ORAcollect®·Dx

Product handbook

DNA genotek

www.dnagenotek.com

Tel.: +1.613.723.5757
support@dnagenotek.com

3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2
Subsidiary of OraSure Technologies, Inc.

Superior samples
Proven performance

IVD CE

Table of contents

EC REP
Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Intended use

ORAcollect®•Dx is intended for use in the non-invasive collection of saliva samples. Human DNA from the saliva sample is isolated, stabilized, and suitable for use in FDA cleared molecular diagnostic applications. Saliva samples collected using ORAcollect•Dx are stabilized and can be transported and/or stored long-term at ambient conditions.

Summary and explanation of use

ORAcollect•Dx is a self-collection kit that provides the materials and instructions for collecting and stabilizing human DNA from saliva samples.

Features

ORAcollect•Dx is a superior alternative to buccal swabs and offers several advantages:

- Collection of sample is simple and gentle for donor
- Efficient collection is ideal for clinical workflows
- DNA integrity is maintained at ambient temperature for transportation via regular post
- Samples can be exposed to temperature fluctuations between -20°C and 50°C during transport
- Bacteriostatic reagent inhibits growth of bacteria from time of sample collection to processing
- Liquid sample (no cutting of tips) eliminates manual steps, reduces the chance of errors and cross contamination, while facilitating efficiency in the lab
- High quality DNA sample enables downstream analysis with proven clinical utility
- Format optimizes laboratory efficiency
  - Use with liquid handling robots
  - Minimal hands on technician time
  - Compatible with standard labware
  - Integrated barcode on tube for workflow efficiency and sample traceability

Materials

Each single-use ORAcollect•Dx kit includes the following:

Format	Stabilizing liquid volume	Device with sponge**	Instructions for use
OCD-100	1 mL	✓	✓
OCD-100A***	1 mL	✓	✓

** Device contains stabilizing liquid.
*** Device contains insert

Warnings and precautions

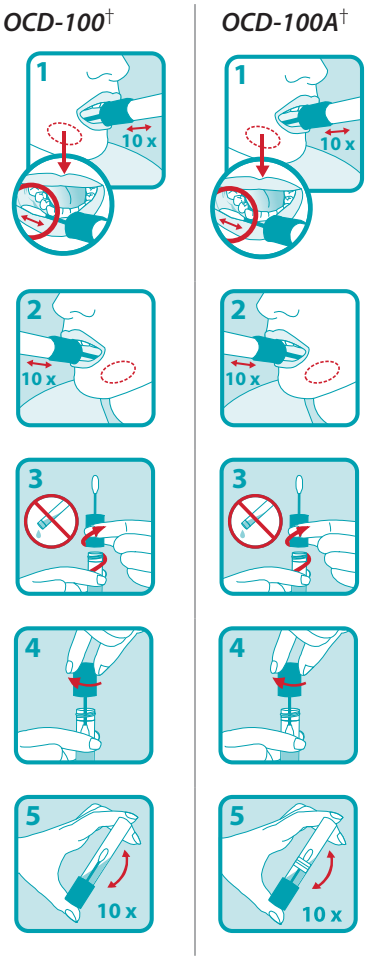
1. IVD In Vitro Diagnostic Medical Device.
2. For In Vitro Diagnostic Use.
3. Rx only. For professional use.
4. Do NOT use if packaging is damaged or device is broken or leaking. Discard unused, damaged or leaking kits in accordance with appropriate regulations.
5. Do NOT use ORAcollect•Dx beyond the "collect saliva by" date indicated on the device.
6. Only use the components and accessories provided with the kit.
7. Collection precautions:
   a. Read all instructions carefully prior to sample collection; deviation may result in inadequate sample and impact DNA yield.
   b. Do NOT eat, drink, smoke or chew gum for 30 minutes before sample collection.
   c. Ensure the sponge tip does not come into contact with any surface prior to collection.
   d. Choking hazard: Caution should be used when inserting the sponge into the donor's mouth.
   e. Donors with xerostomia (dry mouth) may not collect adequate sample using these instructions resulting in lower DNA yield and an invalid sample for use in the GenMark Warfarin Sensitivity Saliva Test.
   f. Wash with water if stabilizing liquid comes in contact with eyes or skin.
   g. Do NOT ingest stabilizing liquid.
8. This device may not collect an adequate DNA sample for your genetic analysis. The concentration and quality of the DNA sample collected with this device should be measured prior to conducting genetic testing.
9. Genomic DNA isolated from saliva samples collected using ORAcollect•Dx will contain a small amount of bacterial DNA (see page 9).
10. Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state and federal regulations.
11. This product requires the handling of human saliva specimens.
12. Material Safety Data Sheet (MSDS) is available at: www.dnagenotek.com.

