

INTERTEK IS UNIQUELY POSITIONED TO DELIVER ATIC SOLUTIONS



46,000+ EMPLOYEES

GLOBAL MARKET LEADER IN ASSURANCE

3,000 AUDITORS

90,000+ AUDITS

100+ COUNTRIES

GLOBAL MARKET LEADER IN TIC

1,000+ LABS & OFFICES

80+ LANGUAGES



INTERTEK CHEMICALS & PHARMACEUTICALS UK





Intertek Pharmaceutical Services Manchester GLP/GCP/GMP/HTA

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

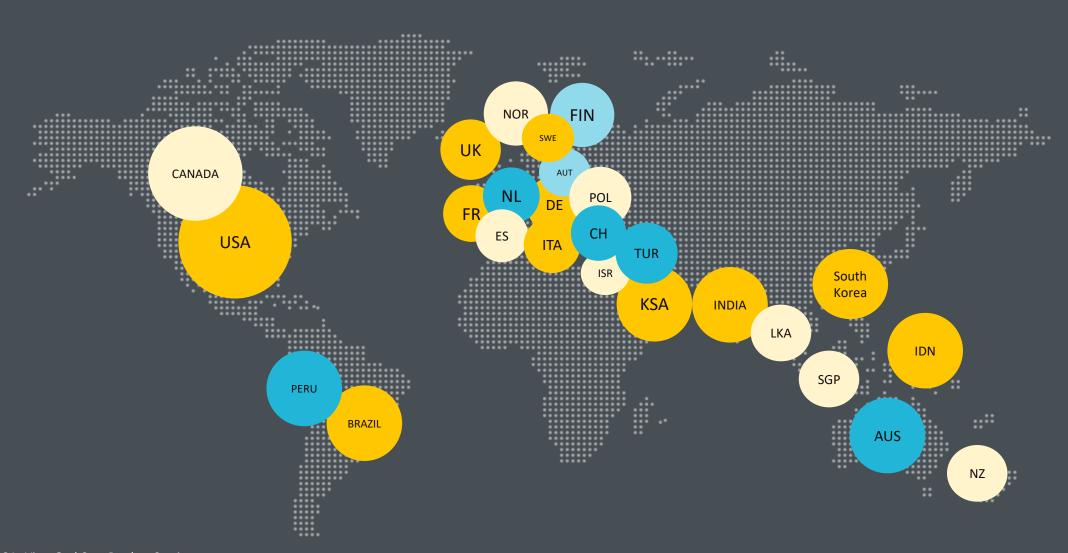
HTA

20+ 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 GLOBAL CLIENTS





Intertek CRS In Vitro Oral Care Product Services 5

MEET OUR MANAGEMENT TEAM





Gavin Thomas

Laboratory Manager

Gavin has over 20 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.

Thomas Badrock

Laboratory Projects Manager

Tom has over 18 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.



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 and *in situ* microhardness studies.

Intertek CRS In Vitro Oral Care Product Services 7

OUR EXPERTISE





A unique in vitro testing expertise applicable to all marketing regions. Our specialised facility is one of a limited number of laboratories worldwide that is focussed on assessing the safety and performance of oral care products.



Our team is highly specialised with over 20 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.



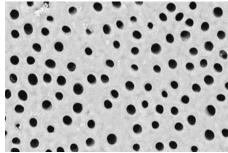
Our data is robust and accepted by global Standards authorities.

We publish peer reviewed studies at the International Association for Dental Research (IADR).

OUR STANDARD SERVICE OFFERING COVERS THE FOLLOWING CLAIM AREAS: (in)

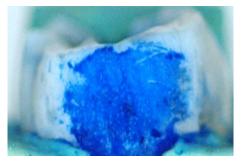












Whitening

Sensitivity

Enamel Repair & Protection

Anti-Plaque

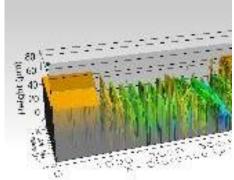
Interproximal Cleaning













Hard Tissue Supply

Gamma Irradiated Saliva

Ion Analysis

Safety

Clinical Support

NON-STANDARD SERVICES:

We have a flexible approach to working and is willing to work with clients to develop new testing methods to meet your R&D needs.



