



QUALITY MANAGEMENT PROGRAM—LABORATORY SERVICES

CERTIFICATE OF ACCREDITATION



OLA 15189PLUS™
ACCREDITED 1612

This is to certify that
Mount Sinai Hospital

600 University Avenue, Suite 6-500-1
TORONTO, ON M5G 1X5
Licence No: 4194, Lab No: 0124

*Met the Ontario Laboratory Accreditation requirements during the assessment
conducted on 2012/10/15 to 2012/10/18*

Valid until 2017/03/17

Accreditation is valid for the specific activities and examinations listed in the attached scope of accreditation provided that the laboratory continues to meet explicit requirements (Version 5.1, December 2011) based on:

- ISO 15189:2007(E) Medical Laboratories-Particular Requirements for Quality and Competence,
- ISO 15190:2003(E) Medical Laboratories-Requirements for Safety,
- ISO 22870:2006(E) Point-of-care Testing (POCT)-Requirements for Quality and Competence (where relevant),
- CSA Standard Z902-10 Blood and Blood Components, February 2010 (where relevant).

December 04, 2013 Replacement,
Signed at Toronto, 2013-12-04

Gregory J. Flynn, MD, FRCPC
Managing Director, QMP-LS

Laboratory Information

Owner: Mount Sinai Hospital
Owner Address: 600 University Avenue
TORONTO, ON M5G 1X5
CANADA

Lab Address: 600 University Ave; Suite 6-500-1
TORONTO, ON M5G 1X5
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Certification

Version: Version 5.1
Issue Date: December 4, 2013
Classification: 4-Yr Certificate Issued
Expiry Date: March 17, 2017



The Quality Management Program - Laboratory Services accredits the capability of the named laboratory to perform the listed tests.

Scope of Accreditation

Bacteriology

- L622 Chlamydia culture isolation or non-cultural assays*
- L623 Antibiotic sensitivity - M.I.C.*
- L624 Cultures - blood (including aerobic, anaerobic, subcultures, smears)*
- L625 Cultures - cervical, vaginal, including GC culture, Gram smear, yeast identification (e.g. Germ tube)*
- L627 Cultures - GC culture and smear*
- L628 Cultures - other swabs or pus-culture and smear*
- L629 Cultures - sputum-culture and smear*
- L630 Cultures - stool culture, including the necessary agglutinations and culture for campylobacter*
- L634 Cultures - urine calibrated volume to include plate, turbidimetric or photometric techniques*
- L638 Streptococcus grouping, coagglutination method*
- L639 Cultures - fluids (CSF, joint, pleural etc. not exudates)*
- L640 Cultures - throat swab, for streptococcus screen only*
- L643 Smear only, Gram or Papanicolaou stain*
- L652 Smear only, special stain, e.g. ZN, inclusions, spores, diphtheria*

Bacteriology

- L653 Wet preparation (for fungus, trichomonas, parasites)*
- L656 Penicillinase production*

Biochemistry

- L001 Acetone, qualitative*
- L005 Albumin, quantitative*
- L006 Alcohol, ethyl - quantitative*
- L015 Ammonia*
- L016 Amniotic fluid scan*
- L018 Amylase*
- L030 Bilirubin, total*
- L031 Bilirubin, conjugated*
- L035 pCO₂, pO₂ and pH in combination*
- L040 Carbamazepine, quantitative (Tegretol)*
- L045 Calcium*
- L046 Calcium ionized*
- L053 Chloride*
- L055 Cholesterol, total*
- L059 Acetaminophen*
- L060 Carboxyhemoglobin*
- L061 CO₂ Content, CO₂ combining power, bicarbonate (measured not calculated)*
- L066 Creatine Phosphokinase*
- L067 Creatinine*
- L068 Creatinine clearance*
- L078 Drugs of abuse screen, urine*
- L085 Electrophoresis, serum - including total protein*
- L086 Electrophoresis, other than serum - including total protein*
- L093 Glycosylated hemoglobin - Hgb A1*
- L103 Glucose tolerance test in pregnancy*
- L104 Glucose tolerance test*
- L107 Gamma glutamyl transpeptidase*
- L111 Glucose, quantitative - not by dipstick*

