

Infinity 8 LLC

FDA approved multifunction
collecting device for bodily fluids
(MCDDBF) for health, wellness and
clinical testing for any number of
diseases



MULTIFUNCTION COLLECTING DEVICE FOR BODILY FLUIDS

Highlights for Patients



Test Privately at Home

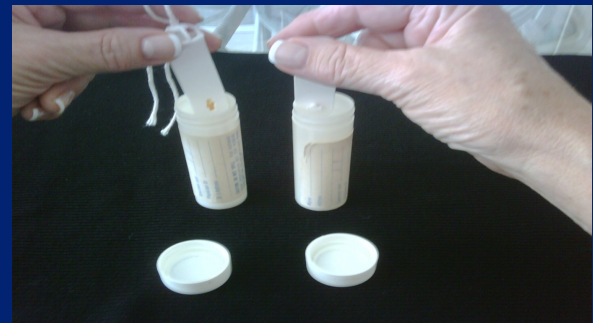


Convenient Result Delivery



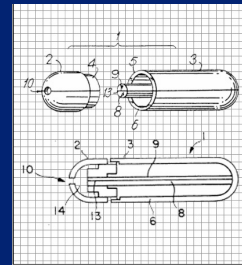
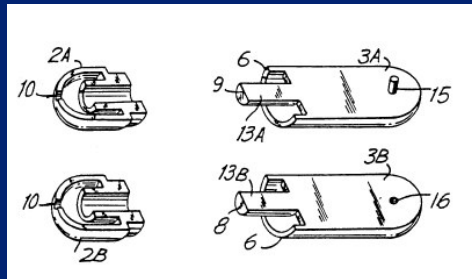
Cost Effective

INF8LLC



Patent Info and FDA Approval

The MCDBF is pre-loaded with appropriate testing reagents that women can self administer in privacy (and without pain, discomfort or humiliation) to collect fluid samples. The samples may be tested for a broad range of diseases including cervical cancer, HIV, HPV and STIs.



Approvals

United States FDA approval as a collection device –

Establishment Registration Number 243114

Product Code: HEB(Tampon, Menstrual, Unscented)

FDA Regulation 884.5470

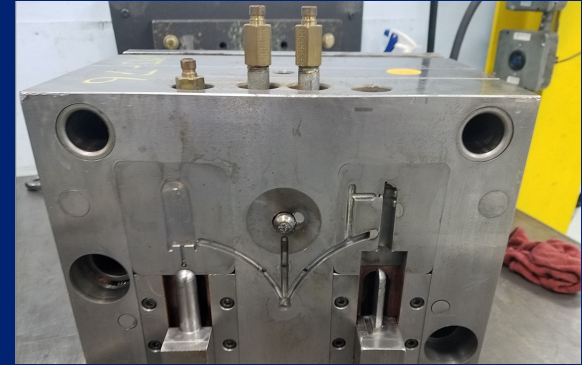
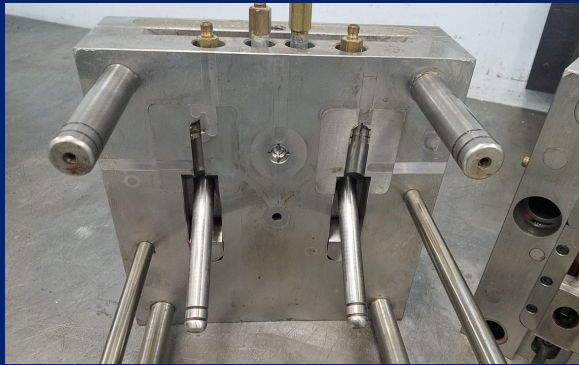
South African Patent No. 2011/05403

We are ready to go to market now!

The Production Mold

- 4 cavity prototype mold
- Capable of producing 300,000 - 400,000 units
- Built by NYPRO Inc, Clinton, MA

We are ready to commence mass production and go to market!



Advantages of MCDBF



Millions of cells are collected versus only an estimated 45,000 with the Pap smear. Cells and blood of interest bring greater results.



Specimen Fixation and Transportation



MCDBF collects menstrual blood for cytology and clinical analysis with an FDA approved device.



Specimen Testing for Oncogenic Proteins



MCDBF TEST can detect HIV/AIDS, HPV, STIs, cervical and endometrial cancers with a 98% accuracy rate. DNA and many other diseases.

