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In This Issue

Point of Care HIV Diagnosis In 60 Seconds!

"HIV infection in humans is now pandemic. As of January 2006, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) estimate that AIDS has killed more than 25 million people since it was first recognized on December 1, 1981, making it one of the most destructive pandemics in recorded history."[1]

[1]Wikipedia. HIV (2006). Retrieved November 22, 2006, from http://en.wikipedia.org/wiki/HIV

Human Immunodeficiency Virus or HIV is a retrovirus that attacks and breaks down the body's immune system and can eventually lead to AIDS (Acquired Immunodeficiency Syndrome). Infection of HIV occurs through the transfer of blood, semen, vaginal fluid or breast milk. The three major routes of transmission are unprotected sexual intercourse, contaminated needles and transmission from an infected mother to her baby at birth or through breast milk.

As HIV and AIDS awareness increases, the availability of a rapid screening test becomes critical. BioLytical Laboratories, a company based out of Richmond, B.C. has worked diligently in developing the INSTI HIV Rapid Antibody Test, the only rapid HIV test approved for point of care use in Canada.

The INSTI is intended for use by trained medical personnel as an in vitro qualitative test for the accurate detection of antibodies to Human Immunodeficiency Virus in EDTA whole blood, finger stick blood, serum or plasma. The test is designed as a screening assay and results are obtained in just **60 seconds**! The INSTI contains all the testing components you need in one convenient package, and the test is performed in 4 simple steps:

Add 1 to 2 drops of blood to the **Sample Diluent.**

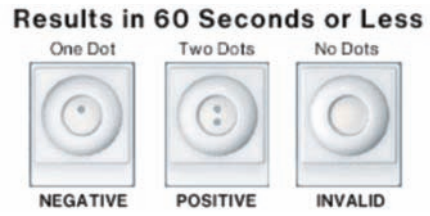
Pour the diluted sample into the **Membrane Unit.**

Re-suspend the **Color Developer** and add it to the Membrane Unit.

Add the **Clarifying Solution.**

Results are clear, concise and extremely accurate showing excellent correlation with the Western Blot Test and ELISA Test. Large scale Canadian clinical trial data show a 99.6% sensitivity and specificity ensuring minimal false readings.

For more information on the INSTI HIV Rapid Antibody Test, please contact Somagen Diagnostics at 1-800-661-9993.



bioLytical LABORATORIES

INSTI™

Implementing Preterm Labor Testing
In the Vancouver Island Health Authority

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Reprinted with permission from the Vancouver Island Health Authority

INTRODUCTION

The Vancouver Island Health Authority (VIHA) is one of 6 Health Authorities in British Columbia. It serves a variety of communities from cities of 300,000 to communities of less than 100 people. It is VIHA's prerogative to provide a seamless service across the islands. Not all services can be provided locally so the VIHA laboratory has adopted a "Hub/Feeder" model in order to achieve this . This model was used in delivery of Preterm labor testing offered across the health authority. VIHA services some very remote communities on Vancouver Island and the Gulf Islands. These locations have limited ferry services or limited road access. There are several reasons why it would be important to know if a patient is at high risk for premature delivery. Obstetrical services and Neonatal units are only available in larger centers. For this reason it's important for a physician to determine if a patient demonstrating symptoms of premature labour needs to be admitted and/or transferred to an acute care hospital. Approximately 2% of babies on Vancouver Island are delivered before 32 weeks[1]. A premature baby will require a greater level of care so it's often necessary for the mother and baby to be transferred.

Another factor to consider is the financial aspect of transferring a patient to other sites, especially if no beds are available within the region, province or country. This can have a profound effect on the expectant mother if she is transferred to a site far from home and family.

The Medical director, Dr Hoag, recognized the need to perform a test that could aid the doctor in determining risk of premature delivery. In 2004 fetal fibronectin (ffn) testing began and the investigation of a second assay, actim Partus, for detection of pIGFBP-1 was implemented at the largest obstetrical site (Victoria General Hospital) of VIHA in 2004.

CONCEPT

Both assays test for proteins that should not be present in cervicovaginal secretions during 22-35 weeks gestation. These 2 assays aid the physician in deciding if a woman is at risk for premature delivery.

The first assay measures fetal fibronectin (ffn), a protein found in the fetal membranes at the choriodecidual interface and amniotic fluid. It can be found in cervico-vaginal secretions when the chorio-decidua junction has been disrupted.