Product use limitations

1. ORAcollect•Dx is intended for collection and stabilization of human DNA from saliva, it is NOT intended for the collection and stabilization of RNA, protein or hormones.
2. Performance characteristics for the ORAcollect•Dx kits were established using Qiagen's Qiamp column-based purification protocol.
3. ORAcollect•Dx was validated using the eSensor® Warfarin Sensitivity Saliva Test from GenMark Diagnostics Inc.

Donor collection instructions for use

Product number	Donor collection instructions for use document number
OCD-100	PD-PR-00380
OCD-100A	PD-PR-00506



† For detailed instructions refer to the full instructions for use, as referenced in the table above. Available at www.dnagenotek.com.

Transportation of ORAcollect•Dx

Pre-collection

ORAcollect•Dx kits can be stored at room temperature (15°C to 25°C) and can tolerate temperature fluctuations between -20°C and 50°C during transport.

Post-collection

ORAcollect•Dx/saliva samples can tolerate temperature fluctuations between -20°C and 50°C during transport.

For domestic or international shipments, specimens should be packaged and labelled in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

Storage of ORAcollect•Dx

Pre-collection

Store ORAcollect•Dx kits at room temperature for up to 24 months.

Post-collection

Store ORAcollect•Dx/saliva samples at room temperature for up to 60 days.

Purification and quantification

ORAcollect•Dx performance has been established using the following protocols:

1. ORAcollect•Dx/saliva samples were purified in accordance to: QIAGEN® QIAamp® DNA Mini Kit (Catalog #: 51304) *DNA Purification from Blood or Body Fluids (Spin Protocol)*
2. We recommend quantifying DNA using fluorescent dyes specific for double stranded DNA (PicoGreen® or SYBR® Green I).

Performance characteristics

The results obtained during studies of product performance support the following claims:

ORAcollect•Dx device performance data

Data from samples collected using the OCD-100 device is used in support of the performance characteristics for ORAcollect•Dx. In this study 80% of donors were naive to the collection device.

OCD-100/ OCD-100A

Overall data

	DNA concentration (ng/uL)	Total DNA yield (ug)	A_{260}/A_{280} ratio
N	156	156	156
Mean ± SD	11.77 ± 6.59	2.94 ± 1.65	1.75 ± .15
Median	10.50	2.63	1.74

Summary of method comparison genotyping results

	Samples tested	Correct calls	Incorrect calls	No-calls	% Agreement
Final-pass	156	155	0	1†	99.4%

† Investigation of original and re-extracted DNA samples found no-call was likely due to extraction procedure or operator error.

Interfering substances

Both endogenous and exogenous potentially interfering substances were added separately to ORAcollect•Dx saliva samples from donors with known genotypes. Addition of tested substances had no effect as demonstrated through testing on eSensor® Warfarin Sensitivity Saliva Test. All samples gave a correct call after retest.

Summary of eSensor® Warfarin Sensitivity Saliva Test results for interfering substances

Method	Samples tested	Correct call	Incorrect call	No-call	% Agreement
Amylase	14	14	0	0	100%
IgA	14	14	0	0	100%
Hemoglobin	14	14	0	0	100%
Total protein	14	14	0	0	100%

Activity	Time-point	Samples tested	Correct call	Incorrect call	No-call	% Agreement
Eating	30 minutes	9	9	0	0	100%
Drinking	30 minutes	9	9	0	0	100%
Chewing gum	30 minutes	7	7	0	0	100%
Smoking	30 minutes	5	5	0	0	100%
Mouthwash	30 minutes	5	5	0	0	100%
Brushing teeth	30 minutes	9	9	0	0	100%

Reproducibility

Three samples (collected using three lots of ORAcollect•Dx format OCD-100) from each of ten donors, were processed by three different operators on multiple days. Each operator extracted DNA from each sample using the QIAGEN QIAamp DNA Mini Kit, followed by determination of DNA concentration and A_{260}/A_{280} ratio for all samples. Three operators tested the extracted DNA samples on the eSensor® Warfarin Saliva Sensitivity Test. Genotyping data was evaluated after first-pass results and all samples were concordant to bi-directional sequencing.

Summary of results stratified by operator

		Operator 1	Operator 2	Operator 3	Combined
Samples tested		20	20	20	60
DNA concentration (ng/uL)	Mean ± SD	11.80 ± 4.72	10.63 ± 4.12	10.54 ± 3.95	10.99 ± 4.24
	Median	10.61	9.86	9.95	10.33
Total DNA yield (ug)	Mean ± SD	3.08 ± 1.27	2.66 ± 1.03	2.64 ± 0.99	2.79 ± 1.10
	Median	2.70	2.46	2.49	2.61
A_{260}/A_{280} ratio	Mean ± SD	1.64 ± 0.07	1.66 ± 0.03	1.68 ± 0.06	1.66 ± 0.06
	Median	1.64	1.66	1.67	1.66

