

Modern Biospecimen Preservation Technologies Allowing Better Specimen Commercialization

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Disclosure

Olga Potapova, Ph.D., is a Founder and CEO of Cureline, Inc., a company specializing in:

- custom human tissue procurement
- biospecimen management
- clinical trial support (Phase I / II)
- tissue research (translational histopathology lab)

Neither Dr. Potapova nor Cureline, Inc., has any commercial involvement with companies producing biospecimen collection and preservation products that will be presented and discussed during this workshop.

What does it take to build a Biobank?

- **Organization**
 - Create the SOPs/protocols
 - Get the IRB approval
 - Select and enroll patients
 - Annotate clinical data
- **Acquisition**
 - Collect specimens
 - Process specimens
- **QC & Analyzes**
- **Annotate technical data**
- **Store specimens**
- **Distribute / ship specimens**
- **Biobank facilities**
- **Qualified personnel**
- **Equipment & consumables**
- **Pathology support (5.5 x \$\$)**
- **Equipment and expertise for the specimen analyses**
- **Database and data management**
- **Marketing & Sales**
- **General management**

\$200/specimen – \$5,000/case

Major Repetitive Technical Effectors of the Specimen Cost

- **Organization**
 - Standard SOPs/protocols
 - IRB approval
 - Patient consent
- **Acquisition**
 - Collection
 - Preservation
 - Processing
 - QC & Analyzes
- **Storage**
- **Distribution / Shipment**
- **Biobank facilities**
- **Qualified personnel**
- **Equipment & consumables**
- **Pathology support**
- **Equipment and expertise for the Specimen analyses**
- **IT (database and data management)**
- **Marketing & Sales**
- **General management**

~\$500/case

How to Improve Return on Investment into These Technical Components?

- **Collection**
 - **Expand collection sets**
 - FF/FFPE tissue → add FRESH tissue
 - Serum / plasma → add blood, PBMC (fresh, fixed, viable)
 - **Collect specimens that later require less energy/space**
- **Processing**
 - **Improve the quality (e.g., PAXgene tubes for RNA)**
 - **“Synergetic” preparation techniques (tissue / RNA)**
- **Storage**
 - **Energy- and space-saving systems (dry blood spot)**
 - **Improve the longevity of the specimens (PAXgene system)**
- **Retrieval, distribution and shipment**
 - **Novel approaches for sampling**

TODAY Presentations:

- **Expansion into FRESH tissue collection** (presented by Cureline)
 - **AQIX – Interstitial fluid for tissue preservation, AQIX, Ltd (UK)**
 - **HypoThermosol solution, BioLifeSolutions, (Seattle, USA)**
- **Collecting energy/space “green” specimens**
 - **Nucleic acids collection & storage:**
 - **Rod Westrop, Ph.D., Director, European Operations, GeneVault, (San Diego, USA)**
 - **Rolf Muller, PhD, Founder, President and CSO, BioMatrica, (San Diego, USA)**

TODAY Presentations (contd):

- **Synergetic preparation techniques**
 - **Dr. Marie McCluskey**, Senior Global Product Manager, **QIAGEN GmbH**, Germany. **PAXgene Tissue System (FFPE tissue/RNA)** available from **PreAnalytix Ltd (BD and Qiagen distribution)**
- **Novel approaches for Sampling**
 - **Dale N. Larson**, Director Biomedical Systems, **Draper Laboratory (USA)**. **CryoXtract's Automated Frozen Sample Aliquotter** (frozen biofluid sampler).
 - **AquaExtract solution**, **MultiTarget Pharmaceuticals LLC (USA)** (presented by Cureline)