The second assay measures phosphorylated insulin growth factor binding protein-1 (pIGFBP-1), another protein found in cervical secretions when the membrane layers detach from one another. pIGFBP-1 is released from the deciduas cells as the cervix ripens. pIGFBP-1 present in cervical secretions is an indicator of cervical ripeness.

Originally, both assays were performed, but only the results of the ffn were released to physicians. The results of the pIGFBP-1 were collected and reviewed. Data was collected for 3 years. It was determined that the laboratory would offer both tests together.

The pIGFBP-1 originally looked like the better stand alone candidate due to its ease of testing. No analyzer or daily QC is required for this assay; therefore it is much easier to train lab staff, physicians and nurses. The cost per assay is much less when compared to fetal fibronectin (~ $35 vs $100).

There is a provincial wide initiative to use fetal fibronectin as the PTL test. Both tests provide very high negative predictability rates. A negative ffn rules out preterm delivery: less than 1% will deliver before 37 weeks[2]. 96% of women with preterm contractions having pIGFBP-1 levels below 10 g/L did not deliver within 2 weeks[4].

After recognizing the costs associated with transferring or admitting patients unnecessarily it seemed logical to have this testing available island wide. The next step was to implement the training so testing could begin across the island.

METHOD AND PROCESS

Larger sites offering obstetrical services were designated as a HUB site and responsible for performing the ffn testing referred from the feeder sites. Feeder sites would perform pIGFBP-1 test.

1. The POC Coordinator and Chemistry Technical Coordinator developed new process flowcharts, procedures and training material for both assays.
2. An island wide group met to discuss training delivery. Representatives from each HUB site were present to receive training and complete initial competency assessments.
3. Each feeder site was provided with the procedure manual, training material and supplies to practice performing the assay(s). Initial competency was obtained by using a written assessment.
4. Once training was complete a teleconference call was held between the feeder sites and Point people from HUBS to answer questions and receive feedback from staff.
5. Dr. J. Dansereau performed the education and training of physicians and nursing staff.

DISCUSSION

How does Preterm Labour testing positively affect patients?

- Patients at risk can be admitted or transferred to a facility providing the service they require.
- Physicians can release patients home with a degree of certainty they will not be delivering in the next 7-14 days.
- Beds are made available when patients not at risk for premature delivery are sent home.
- Reduces costs to medical system, which benefits all customers. Cost/day of a maternity bed at VGH: $3000[5]. Transfer costs: ~$10-15,000.

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How does this service meet VIHA's mission of "serving and involving the people of the islands to maintain and improve health"?

- By performing preliminary testing on site in remote areas, smaller laboratories become involved in an island wide testing process.
- Premature delivery is one of the greatest factors in perinatal morbidity and mortality. By providing testing that helps predict this event we are increasing our ability to be prepared for such an event; therefore improving the outcome of the delivery.

How did this service delivery model (HUB-feeder) perform?

Stay tuned! Feedback has been very positive to date. We are optimistic it will be a success.

CONCLUSION

The fetal fibronectin and pIGFBP-1 assays are valuable tools when used in conjunction with clinical symptoms in determining the probability of premature delivery.

The laboratory, physicians, nurses, BC Bedline and the paramedical teams work together to deliver the best possible care.

ACKNOWLEDGEMENTS

1. *Department of Obstetrics and Gynecology – VIHA South Island Region. "Fibronectin Clinical Protocol (For Patients With Symptoms of Preterm Labour)." (Feb 2004). Presented as a letter.*
2. *British Columbia Reproductive Care Program website. "Fetal Fibronectin." (Winter 2004). (www.rcp.gov.bc.ca)*
3. *Vancouver Island Health Authority website. (www.viha.ca)*
4. *Medix Biochemica actim™ PARTUS test kit information brochure.*

Special thanks to Somagen Diagnostics for their generous support, and Sheila Vickery, POC Coordinator, and Dr. P Desjardins for their valuable advice and assistance.

