ARUP LABORATORIES

As a nonprofit, academic institution of the University of Utah and its Department of Pathology, ARUP believes in collaborating, sharing knowledge, and contributing to laboratory science in ways that benefit our clients and their patients.

Our test menu is one of the broadest in the industry, encompassing more than 3,000 tests, including highly specialized and esoteric assays. We offer comprehensive testing in the areas of genetics, molecular oncology, pediatrics, and pain management, among others.

ARUP’s clients include many of the nation’s university teaching hospitals and children’s hospitals, as well as multihospital groups, major commercial laboratories, and group purchasing organizations. We do not compete with our clients for physician office business, choosing instead to support clients’ existing test menus by offering highly complex assays and accompanying consultative support so clients can provide exceptional patient care in their local communities.

Offering analytics, consulting, and decision support services, ARUP provides clients with the utilization management tools necessary to prosper in this time of value-based care. Our UM+ program helps clients control utilization, reduce costs, and improve patient care. In addition, ARUP is a worldwide leader in innovative laboratory research and development, led by the efforts of the ARUP Institute for Clinical and Experimental Pathology®.

ARUP’s reputation for quality is supported by our ability to meet or exceed the requirements of multiple regulatory and accrediting agencies and organizations. ARUP participates in the CAP laboratory accreditation program and has CLIA certification through the Centers of Medicare and Medicaid Services. In December 2016, ARUP earned accreditation to the ISO 15189:2012 standard under CAP.

We believe in collaborating, sharing knowledge, and contributing to laboratory science in ways that provide the best value for the patient. Together, ARUP and its clients will improve patient care today and in the future.

patients. answers. results.

A laboratory test is more than a number; it is a person, an answer, a diagnosis.
<table>
<thead>
<tr>
<th><strong>CHEMISTRY DIVISION</strong></th>
<th>1-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analytic Biochemistry</td>
<td>1</td>
</tr>
<tr>
<td>Automated Core</td>
<td>1</td>
</tr>
<tr>
<td>Calculi and Manual Chemistry</td>
<td>2</td>
</tr>
<tr>
<td>Clinical Toxicology I</td>
<td>2</td>
</tr>
<tr>
<td>Clinical Toxicology II</td>
<td>3</td>
</tr>
<tr>
<td>Clinical Toxicology III</td>
<td>3</td>
</tr>
<tr>
<td>Automated Endocrinology</td>
<td>4</td>
</tr>
<tr>
<td>Endocrinology/Electrophoresis</td>
<td>4</td>
</tr>
<tr>
<td>Hemostasis/Thrombosis</td>
<td>5</td>
</tr>
<tr>
<td>Manual Endocrinology</td>
<td>5</td>
</tr>
<tr>
<td>Mass Spectrometry I and II</td>
<td>6</td>
</tr>
<tr>
<td>Special Chemistry</td>
<td>6</td>
</tr>
<tr>
<td>Trace and Toxic Elements</td>
<td>7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>IMMUNOLOGY DIVISION</strong></th>
<th>8-11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoimmune Immunology I</td>
<td>8</td>
</tr>
<tr>
<td>Autoimmune Immunology II</td>
<td>8</td>
</tr>
<tr>
<td>Cellular and Innate Immunology</td>
<td>9</td>
</tr>
<tr>
<td>Immunologic Flow Cytometry</td>
<td>9</td>
</tr>
<tr>
<td>Immunology Core</td>
<td>10</td>
</tr>
<tr>
<td>Microbial Immunology I</td>
<td>10</td>
</tr>
<tr>
<td>Microbial Immunology II</td>
<td>10</td>
</tr>
<tr>
<td>Protein Immunology</td>
<td>11</td>
</tr>
<tr>
<td>Serologic Hepatitis/Retrovirus</td>
<td>11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>INFECTIOUS DISEASE</strong></th>
<th>12-16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteriology</td>
<td>12</td>
</tr>
<tr>
<td>Infectious Disease Antigen Testing</td>
<td>12</td>
</tr>
<tr>
<td>Microbial Amplified Detection</td>
<td>13</td>
</tr>
<tr>
<td>Molecular Hepatitis/Retrovirus</td>
<td>13</td>
</tr>
<tr>
<td>Molecular Infectious Disease</td>
<td>14</td>
</tr>
<tr>
<td>Mycology AFB</td>
<td>14</td>
</tr>
<tr>
<td>Parasitology and Fecal Testing</td>
<td>15</td>
</tr>
<tr>
<td>Sequencing Infectious Disease</td>
<td>15</td>
</tr>
<tr>
<td>Special Microbiology</td>
<td>16</td>
</tr>
<tr>
<td>Virology</td>
<td>16</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>INTEGRATED ONCOLOGY AND GENETICS</strong></th>
<th>17-25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomic Pathology</td>
<td>17</td>
</tr>
<tr>
<td>Biochemical Genetics</td>
<td>17</td>
</tr>
<tr>
<td>Cytogenetics and Genomic Microarray</td>
<td>18</td>
</tr>
<tr>
<td>Cytopathology</td>
<td>18</td>
</tr>
<tr>
<td>Fragment Analysis</td>
<td>19</td>
</tr>
<tr>
<td>Genetics Sequencing</td>
<td>20</td>
</tr>
<tr>
<td>Genomics</td>
<td>21</td>
</tr>
<tr>
<td>Hematologic Flow Cytometry</td>
<td>22</td>
</tr>
<tr>
<td>Special Hematology</td>
<td>22</td>
</tr>
<tr>
<td>Histology</td>
<td>23</td>
</tr>
<tr>
<td>Immunohistochemistry</td>
<td>23</td>
</tr>
<tr>
<td>Molecular Genetics</td>
<td>24</td>
</tr>
<tr>
<td>Molecular Oncology</td>
<td>25</td>
</tr>
<tr>
<td>Supplemental Newborn Screening</td>
<td>25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>ARUP INSTITUTE FOR CLINICAL &amp; EXPERIMENTAL PATHOLOGY</strong></th>
<th>26-27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Development</td>
<td>26</td>
</tr>
<tr>
<td>Specialized Technologies and Manufacturing</td>
<td>26-27</td>
</tr>
<tr>
<td>Technology Transfer</td>
<td>27</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>TECHNICAL SUPPORT DIVISION</strong></th>
<th>28-29</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated Specimen Management (ASM)</td>
<td>28</td>
</tr>
<tr>
<td>Infectious Disease Processing</td>
<td>28</td>
</tr>
<tr>
<td>Integrated Oncology and Genetics</td>
<td>28</td>
</tr>
<tr>
<td>Services Laboratory</td>
<td>29</td>
</tr>
<tr>
<td>Specimen Processing</td>
<td>29</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>TRANSFUSION MEDICINE DIVISION</strong></th>
<th>30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Services</td>
<td>30</td>
</tr>
<tr>
<td>Immunohematology Reference Laboratory (IRL)</td>
<td>30</td>
</tr>
<tr>
<td>Transfusion Services</td>
<td>30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>UNIVERSITY OF UTAH HEALTHCARE DIVISION</strong></th>
<th>31</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Hospitals and Clinics, Clinical Laboratories</td>
<td>31</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CLIENT COMMITMENT</strong></th>
<th>31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client Commitment Statement</td>
<td>31</td>
</tr>
</tbody>
</table>
ANALYTIC BIOCHEMISTRY

