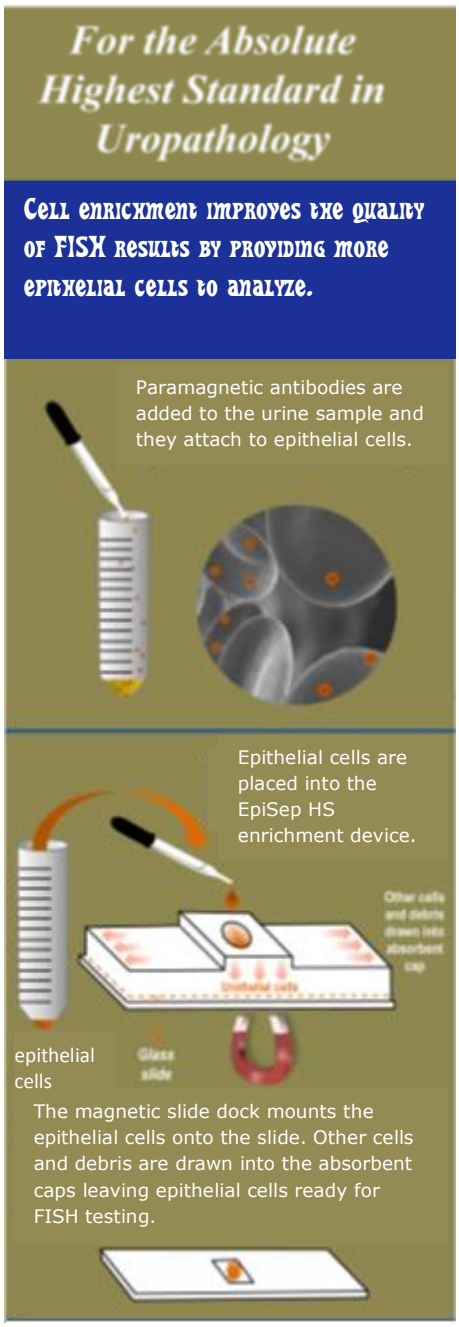
3030 Venture Lane, Suite 108 • Melbourne, Florida 32934 • Phone 321-253-5197 • Fax 321-253-5199



CELL ENRICHMENT TECHNOLOGY

Studies have reported up to 82% capture of prostatic cells in voided urine after digital rectal prostate massage. This allows for a non-invasive evaluation of patients with an increased PSA. may also prevent subsequent biopsy procedure, in those patients with previous malignant diagnosis that have not had radiation therapy.

Using EpiSep cell enrichment technology, SunCoast Pathology is able to isolate Prostatic Glandular Epithelial Cells from the specimen and concentrate them onto a slide for genomic Fluorescent in-situ Hybridization (FISH) testing. This is achieved by using a paramagnetic antibody to malignant prostate cells (EpCam 323/3a) which adheres to the malignant cells and allows them to be deposited on a slide using the EpiSep HS enrichment device. The untagged cells are then wicked away from the target area and the preparation is then ready for genomic FISH testing.

EpiSep is an FDA approved device for detecting, isolating, and helping characterize Circulating Tumor Cells.

