

Certificate of Analysis & Product Manual

Swab Collection Device (SCD), Swabs, Trace Samples, Touch DNA, Direct Touch DNA,
DNA Biometrics, SNP Genotyping, Pathogen Genotyping

Omni-Matrix™ Sample Collection Kit

Catalog No.: 80-2100-01

Storage Condition: Room Temperature

US Patent: 10,228,307

For Research, Forensic or Paternity Use Only

Not for use in diagnostic procedures for clinical purposes

Omni-Matrix™ Sample Collection Kit | Evaluation Version | Not for General Distribution



Material Supplied

The kit is good for a minimum of 20 independent sample collection sessions and we recommend discarding the unused matrix after the session. There is sufficient matrix for each session for more than 10 sample collection. Thus a total of ~200 sample collection equivalent swabs can be performed.

Storage Condition

Store all components at Room Temperature.

Omni-Matrix™ Z20 & K105 solution may become viscous and solidify below 25°C. **The Omni-Matrix™ Z20 is a free flowing viscous solution, check by inverting the tube if the content flows freely and has not solidified. If solidified then warm tubes at 50°C to 60°C prior to use.**

Beta Evaluation Version Omni-Matrix™ Sample Collection Kit

Content	Catalog No.	Product	Size
□	80-2020-01	Omni-Matrix™ K105 Solution*; 10 X 1 mL Spray bottles	10 x 1 mL
□	80-2030-02	Omni-Matrix™ Z20 Solution*; 10 x 2 mL dropper bottles	10 x 2 mL
□	80-2001-15	Scraper; 15 each	15

*Omni-Matrix™ solution may become viscous and solidify below 25°C.

The Omni-Matrix™ is a free flowing viscous solution, check by inverting the tube if the content flows and has not solidified. If solidified, prior to use warm tubes at 50°C to 60°C.

Certificate of Analysis & Product Specifications

Omni-Matrix™ Kit components are specifically designed and manufactured for collection of trace amount of dried biological sample for forensic analysis. This is specifically applicable to touch samples. All components are validated to collect, retrieve and yield DNA profile from trace amount (~40 cells) using Gene Link's Omni-Mag™ [Catalog#: 40-4100-XX], ABI PrepFiler®, Promega DNA-IQ® DNA extraction kits and with slight modification to Qiagen EZ1 & Investigator DNA extraction protocols.

Omni-Matrix™ Z20 and K105 matrix have been tested on all types of non-porous substrates (wood, plastic, glass, leather, ceramic etc.) to capture the biological samples with high efficiency and quantitatively release the captured material.


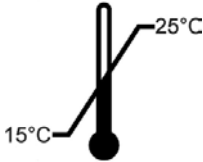

All components are certified to be free of nucleases. Appropriate nuclease free handling, dispensing and storage conditions required.




Omni-Matrix™ may solidify below 25°C. Prior to use, warm by immersing tube in ~60°C water bath, or by incubating in an oven at ~60°C until liquefied.

Manufacturing lot numbers are stated on the label of each product and accompanying packing slip.

Product Label Information

REF	Catalog No.	Description	Size
	80-2020-01	Omni-Matrix™ K105 Solution*; 10 X 1 mL Spray bottle	10 X 1 mL
	80-2030-02	Omni-Matrix™ Z20 Solution*; 10 X 0.5 mL	10 X 2 mL
	80-2001-15	Scraper; 15 each	15

		
Research Use Only	Storage Store at 15°C to 25°C	Lot Number Stated on product tube and packing slip

		
Expiry As marked on product	Instructions Consult product manual	QR Code Visit BioFunctions website for product details

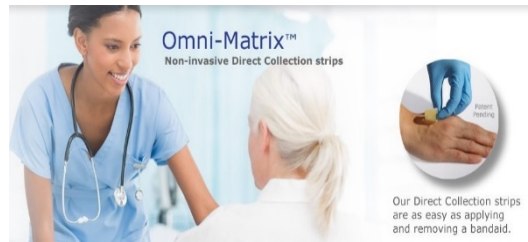
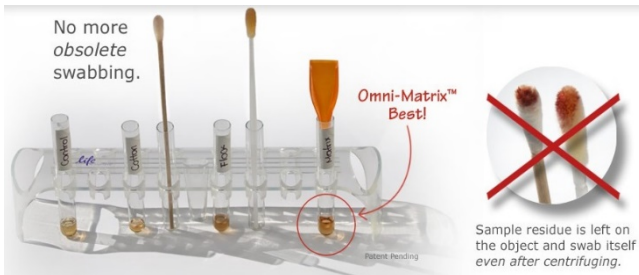
Omni-Matrix™ Sample Collection Kit

Product Description & Application

Currently available sample collection devices (SCD's) for human cellular materials especially destined for forensic analysis have not kept pace with the trace quantity (few nanogram to touch DNA ~100 picogram) of DNA required for sensitive and reliable genetic profiling technology (1). The currently available SCD's swab fiber materials are manufactured from the classic cotton to more recently with available rayon, nylon, foam and inorganic polysilane derivatives (2,3). Some of these perform well in collection but to a varying degree in the eventual release and retrieval of DNA; typically, 50-80% of the trace material is lost (4). The inherent problem lies in the fiber material of some of the SCD's as they trap and bind irreversibly to biological material while others are not able to collect samples quantitatively (4).

