

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION MEMORANDUM  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

K141410

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Not applicable.

**D. Type of Test:**

Collection and stabilization of genomic DNA from saliva for use in molecular genotyping testing

**E. Applicant:**

DNA Genotek, Incorporated

**F. Proprietary and Established Names:**

Oragene®•Dx Collection Device, model OGD-500.001

**G. Regulatory Information:**

1. Regulation section:

21 CFR §862.1675 - Blood specimen collection device

2. Classification:

Class II

3. Product code:

OYJ

4. Panel:

Chemistry (75)

## **H. Intended Use:**

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

Oragene®•Dx OGD-500.001 is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for over-the-counter use with FDA cleared, approved, or legally marketed exempt DNA carrier screening genotyping tests. Saliva samples collected using Oragene®•Dx OGD-500.001 are stabilized and can be transported and/or stored long term at ambient conditions.

3. Special conditions for use statement(s):

For over-the-counter use.

For use in adults of reproductive age.

4. Special instrument requirements:

None.

## **I. Device Description:**

The Oragene®•Dx OGD-500.001 collection device consists of a collection tube containing stabilizing liquid. The device consists of a tube and funnel with lid attached. Saliva is delivered directly by expectorating into the collection tube. A small cap is provided to close the tube for transport and storage (funnel with lid is detached and discarded).

## **J. Substantial Equivalence Information:**

1. Predicate device name(s):

Oragene®•Dx Collection Device, models OGD-500, OGD-575, OXD-525 and OYD-500

2. Predicate 510(k) number(s):

k110701

3. Comparison with predicate:

<b>Similarities and Differences</b>		
<b>Item</b>	<b>Candidate Device</b>	<b>Predicate (k110701)</b>
Intended Use	Intended for use in the non-invasive collection of saliva samples.	Same
Intended Use Population	Over-the-Counter	Prescription Use
Collection Device Contents	Nucleic acid stabilizing solution	Same
Sample Source	Saliva	Same

**K. Standard/Guidance Document Referenced (if applicable):**

- ISO 13485:2003 Medical Device – Quality Management Systems
- ISO 14971:2007 Medical Device – Application of Risk Management in Medical Devices

**L. Test Principle:**

The Oragene•Dx OGD-500.001 collection device collects and stabilizes human DNA from saliva; it can also be used for the transportation and long-term room temperature storage of a sample. Oragene•Dx is a non-invasive alternative for collecting high quality and quantity DNA for use in molecular genotyping applications.

The collection device consists of a collection tube, stabilizing liquid. After saliva is collected, the stabilizing liquid is mixed with the sample. Upon contacting saliva cells, the stabilizing liquid lyses cellular and nuclear membranes to release and stabilize nucleic acids. Samples can be immediately processed, transported or stored for future use. Device and sample integrity are preserved during typical ambient transport and storage conditions for up to 12 months. DNA extraction from Oragene•Dx can be performed using alcohol precipitation or other methods for the purpose of molecular genotyping applications.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

A reproducibility study was performed at 2 laboratory sites with a total of 105 BLM<sup>Ash</sup> homozygous common (“DD”) saliva samples to evaluate the reproducibility of the performance of the Oragene•Dx OGD-500.001 when used with the 23andMe PGS Bloom Syndrome Carrier Screening Test (See DEN140044 for additional information). The percent of saliva samples that failed QC on the second run was

7.6% (8/105) at site 2, with one sample failing QC on both runs due to a DNA concentration less than 15 ng/μL. All remaining samples that were tested provided 100% correct calls.

*b. Linearity/assay reportable range:*

Not applicable.

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

The Oragene·Dx OGD-500.001 format is comprised of the same physical and chemical components as the FDA cleared Oragene·Dx OGD-500 format (See k110701). Pre-collection shelf-life stability of the collection device, stability of samples post-saliva collection, and freeze-thaw stability of samples stored in the Oragene·Dx collection device has been evaluated (See k110701).

*d. Detection limit:*

The Oragene·Dx OGD-500.001 format has the same sample volume requirements as the FDA cleared Oragene·Dx OGD-500 format. Sample volume tolerance (the effect over-filling or under-filling the collection device) has been previously evaluated (See k110701).

The 23andMe PGS Carrier Screening Test requires a minimum DNA concentration. To ensure the minimum concentration is met, the DNA concentration of every sample submitted for testing is measured. If the extracted DNA concentration is below the minimum DNA concentration, re-extraction is attempted. If re-extraction is unsuccessful, the customer is contacted to submit a new saliva sample.

*e. Analytical specificity:*

The effect of endogenous interfering substances, exogenous interfering substances, smoking, and the effect of microbial DNA contamination was evaluated with the Oragene·Dx OGD-500.001 when used with the 23andMe PGS Carrier Screening Test. The endogenous, exogenous, smoking and microbial interference studies yielded 100% concordant genotype calls for all samples that were re-run after failing QC on the first run. See DEN140044 for additional study details.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison:*

A method comparison study was performed in order to determine the accuracy of the genotype obtained on the 23andMe PGS Carrier Screening Test using 65 saliva samples collected by the Oragene•Dx OGD-500.001 collection device as compared to bi-directional DNA sequencing. The total assay correct call rate for this study was 100% (65/65) See DEN140044 for additional information.

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Performance of the Oragene•Dx OGD-500.001 device when used in the over-the-counter setting of the 23andMe PGS Carrier Screening Test was evaluated. New 23andMe customers who registered their kit within consecutive 24-hour periods were invited to participate in the study survey via email. Samples from customers who completed the survey were shipped to the testing laboratory. Upon receipt at the testing laboratory, each study sample was assessed for compliance to collection instructions and sample volume, DNA concentration, and DNA purity (A260/A280 ratio) was assessed. User comprehension of test instructions, including comprehension of sample collection instructions was also assessed.

A total of 302 individuals completed the user comprehension survey and provided a saliva sample for analysis. The majority of participants (96.3%) were naïve to the device and saliva collection process. Of the 302 samples evaluated, 98.3% contained the minimum amount of DNA required for testing, demonstrating that customers were able to follow sample collection instructions to obtain adequate sample for testing. See PGS co-submission DEN140044 for additional user study information.

A Flesch-Kincaid reading analysis was performed on the collection device labeling and a reading grade level of 7.1 was obtained.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.