



Incisive Technologies announces the US Food and Drug Administration (FDA) has issued 510K clearance for BlueCheck™ Caries Detection and Monitoring, a novel caries detection device used by clinicians in dental examinations to aid the detection of early caries (tooth decay). Early caries is the precursor to cavities and is recognised by the World Health Organisation (WHO) as the world's most prevalent chronic disease.

BlueCheck specifically binds to active caries lesions and provides a visible blue color, aiding dental professionals by providing a direct and objective measure of disease. Covered by global patents for its novel mode of action; "by using the natural hydroxyapatite-binding chemistry of proteins the BlueCheck molecule has an affinity for and targets porous surface and sub-surface lesions" says Dr Jonathan Mangum, Chief Scientific Officer and inventor of the technology. "It is a specifically designed biomolecule, consisting of a protein, linker and dye, that selectively and reversibly binds to sites of dental demineralisation. BlueCheck is painted on, then a simple rinse washes away unbound BlueCheck, to reveal the active caries via the remaining bound blue color" he says. Due to the electrostatic interaction, removal of any bound BlueCheck is via brushing with toothpaste and interaction with saliva.

According to the US Centers for Disease Control and Prevention, dental caries affects more than 95% of Americans over their lifetime and leads to dental cavities, which require more invasive and costly restorations. "This decision represents a major milestone towards ensuring that millions of people in the US, especially those in underserved communities, have access to best-in-class oral health solutions with the potential to meaningfully improve health outcomes. As one of the early investors in Incisive Technologies, we believe in the significant market opportunity here, but we are most excited about the potential for BlueCheck to directly impact people's lives for the better" commented Mariya Filipova, Chief Innovation Officer, CareQuest Innovation Partners.

The WHO in their briefing on the prevention and treatment of dental caries recognise that "minimally invasive intervention approaches avoid unnecessary pain, infection and permanent damage to teeth while preventing and treating caries" and BlueCheck's aim is to support this by simplifying early caries detection. "Dentists are notoriously bad at determining if enamel tooth decay is active/progressing, needing prevention and what part of the dentin is infected tooth decay, needing removal. Indicators that aid the dentist in finding active enamel and infected dentin are extremely useful." Joel White, DDS, MS, Distinguished Professor in Restorative Dentistry, Department of Preventive and Restorative Dental Sciences, School of Dentistry, University of California, San Francisco.

Incisive appreciates that despite all the advances in dental care, caries remains one of the most prevalent chronic diseases, even though it is largely preventable. "We saw that global experts and thought leaders are driving a shift to a prevention focus, whereby earlier detection of caries enables prevention medicaments to be used, effectively halting the demineralisation process. However, finding dental caries early is challenging. The use of BlueCheck lets clinicians quickly and accurately supplement their evaluation, thereby aiding the identification of early caries. Earlier diagnosis of dental caries is key to patient education, use of remineralisation therapies and ongoing monitoring for caries progression." Kerry Hegarty, CEO, Incisive Technologies, states. "We've worked directly with dentists, orthodontists and



research collaborators to understand how our technology can support that shift to uplift care and improve patient outcomes. Early detection of dental caries and the differentiation of their activity status has consistently been mentioned as a top concern, in part because of the challenges with caries diagnosis. What we understand is that BlueCheck gives the clinician objective evidence in detecting and monitoring early caries. Our aim is to help simplify the management of caries” Kerry says.

BlueCheck is the first product to be commercialised by Incisive Technologies. Incisive is committed to advancing oral healthcare and the company aims to equip oral health professionals with the tools they need to prevent cavities. Incisive Technologies will continue to work with leading clinicians, academics and stakeholders to support the drive towards earlier caries detection and improved prevention to support minimally invasive care. Incisive has a number of research and collaboration projects to understand BlueCheck’s role in clinical management and develop the technology for other innovations.

This technology is said to seamlessly integrate with standard of care aiding clinicians to find demineralization prior to cavities forming, “it has the potential to improve accuracy and efficiency of the routine examination” says Incisive CEO, Kerry Hegarty. BlueCheck will initially be launched in the United States of America, with other markets to follow and will be available from September through US dental sales and distribution channels.

About Incisive Technologies

Incisive Technologies advances oral healthcare, our mission is to equip oral healthcare professionals with the tools they need to address the global challenge of tooth decay. Headquartered in Melbourne, Australia, Incisive Technologies is a private company that develops, manufactures and markets dental products supporting prevention. To learn more, visit incisive-technologies.com.

About CareQuest Innovation Partners

CareQuest Innovation Partners propels solutions that transform oral health. Together with investors, innovators, entrepreneurs, care providers, and community partners, we validate and scale new ways to improve overall health through oral health. Joined by the shared mission to improve the oral health of all, CareQuest Innovation Partners is the for-profit subsidiary of CareQuest Institute for Oral Health. To learn more, visit carequestinnovation.com.

About PaxMed International

PaxMed International is a leader in regulatory affairs for the medical device industry. To learn more, visit paxmed.com.

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