WHITENING Intertek CRS In Vitro Oral Care Product Services

WHITENING

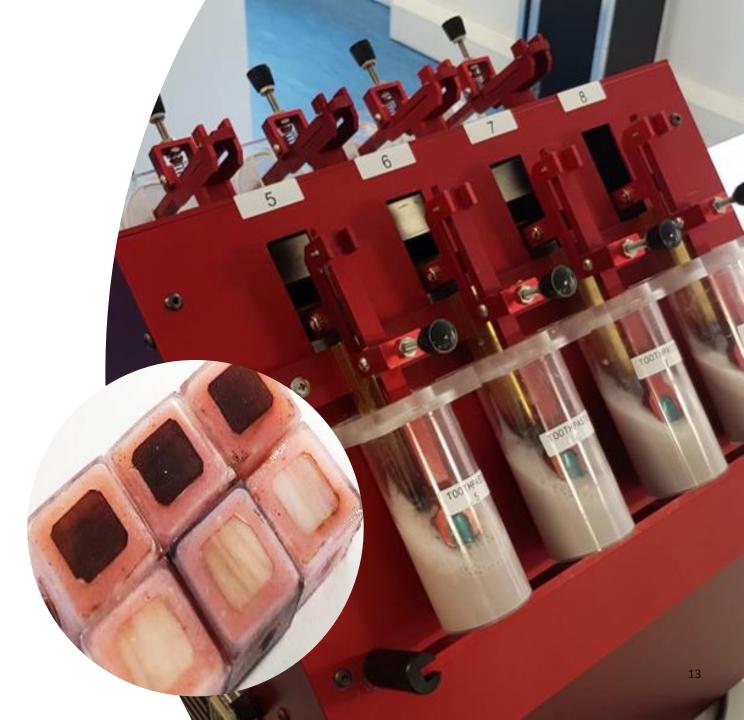
We offer a portfolio of tests designed to assess the whitening efficacy of oral care products:

- PCR
- Tooth Shades Whiter
- Non-abrasive Stain Removal
- Denture Cleaning
- Mouthwash Stain Removal
- Bespoke Whitening
- Enamel Polishing
- Stain Prevention
- Propensity to Stain



PELLICLE CLEANING RATIO TEST (PCR)

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



TOOTH SHADES WHITER

- Modified PCR test that converts stain removal into tooth shades whiter, over varying time periods e.g., one week, or one month.
- Human or bovine enamel samples are stained to the darker end of an internationally recognised shade guide.
- Oral care products are applied under standardised test conditions.
- A precision spectrophotometer is used to measure colour pre and post treatment.
- The number of tooth shades whiter is calculated after treatment.





NON-ABRASIVE STAIN REMOVAL

- Evaluates the ability of oral care products to whiten teeth by a non-abrasive mode of action.
- Compares the ability of whitening gels or strips, toothpastes or mouthwashes to remove stains from extrinsically stained enamel or human teeth with natural intrinsic stain.
- A precision spectrophotometer is used to measure colour pre and post treatment.
- Whitening efficacy can be expressed using a range of end-points.



DENTURE CLEANING

 Compares the ability of oral care products to remove stains from denture materials.

 Denture materials are stained with an inhouse staining protocol.

 Oral care products are applied under standardised test conditions.

 A precision spectrophotometer is used to measure colour pre and post treatment.



MOUTHWASH WHITENING

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



BESPOKE WHITENING STUDIES

• We can tailor tests to assess end-points such as:

- Instantly whiter.
- Progressively whiter.
- Maximum level of stain removal.
- Restores natural tooth brightness.
- Conceals tooth stains.



ENAMEL POLISHING

- Compares the ability of oral care products to improve enamel gloss and to reduce enamel surface roughness.
- Oral care products are applied under standardised test conditions.
- A precision spectrophotometer is used to measure enamel gloss pre and post treatment.
- A 3D profilometer is used to measure enamel roughness pre and post treatment.







STAIN PREVENTION

- Compares the ability of oral care products to prevent stains from being deposited onto human or bovine enamel, versus a negative control.
- 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.
- A precision spectrophotometer is used to measure tooth brightness pre and post treatment.

