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Foundation scientists are supported by all proceeds from laboratory tests and by generous contributions from benefactors.

Research Funds are dedicated to research on diseases of the prostate and bladder, including cancer. The current focus is the development of innovative, early detection screening tests for infection and cancer.

**The Foundation has far lower operating costs than larger institutions, leading to more research per dollar donated.** All contributions are fully tax deductible.

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*Changing the pace of progress*

# SEMEN ANALYSES

*New diagnostic procedures  
for diseases and  
fertility assessment*

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Over the last 15 years, the development of techniques to study Human Immunodeficiency Virus in semen has led to new, reliable, patented methods of semen stabilization, cytologic assessment, and PCR detection of pathogens. To utilize these methods, scientists have developed semen transport kits that allow the man to collect a semen specimen at home, stabilize it in preservatives, and mail it to the laboratory for analysis.

These advances make possible the analysis of semen specimens not only for fertility assessment, but also for disease markers from the organs that contribute to semen: the testis, epididymis, prostate, seminal vesicles, ejaculatory ducts, and urethra. Semen analysis is becoming an effective diagnostic procedure for diseases other than infertility assessment.

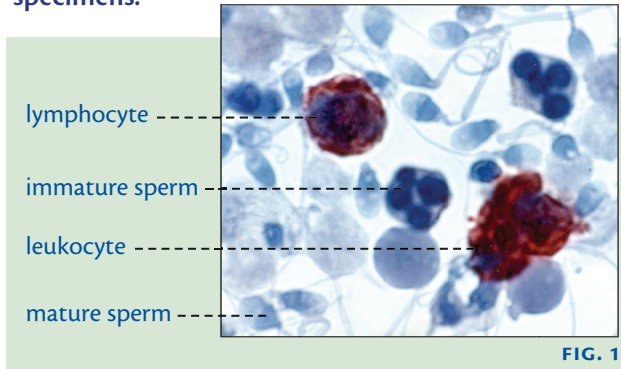
Two new analyses are currently available, and others are under development by Bedford Research Foundation scientists.

## LEUKOCYTE IMMUNOSTAIN

In the past, distinguishing leukocytes from immature sperm forms in semen was limited to the detection of leukocyte peroxidases. These tests are technically difficult and do not detect lymphocytes and monocytes.

The patented method developed at Bedford Research Foundation preserves semen cells in suspension, allowing cytologic assessments not possible with unfixed specimens. Monoclonal antibodies used routinely by pathology laboratories to distinguish leukocytes and their subtypes tag the same cells in the fixed semen specimens red-brown. (Fig. 1) This approach makes it possible to distinguish leukocyte subtypes such as lymphocytes and granulocytes from immature sperm.

Bedford Research Foundation is the only clinical lab in the United States licensed to immunostain semen specimens.



## PCR DETECTION OF BACTERIA

Bacterial gene sequencing is revolutionizing the detection of pathogens. PCR (Polymerase Chain Reaction) amplification procedures make it possible to detect bacteria from all known genera in one test, and allow scientists to identify new pathogens. PCR analyses of clinical specimens have led to estimates that as few as 5% of pathogens have ever been detected by clinical laboratory cultures.

Bedford Research Foundation scientists adapted PCR techniques employed to detect HIV in semen to the detection of bacteria in semen. Test sensitivity is set to detect only abundant organisms—greater than 20,000 per ml of semen. A study to measure the incidence of abundant organisms in semen revealed:

- › 60% of men had positive specimens.
- › Elevations in semen leukocytes did not reliably predict bacteria in the specimens.
- › *Staphylococcus*, *Anaerococcus*, *Peptoniphilus*, *Peptostreptococcus* and *Pseudomonas* were frequently detected organisms in men with infertility.

Preliminary studies of semen specimens from men with prostatitis indicate that this will be a useful test to determine if they have bacterial or non-bacterial prostatitis. With this information, the effectiveness of antibiotic treatments can be monitored.

## Semen Test Kits

Bedford Research Foundation scientists have developed four unique Semen Test Kits, each offering specific advantages and applications.

- › **Fixed Kit:** Used for simple sperm count, post-vasectomy, or to monitor treatment. Specimen is collected at home and mailed to the lab.
- › **Prostatitis Kit:** Contains two preservatives and is used for simple sperm count, leukocyte count and bacteria (or HIV) testing. Specimen is collected at home, divided into two parts, and mailed to the lab.
- › **Walk-In Collection Kit:** Used for live sperm analysis. Specimens are collected at home in a special condom, and delivered to the laboratory within 90 minutes.
- › **Live Semen Transport Kit:** Specimens collected at home and stabilized with Transport Medium for delivery to the lab 18 hours after collection, or shipped to the lab via overnight courier. Sperm can be cryopreserved and the specimen tested for bacteria or HIV as needed.