Description
This technical section primarily uses high-performance liquid chromatography (HPLC) combined with various detection systems, including mass spectrometry (MS), electrochemical, UV, and fluorometric. Testing is focused on nutritional assessment, porphyrins, and biogenic amines.

Testing Areas
- 5-HIAA
- Catecholamines
- Coenzyme Q10
- Fractionated Carotenes
- HVA
- Metanephrines
- Porphyrins
- Serotonin
- Sulfate, Supersaturation
- Vitamin A
- Vitamin B1
- Vitamin B2
- Vitamin B6
- Vitamin C
- Vitamin E
- Vitamin K
- VMA

Methodologies
Spectrophotometry, chromatography, mass spectrometry, and fluorometry

Instrumentation
HPLC, MS, electrochemical detector (ECD), UV detector, spectrophotometer, and fluorometer

AUTOMATED CORE

Description
This technical section primarily uses high-throughput automated analyzers. Test selection is focused on assays requiring no manual manipulation. The lab currently performs more than 20 percent of all testing performed at the central facility.

Testing Areas
200 different assays performed on various types of samples (serum, urine, CSF, and amniotic fluid), including:
- Drugs of abuse screening by immunoassay
- Endocrine testing: T3, T4, TSH, testosterone, SHBG, ferritin, folate, B12, insulin, PTHI, and thyroglobulin
- General chemistries: electrolytes, enzymes, BUN, creatinine, and glucose
- Maternal serum screen: alpha fetoprotein, hCG, estriol, and inhibin A
- Tumor markers: CA 125, CA 15-3, CA 19-9, CEA, PSA, AFP TM, and hCG

Methodologies
Ion-selective electrode/ enzymatic, chemiluminescent immunoassay, electrochemiluminescent immunoassay, immunoturbidimetric, spectrophotometry

Instrumentation
Ortho ECI, Beckman Dxl, Roche Cobas 8000, Beckman AU5810
CALCULI AND MANUAL CHEMISTRY

Description
This technical section primarily uses Fourier-transform infrared spectroscopy (FT-IR) for calculi analysis. Testing specializes in calculi (stone) analysis, calculi photomicrographs, calculi risk assessments, viscometry assessment, and nutritional status.

Testing Areas
- Calculi
- Calculi photomicrographs
- Sulfate
- Supersaturation risk calculations
- Calculi risk assessments
- Carotenes
- Viscosity

Methodologies
Fourier Transform Infrared Spectroscopy (FT-IR), FT-IR microscopy, polarizing microscopy, photomicroscopy, spectrophotometry, viscometry

Instrumentation
FT-IR, FTIR microscope, stereomicroscope, spectrophotometer, cone-plate viscometer

CLINICAL TOXICOLOGY I

Description
This laboratory analyzes urine, serum, and plasma to detect drugs of abuse for treatment-rehabilitation centers, pain management clinics, and hospitals. No chain of custody, employment, or forensic sample testing is performed.

Testing Areas
Qualitative and quantitative testing for commonly abused prescription and illicit drugs. Screens with reflex to confirmation and confirmation-only testing are available. Drug testing is designed to support clinical applications, including:
- Compliance testing for pain management clinics
- Qualification for patients for surgery or other interventions
- Verification of drug abstinence
- Confirmation of previously obtained screening results

Methodologies
GC-MS, LC-MS/MS

Instrumentation
Agilent 6890/5973 GC/MS, API 5500 LC-MS/MS, API 4000 LC-MS/MS, Waters ACQUITY TQD LC/MS/MS
CLINICAL TOXICOLOGY II

Description
This laboratory performs approximately 65 quantitative assays for more than 80 drugs. Comprehensive screening is also performed to detect the presence of up to 250 drugs, including over-the-counter and prescription drugs, as well as some drugs of abuse.