PROPENSITY TO STAIN

- Measures the propensity of foods, drugs or cosmetic products to stain denture materials, enamel or dentine.
- Samples are subjected to a defined number of treatment applications under controlled conditions.
- A precision spectrophotometer is used to measure colour pre and post treatment.





DENTINE OCCLUSION

DENTINE OCCLUSION

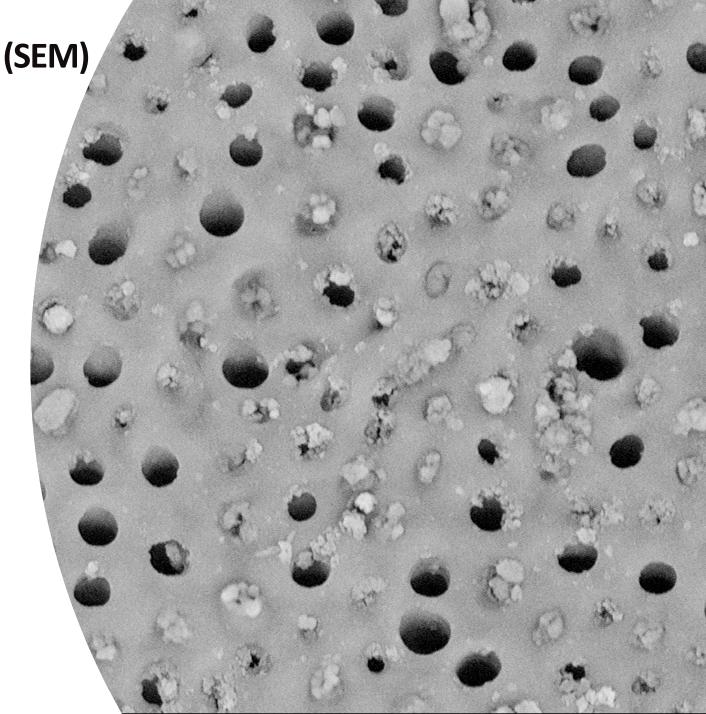
- Dental sensitivity is linked to the movement of fluid within the dentine tubules.
- The physical occlusion of dentine tubules is reported to restrict fluid movement and relieve dental sensitivity.
- Intertek CRS offers two models to evaluate the ability of oral care products to occlude dentine tubules:
 - SEM Dentine Occlusion Studies
 - Hydraulic Conductance Studies



SCANNING ELECTRON MICROSCOPE (SEM)
DENTINE OCCLUSION

 Compares the ability of oral care products to physically occlude dentine tubules.

- A variety of protocols are available such as single use, or 5 day occlusion studies.
- SEM is used to capture images of dentine occlusion.
- Our trained assessors can grade dentine occlusion on a 5-point occlusion scale, which is converted to the percentage of dentine tubule occlusion.



HYDRAULIC CONDUCTANCE

- Compares the ability of oral care products to reduce fluid flow through dentine tubules.
- Dentine samples are prepared to precise specifications.
- Microfluidic flow equipment is used to determine changes in the flow of perfusion solution through dentine tubules before and after treatment.



ENAMEL REPAIR & PROTECTION



ENAMEL REPAIR & PROTECTION

Maintaining strong enamel is important for tooth functionality and durability.

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

- Enamel remineralisation / demineralisation studies
- Fluoride uptake studies
- Enamel and dentine erosion studies

