DNA from saliva: Oragene®•Dx performance as demonstrated through 510(k) validation studies

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Abstract
Molecular diagnostic tests allow for the rapid and accurate detection of biomarkers. Achieving high sensitivity and specificity of a diagnostic test requires a reliable and high quality sample. While traditionally blood was considered the preferred sample type for diagnostic applications, DNA from saliva is non-invasive and is more proven to be stable and beneficial alternative. DNA from saliva improves patient care and convenience with point-of-care sample collection while enabling efficient storage and transportation of stable samples at ambient temperature. DNA from saliva is reliably and easily collected using Oragene®•Dx. Oragene®•Dx is a device for the collection, stabilization and transportation of DNA from saliva and offers a non-invasive, reliable method for full collection or assisted collection of samples. A 10(k) validation study was performed to demonstrate the safety, effectiveness and robustness of the product. The Oragene®•Dx validation studies demonstrated that prior to collection, the kits can be transported at temperatures ranging from -20°C to 40°C and can be stored at room temperature for up to 24 months. Once saliva is collected, Oragene®•Dx saliva can be transported at temperatures ranging from -20°C to 50°C, without compromising the quality of the DNA present in the sample. DNA from 450 samples (245 unique donors) extracted using the manual preparation protocol for OGD-575. Oragene®•Dx saliva sample (DNA Genotek) was used to demonstrate performance characteristics for OGD-500 (DNA yield, DNA concentration and A260/A280 ratio). A subset of 45 donors was used to demonstrate performance characteristics for OGD-575. Performance of DNA extracted from Oragene®•Dx saliva was analyzed on Gentek’s eSensor® Warfarin Sensitivity Saliva Test.

Device stability
Short-life conditions were evaluated by storing unused devices at room temperature (RT), 6°C ± 4°C or 4°C ± 5°C for 10 months. Other devices were exposed to multiple freeze/thaw cycles of -20°C ± 5°C/50°C ± 5°C. At all study time-points a subset of devices were evaluated for physical and chemical properties to ensure the product was maintained within acceptable tolerances. A subset of devices was used to collect saliva from which DNA was extracted and analyzed for yield and A260/A280 ratio. In conclusion, the Oragene®•Dx validation studies demonstrated that Oragene®•Dx allows for a viable alternative for blood for use in molecular diagnostic applications.

Sample stability
Thirty (30) donors each self-collected four saliva samples using Oragene® format OGD-500 for a total of 120 samples. Samples were stored at room temperature (RT), 6°C ± 4°C or 4°C ± 5°C for 12 months, or at -20°C ± 5°C for 3 months without deterioration of DNA quality. Interfering substances were assessed through additional experiments, there was no effect of endogenous and exogenous potentially interfering substances (i.e. amylase, hemoglobin, eating, drinking, chewing gum) on performance. In conclusion, the Oragene®•Dx validation studies demonstrated that Oragene®•Dx allows for a viable alternative to blood for use in molecular diagnostic applications.

Reproducibility
The device reproducibility study was conducted at three sites. Three samples (collected using three lots of OGD-500) from each of ten donors, covering all possible genotypes for three alleles for the eSensor® Warfarin Sensitivity Saliva Test, were tested in triplicate by four different operators at three different sites. Each operator extracted DNA from each sample using the same alcohol precipitation method, followed by determination of DNA concentration and A260/A280 ratio for all samples by an independent operator at one of the sites. Four operators at three sites tested the extracted DNA samples on the eSensor® Warfarin Sensitivity Saliva Test. A total of 120 samples were collected using OGD-500 with modified 68 lines in order to simulate both under and over spitting based on user adherence to the recommended Instructions for Use included with the kit. DNA was extracted and analyzed for yield and A260/A280 ratio. In conclusion, Oragene®•Dx has been cleared for in vitro diagnostic use in the U.S.A. in accordance with 21 CFR 804.30. Oragene®•Dx is an registrered trademark of DNA Genotek Inc. All other brands and names contained herein are the property of their respective owners.

Summary
Oragene®•Dx is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for use in FDA cleared molecular diagnostic applications. Saliva may be collected by spitting directly into the Oragene®•Dx container or be transferred into the Oragene®•Dx container using a sponge. Saliva samples collected using Oragene®•Dx are stabilized and can be transported (and stored) at ambient temperatures. DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved.

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