For more information on the benefits that actim™ Partus and/or actim™ PROM can provide your facility and patients, please contact Somagen Diagnostics at 1-800-661-9993.

actim™ PARTUS

- A fast and simple bedside test for determining the risk of preterm labor
- Detects the level of phosphorylated IGFBP-1, taken from a cervical sample
- A negative test result effectively rules out the risk of imminent or preterm delivery
- Actim Partus is an economical adjunct to your clinical judgment and testing does not require any additional equipment
- Concrete results are available immediately

actim™ PROM

- A fast and simple bedside test for the detection of premature rupture of fetal membranes
- Suspect PROM is often difficult to diagnose as traditional methods often provide insufficient or incorrect information because they are subject to contaminating substances such as blood, semen, urine and cervical mucus
- Actim PROM is a highly sensitive and specific test that detects IGFBP-1 present in amniotic fluid, allowing for diagnostic confidence when assessing patients with suspect PROM

Stabilization of White Blood Cells and Immunologic Markers for Extended Analysis Using Flow Cytometry

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ABSTRACT

Background: Accurate and reliable measures of CD4+ T lymphocytes (CD4+ T cells) are essential for the evaluation and management of human immunodeficiency virus (HIV)-infected persons. Transportation to a laboratory capable of these analyses in a timely fashion may be difficult to accomplish, especially in resource-poor settings. The Cyto-Chex® Blood Collection Tube (BCT) contains an anticoagulant and fixative to preserve blood samples prior to immunophenotyping by flow cytometry (Streck Laboratories, Omaha NE).

Methods: Blood samples were collected by venipuncture from 40 HIV-infected donors into both a K 3EDTA tube and Cyto-Chex® BCT and evaluated for lymphocyte subsets by flow cytometry at 6h, 72h and 7days after collection. Samples were stored at ambient temperatures.

Results: Subjects ranged in age from 24-65 years and 15% were female. Using single platform technology linear regression analyses showed that results from 6h K3EDTA samples correlated with those from Cyto-Chex® BCT samples at 7 days for CD4, CD8, and CD3 absolute cell counts/ul. Additionally, samples collected in Cyto-Chex® BCT preserved leukocyte differentiation up to 7 days.

Conclusion: Using Cyto-Chex® BCT, immunophenotyping results were equivalent to 6h K3EDTA for as long as one week after collection. Importantly, samples in Cyto-Chex® BCT did not require refrigeration or other special handling. This new blood collection system may be a valuable tool for patients without ready access to a flow cytometry laboratory and particularly in resource-poor settings.

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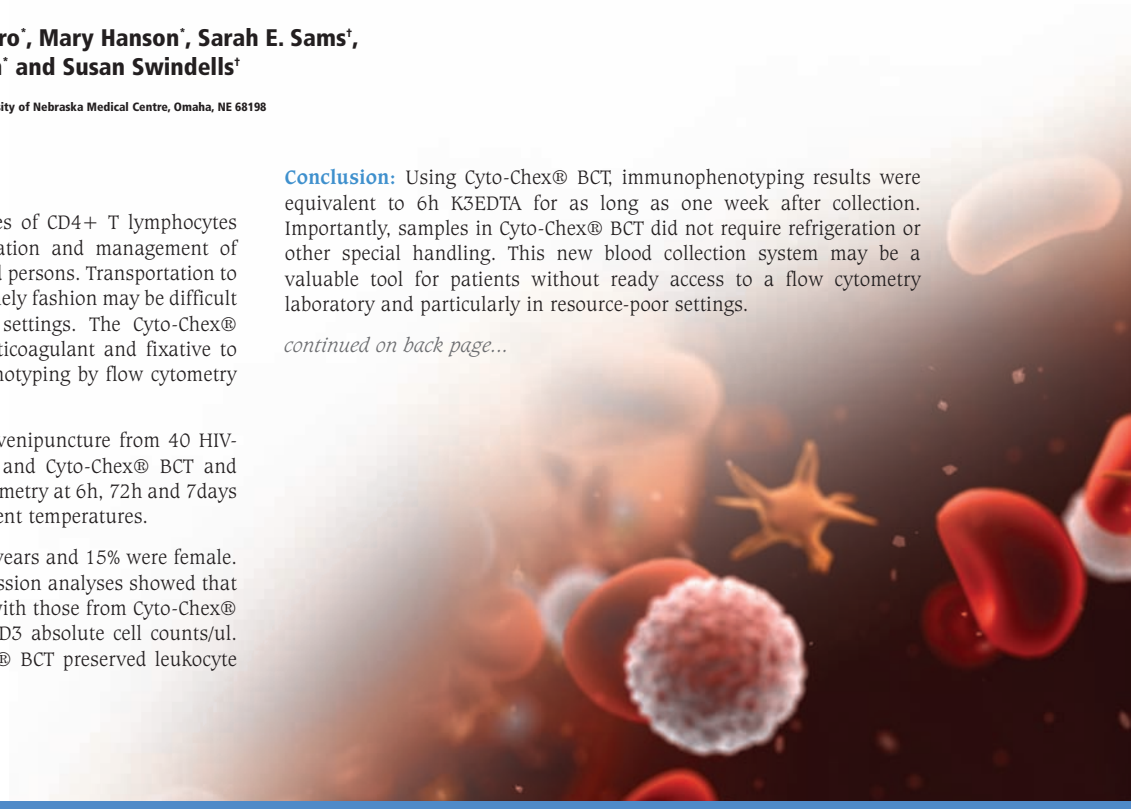