2.5 bn

people worldwide are estimated to suffer from dental caries³

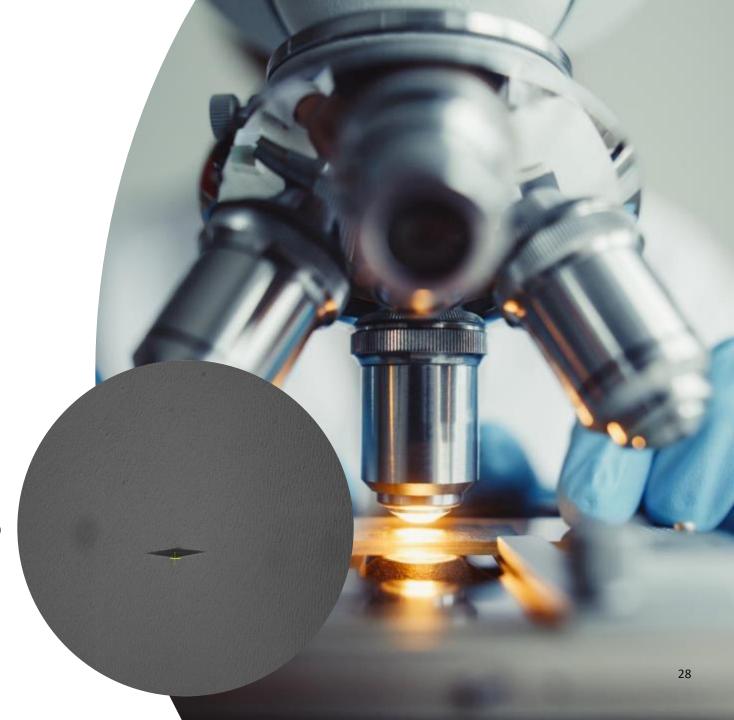
Repair and Protection Products Market Growth driven by:

- 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

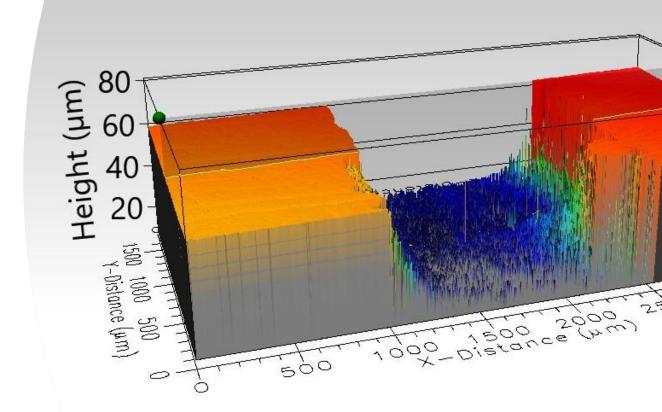


- Compares the ability of oral care products to deliver fluoride into the surface of enamel lesions.
- Oral care products are applied as part of a pH cycling regime under standardised test conditions.
- A vacuum and acid system is used to extract fluoride from enamel lesions.
- The fluoride concentration of the samples is measured pre and post treatment with a calibrated fluoride ion selective electrode to determine the enamel fluoride uptake.



ENAMEL AND DENTINE EROSION STUDIES

- Compares the ability of oral care products to prevent enamel and dentine erosion.
- Assess the potential of oral products to erode enamel or dentine.
- Oral care products are applied under standardised test conditions.
- Erosion is measured by 3D profilometry.





ANTI-PLAQUE

Plaque control is required to maintain a healthy oral cavity.

Intertek CRS offers a range of tests designed to assess the ability of oral care products to control plaque.

- Anti-plaque studies
- Plaque pH buffering studies
- Plaque removal studies



ANTI-PLAQUE



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



Intertek CRS In Vitro Oral Care Product Services 33

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 enamel demineralisation during a sucrose challenge.
- Dental plaque is seeded from pooled human saliva and treated with oral care products.
- Treated dental plaque is exposed to sucrose and the pH measured with a pH electrode over 20 minutes.
- Test product anti-plaque efficacy is compared against a negative control.





(N)

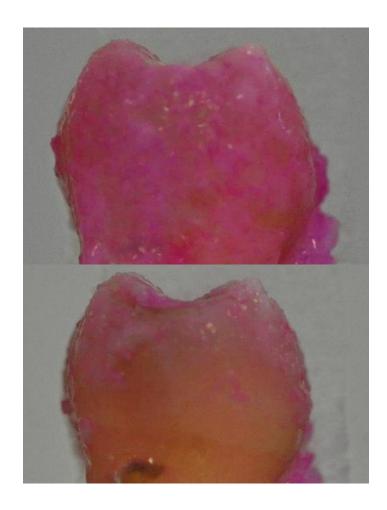
- Compares the ability of oral care products to remove dental plaque.
- Dental plaque is seeded from pooled human saliva and is grown on the surface of various substrates e.g., human enamel, restoration materials and acrylic teeth.
- A disclosing solution is used to quantity the plaque coverage pre and post treatment.
- Image analysis software is used to assess the removal of dental plaque.
- Various study designs can be utilised using this method:
 - Non-mechanical plaque removal (mouthwash)
 - Removal of plaque via mechanical brushing
 - Removal of plaque following water flosser treatments
 - Removal of plaque following flossing treatment





