

Prenatal Biochemistry Laboratory Storage, Use, Retention and Disposal of Maternal Serum and Amniotic Fluid specimens: Policy and Procedure

Introduction

Prenatal screening informs a woman of the chance that her baby will be born with Down syndrome, trisomy 18 or an open neural tube defect. Maternal serum samples from across the province are sent to the Prenatal Biochemistry lab at BCCH for testing. Approximately 22,000 women are screened each year. Serum samples are collected during the 1st and / or 2nd trimester. The 1st trimester specimens (Part 1 samples) are collected between 10 and 13⁺⁶ weeks of gestation. The 2nd trimester specimens (Part 2 samples) are collected between 15 and 20⁺⁶ weeks gestation.

The different screening tests include:

- 1) Serum Integrated Prenatal Screen (SIPS): First Trimester (Part 1) samples are tested for PAPP_A; second trimester (Part 2) samples are tested for 4 markers (HCG, uE3, AFP and InhA). The final result is not reported until testing of the Part 2 specimen is complete.
- 2) Integrated Prenatal Screening (IPS): involves SIPS (as described above) and a Nuchal translucency (NT) measurement by ultrasound. The final result is not reported until testing of the Part 2 specimen is complete.
- 3) Quad: Only the second trimester specimen is collected and tested for the 4 markers listed above.

The test offered to each woman is dependant on maternal age, family history, obstetrical history and whether the pregnancy is a singleton or multiple gestation.

In addition, the Prenatal Biochemistry Laboratory performs an AFP assay on selected amniotic fluid samples. This provides a risk estimate for an open neural tube defect and is performed when a 2nd trimester serum sample (Quad or Part 2 of SIPS/IPS) has either not been collected or shows an abnormally high level of AFP.

The following policy aligns with all related policies and applicable legislation including:

- The Freedom of Information and Protection of Privacy act
- Document disposal act
- Hospital act regulation, destruction of health record documents, June 1 2009
- C&W storage and retention of clinical samples
- Diagnostic accreditation program, laboratory medicine, sample collection, transport and accessioning July 2007 and

- Ethical conduct for research involving humans, Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social science and humanities research Council of Canada (Tri-council) Aug 1998

Storage, Use, Retention and Disposal

Storage & Retention:

Maternal serum samples are securely stored within the Prenatal Biochemistry laboratory (PBL). Upon completion of testing, serum aliquots are stored in -70 C freezers.

The 1st trimester (Part 1) samples are retained in the lab for sufficient duration to ensure expected receipt of the 2nd trimester sample (Part 2). Minimum duration: 3 months

The 2nd trimester samples (Part 2 or Quad) are retained following the completion and reporting of the screening results. Minimum duration: 4 weeks

The amniotic fluid samples are retained following completion and reporting of screening results. Minimum duration: 3 months

Maternal serum and amniotic fluid samples may be stored for up to 5 years, space permitting.

Clinical Uses:

Future clinical uses of stored samples may include:

- 1) Re-running a specimen in the event a sample is reclassified.
Example: The PBL may receive a dating ultrasound that changes the initial gestational age estimate of the pregnancy. A change in gestational age can mean change of a Part 1 (1st trimester) sample to a Part 2 (2nd trimester) sample.
- 2) Laboratory method improvements, test protocol refinement and development of new tests and/or methodologies.

Research Uses:

There is great potential to advance science and clinical care for children and women's health utilizing stored maternal serum samples for health research. Public health research contributes to the public good through increased scientific knowledge. Therefore, residual serum specimens may be used for health research. All research must be approved by a Clinical Research Ethics Board.

Disposal:

All samples are disposed of by incineration according to standard operating procedure for biohazardous materials.