intertek
Total Quality. Assured.

IN VITRO RESEARCH SERVICES

Expert assistance with *in vitro* oral care studies from our dedicated analysts and multi-disciplinary scientists

Ensuring the safety and efficacy of your oral care products is critical to success. In an era where financial prudence is a necessity, designed *in vitro* testing offers a more rapid and cost-effective route to obtaining the data you need to support marketing claims.

We understand the need to have a responsive, flexible testing resource, with experienced project management to meet your critical milestones and deliver robust data every time. Our *in vitro* team have been a trusted partner for those manufacturing oral care products for many years and is now a leading service provider in the oral care sector. *In vivo* clinical studies for oral care products are the gold standard in terms of product assessment, however, these can be rather complex, time-consuming and expensive. Instead, a well-designed *in vitro* test can often yield the required data much more quickly and at a lower cost. Such studies – whether they are to support early-stage development of a product formulation or in support of marketing claims or pack claims - may be routinely carried out.

With over 19 years of experience *in vitro* oral care studies we have been a trusted partner for developers and manufacturers of oral care products. Our scientists deliver Total Quality Assurance for our customers, enabling them to power ahead safely by offering *in vitro* method development for bespoke models and screening of oral care products to target those most promising for human dental clinical trials or oral care clinical studies with rigorous assessment supporting safety, product development, regulatory compliance and advertising claim support.

Hard tissue preparation

Intertek can assist you with your own laboratory studies through the provision of human and bovine hard tissue samples (enamel or dentine). Discs or blocks can be supplied to any specification and finish, using a wide range of specialized saws, abraders and polishing machines. Complete tooth specimens (subject to regulatory requirements) can also be provided mounted in acrylic or resin supports.

Stain prevention / stain removal

We offer artificial stain build-up protocols using a bespoke staining rig that slowly cycles samples in and out of the staining mixture. Artificial staining solutions typically contain tea, coffee, red wine and/or tobacco extract and can be formulated according to published methods or specifically blended to the client's requirements. Colour assessments (L*a*b*) can be carried out at various time points using a chromameter. Performance of mouthwashes and toothpaste slurries at either preventing or removing stain can be compared to benchmark products and controls.

Enamel erosion

Erosion of enamel by acidic drinks or foods is of increasing concern to consumers and manufacturers alike. We can test your product's efficacy at preventing or treating this issue.

Scanning electron microscopy (SEM)

We can now offer scanning electron microscopy enabling you to visualize enamel or dentine surfaces to a high degree of magnification. This is particularly useful for observing dentin tubule occlusion or analysing repaired enamel. Our instrument also has the ability to perform EDS X-ray elemental analysis enhancing its investigative capabilities.

Anti-plaque and anti-calculus

Anti-plaque and anti-calculus testing is offered for mouthwash and toothpaste products / ingredients. Plaque is seeded from pooled human saliva and grown on roughened Perspex rods adding sucrose to promote growth. The rods are periodically exposed to test products and after several days the plaque is harvested, weighed and analysed for Total Viable Counts (TVC). Rods can alternatively be exposed to mineralising solution to promote calculus formation followed by acid digestion and calcium analysis by ICP-OES.

FOR MORE INFORMATION

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Enamel / dentine abrasivity
Intertek offers both 2-D and 3-D surface profilometry to measure abrasion (RDA), roughness, and tissue loss from dentine and enamel blocks.

Remineralisation / demineralisation testing
Artificial lesions can be prepared in enamel or dentine blocks using dietary acid solutions or gels. The blocks are then subjected to pH cycling protocols followed by microhardness or microradiography evaluation. Data can be used to support fluoride delivery claims, rehardening of enamel (tooth strengthening) and resistance to acid erosion.

Cleaning efficacy
We offer cleaning evaluation of dentifrices, toothbrushes, interdental brushes, flosses and tapes. We have a bespoke artificial brushing machine that can be used for abrasivity, stain removal, gloss and pellicle cleaning ratio (PCR) testing. Where appropriate, image analysis can also be used to quantify removal of artificial plaque.