WATER FLOSSER PLAQUE REMOVAL





- Intertek has developed a model to compare the ability of a water flosser device to remove plaque from treated areas of teeth.
- The model is suitable for determining the cleaning efficacy of water flosses.
- Human teeth are used to create models with different sized interproximal spaces.
- Plaque biofilms are seeded from pooled human saliva.
- The tooth model exposed to a water flosser treatment.
- Image analysis software is used to quantify the level of plaque removal.

Intertek CRS In Vitro Oral Care Product Services



INTERPROXIMAL CLEANING

Interproximal cleaning is essential for dental health, because it helps remove debris and interproximal dental plaque, which can lead to gum disease, tooth decay, and bad breath.

Intertek CRS offers a range of tests designed to assess the ability of oral care products to clean interproximally:

- Interdental brush interproximal cleaning
- Toothbrush interproximal cleaning
- Floss interproximal cleaning

\$5.5

billion

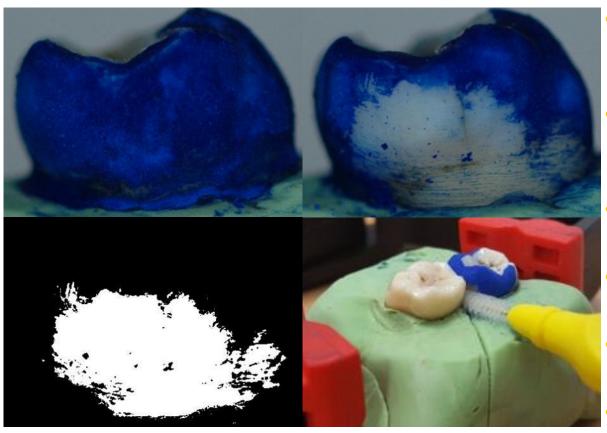
The Global
interproximal market
is expected to reach
by 2034⁴

Key Drivers:

- Rising Awareness of Oral-Systemic Health Links
- Shift Toward Preventive Oral
- Innovation & Personalization in Oral Care
- Aging population is strongly adopting interproximal cleaning

INTERDENTAL BRUSH INTERPROXIMAL CLEANING



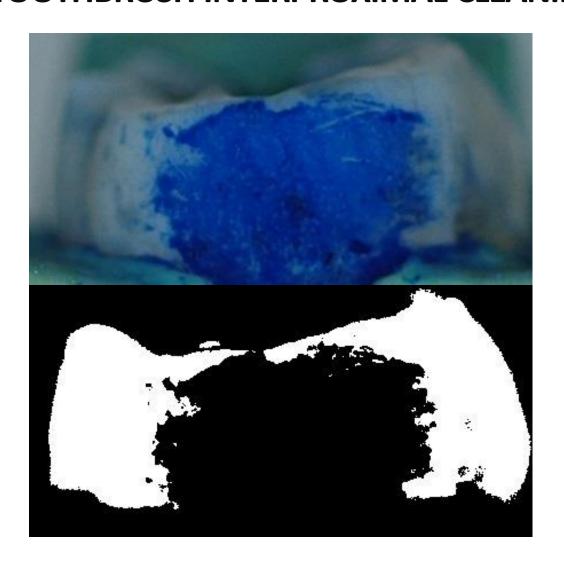


- Intertek has developed a model to compare the ability of oral care products to clean the interproximal areas of teeth.
- The model is suitable for determining the interproximal cleaning efficacy of interdental brushes.
- Human teeth are used to create models with different sized interproximal spaces.
- A Vaseline and blue dye system is used to replicate dental plaque.
- The model is brushed in a reciprocal motion to remove the blue dye.
- Image analysis software is used to quantify the level of interproximal cleaning.
- The method can be adapted to use real plaque biofilms.