Testing Areas
• Anticonvulsant drugs
• Antidepressant drugs
• Antifungal drugs
• Antipsychotic drugs
• Cardiac drugs
• Immunosuppressant drugs

Methodologies
Spectrophotometric assays, immunoassay (ELISA), GC-MS, LC-MS/MS

Instrumentation
GC-MS, LC-MS/MS, spectrophotometer

CLINICAL TOXICOLOGY III

Description
This lab is the first lab in the country to incorporate time-of-flight mass spectrometry in clinical toxicology testing. Serum, plasma, meconium, and umbilical cord tissue are analyzed to detect drugs of abuse for hospitals, pain management clinics, and treatment-rehabilitation centers. No chain of custody, employment, or forensic sample testing is performed.

Testing Areas
Qualitative and quantitative testing for commonly abused prescription and illicit drugs. Screens with reflex to confirmation and confirmation-only testing are available. Drug testing is designed to support clinical applications, including:
• Identification of in utero drug exposure
• Compliance testing for pain management clinics
• Qualification for patients for surgery or other interventions
• Verification of drug abstinence
• Confirmation of previously obtained screening results

Methodologies
ELISA technology (immunalysis), GC-MS, LC-MS/MS, LC-TOF/MS

Instrumentation
AB SCIEX 5500 LC-MS/MS, Agilent 6460 LC-MS/MS, Agilent 6230 TOF-MS
AUTOMATED ENDOCRINOLOGY

**Description**
This technical section primarily uses high-throughput automated analyzers. Test selection is focused on assays not fitting into the Automated Core Lab that may require limited manual manipulation prior to analysis.

**Testing Areas**
- Adrenal cortical
- Aldosterone
- Bone metabolism
- Endocrine uniformity
- Epstein-Barr Virus (EBV G, EBV M, EBV NA, and EBV EAD)
- Gonad responsiveness
- Growth status
- Pancreas
- Pediatric and adult functional testing
- Pituitary secretion
- Thyroid
- Torch testing: cytomegalovirus, *Toxoplasma gondii*, rubella, and herpes
  - Tumor markers: CA27.29, PAP
  - Vaccine response: measles, mumps, varicella (MMV)
- Vitamin status
- Water metabolism

**Methodologies**
Immunoassays, chromatography

**Instrumentation**
DiaSorin LIAISON XL, Siemens IMMULITE 2000, Siemens ADVIA Centaur XP, Premier HPLC

ENDOCRINOLOGY/ELECTROPHORESIS

**Description**
This technical section primarily uses electrophoretic, radioimmunoassay (RIA), and enzyme-linked immunosorbent assay (ELISA) methodologies. The testing encompasses a wide array of disease states, particularly those that are best diagnosed using electrophoretic methods.

**Testing Areas**
- Alpha-1-antitrypsin phenotyping
- Aldosterone
- 17-OH progesterone
- Vasopressin
- AMH
- Inhibin B
- Fetal lung-maturity evaluations
- LDL subclasses
- Lipoprotein and CSF electrophoresis
- Lipoprotein quantitation
- Oligoclonal banding and MBP
- Quantitative measurement of isoenzyme electrophoresis
- Somatostatin
- von Willebrand factor multimer panels

**Methodologies**
Electrophoresis, ELISA, Western blot, ELISA, CLIA, RIA

**Instrumentation**
Gamma counter, microplate reader and washer, cell counter, tube-gel electrophoresis, robotic pipettor-automated liquid handler, chemiluminescent plate reader, NMR, isoelectric focusing
HEMOSTASIS/THROMBOSIS

Description
This laboratory performs routine and esoteric testing for bleeding, thrombotic (clotting), and hypercoagulable disorders.

Testing Areas
• APC resistance studies
• AT3
• Factor assays
• Lupus anticoagulant panels; highest volume test at 2,000 per month
• PAI-1 (plasminogen activator inhibitor 1 activity)
• Platelet aggregations (local clients only)
• Protein C and S—both antigenic and functional
• PT and INR, PTT, and thrombin time
• Serotonin release assay (heparin dependent platelet antibody), unfractionated heparin
• TPA AG (tissue plasminogen activator and antigen)
• von Willebrand studies

Methodologies
EIA, mechanical clot detection, photo-optical

Instrumentation
Stago STA-R, Dade Behring BCS

MANUAL ENDOCRINOLOGY I

Description
This technical section primarily uses radioimmunoassay (RIA), enzyme-linked immunosorbent assay (ELISA), and chemiluminescent methodologies. The testing is generally manual and is specialized in testing related to the endocrine system.

Testing Areas
• Adrenal
• Bone/calcium metabolism
• Obesity markers
• Pituitary
• Gonadal
• Hypertension/renal
• Inflammatory markers
• Diabetes
• Tumor marker
• Thyroid function

Methodologies
RIA, ELISA, electrochemiluminescence (ECL), chemiluminescent immunoassay

Instrumentation
Gamma counter, microplate reader and washer, robotic pipettor, automated liquid handler, automated analyzer, chemiluminescent plate reader
MASS SPECTROMETRY I AND II

Description
Mass spectrometry uses mass selective detection systems (LC-MS/MS). These technical sections specialize in the utilization of highly sensitive mass spectrometers to report low-level values that other methodologies cannot detect.