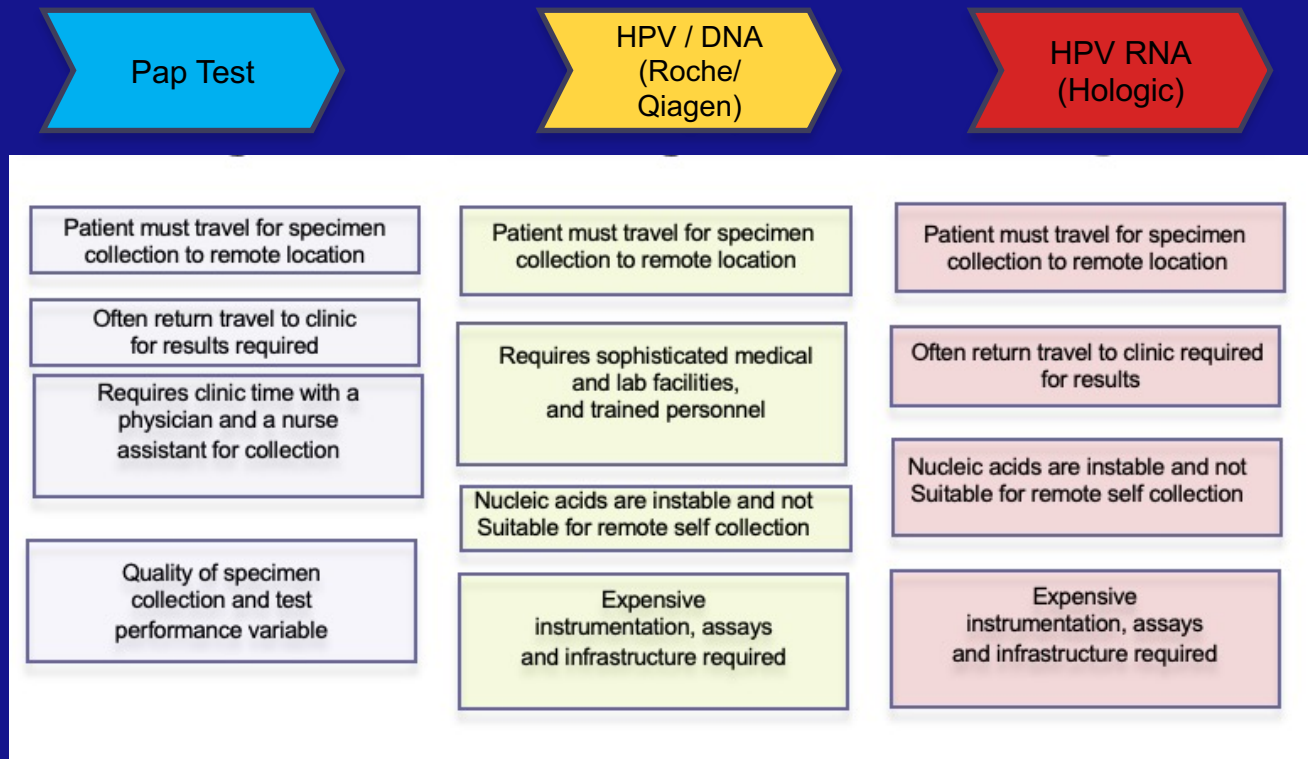


Self-administered testing promotes early detection, which is key to fighting disease.



Self Collection at Home / No Medical Staff Needed
Patient sample never interacts with other lab specimens
reducing error rates.