Working with trace material, especially in a forensic setting requires maximum DNA capture and retrieval. The Omni-Matrix™ Z20 and K105 matrix are a blend of biopolymer(s), excipients and optimized reagents. **The premise of sample collection is not of the typical swabbing technique but by coating and blending the biological sample by spraying of the Omni-Matrix™ K105 or direct application of the Z20 matrix, followed by essentially "picking up" the dried matrix film.** The resulting sample collection is almost quantitative without the need for multiple applications. The collected biological sample is embedded in the matrix thus allowing almost complete release and extraction of the quantitative DNA content of the collected sample. The Omni-Matrix™ is completely compatible with Gene Link's Omni-Mag™ [Catalog#: 40-4100-XX], ThermoFisher ABI PrepFiler® and Promega DNA-IQ® DNA extraction kits and with slight modification to Qiagen EZ1 & Investigator DNA extraction protocols.

The quantitative collection and retrieval of sample DNA using Omni-Matrix™ Z20 and K105 matrix has been tested on all types of non-porous substrates (wood, plastic, glass, leather, ceramic etc.) and it captures the biological samples with high efficiency and releases the cellular material quantitatively by determined external stimuli.



The Omni-Matrix™ has been tested and validated by NFSTC (National Forensic Science Technology Center) Largo, FL, USA at blood dilutions of 1:10; 1:100 and 1:200 and fingerprint studies for sample recovery, DNA yield and STR allele recovery of 97.7% at the lowest dilution of 1:200 blood (equating to ~50 cells and ~300 pg DNA) and 100% STR allele recovery for other dilutions using ThermoFisher GlobalFiler® Trio Chemistry and samples run on the 3500 genetic analyzer using GeneMapper® ID X Version 1.5.

The Omni-Matrix™ is superior to all tested swab sample collection devices in the total yield of DNA.

Email support@genelink.com to request a copy of the complete NFSTC 2016 Omni-Matrix DNA Collection Study report.

References

1. Verdon TJ, Mitchell RJ, Oorschot RA. Swabs as DNA collection devices for sampling different biological materials from different substrates. *Journal of forensic sciences*. 2014;59(4):1080-9.
2. Marshall PL, Stoljarova M, Larue BL, King JL, Budowle B. Evaluation of a novel material, Diomics X-Swab™, for collection of DNA. *Forensic Science International: Genetics*. 2014;12(0):192-8.
3. O'Brien R, Sutherland C, Figarelli D. Swab collection study, http://www.nfstc.org/?dl_id=267 NFSTC, Largo, FL2012.
4. E. Butts, Presentation at the American Academy of Forensic Sciences meeting (Washington, D.C.), February 21, 2013, "Evaluation of DNA Extraction Efficiency".

Procedure

Important Information

Omni-Matrix™ solution is a free-flowing viscous solution that may solidify below 25°C. Prior to use check the consistency of the matrix. Ascertain consistency by shaking, vortexing or inversion to determine if the contents are liquid or solidified. **If solidified, prior to use warm tubes at 50°C to 60°C to liquefy the matrix.**

General Background

There is two different Omni-Matrix™ matrices in the kit. The kit is designed to collect samples from non-porous or semi-porous (e.g leather, wood) surfaces.

- A. **Visible Samples:** The **Omni-Matrix™ Z20** is supplied as 0.5 mL volume in dropper bottles; it is for use as spotting with a drop on small discrete isolated samples.

The Omni-Matrix™ Z20 is specifically for use when the biological sample material to be collected is localized in a small area and can easily be visually identified as discrete spots.
- B. **Trace or Suspect Sample Area:** The **Omni-Matrix™ K105** supplied in a spray bottle is for use for all trace sample types of particularly touch DNA samples and other samples spread on a wider area with no distinct spots. The spray thus covers the required surface area to be collected.