Biochemistry

- L112 Glucose, semi-quantitative (dipstick if read with reflectance meter)*
- L117 High density lipoprotein cholesterol*
- L139 Iron, total - with iron binding capacity and per cent saturation*
- L145 Lactic acid (lactate)*
- L146 Lactic dehydrogenase (L.D.H.), total*
- L157 Lithium*
- L165 Magnesium*
- L172 Methemoglobin*
- L181 Occult blood*
- L183 Osmolality (osmolarity)*
- L184 Oxalic acid (oxalate) - U*
- L191 Phosphatase, alkaline*
- L192 Phosphatase, alkaline fractionation*
- L194 Phosphorus (inorganic phosphate)*
- L204 Potassium*
- L208 Protein, total*
- L221 Salicylate, quantitative*
- L222 SGOT (AST)*
- L223 SGPT (ALT)*
- L226 Sodium*
- L243 Triglycerides*
- L251 Urea nitrogen (B.U.N.)*
- L252 Uric acid (urate)*
- L253 Urinalysis, routine chemical (any of S.G., pH, protein, sugar, hemoglobin, ketones, urobilinogen, bilirubin, leukoc
- L254 Urinalysis, microscopic examination of centrifuged specimen*
- L257 Valproic acid (valproate)*
- L354 Prostate Specific Antigen (PSA), Free
- L358 Prostate Specific Antigen (PSA), Total
- U013 Angiotensin Converting Enzyme (ACE)
- U021 Apolipoproteins A and B
- U097 Prostate Specific Antigen (PSA), Total
- U116 Troponin

Biochemistry

U121 Mucin Clot (synovial fluid)
U195 Sex Hormone Binding Globulin (SHBG)
U221 Intralipid
U354 Prostate Specific Antigen (PSA), Free
U369 Citrate
U429 Lactose Intolerance - Methane and Hydrogen
U432 Natriuretic Peptide - Brain (BNP)
U435 Foetal Fibronectin
U719 Bioavailable Testosterone
U869 Anti-Mullerian Hormone (AMH)

Cytogenetics

U736 Constitutional Chromosome Analysis, Routine GTG banding (Blood)
U737 Constitutional Chromosome Analysis, Routine GTG banding (Amniotic Fluid, CVS and Tissue)
U738 Constitutional FISH test (Blood, Amniotic Fluid, CVS, Tissue)
U739 Constitutional FISH Panel (Blood, Amniotic Fluid, CVS, Tissue)
U763 Genetics - Microarray-constitutional, whole genome
U764 Genetics - Microarray-constitutional, locus specific

Cytology

L705 Aspiration biopsy (lung, breast, thyroid, etc.)*
L706 Bronchial washings or brushings*
L708 Esophageal, gastric or endometrial washings or brushings*
L710 Direct smears - oral, larynx, nipple discharge, vulvar*
L711 Fluids (pleural, ascitic, cyst, aspirate, pericardial, joint, CSF, and urine)*
L713 Cervicovaginal specimen (including all types of cellular abnormality, assessment of flora and/or cytohormonal eval)
L715 Smear for eosinophils (nasal, sputum, ocular, etc.)*
L716 Sputum per specimen for general and/or specified assessment (e.g. cellular abnormality, asbestos bodies, lipid, hem)
L718 Seminal fluid examination (complete)*

Cytology

- L719 Smear for spermatozoa only (post-operative)*
- L733 Cervicovaginal Specimen (monolayer cell methodology)

Hematology

- L370 Assay of Factors II, V, VII, VIII, IX, X, XI, and XII*
- L373 Antithrombin III assay*
- L375 Blood film - special stain*
- L377 Bleeding time - Ivy method*
- L378 Bone marrow - film preparation*
- L379 Bone marrow - staining (Romanowski and iron)*
- L386 Circulating anticoagulant (e.g. lupus anticoagulant)*
- L391 C.S.F. cell count (to include differential)*
- L393 Complete Blood Count (any method)*
- L398 Reticulocyte count*
- L402 Fibrinogen, quantitative*
- L405 Fibrin split products, quantitative*
- L410 G-6-PD screen*
- L415 Haptoglobin*
- L416 Heinz bodies*
- L419 Hemoglobin electrophoresis to include Hb A2 fraction*
- L420 Hemoglobin, foetal*
- L425 Heparin assay*
- L431 Kleihauer stain*
- L432 Malaria smear or other parasites*
- L439 Preparation of cryoprecipitate*
- L440 Preparation of platelet (thrombocyte) concentrates*
- L441 Preparation of washed red cells*
- L442 Preparation of leukocyte-poor blood*
- L445 Prothrombin time*
- L451 Sedimentation rate*
- L453 Sickle cell solubility test (screen)*
- L460 Thrombin time*

