



Histology Research Services

HISTOLOGY SERVICES

Processing:

- Paraffin
- Plastic/Resin
- Frozen tissue

Cutting and staining:

- Soft tissue
- Hard tissue (e.g. Tissue implanted with stents and undecalcified bone)
- Whole mount preparation and cutting

Tissue microarrays:

- Construction
- Cutting and staining

Staining procedures:

- H&E
- Special stains
- Whole mount staining
- In situ hybridization/FISH staining
- RNA and DNA studies

Immunohistochemistry:

- Optimization of new antibodies
- Staining of routine and new antibodies (paraffin, tissue microarrays, and plastic)
- Immunofluorescence staining
- Double staining

SPECIALIZED TESTING

MSS also offers sophisticated specialty and esoteric tests in the following fields:

- Cytogenetics (e.g. FISH)
- Electron microscopy
- Flow cytometry
- Liquid chromatography and mass spectrometry
- Microbiology and virology
- Molecular assays (e.g. RT-PCR, microarrays)
- Multiplex array immunoassays
- Pharmacogenomics (e.g. CYP450)

IMAGING & MORPHOMETRY

MSS in collaboration with one of our global Contract Research Organization (CRO) clients, established digital pathology for global clinical trials through secure networks and for 21 CFR Part 11 compliant system. This system allows pharmaceutical companies to use our digital pathology as part of their eligibility criteria in phase II and III clinical trials.

- Muscle, bone and stent morphometry
- Digital imaging of slides using brightfield and fluorescence microscopy including TMA imaging
- Image analysis and whole slide stereology
- Digital pathology, pathological scoring/analysis and report generation

ADVANCED BIOIMAGING

- Analytical transmission electron microscopy (TEM)
- Scanning probe microscopy
- Confocal microscopy
- Special specimen preparation, including cryopreparation



Central Laboratory/Testing Services

CLINICAL TESTING SERVICES

MSS utilizes the high-volume Rapid Response Laboratory (RRL) at Mount Sinai Hospital for routine clinical safety testing. Client samples are bar-coded on delivery to the laboratory and interfaced to MSS' Laboratory Information System. Our clinical safety test menu encompasses:

- Biochemistry
- Coagulation
- Therapeutic drug monitoring and toxicology
- Hematology
- Histopathology
- Microbiology
- Serology
- Urinalysis

SPECIALITY & ESOTERIC TESTING

MSS also offers sophisticated specialty and esoteric tests in the following fields:

- Circulating tumour cells
- Cytogenetics (e.g. FISH)
- Electron microscopy
- Flow cytometry
- Liquid chromatography and mass spectrometry
- Microbiology and virology
- Molecular assays (e.g. RT-PCR, microarrays)
- Multiplex array immunoassays
- Pharmacogenomics (e.g. CYP450)

GENOMIC SERVICES

MSS provides a variety of highly reproducible, efficient and cost-effective options for studying gene expression, including microarray and Next Generation Sequencing approaches. Typical projects have included:

- Quantitative expression analysis
- Transcriptome sequencing (RNA sequencing)
- Genome-wide protein-DNA interactions by ChIP sequencing

HISTOLOGY RESEARCH SERVICES

- Processing, cutting and staining
 - Tissue microarrays
 - Immunohistochemistry
 - Imaging and morphometry
 - Advanced bioimaging
 - Consultation
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Personalized Medicine Development & Testing Services

BENCH-TO-BEDSIDE DEVELOPMENT SERVICES

MSS has specialized expertise in the discovery, development and validation of prognostic, diagnostic and theranostic biomarker assays:

- Experienced partner for clinical validation studies
- Companion Diagnostic development from proof of concept to pivotal trials
- GcLP-compliant support for FDA & Health Canada regulatory submissions (LDTs and IVDs)
- Conventional and multiplex immunoassays (chip- and bead-based)
- Histopathological markers (FISH, IHC)
- Genetic markers (PCR, microarrays, conventional and Next-Generation Sequencing (NGS))
- Close connections to world-leading experts in personalized healthcare and diagnostic innovation

MOLECULAR DIAGNOSTIC TESTING SERVICES

MSS is an experienced partner in the commercialization and launch of molecular and companion diagnostic assays. We offer a range of advanced molecular tests through our Good Clinical Laboratory Practice-compliant clinical diagnostic laboratories:

- First in Canada to offer the *KRAS/NRAS* companion diagnostic assay for patients with colorectal cancer
- Provides access to one of only two reference centres for *HER2/neu* testing in Ontario, which helps determine the best course of therapy for patients with breast cancer.

MSS' offering of pharmacogenomics and companion diagnostic assays will continue to expand across a wide range of therapeutic areas.



Genomic Services

NEXT GENERATION SEQUENCING

MSS is proud to offer next generation sequencing services using Illumina's advanced HiSeq 3000, NextSeq 500 and MiSeq platforms. The HiSeq 3000 delivers up to two billion reads/run, dramatically improving the speed and reducing the costs of sequencing. Typical applications for NGS include:

- Genome sequencing
- Exome sequencing
- Transcriptome sequencing
- ChIP sequencing
- Targeted sequencing

GENOTYPING

MSS offers a variety of genotyping platforms including the Illumina iScan system, HiSeq 3000, NextSeq 500 and MiSeq to meet the diverse requirements of our clients in applications including quantitation of gene expression and the detection of single nucleotide polymorphisms. Our team is ready to assist with:

- Fine mapping SNP studies
- Whole genome loss of heterozygosity and copy number variation analysis
- Disease-associated copy number variation analysis
- Rare somatic mutation detection

GENE EXPRESSION

MSS provides a variety of highly reproducible, efficient and cost-effective options for studying gene expression, including microarray and Next Generation Sequencing approaches. Typical projects have included:

- Standard whole genome expression analysis for human, rat and mouse
- Quantitative expression analysis
- Transcriptome sequencing (RNA sequencing)
- Genome-wide protein-DNA interactions by ChIP sequencing

EPIGENETICS, METHYLATION & GENE REGULATION

Gene expression may be regulated by a number of factors including DNA methylation, small RNA-mediated regulation, and alterations in DNA-protein interactions (e.g. transcription factor binding). MSS offers expertise across a broad variety of platforms for epigenetics analysis, including microarray and NGS tools, and provides assistance in developing appropriate approaches for studies such as:

- Large-scale quantitative methylation analysis
- Targeted gene methylation analysis
- Discovery and profiling of microRNAs and other non-coding RNA
- DNA-protein interaction analysis (ChIP sequencing)



Consultation Services

Mount Sinai Services integrates deep scientific and clinical expertise with industry leading technologies resulting in a proven flexible approach to streamline the development process.

CLINICAL PROGRAM SUPPORT

- Project feasibility assessment
- Clinical and Non-clinical Project Requirements
- Quality Management
- Project coordination with academia and industry (including compliance with FDA)
- Pre-IDE Development, Regulatory Strategy, and Predicate Determination
- Health Technology Assessment
- FDA Interactions, Submission Assembly and Follow-up
- Report of Prior Investigations
- Protocol Development
- Reimbursement Strategies
- Post-Market Support
- Device Specific SOP Development
- Safety Reporting

DATA MANAGEMENT

MSS also offers sophisticated specialty and esoteric tests in the following fields:

- Statistical Analysis Plans
 - Statistical Project Management and Support
 - Statistical Analysis, Reports and Tables
 - Data Management Plans
 - Data Project Management and Support
 - Data Collection Tools (Worksheets, CRF, eCRF)
 - Database Development, Validation and Management
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