Intertek CRS In Vitro Oral Care Product Services 39

TOOTHBRUSH INTERPROXIMAL CLEANING



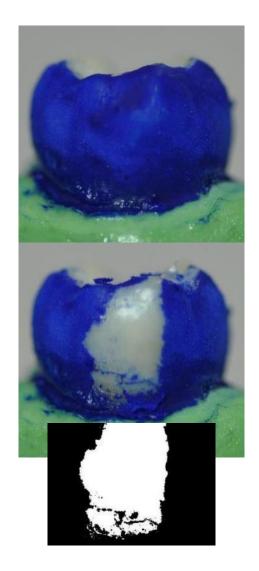


- Intertek has developed a model to compare the ability of oral care products to clean the interproximal areas of teeth.
- The model is suitable for determining the interproximal cleaning efficacy of toothbrushes.
- Human teeth are used to create models with different sized interproximal spaces.
- A Vaseline and blue dye system is used to replicate dental plaque.
- The model is brushes across the buccal, lingual and occlusal surfaces.
- Image analysis software is used to quantify the level of interproximal cleaning.
- The method can be adapted to use real plaque biofilms.

Intertek CRS In Vitro Oral Care Product Services 40

FLOSS INTERPROXIMAL CLEANING





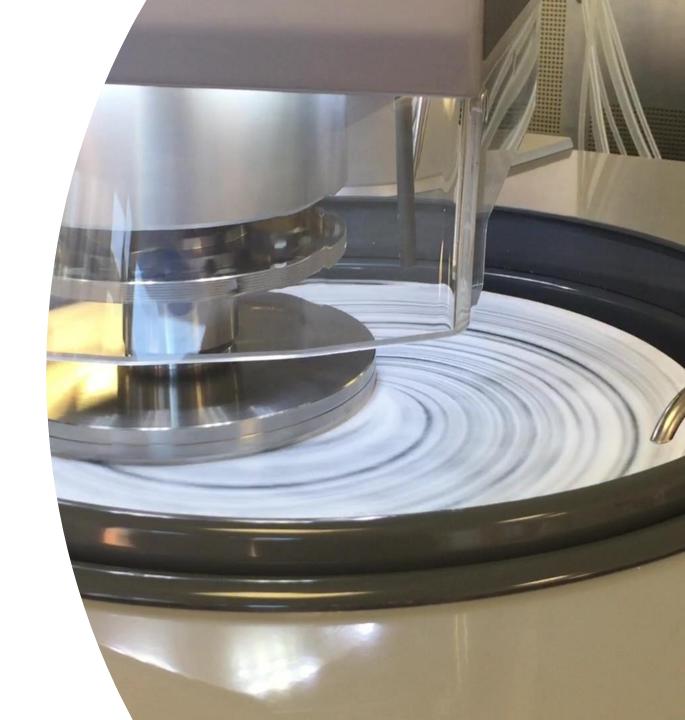
- Intertek has developed a model to compare the ability of oral care products to clean the interproximal areas of teeth.
- The model is suitable for determining the interproximal cleaning efficacy of flosses.
- Human teeth are used to create models with different sized interproximal spaces.
- A Vaseline and blue dye system is used to replicate dental plaque.
- The tooth model is flossed using a single downwards and upwards stroke.
- Image analysis software is used to quantify the level of interproximal cleaning.
- The method can be adapted to use real plaque biofilms.





SUPPLY OF HARD TISSUE SAMPLES

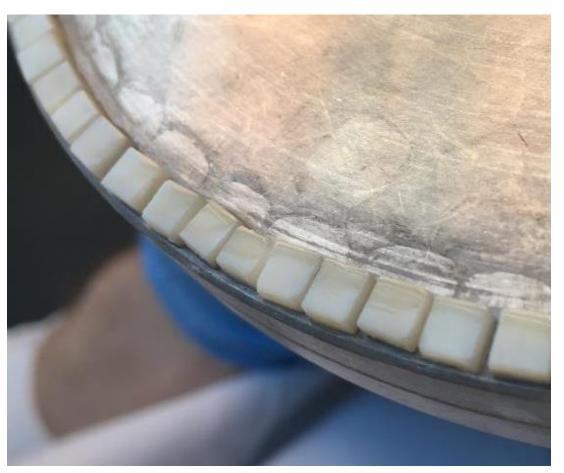
- Intertek can supply samples of hard tissue to support your internal research and development.
- Intertek CRS is licensed by the Human Tissue Authority to store and use human teeth for research purposes.
- Intertek CRS is licensed by DEFRA to use bovine teeth for research purposes.
- Intertek can supply samples of acellular human or bovine tissue to be used as a test substrate to be evaluate the efficacy of oral care products.