Testing Areas
• Endocrine hormones
• Vitamin D2 and D3
• Bile acids
• Methylmalonic acid
• Catecholamines and metanephrines

Methodologies
Liquid phase extraction, solid phase extraction, equilibrium dialysis, LC-MS/MS

Instrumentation
Automated liquid handlers, LC-MS/MS systems

SPECIAL CHEMISTRY

Description
The Special Chemistry Laboratory uses a variety of testing methods, including enzyme kinetics and manual colorimetric methods. Esoteric tests performed in this section include alkaline phosphatase isoenzyme identification, oxalate quantification, and red blood cell glucose-6-phosphate dehydrogenase (G6PH) studies. Additional services include tumor markers, oncoproteins, suppressor mutant proteins, and pseudocholinesterase phenotyping.

Testing Areas
• Enzymology
• Immunochemistry
• Spectrophotometry
• Colorimetry

Methodologies
Spectrophotometry, infrared breath analysis, fluorescence, ELISA

Instrumentation
Automated analyzer, robotic pipettor-automated liquid handler, scanning spectrophotometer
TRACE AND TOXIC ELEMENTS

Description
This technical section primarily uses inductively coupled plasma mass spectrometry (ICP-MS) technology for element analysis. The testing performed in this area is often workplace or regulatory in nature.

Testing Areas
• Aluminum
• Arsenic
• Cadmium
• Chromium
• Copper
• Lead
• Manganese
• Mercury
• Nickel
• Selenium
• Various elements used in pesticides
• Zinc

Methodologies
ICP-MS, LC-ICP-MS

Instrumentation
PerkinElmer, Agilent ICP-MS, HPLC
AUTOIMMUNE IMMUNOLOGY I

Description
Autoimmune Immunology I is a rapidly growing lab specializing in testing for antibodies utilized in the diagnosis and monitoring of a variety of autoimmune diseases.

Testing Areas
• Antibodies against extractable nuclear antigens (ENA), such as RNP (U1) Smith, Sm/RNP, SSA, SSB, Scl-70, Jo-1, and Ribosome P
• Antibodies against neutrophil cytoplasm components (ANCA, MPO, and PR3), including atypical pANCA for IBD testing
• Antibodies against tissues, (e.g., striated muscle, smooth muscle, islet cells)
• Anti-nuclear antibodies (ANA) by IFA and centromere antibodies
• Heat-shock protein antibody
• Hypersensitivity pneumonitis testing
• Myositis antibodies
• Neuronal antibodies (Hu, Yo, Amphiphysin, CV2.1, NMDA receptor, AQP-4 receptor, LGI1, and CASPR2)
• Systemic sclerosis
• Paraneoplastic syndromes
• Testing for humoral immunodeficiency: Diptheria antibody, Tetanus antibody, Haemophilus influenzae type b antibody, Neisseria meningitides (meningococcal) antibodies, and Streptococcus pneumoniae (pneumococcal) antibodies

In addition to pneumococcal antibodies, the connective-tissue disease panels, vasculitis panel, and diphtheria/tetanus/H. influenzae type B are performed by multiplex bead assay.

Methodologies
Multiplex bead assay, IFA, immunoblot, radioimmunoprecipitation, Ouchterlony double immunodiffusion

Instrumentation
Luminex 200, Euroimmun Blot One, IFA slide processors (HELMED, Quanta-lyser), Perkin Elmer JANUS, LED microscopes, CCD camera

AUTOIMMUNE IMMUNOLOGY II

Description
Autoimmune Immunology II exclusively performings ELISA testing for antibodies that aid in the diagnosis and monitoring of a variety of autoimmune diseases.

Testing Areas
• Anti-phospholipid syndrome (APS) antibody testing (cardiolipin G/M/A, B2GPI G/M/A, phosphatidyl-serine/ethanolamine/glycerol/inositol/choline G/M/A, and prothrombin G)
• Autoimmune liver disease antibody testing (M2, actin IgG, LKM1, and SLA)
• Celiac disease antibody testing (tTG IgA and IgG, deamidated gliadin peptide [DGP] IgA and IgG, and endomysial IgA and IgG)
• Inflammatory bowel disease (IBD) antibody testing (ASCa IgA and IgG, gASCa, ALCA, AMCA, and ACCA)
• Lupus and other connective-tissue disease antibody testing (ANA by ELISA, dsDNA and ssDNA by ELISA, RNA polymerase III, and histone)
• Motor and/or sensory neuropathy antibody testing (gangliosides, MAG, and SGPG)
• Rheumatoid factor (RF) isotypes by ELISA

Methodologies
ELISA

Instrumentation
ELISA plate processors (Quanta-Lyser), manual ELISA plate washers and readers
CELLULAR AND INNATE IMMUNOLOGY

Description
Cellular Immunology performs highly esoteric assays that test functional components of the cell-mediated and innate branches of the immune system. These include microbicidal killing potential in neutrophils, proliferation and cytokine production in lymphocytes, the innate protection in toll-like receptor functionality, immunogenicity directed against TNF-blocking drugs infliximab and adalimumab, as well as detection of functional drug activity. Cellular and flow cytometric methodologies are also utilized to detect auto-antibodies to acetylcholine receptor, calcium and potassium channels, and other antibodies present in neuromuscular diseases.