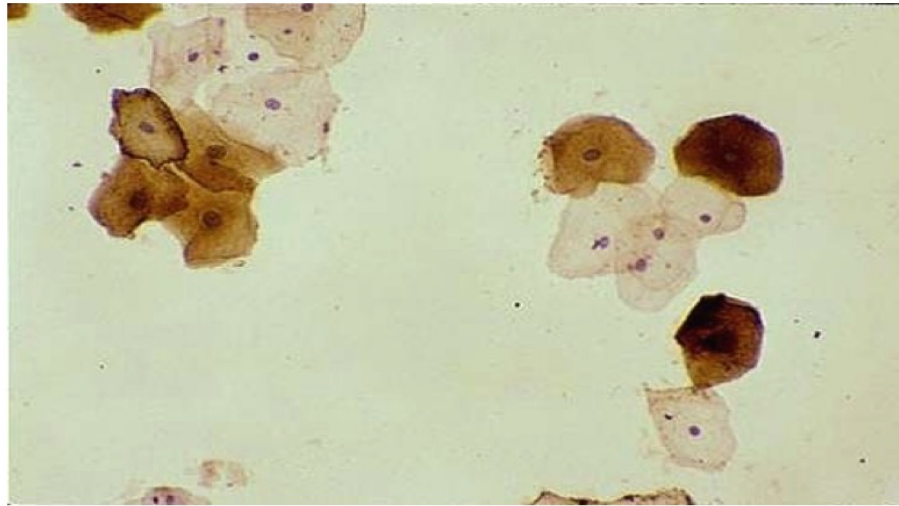
Issues with Current Competitor Products



The Multifunction Collecting Device for Bodily Fluids Addresses These Barriers:

- No travel required, convenient home collection
- Allows scarce health center resources to focus on patients with positive patients
- Robust and Simple Test Methodology – Accurate and Reproducible
- Cervical cancer proteins are stable during transportation
- Requires simple facilities and moderately skilled lab personnel

Brown stained cells have genetically transformed to malignancy



MCDBF will utilize off the shelf antibodies to test indications of a woman's self-sampling cervical cell collection, stabilization and transportation device that will permit women in very remote areas, to collect and ship a cervical specimen to a distant testing laboratory or clinic, or to store their specimens waiting for visit by mobile health care providers. MCDBF will utilize unique and proprietary antibodies to detect the presence or absence of pre-cancerous and cancerous cervical cells. These antibodies will be formatted into simple and rapid detections technologies, allowing for cervical cancer screening to be performed by lesser skilled medical personnel in unsophisticated test environments.

Self-Collection
at home

Specimen Fixation
and Transport

Specimen testing for
oncogenic proteins

Cervical Cancer Statistics

2.784 Billion Women Aged 15+ at Risk of Developing Cervical Cancer

13.1 Cervical Cancer Incidence (Age-Standardized Rate Per 100,000)

569,847 Annual Number of New Cervical Cancer Cases

311,365 Annual Number of Cervical Cancer Deaths

* Source HPV Information Centre

Market Size and Potential

- Gender inequality, cultural taboos and poverty are bars to testing via Pap Smear in large parts of the World
- Every month, **1.8 billion** people across the world menstruate and would be able to utilize the MCDBF collection system.
- Statistic Source: www.unicef.org

Test Volume Estimates

Global potential test volume estimates for MCDBF self-collection specimen, transportation and antibody detection system range from 35 million to 70 million tests per year, at market penetration rates of 5 to 10% of total market potential within 5 years post introduction.

Country/Region	Total Population	Estimated Size of Female Cervical Cancer Testing Population
Africa	1.17 billion	175 million
South-East Asia	628 million	94 million
South America (excl Brazil)	204 million	30 million
India	1.30 billion	195 million
China	1.37 billion	205 million
Total		699 million

Study References

- ❖ *A Method for the Collection and Examination of the Exfoliative Cytology of the Human Female Reproductive Tract from Menstrual Blood Flow*, by Matthew Freund, Ph.D and Alexander Sedlis, M.D., pp.497-500, Jul-Aug 1977, vol. 21, no. 4, Acta Cytologica
- ❖ *The Normal Exfoliative Cytology of Menstrual Blood*, by Margaret L. Couture, B.S. Matthew Freund, Ph.D., and Alexander Sedlis, M.D., pp. 85-89, Jan-Feb 1979, vol. 23, no. 1, Acta Cytologica
- ❖ *Diagnostic Value and Potential of Menstrual Blood Flow for the Collection and Examination of the Exfoliative Cytology of the Human Female Reproduction Tract*, by Matthew Freund, Ph.D. and Margaret Couture, B.S., Proc. 26th Annual AOA/NOF Research Conference, JOAO, 82:142, 1982.
- ❖ *The Presence of Endocervical Cells in the Exfoliative Cytology of Menstrual Blood*, by Margaret L. Couture, B.S. and Matthew Freund, Ph.D., pp. 827-832, 1983, vol. 48, Cytologica
- ❖ *Menstrual Flow Collecting Device Study – 50 patient study -* by Dr. G. Zanetti and Dr. I. Werner, Basel, Switzerland, 1988

❖ Additional references available upon request

MCDBF collection system will transform
and extend the interventive screening
capabilities for women worldwide.

Visit our website for more information on the MCDBF:
liquid based collection for testing, tracking health and treating disease

www.inf8health.com

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