Hematology

L462 Partial thromboplastin time*
U002 APC Resistance (Active Protein C Resistance)
U093 Platelet neutralization (PNP)
U105 Russell Viper Venom Time (RVVT)
U140 Rh Rosette Test
U311 Lamellar Body Counts (LBC)
U314 Factor V Leiden (F5 gene)
U321 Prothrombin Gene 20210A Mutation/Variant (F2 gene)

Histology (Pathology)

L717 Electron microscopy*
L720 Surgical pathology*
L721 Operative consultation - with or without frozen section*
L722 Operative consultation - for each specimen over 3*
L723 Metabolic bone study - morphologic and morphometric assessment*
L724 Metabolic bone study - kinetic assessment including fluorescent label studies*
L725 X-ray diffraction analysis of calculi*
L726 Analytical electron microscopy-elemental detection, mapping/electron diffraction, per specimen*
L728 Histochemistry of muscle - 1 to 3 enzymes*
L729 Histochemistry of muscle - each additional enzyme, per label
L731 Immunoperoxidase technique - per label*
U363 HER2/neu

Immunoassays

L303 Cortisol*
L304 Aminoglycosides (e.g. gentamicin, tobramycin)*
L306 Digoxin*
L307 ACTH (adrenocorticotrophic hormone)*
L309 Folate, in red cells, to include hematocrit and if requested, serum folate*
L310 Estradiol*

Immunoassays

- L311 Estriol*
- L315 FSH (pituitary gonadotrophins)*
- L317 Growth hormone*
- L318 HCG (human chorionic gonadotrophins)*
- L319 Hepatitis associated antigen or antibody immunoassay - per assay (e.g. hepatitis B surface antigen or antibody, hep
- L321 Aminophylline (theophylline)*
- L324 Diphenylhydantoin (phenytoin), quantitative (dilantin)*
- L325 Insulin*
- L328 LH (luteinizing hormone)*
- L329 Ferritin*
- L330 Parathyroid hormone*
- L331 Progesterone*
- L332 Prolactin*
- L333 17-OH progesterone*
- L339 T4, free - absolute (includes T-4 total)*
- L340 Testosterone*
- L341 TSH (thyroid stimulating hormone)*
- L343 Phenobarbitone*
- L345 Vitamin B12*
- L346 C-peptide immunoreactivity*
- L347 Dehydroepiandrosterone sulphate (DHEAS)*
- L350 Inhibin
- L351 Pregnancy Associated Plasma Protein type A (PAPP-A)
- L588 1,25 dihydroxy Vitamin D
- L606 25 hydroxy Vitamin D*
- L607 T-3, free*
- L609 Thyroglobulin*
- L690 Carcinoembryonic antigen (CEA)*
- L691 Alphafetoprotein*
- U792 25 hydroxy Vitamin D

Immunoematology

- L471 Antibody identification - per specimen*
- L473 Parallel titration on two specimens to include confirmation of previously detected antibody*
- L481 Antibody titre per antibody, per specimen*
- L482 Antibody screening*
- L490 Blood Group - ABO and RhD*
- L492 Crossmatch per unit of blood*
- L493 Blood Group - ABO and Rh Phenotype*
- L494 Blood Group per antigen*
- L495 Direct anti-human globulin test*

Immunology

- L501 Agglutination Reaction - Titre - serial tube, single antigen*
- L535 Fluorescent Antibody Tests (Immunofluorescent Studies), Tests for serum antibodies to tissue and cell components -
- L544 Fluorescent Antibody Tests (Immunofluorescent Studies), Tests for serum antibodies to tissue and cell components -
- L550 Single gel diffusion and nephelometric quantitative assays - Immunoglobulin G, A, D, M*
- L551 Complement proteins - C3(B1C)*
- L552 Complement proteins - C4(B1E)*
- L554 Miscellaneous proteins - Transferrin*
- L575 Gammopathy Screen by immunoelectrophoresis or immunofixation*
- L596 Sperm antibodies - screen*
- L600 Cryoglobulin - qualitative*
- L601 Cryoglobulin - quantitative*
- L610 Concentration of sample before testing (any method)*
- L660 Cold agglutinins - screen*
- L661 Cold agglutinins - titre*
- L665 C-Reactive protein*
- L667 Non-cultural direct bacterial antibody or antigen assays by fluorescence, agglutination or ELISA techniques*
- L668 Heterophile antibodies - screen (slide or single tube) - with or without absorption*
- L679 Virus antibodies - hemagglutination inhibition or ELISA technique*