Testing Areas
- Acetylcholine receptor antibodies
- Cytokine production in activated lymphocytes
- Lymphocyte proliferation
- Neutrophil oxidative burst
- Urticaria induced basophil activation
- Immunogenicity

Methodologies
Flow cytometry, cell culture, tritium incorporation, multiplex bead assay, ELISA, radioimmunoassay, chemiluminescence

Instrumentation
BD FACSCanto II, Luminex200, manual methods

IMMUNOLOGIC FLOW CYTOMETRY

Description
Flow cytometry is a technologically advanced method utilizing laser detection of fluorescent-labeled antibodies to identify cells by their antigen expression.

Testing Areas
- Anti-neutrophil antibodies
- CD4+T-cell recent thymic emigrants
- CD57+NK cells
- Congenital immunodeficiencies—PIP, CVID, BTK, and ALPS
- DNA content cell cycle analysis
- Fetal hemoglobin for fetomaternal hemorrhage
- HLA-B27
- Immune complexes—RAJI, C3d assay
- Immunophenotyping—from CD4 detection to complex marker panels
- Natural killer-cell and natural killer t-cell panel
- Leukocyte-adhesion deficiency (LAD) testing panel
- Platelet-associated antibodies
- Platelet glycoprotein expression
- PNH RBC and PNH WBC (high sensitivity)
- RBC band 3 protein reduction in hereditary spherocytosis
- Regulatory T-cell panel
- Transplant patient monitoring—LymphPro and CD3
- CD4:CD8 ratio for bronchoalveolar lavage specimens

Methodologies
Flow cytometry

Instrumentation
BD FACSCanto II
IMMUNOLOGY CORE

Description
The Immunology Core Section performs highly automated, high-volume assays with rapid throughput. The section performs tests for IgE-specific allergic responses, IgG-specific allergens, total IgE, and Tryptase.

Testing Areas
More than 300 IgE-specific allergens

Methodologies
ImmunoCAP fluorescent enzyme immunoassay

Instrumentation
ImmunoCAP 1000, Phadia 250, Phadia 5000

MICROBIAL IMMUNOLOGY I

Description
This section performs assays to aid in the serologic diagnosis of bacterial, viral, mycoplasma, and parasitic infections.

Testing Areas
- Bordetella pertussis A/G/M
- Chikungunya G/M
- Dengue fever virus G/M
- Influenza virus
- Lyme disease ELISA and Western blot
- Mycoplasma pneumoniae G/M
- Parvovirus B19 G/M
- Platelet antibodies
- QuantiFERON-TB Gold In-Tube
- West Nile virus G/M
- Zika IgM (MAC)

Methodologies
ELISA, immunoblot

Instrumentation
Perkin Elmer JANUS, ELISA plate processors (Quanta-Lyser), BeeBlot

MICROBIAL IMMUNOLOGY II

Description
Using a variety of classic methodologies, this section has a vast test menu of serologic assays to aid in the diagnosis of bacterial, viral, and parasitic infections.

Testing Areas
- Bartonella
- Brucella, Entamoeba, Leptospira, and Coxiella
- Chlamydia
- Cold agglutinins
- Ehrlichia
- Fungi (Coccidiodes, Blastomyces, Candida, Aspergillus, and Histoplasma)
- Infectious mononucleosis (heterophile and latex agglutination)
- Malaria and Schistosoma parasites
- Mycosal Q fever (Coxiella burneti)
- Rickettsia rickettsii and Rickettsia typhi
- Toxocara
- Treponema pallidum (by RPR, VDRL, IFA, ELISA, and particle agglutination)

Methodologies
ELISA, IFA, complement fixation, immunoblot, agglutination

Instrumentation
Perkin Elmer JANUS, ASI (RPR) reader, LED microscopes
PROTEIN IMMUNOLOGY

Description
This section employs a wide variety of methods to test for complement deficiencies, monoclonal and polyclonal gammapathies, and immunoglobulin deficiencies.

Testing Areas
• Bence-Jones protein
• Beta-2 transferrin (CSF leakage and compromise of the blood/brain barrier)
• Complement pathway and regulation
• Cryoglobulins
• Histamine
• IgG and IgA subclasses
• Immune complex, C1Q binding
• Immunoglobulins G, A, M, and D
• Kappa and lambda free light chains in serum and urine
• Miscellaneous nephelometric assays (e.g., cystatin C, ASO, DNSB)
• Monoclonal protein detection, quantification, and characterization
• Retinol-binding protein
• Teichoic-acid antibodies
• Total hemolytic complement
• Urticaria inducing activity

Methodologies
Nephelometry, capillary electrophoresis, immunofixation electrophoresis, ELISA, and radial immunodiffusion

Instrumentation
Siemens BN II, Sebia Capillars, and Sebia HYDRASYS

SEROLOGIC HEPATITIS/RETROVIRUS

Description
Serologic aid in diagnosis of viral hepatitis, HIV, and HTLV is performed in this laboratory.

Testing Areas
• Hepatitis A
• Hepatitis B
• Hepatitis C
• Hepatitis D
• Hepatitis E
• HIV
• HTLV I and II

Methodologies
Chemiluminescence (CIA), enzyme immunoassay (EIA) neutralization, Western blot, supplemental immunoassay

Instrumentation
Siemens Centaur XP, manual EIA
BACTERIOLOGY

Description
Bacteriology performs routine cultures, stains, and susceptibility tests for the University of Utah Hospital and Clinics.