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Pittsburgh, PA
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Saskatoon, SK
October 2 - 4, 2008

SQBC: Société Québécoise de Biologie Clinique
Bromont, QC
October 1 - 4, 2008

CSACI: Canadian Society of Allergy and Clinical Immunology
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October 23 - 26, 2008

CCC: Canadian Cardiovascular Congress
Toronto, ON
October 24 - 28, 2008

Manitoba Society of Medical Laboratory Technologists
Winnipeg, MB
October 28 - 29, 2008

CFAS: Canadian Fertility and Andrology Society
Calgary, AB
November 26 - 29, 2008

Maritech Scientific Conference
Charlottetown, PEI
November 14, 2008

NLSLT: Newfoundland and Labrador Society of Laboratory Technologists
Corner Brook, NL
October 29 - November 1, 2008

Stabilization of White Blood Cells and Immunologic Markers

for Extended Analysis Using Flow Cytometry

OVERVIEW & RESULTS

Extending the stability of immune markers used for monitoring diseases by flow cytometry would have great practical significance:

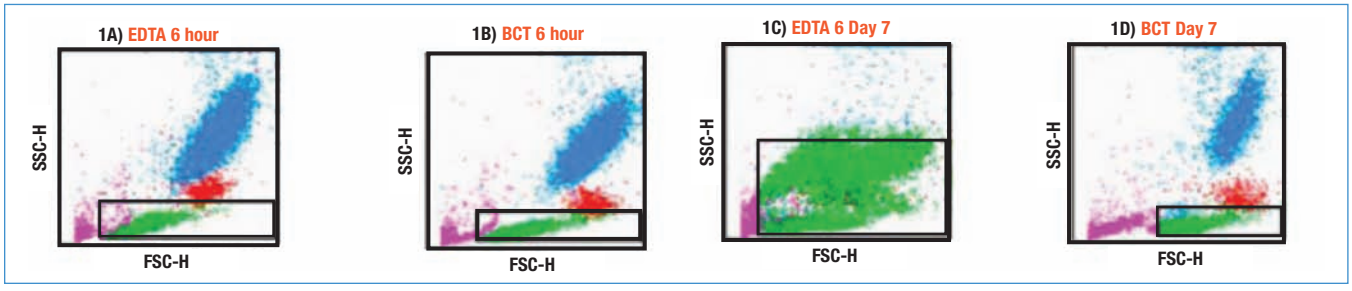
- Instrument setup/maintenance and processing time can be reduced by batching samples.
- Personnel costs for weekend samples can be reduced since staff need not be on-call for routine flow cytometry analysis.
- Extending stability for repeat analysis eliminates the need for redraws if a spurious result is yielded during the first analysis.
- Extended stability would likely result in cost savings due to the processing of fewer expired samples.
- An especially important benefit of extended stability may be realized in resource-poor settings where patients may reside in rural areas at a great distance from central laboratory facilities.

In this study, we examine the use of a novel blood collection tube, Cyto-Chex® BCT (Streck Laboratories, Omaha, NE), which is engineered to stabilize white blood cells for up to 7 days prior to immunophenotyping by flow cytometry. CD4, CD3, and CD8 absolute cell counts/ul were measured in 40 HIV-infected subjects.

Flow cytometry has emerged as a major tool in the diagnosis of immune system disorders (Most notably HIV/AIDS).

- The measurement of CD4+ lymphocyte counts by flow cytometry is presently the gold standard for monitoring the immune status of HIV-infected subjects.
- CDC guidelines for the analysis of CD4+ T cells recommend that a typical collection tube containing K3EDTA or heparin is only suitable for testing within 72 hours of collection (MMWR 2003; 52(RR-2)). Generally, results from specimens > 48 hours old may be unreliable.
- A major obstacle for this type of clinical testing is the lack of stability of immunologic markers during storage and transportation.

Figure 1: Light Scatter of EDTA 6 hours and Day 7 compared to BCT 6 hours and Day 7



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