Immunology

- L683 Non-cultural indirect antibody or antigen assays by fluorescence, agglutination or ELISA techniques*
- L685 Leukocyte phenotyping by monoclonal antibodies - first antibody*
- L686 Leukocyte phenotyping by monoclonal antibodies - each additional antibody, to a maximum of 20 antibodies*
- L888 VDRL*
- U011 ANCA - C
- U012 ANCA - P
- U015 Anti - Cardiolipin Antibody
- U029 CA 125
- U110 Insulin-Like Growth Factor 1 (IGF 1, Somatomedin C)
- U223 HPV Testing
- U359 Crosslinked Telopeptides of type 1 collagen (C-telopeptides and N-telopeptides)
- U447 West Nile Virus - for Transfusion and/or Transplant purposes only
- U707 Cyclic Citrullinated Peptide Antibody (Citrulline Antibody)

Molecular Genetics

- U070 Genetics - Familial Breast Cancer (BRCA1 gene)
- U248 Genetics - DNA/RNA banking
- U257 Genetics - Haemochromatosis (HFE gene)
- U347 Genetics - Hereditary Non-Polyposis Colorectal Cancer (HNPCC) (MLH1 gene)
- U401 Genetics - Hereditary Thrombosis (Methylene Tetrahydrofolate Reductase (MTHFR gene)
- U493 Genetics - Familial Adenomatous Polyposis (FAP - colon) (APC gene)
- U515 Genetics - Familial Breast Cancer (BRCA1/BRCA2 dosage)
- U517 Genetics - Familial Breast Cancer (AJ mutations)
- U528 Genetics - Hereditary Non-Polyposis Colorectal Cancer (HNPCC) (MYH gene)
- U529 Genetics - Hereditary Non-Polyposis Colorectal Cancer (HNPCC) (MSH6 gene)
- U538 Genetics - Trisomy (markers 21, 18, 13)
- U544 Genetics - Familial Breast Cancer (BRCA2 gene)
- U557 Genetics - Hereditary Non-Polyposis Colorectal Cancer (HNPCC) (MSH2 gene)

Molecular Genetics

U571 Genetics - Gastrointestinal Stromal Tumour (GIST), C-KIT mutation
U572 Genetics - Gastrointestinal Stromal Tumour (GIST), PDGFRA
U578 Genetics - Sarcoma, Ewings translocations
U583 Genetics - Carcinoma (HPV genotyping)
U609 Genetics - Infertility (Y-Chromosome deletion mapping)
U638 Genetics - Hereditary Non-Polyposis Colorectal Cancer (HNPCC) (MSI testing (E.G.BAT26)
U640 Genetics - Sarcoma [t(1;13) (PAX7/FKHR gene)
U645 Genetics - Sarcoma [t(2;13) (PAX3/FKHR gene)
U646 Genetics - Sarcoma [t(X;18 (SYT/SSXgene)
U745 Genetics - Colon Cancer (K-Ras gene)
U774 Genetics - Familial Breast Cancer (Familial Mutation)
U863 Genetics- Carcinoma/Melanoma/Astrocytoma; BRAF mutations/translocations
U871 Genetics - Familial Adenomatous Polyposis (FAP - colon) (gene dosage analysis)
U872 Genetics - Sarcoma, Myxoid Liposarcoma FUS/CHOP t(12;16)
U873 Genetics - Nodular fasciitis (MYH9/USP6)
U874 Genetics - Hereditary Non-Polyposis Colorectal Cancer (HNPCC) (gene dosage analysis)

Mycology

L626 Cultures - fungus, including KOH preparation and smear*

Serology HIV Antibody

L887 Serology HIV Antibody*
L889 HIV Viral Load Test

Virology

L637 Virus isolation*