companies have internal research and development
- Intertek CRS supports clients internal R & D by suppling a range of hard tissue samples
 - Human and bovine enamel or dentine samples
 - Dental restoration materials



DENTAL HARD TISSUE PREPARATION

- Intertek CRS is licensed by the Human Tissue Authority to store and use human teeth for research purposes
- Intertek has network of dental practices who supply us with extracted human teeth
- We collect bovine incisors for a range of abattoirs
- Our team can prepare a vast array of enamel and dentine samples
- We can supply enamel samples with lesions formed in the enamel surface layers of the samples.



DENTAL RESTORATION MATERIAL PREPARATION

• We can prepare a wide range of dental restoration materials to professional standards in bespoke sizes and thicknesses from an array of materials.



Intertek CRS In Vitro Oral Care Product Services

SAFETY

- Manufactures of oral care products have a legal obligation to ensure the safety of their oral care products
- Intertek CRS offers a range of tests deigned to assess the safety of oral care products:
 - Relative dentine abrasivity (RDA); ISO 11609
 - Erosive capacity of whitening treatments;
 ISO 28399
 - Manual toothbrush testing BS EN ISO 20126



RELATIVE DENTINE ABRASIVITY (RDA)

- Compares the abrasivity of toothpaste formulations to an ADA refence abrasive to determine safety of the oral care product
- Performed in accordance with ISO 11609
- Tissue loss is measured 3-D laser profilometry across the reference and brushed regions of a sample
- Enamel can also be used as the test substrate (REA)



EROSIVE CAPACITY OF WHITENING PRODUCTS

- Compares the erosive capacity of whitening products to a positive control to determine the safety of an oral care product.
- Performed according to ISO 28399
- Erosive capacity assessed via surface microhardness and 3D profilometry



MANUAL TOOTHBRUSH TESTING

- This International Standard is intended to determine the physical properties of manual toothbrushes, including impact resistance.
- Performed according to BS EN ISO 20126:2012+A1:2018



CLINICAL STUDY SUPPORT

Intertek CRS In Vitro Oral Care Product Services

CLINICAL SUPPORT

Supporting stronger claims support through flexible partnerships

Working with your CRO or our established CRO partners

Or

Provision of analytical support for clinical studies

- Oral malodor
- Fluoride and calcium salivary clearance studies
- In situ surface microhardness studies



ORAL MALODOUR

- Analysts with extensive experience in analysing oral malodour by GC, SIFT-MS and oral chromas are available
- Volatile Sulphur compounds are currently measured with Oral Chromas



SALIVARY CLEARANCE STUDIES

- Analysts with extensive experience of analysing samples for salivary clearance studies are available.
- Ion selective electrodes are used to measure the concentration of fluoride and calcium in saliva



IN SITU SURFACE MICROHARDNESS (SMH) STUDIES

 Our analysts have extensive experience in preparing samples and measuring surface microhardness for clinical in situ SMH studies





MEET OUR MANAGEMENT TEAM





Gavin Thomas

Laboratory Manager

Gavin has over 16 years of experience working within the in vitro oral care sector. He is currently the Laboratory Manager at Intertek Clinical Research Services and leads Intertek's team of scientists delivering a variety of in vitro methodologies for product evaluation and claim support, including enamel remineralization, stain prevention/ removal and chemical whitening.



Thomas Badrock

Laboratory Projects Manager

Tom has over 12 years of experience working within the in vitro oral care sector. He is currently the Laboratory Projects Manager at Intertek Clinical Research Services and assists the team with delivering a variety of in vitro methodologies for product evaluation and claim support, including enamel remineralization, stain prevention/ removal and chemical whitening.



SUMMARY



- Provider of laboratory services
- Use a partnership approach to support clients
- Always keen to grow services and develop new methodologies
- Global network supporting all aspects of product development
- Quality driven

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Visit us Online <u>www.intertek.com/oral-care</u>

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