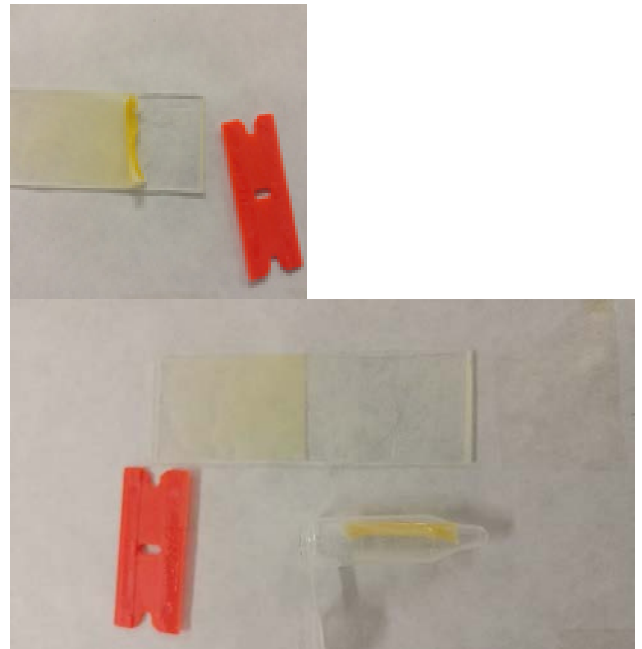
A. Visible Samples Omni-Matrix™ Z20 Dropper Application

1. Ascertain the Omni-Matrix™ Z20 is in liquid form. If not, warm at ~60°C until liquefied. Use a new tube for each session.
2. Dispense dropwise the Omni-Matrix™ Z20 directly on top of the biological sample spot. Ascertain to cover the entire sample and especially the edges. Do not over soak the sample with the Omni-Matrix™ Z20.
3. Repeat step#2 above for other localized spots.
4. Discard unused portion of the Omni-Matrix™ Z20 tube as standard laboratory waste. Do not save unused tube.
5. Allow matrix to dry and solidify for 5-10 minutes. Drying time varies depending on room temperature.
6. Using the provided scraper, start to slowly scrape the matrix film and pick it on the scraper.
7. Deposit the collected spot in a sterile 1.5 mL microcentrifuge tube.
8. Pool maximum of 2 spots (each approximately 1 cm square) in one tube.
9. Seal and label the tube appropriately.
10. The collected sample can be transported at room temperature and stored indefinitely at room temperature.
11. The collected sample can be processed directly for DNA extraction.
12. The Omni-Matrix™ Z20 with the collected biological sample will dissolve in the lysis solution of Gene Link Omni-Mag™, ABI PrepFiler® and Promega DNA-IQ™ DNA extraction kits and directly in Buffer AL of Qiagen Investigator extraction kit without addition of ethanol.
13. Continue DNA extraction following the manufacturer protocol after sample is in lysis buffer.



B. Trace or Suspect Sample Area Omni-Matrix™ K105 Spraying

1. Shake the Omni-Matrix™ K105 spray bottle to mix the contents before spraying.
2. Identify the specific area for sample collection.
3. Spray Omni-Matrix™ K105 to form a thin layer.
4. Areas missed may be sprayed again. DO NOT OVER SPRAY.
5. Allow to dry and solidify for 5-10 minutes. Drying time varies depending on room temperature.
6. Using the provided scraper, start slowly to scrape the matrix film and collect it on the scraper.
7. Approximately 0.5 x 0.5 inch area scraped film can be pooled in one 1.5 mL microcentrifuge tube.
8. Periodically transfer the accumulated matrix film to a 1.5 mL microcentrifuge tube.
9. Seal and label the tube appropriately.
10. The collected sample can be processed directly for DNA extraction.
11. The Omni-Matrix™ K105 with the collected biological sample will dissolve in the lysis solution of Gene Link Omni-Mag™, ABI PrepFiler® and Promega DNA-IQ™ DNA extraction kits. The matrix and directly in Buffer AL of Qiagen Investigator extraction kit without addition of ethanol.
12. For automated DNA extraction see specific protocol in the Appendix.
13. Continue DNA extraction following the manufacturer protocol after sample is in lysis buffer.



APPENDIX

ThermoFisher PrepFiler® Express Chemistry on the Automate Express™ Robot from Thermo Fisher.

No changes from protocol.

Qiagen EZ1® Investigator® Automated DNA Extraction Kit

The following changes in the protocol are required.

1. Additional Qiagen buffer required. Qiagen Buffer MTL; Catalog No.: 19112.
2. Instead of prelysis/pretreatment in Qiagen Buffer G2 and Proteinase K substitute the buffer G2 with Qiagen Buffer MTL.
3. Use exactly the same volume as listed in the Qiagen EZ1 Investigator protocol table.
4. Follow all other protocols.

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