Testing Areas
• Routine aerobic cultures
• Automated blood cultures
• Automated identification of routine organisms with Phoenix, 16S rRNA sequencing, and MALDI-TOF technologies
• Automated and manual susceptibility testing
• Rapid identification of organisms from blood culture using film array
• Rapid identification of organisms from CSF using film array

Instrumentation
Film Array, Phoenix instruments, BACTEC FX-automated blood cultures, Bruker LT for MALDI-TOF assays

INFECTIOUS DISEASE ANTIGEN TESTING

Description
This section provides antigen testing for a variety of bacterial diseases. Quantitative fecal fat testing by nuclear magnetic resonance spectroscopy is also performed in this section.

Test Menu
• ELISAs for: Cryptosporidium antigen, E. histolytica antigen, Giardia antigen, Legionella antigen, E. coli Shiga-like toxin antigen, pancreatic elastase, lactoferrin, and calprotectin
• Fecal analysis: quantitative fecal fats by NMR
• Fecal analysis; alpha-1-antitrypsin (random and clearance testing)
• Immunochromatographic: Streptococcus pneumoniae, Campylobacter, and malaria
• Fecal occult blood immunoassay

Methodologies
ELISA, NMR, immunochromatographic assay, fecal occult blood immunoassay

Instrumentation
Quantalyser automated platform, SMART Trac-nuclear magnetic resonance spectroscopy, OC-Auto Micro 80
MICROBIAL AMPLIFIED DETECTION

Description
Microbial amplified detection provides rapid molecular testing for the detection of sexually transmitted diseases such as HPV and chlamydia. This high-volume testing is performed in an automated molecular laboratory using the latest technology.

Testing Areas
- C. difficile toxin B by PCR
- Chlamydia trachomatis and Neisseria gonorrhea testing by TMA
- HPV by PCR
- HPV by TMA
- HPV genotyping
- PCA3 by TMA
- Vaginal pathogens: Trichomonas, Candida, and Gardnerella
- Group B strep by PCR
- Trichomonas vaginalis by TMA

Methodologies
Transcription-mediated amplification (TMA), nucleic acid probe, PCR

Instrumentation
BD MAX, TIGRIS, Panther, COBAS, BD MicroProbe Processor

MOLECULAR HEPATITIS/RETROVIRUS

Description
This laboratory performs testing to monitor the quantity of HIV, HCV, and HBV virus in the blood of patients and provides a qualitative assay assisting in diagnosis of HIV infection.

Testing Areas
- Hepatitis B viral load—quantitative PCR
- Hepatitis B viral load with reflex to HBV genotype and drug resistance by sequencing
- Hepatitis C viral load—quantitative PCR
- Hepatitis C viral load with reflex to HCV genotype by sequencing
- HIV DNA qualitative PCR
- HIV viral load—quantitative PCR
- HIV viral load with reflex to HIV drug resistance by sequencing

Methodologies: Real-time PCR

Instrumentation: Roche COBAS AmpliPrep, Roche COBAS Taqman
MOLECULAR INFECTIOUS DISEASE

Description
The Molecular Infectious Disease Laboratories perform nucleic acid testing for infectious organisms by PCR, providing qualitative and quantitative results. Some assays in these laboratories are commonly used to monitor transplant patients who are often immunocompromised during their treatment. The laboratories also test for many infectious agents that are significant in the public health sector, such as *Bordetella pertussis*, influenza, and norovirus. Many of the assays performed in these sections, such as enterovirus and HSV on spinal fluid specimens, require rapid turnaround time in order to provide optimal patient care.

Testing Areas: MID 1
- *Babesia* species
- *Bartonella*
- *Bordetella pertussis* and *Bordetella parapertussis*
- *Chikungunya*
- Dengue types 1–4
- *Ehrlichia* and *anaplasma* species
- Influenza A subtyping
- Influenza A subtyping with reflex to H1N1 drug resistance by sequencing
- Gastrointestinal bacterial and viral panel
- Human metapneumovirus
- *JC* virus
- Lyme disease (*Borrelia spp*).
- *Malaria* species
- *Microsporidia*
- *Norovirus*
- Parainfluenza types 1–4
- Gastrointestinal parasite and microsporidia by PCR
- Tick-borne disease panel, blood
- *Toxoplasma gondii*
- *Tropheryma whippelii*
- Urogenital ureaplasma and mycoplasma species
- West Nile virus
- *Zika* virus

Testing Areas: MID 2
- Adenovirus, quantitative
- Adenovirus, qualitative
- BK virus, quantitative
- Cytomegalovirus (CMV), quantitative
- Cytomegalovirus (CMV), qualitative
- Epstein-Barr virus, quantitative and qualitative
- Hepatitis D virus, quantitative
- Hepatitis E virus, quantitative
- Malaria species
- Microsporidia
- Norovirus
- Parainfluenza types 1–4
- Human herpesvirus 6 (HHV-6A and HHV-6B), quantitative
- Human herpesvirus 8 (HHV-8), quantitative
- Parvovirus, quantitative
- Parvovirus, qualitative

Testing Areas: MID R
- *Chlamydia pneumoniae*
- Enterovirus
- Herpes simplex virus (HSV)
- HSV-1 and HSV-2 subtype by PCR
- Legionella species
- *Mycoplasma pneumoniae*
- *Pneumocystis jirovecii*
- Respiratory mini panel (flu A, flu B, and RSV)
- Respiratory virus panel (flu A, flu B, RSV, parainfluenza, HMPV, rhinovirus, and adenovirus)
- Varicella-Zoster virus

Methodologies
Real-time PCR, PCR with electrochemical detection

Instrumentation
Promega Maxwell, Perkin Elmer Chemagic MSM1, Biosystems QuantStudio, GenMark XT-8

MYCOLOGY AFB

Description
Mycology AFB provides full-service mycobacteriology (AFB) and mycology. Identification is performed by classical means, as well as 16S rRNA sequencing, PCR, and MALDI-TOF methods.