	SNP	Samples tested	Correct calls	Incorrect calls	No-calls	% Agreement
Operator 1	2C9*2	20	20	0	0	100%
	2C9*3	20	20	0	0	100%
	VKOR	20	20	0	0	100%
Operator 2	2C9*2	20	20	0	0	100%
	2C9*3	20	20	0	0	100%
	VKOR	20	20	0	0	100%
Operator 3	2C9*2	20	20	0	0	100%
	2C9*3	20	20	0	0	100%
	VKOR	20	20	0	0	100%
Combined	2C9*2	60	60	0	0	100%
	2C9*3	60	60	0	0	100%
	VKOR	60	60	0	0	100%

For multi-site device reproducibility a total of 90 ORAcollect•Dx samples were extracted by three operators at three sites for a total of 270 sample aliquots extracted (90 aliquots per operator). Each operator analyzed the 90 extracted DNA samples for DNA concentration and A_{260}/A_{280} ratio.

		Site 1	Site 2	Site 3	Combined
Samples tested		90	90	90	270
DNA concentration (ng/uL)	Mean ± SD	11.01 ± 6.43	18.00 ± 8.71	13.87 ± 10.57	14.29 ± 9.17
	Median	9.70	16.04	11.58	12.50
Total DNA yield (ug)	Mean ± SD	2.75 ± 1.61	4.50 ± 2.18	3.47 ± 2.64	3.57 ± 2.29
	Median	2.42	4.01	2.89	3.12
A_{260}/A_{280} ratio	Mean ± SD	1.65 ± 0.06	1.79 ± 0.13	1.79 ± 0.07	1.74 ± 0.11
	Median	1.66	1.80	1.79	1.75

Sample stability

Samples were stored at room temperature (RT) for 60 days or subjected to 3 freeze (-20°C)/thaw (50°C)cycles. At the study time-point, DNA was extracted and analyzed for yield and A_{260}/A_{280} ratio. Samples stored at room temperature were analyzed for microbial content using a real-time PCR-based assay. A sub-population of samples were tested on the eSensor® Warfarin Sensitivity Saliva Test.

Summary of post-collection (sample) stability study results

	Temperature	RT	Freeze (-20°C)/ thaw (50°C)
	Time (days)	60	
ORAcollect•Dx	Yield	●	●
	A_{260}/A_{280} ratio	●	●

● Samples meet acceptance criteria (yield ≥ 10 ng, A_{260}/A_{280} ratio 1.2 – 2.3).

Summary of eSensor® Warfarin Sensitivity Saliva Test results for sample stability study

First-pass					
Format	Samples tested	Correct calls	Incorrect calls	No-calls	% Correct calls
ORAcollect•Dx	40	40	0	0	100%

Microbial content of samples stored at room temperature for 60 days

Samples stored at room temperature for 60 days exhibited no significant change in microbial content.

ORAcollect•Dx		Baseline	60 days
Samples tested		30	30
% Microbial content	Mean ± SD	5.35% ± 3.79%	5.19% ± 3.70%
	Median	4.38%	4.07%
	Min, Max	0.70%, 14.43%	0.86%, 14.45%
	p-value	0.7958	

Medical device symbol chart

	Use by
IVD	In vitro diagnostic medical device
REF	Catalog number
CE	CE Marking
15°C 25°C	Storage instructions
EC REP	Authorized Representative
	Manufacturer
LOT	Lot number

Patent information

Patent (www.dnagenotek.com/legalnotices)

Troubleshooting

Collection

Observation	Action
There is no stabilizing liquid in the device or the decive is leaking.	Do NOT allow donor to use the product; discard and request a replacement kit.
Stabilizing liquid comes into contact with eyes or skin.	Get donor to wash with water if stabilizing liquid comes in contact with eyes or skin. For safety data information consult the MSDS at www.dnagenotek.com.

Before purifying (post-collection)

Observation	Action
Saliva sample is cloudy, discoloured, and/or has floating particles.	Sample appearance may indicate that the donor did NOT follow the instructions for use. However this is unlikely to affect sample quality or performance as evaluated on GenMark Diagnostics' eSensor® Warfarin Sensitivity Saliva Test. Interference studies have demonstrated that such samples should not impact the genotyping results. Substances outside the scope of the interference study have not been evaluated thus caution should be taken when testing samples of abnormal appearance, such samples may require re-collection in accordance to the instructions for use. According to donor instructions for use, ensure donor abstains from eating, drinking, smoking or chewing gum for 30 minutes prior to donating a sample.
Sample is difficult to pipette.	Prior to sample purification, heat the entire sample in its original container at 50°C for at least an hour.
Sample leaked.	Donor error. Recollect sample.

DNA yield

Observation	Action
Low DNA yield and invalid sample use due to dry mouth (xerostomia).	Sample recollection is recommended.

Some DNA Genotek products may not be available in all geographic regions.

All DNA Genotek protocols, white papers and application notes, are available in the support section of our website at www.dnagenotek.com.

DNA genotek

www.dnagenotek.com

PD-HB-00010 Issue 4/2018-12