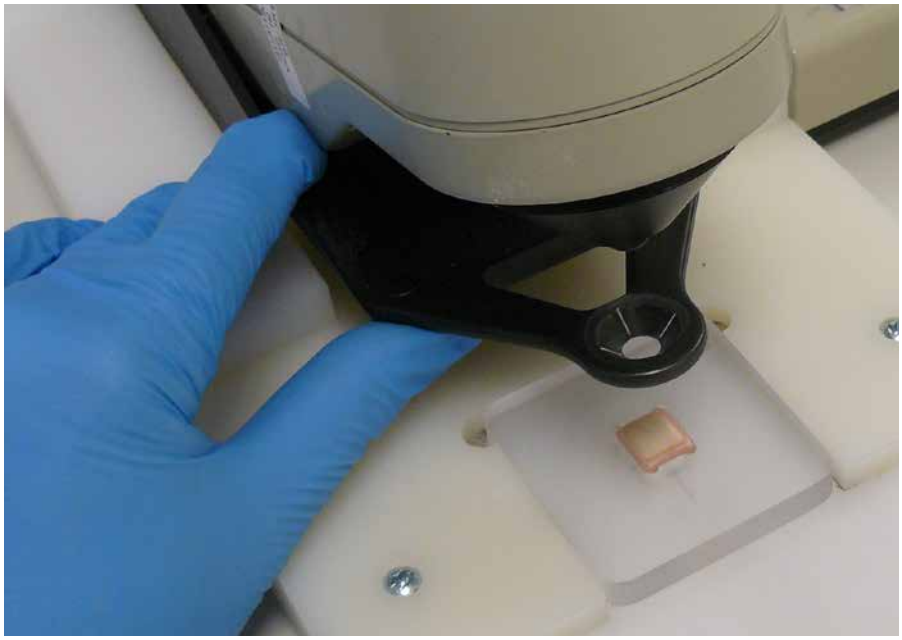
Denture cleaning
We can design bespoke models to test the efficacy of denture cleaning tablets at removing built-up stain and dental plaque deposits. Stain can be generated using various dietary foodstuffs and measured using a chromameter. *In vitro* plaque (seeded from human saliva) can be grown on dentures and removal quantified by staining followed by image analysis.

Analytical R&D support
Supporting the *in vitro* work, Intertek can provide the following services to assist with your product development:

- Product – substrate interactions - Examination of active delivery and product efficacy
- Product characterisation - This includes de-formulation, physical specifications and active ingredient
- Quantification
- Product safety - Assessments of contaminants / prohibited materials assessment, as well as stability studies and microbiological control

Bioanalytical services
With a network of technical, specialized partners Intertek can provide quantitative measures of active compounds in biological fluids, specifically saliva, plaque and gingival circular fluid. In this way we can support pharmacokinetic studies, investigate bioequivalence and identify key protein markers for oral care conditions. Techniques include:

- Chromatographic method such as HPLC and GC
- Electrophoresis
- Ligand binding assays such as ELISA
- Mass spectrometry
- Nuclear magnetic resonance



Chromameter and Jig during analysis

CASE STUDY

In vitro testing for a novel stain removing toothpaste
A client was developing a novel stain removing toothpaste aimed removing tobacco stains and needed robust data to support marketing claims.

Our Solution
The established PCR test is ideal to support claims related to tea and coffee stains, however, this product formulation was specifically targeted at smoking-related staining for which an equivalent model does not exist. We designed a robust model involving aqueous extraction of loose tobacco to produce a staining solution and applied this to a controlled study to measure the stain removing efficacy of the dentrifice.

Benefit Delivered to our Client
This data allowed the client to differentiate toothpastes of varying stain removal capacity allowing the manufacturers to derive specific claims for advertising and pack copy. It also allowed them to rank experimental formulations under development and benchmark them against competitor products. This cost effective route gave valuable support to clients during their development and market launch of new effective products.

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