Testing Areas
- Direct DNA probes for identification of *Mycobacterium tuberculosis* species, as well as dimorphic fungi
- Identification of mycobacterial and fungal isolates using classical as well as 16S rRNA sequencing, PCR, and MALDI-TOF methods
- Esoteric antimicrobial susceptibility testing for fungi and mycobacteria isolates
- Molecular direct amplified detection of *M. tuberculosis* and rifampin resistance from CSF, pleural, and respiratory specimens

Methodologies
Classical and molecular assays for the identification of mycobacterial and fungal species

Instrumentation
BD BBL MGIT, GeneXpert, Bruker LT for MALDI-TOF assays
PARASITOLOGY AND FECAL TESTING

Description
This section provides full-service parasitology, ectoparasite examination, and rapid antigen detection for a variety of bacterial, fungal, viral, and parasitic diseases, as well as a variety of complex stool chemistries.

Test Menu
- ELISAs for: Cryptococcus antigen, Aspergillus galactomannan, H. pylori antigen, rotavirus, adenovirus antigen, and Histoplasma antigen
- Colorimetric: (1,3) beta-D-glucan
- Giesma stain
- Urine hemosiderin and melanin
- Fecal analysis: qualitative fecal fats, fecal-reducing substances, fecal pH, and fecal osmolality
- Parasitology: ova and parasite examination, microsporidium stains, modified acid-fast stains, and culture/stains for the detection of free-living amoeba

Methodologies
ELISA, colorimetric, culture, microscopy

SEQUENCING INFECTIOUS DISEASE

Description
Sequencing Infectious Disease provides sequence-based testing on a variety of infectious agents. Sequencing is performed to determine drug resistance in patients infected with mycobacterium, HIV, HBV, or CMV. HCV sequencing is performed to determine subtype for prognosis for those infected with HCV. This lab also performs bacterial and fungal identification by sequencing, which greatly reduces the amount of time for difficult organism identification over traditional culture-based methods.

Testing Areas
- Hepatitis C high-resolution genotyping
- Hepatitis C genotyping
- HIV genotyping for drug resistance (PI, NRTI, NNRTI, and INT)
- Mycobacterium tuberculosis drug resistance by sequencing
- Organism identification for mycobacterial, bacterial, and fungal isolates
- Hepatitis B genotyping and drug resistance testing
- Cytomegalovirus drug resistance testing

Methodologies
Polymerase chain reaction/sequence analysis

Instrumentation
QIAGEN QIAsymphony, ABI 3730 Genetic Analyzer, Perkin Elmer Chemagic MSM1
SPECIAL MICROBIOLOGY

Description
Special Microbiology performs a variety of complex reference work for regional and national clients, including strain typing by pulsed-field gel electrophoresis, unusual organism identifications by DNA sequencing and MALDI-TOF technology, and esoteric antimicrobial susceptibility testing. Susceptibility testing is performed by CLSI-approved methods using classical methods and custom-made MIC panels.

Testing Areas
- Anaerobic cultures
- Automated identification of unusual organism with MALDI-TOF technologies and 16s rRNA sequencing
- *Bordetella pertussis* cultures
- Esoteric antimicrobial susceptibility testing for bacteria
- *Legionella pneumophila* cultures
- *Leptospira* cultures
- Pulsed-field gel electrophoresis for bacterial strain characterization (microrganism typing)
- Ureaplasma/mycoplasma identification using the MYCOFAST system

Instrumentation
Vizion, BioMic, Phoenix instruments, Bruker LT for MALDI-TOF assays

VIROLOGY

Description
Virology offers centrifugation-enhanced isolation (culture) of cultivatable viruses and direct specimen detection using direct fluorescent antibody (DFA) stains and performs viral-neutralization serology tests for enteroviruses.

Testing Areas
- Cell-neutralization technology for poliovirus, coxsackie B virus, and echovirus antibody identification
- Cytopathic effect (CPE) and growth in specific cell lines; virus identity confirmed with specific stains
- Direct specimen staining to identify herpes simplex virus, varicella-zoster virus, respiratory syncytial virus, human metapneumovirus, influenza virus, and other respiratory viruses (rapid stain resulted within hours of preparation)
- Shell-vial culture technology to enhance rapid viral detection using immunofluorescent screening to decrease turnaround time
- *Clostridium difficile* cytotoxin assay
- Viral susceptibility
- Microscopy: *B. pertussis* DFA, *L. pneumophila* DFA, and *Pneumocystis* DFA

Methodologies
Immunofluorescence, rapid shell-vial culture, neutralization
ANATOMIC PATHOLOGY

Description
This technical section consists of more than 50 expert pathologists, all of whom are faculty members in the Department of Pathology at the University of Utah School of Medicine. These pathologists provide a full range of consultative and diagnostic services. Consultation and second opinions are provided in all areas of pathology.

Testing Areas
• Bone and soft tissue
• Breast
• Cardiac
• Cytopathology
• Dermatopathology
• FISH

• Gastrointestinal
• Genitourinary
• Gynecologic
• Head and neck
• Hematopathology
• Histochemical stains

• Immunohistochemistry
• Molecular oncology
• Neuropathology
• Pulmonary
• Renal

Methodologies
Histochenity, immunohistochemistry, FISH, molecular oncology, next-generation sequencing

Instrumentation
See instrumentation for histology, immunohistochemistry, molecular oncology.