SUPPLY OF HARD TISSUE SAMPLES



- Intertek CRS supports client's internal R&D by supplying a range of hard tissue samples:
 - Human or bovine enamel blocks or discs.
 - Human or bovine dentine blocks or discs.
 - Samples made to specific dimensions or surface finishes.
 - Samples cast into specific moulds.
 - Stained enamel samples.
 - Artificial enamel lesions.
 - Blocks or discs of dental restoration materials.
 - Gamma-irradiated human saliva.



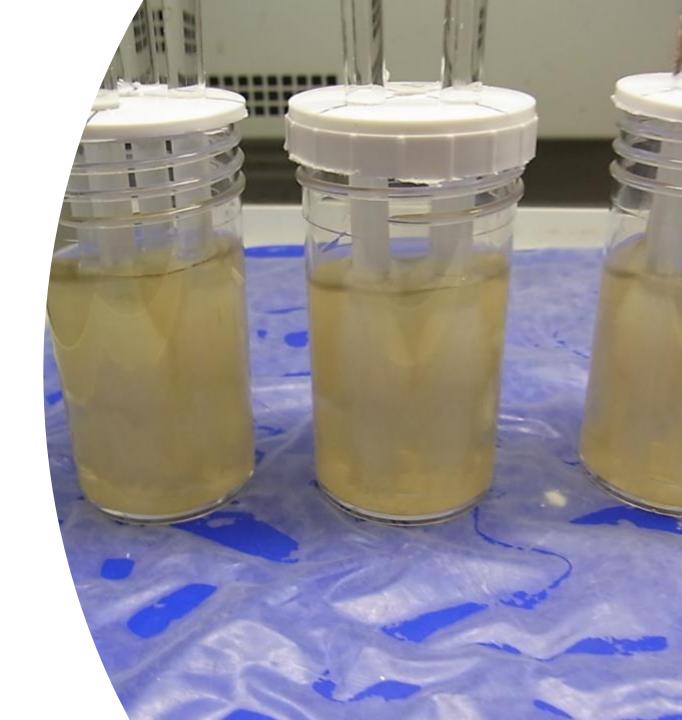
Intertek CRS In Vitro Oral Care Product Services 44

SUPPLY OF GAMMA IRRADIATED SALIVA



SUPPLY OF GAMMA IRRADIATED SALIVA

- Intertek can supply sterile, gamma irradiated saliva to support your internal research and development programmes.
- Intertek CRS is licensed by the Human Tissue Authority to collect, store and use human saliva for research purposes.
- Intertek can supply gamma irradiated saliva to be used as a test substrate to be evaluate the efficacy of oral care products.
- Intertek can also supply artificial saliva, using a range of recipes.



ION ANALYSIS Intertek CRS In Vitro Oral Care Product Services

ION ANALYSIS

- Intertek CRS supports client's internal R&D by analysing the active ingredient content of toothpastes, mouthwashes or alternative oral care products.
- Intertek has the capability to analyse, the fluoride and potassium ion concentration of oral care products by Ion Selective Electrode (ISE).



FLUORIDE ION ANALYSIS

- Intertek CRS supports client's internal R&D by analysing the free and total fluoride content of toothpastes.
- Free fluoride is a measure of the bioavailable (water soluble) fluoride concentration of an oral care product.
- Total fluoride is a measure the whole fluoride concentration of an oral care product. In this method, the formulation is broken down using acid to digest insoluble fluoride.



POTASSIUM ION ANALYSIS

- by analysing the free potassium ion concentration of oral care products and analysing the delivery of potassium ions to dentine tubules.
- Potassium nitrate plays a key role as a desensitising agent, to reduce nerve pain, alleviating sensitivity.
- Intertek's potassium dentine delivery model, provides evidence to show potassium is delivered to the dentine tubules.