References

1. Fernando Tadeu Andrade-Rocha, Assessment of Exfoliated Prostate Cells in Semen, *American Journal of Clinical Pathology,* Nov 2007, 128 (5) 788-793; DOI:10.1309/9ELYPH61DBD8AXYC.
2. Went PT, Lugli A, Meier S, et al. Frequent EpCam protein expression in human carcinomas. *Hum Pathol* 2004;**35**:122–8.
3. Mukherjee S, Richardson AM, Rodriguez-Canales J, Ylaya K, Erickson HS, et al. (2009) Identification of EpCAM as a molecular target of prostate cancer stroma. *Am J Pathol* 175: 2277–2287. doi: 10.2353/ajpath.2009.090013. pmid:19850885.
4. Drake RR, Elschenbroich S, Lopez-Perez O, Kim Y, Ignatchenko V, Ignatchenko A, Nyalwidhe JO, Basu G, Wilkins CE, Gjurich B, Lance RS, Semmes OJ, Medin JA, Kislinger T: In-depth proteomic analyses of direct expressed prostatic secretions. *J Proteome Res*. 2010, 9: 2109-2116.
5. Knuth, S., M. Glidea, R. Tinawi-Aljundi et al. Minimally Invasive OligoFISH Prostate Cancer Screening Test. *Journal of Mol Diagnostics* 2013 Nov;15(6), #ST72
6. Nakai Y, Anai S, Kuwada M, Miyake M, Chihara Y, Tanaka N, Hirayama A, Yoshida K, Hirao Y, Fujimoto K. Photodynamic diagnosis of shed prostate cancer cells in voided urine treated with 5-aminolevulinic acid. *BMC Urol*. 2014 3;14:59.doi: 10.1186/1471-2490-14-59.
7. Furubayashi, N., Negishi, T., Ura, S., Mutaguchi, J., Taguchi, K., Shimokawa, M., & Nakamura, M. (1899). Patients treated with radical prostatectomy with positive digital rectal examination findings in the intermediate-risk group are prone to PSA recurrence. *Oncology Letters*, 0, 0-0. http://dx.doi.org/10.3892/ol.2016.4485.
8. Miyamoto DT, Sequist LV, Lee RJ. Circulating tumour cells-monitoring treatment response in prostate cancer. *Nat Rev Clin Oncol* 2014;11: 401–12.
9. Hu B, Rochefort H, Goldkorn A. Circulating tumor cells in prostate cancer. *Cancers* (Basel) 2013;5(4):1676–1690. doi: 10.3390/cancers5041676
10. de Bono JS, Scher HI, Montgomery RB, Parker C, Miller MC, Tissing H, Doyle GV, Terstappen LW, Pienta KJ, Raghavan D: Circulating tumor cells predict survival benefit from treatment in metastatic castration-resistant prostate cancer. *Clin Cancer Res* 2008;14:6302-6309. doi: 10.1158/1078-0432.CCR-08-0872.

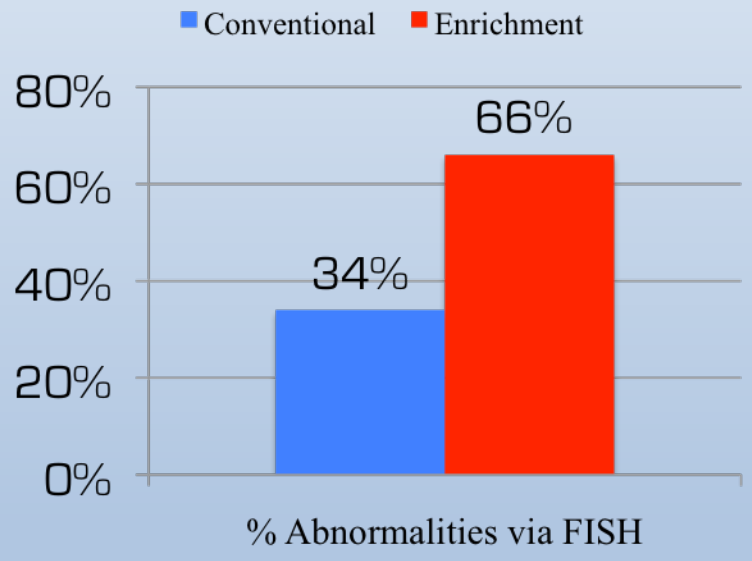
Clinical Validation for EpiSep® Hybridization Slide with +CD138 Plasma Cell Enrichment

Ms. Stephanie Lashbrook
Senior Cytogenetic Technologist
HematoGenix
Tinley Park, IL.

15339 Barranca Parkway
Irvine, CA 92618
800.807.7760
www.wavesense.net

Multiple Myeloma FISH Panel Clinical Validation Study

- <u>Overview</u>
- 42 Patients in initial cohort
- 8 probe molecular panel to stratify patients into risk groups*
- 32 patients in final cohort



With sample enrichment:

- 66% of patients with new or additional abnormalities.
- 36% of patients would shift in prognosis from standard risk to high risk.
- 21% increase in patients with uncharacterized IGH rearrangement revealed.
- An average yield increase of 9.7 times more plasma cells (1.2x – 44x range).

*Due to sample and assay conditions, not all patients were screened for all 8 probes

Source: E. Crawford, V. Golembiewski-Ruiz, et al. *Validation of Immuno-Magnetic Chromatography As a Novel Method for the in Situ enrichment of Plasma Cells in Bone Marrow*. ASH 2012 Poster