SAFETY 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
 - Relative enamel abrasivity (REA); ISO 11609
 - Erosive capacity of whitening treatments;
 ISO 28399
 - Manual toothbrush testing BS EN ISO 20126



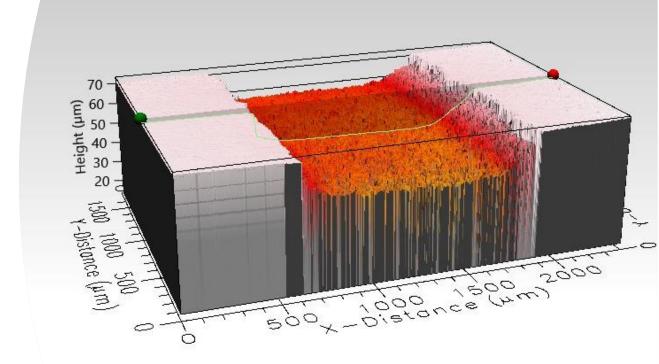
RELATIVE DENTINE ABRASIVITY (RDA) & RELATIVE ENAMEL ABRASIVITY (REA)

- Compares the abrasivity of toothpaste formulations to an ISO reference abrasive to determine safety of the oral care product.
- Performed in accordance with ISO 11609.
- Tissue loss is measured using a 3D profilometer across the reference and brushed regions of a sample.
- RDA and REA values are calculated relative to a reference abrasive.



EROSIVE CAPACITY OF EXTERNAL TOOTH BLEACHING PRODUCTS

- Compares the erosive potential of external tooth bleaching products versus a positive control.
- Performed according to ISO 28399.
- Erosive capacity assessed via surface microhardness and 3D profilometry.



TOOTHBRUSH TESTING

- This International Standard is intended to determine the physical properties of manual and electric toothbrushes.
- Performed according to BS EN ISO 20126
- Performed according to ANSI/ADA 119
- Performed according to EN ISO 20127:2020
- Performed according to ISO 22254:2005





CLINICAL SUPPORT

Intertek CRS can provide analytical support with clinical studies, by partnering with CROs.

Intertek CRS offers the following analytical support for clinical studies:

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



ORAL MALODOUR

- Intertek CRS can provide on-site analytical support for oral malodour clinical studies.
- Our analysts have experience in analysing oral malodour by GC, SIFT-MS and Oral Chromas.
- Volatile Sulphur compound levels are assessed pre and post product use using Oral Chromas.



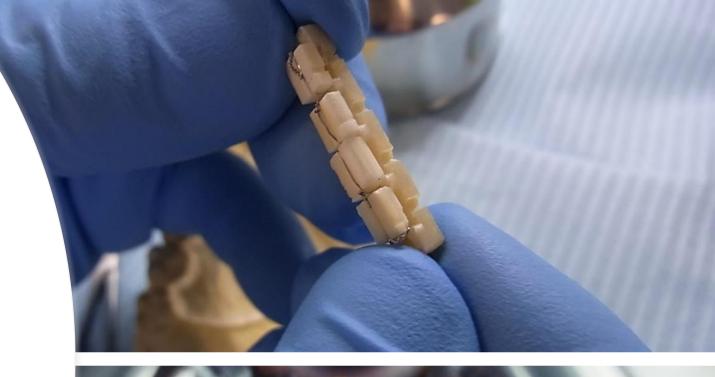
SALIVARY CLEARANCE STUDIES

- Intertek CRS can provide analytical support for salivary clearance clinical studies.
- Our analysts have extensive experience of analysing samples for salivary clearance studies.
- Ion selective electrodes are used to measure the concentration of fluoride and calcium in saliva and plaque.



IN-SITU SURFACE MICROHARDNESS (SMH) STUDIES

- Intertek CRS can provide analytical support for in-situ surface microhardness studies.
- Our analysts have extensive experience in preparing samples and measuring surface microhardness for clinical in-situ SMH studies.
- Intertek can arrange sterilisation of insitu samples via third party gamma irradiation.







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

Contact Us

Tel: +44 151 347 4810

Email: oral-care@intertek.com

Visit us Online www.intertek.com/oral-care

Intertek CRS, Elm House, Unit A4, Oaklands Office Park, Hooton Road, Hooton, CH66 7NZ