BIOCHEMICAL GENETICS

Description
This technical section tests for analytes and enzymes to identify inborn errors of metabolism and to monitor their therapy. The testing includes amino acid, organic acid, acylcarnitine, and acylglycine profiles.

Testing Areas
• Amino acids (plasma, urine, and CSF) by LC-MS/MS
• Biotinidase enzyme activity (serum)
• Carnitine (plasma and urine), free and total
• Carnitine transport, fibroblasts
• Creatine disorders panel (urine and plasma)
• Creatine transport in fibroblasts
• Ehlers-Danlos syndrome type VI screen in urine
• Fatty acids profile, essential serum or plasma
• Galactose-1-phosphate in red blood cells
• Galactose-1-phosphate uridytransferase enzyme activity in red blood cells
• Hexosmainidase A activity in serum/plasma and leukocytes
• Hexosaminidase in serum/plasma and leukocytes
• Keratan sulfate, quantitative by LC-MS/MS, urine

• Lysosomal acid lipase activity, dried blood spot
• MPS I and MPS II—total heparan sulfate and NRE in serum/plasma and urine
• Organic acids (urine and plasma) by GC/MS
• Pipecolic acid in serum/plasma, urine, and CSF
• Plasma acylcarnitines by LC-MS/MS
• Pyridoxine-dependent epilepsy panel, serum, plasma, and urine
• Urinary acylglycines by LC-MS/MS
• Urinary mucopolysaccharides, screening and quantitation
• Urinary orotic acid and orotidine
• Urinary pyridinoline and deoxypyridinoline
• Very long-chain and branched-chain fatty acids profile (plasma)

Methodologies
Ion exchange chromatography, LC-MS/MS, HPLC, GC-MS, spectrophotometry

Instrumentation
Amino acid analyzer, spectrophotometer, fluorimeter LC-MS/MS, GC-MS, HPLC, UPLC-MS/MS
CYTOGENETICS AND GENOMIC MICROARRAY

Description
This technical section performs microarray, karyotype, and FISH analysis to identify chromosomal abnormalities related to both constitutional and cancer diagnoses.

Testing Areas
The following testing can be performed on a variety of sample types for prenatal diagnosis, pregnancy loss, congenital disorders, infertility, and hematologic/oncologic disorders:

• Chromosome (karyotype) analysis
• Genomic microarray
• Metaphase and interphase FISH

Methodologies
Cell culturing and harvesting, fluorescence in situ hybridization, genomic microarray (copy number and SNP based)

Instrumentation

CYTOPATHOLOGY

Description
The ARUP Cytopathology Laboratory is a full-service laboratory providing screening and diagnostic testing on gynecological, non-gynecological, and fine-needle aspiration specimens. This laboratory is affiliated with the fully accredited School of Cytotechnology at the University of Utah School of Medicine.

Testing Areas
• Fine-needle aspiration (FNA) on-site service at the University of Utah Hospital, Huntsman Cancer Hospital, and Primary Children’s Medical Center
• Consultation for difficult gynecologic, non-gynecologic, and fine-needle aspiration biopsy specimens available from ARUP’s board-certified cytopathologists.
• Gynecological testing, including conventional Pap smears, as well as ThinPrep and SurePath liquid-based preparations
• Non-gynecological testing of specimens from most body sites, such as gastrointestinal, body cavity fluid, cerebrospinal fluid, urologic cytology (UroVysision and pancreatobiliary FISH, as well as BTA testing), and ophthalmologic cytology
• Molecular testing available, including UroVysision FISH for urinary and pancreatobiliary specimens; BTA testing for urothelial carcinoma; EGFR or BRAF mutation testing for lung or thyroid/melanoma/lung FNA specimens, respectively; HPV testing of cervical specimens using Hybrid Capture II or mRNA transcription mediated amplification; and solid tumor mutation panel by next-generation sequencing for FNA smears

Methodologies
Slide preparation and staining; microscopic screening and interpretation of stained GYN, nonGYN, and FNA slides; s interpretation of BTAT for urinary samples; UroVysision FISH tests for urinary or pancreatobiliary specimens.

Instrumentation
Hologic ThinPrep processors, Becton Dickinson PrepStain slide processor, Sakura Tissue-Tek DRS-601 automated stainer, various brightfield microscopes, Bioview Automated Imaging System to aid in FISH interpretations
FRAGMENT ANALYSIS

Description
This section focuses on targeted mutations for inherited diseases, pharmacogenetics, STR analysis, and microsatellite instability by fragment analysis, as well as large deletion/duplication detection for inherited diseases.

Testing Areas
- 5-fluorouracil (5-FU) toxicity and chemotherapeutic response
- Alpha thalassemia (HBA1 and HBA2) 7 deletions
- Biotinidase deficiency (BTD) 5 mutations
- Fragile X (FMR1)

- Galactosemia (GALT) 9 mutations
- Huntington disease (HD)
- STR analysis for:
  - Bone marrow transplant monitoring
  - Maternal cell contamination studies

- Molar pregnancy
- Specimen identity
- Twin zygosity
- Thanatophoric dysplasia type I/II (FGFR3) 13 mutations

- Duchenne/Becker muscular dystrophy (DMD)
- Spinal muscular atrophy (SMA) copy number analysis

- X-Chromsome inactivation analysis

Deletion/duplication for:
- Alpha globin (HBA1 and HBA2)
- Charcot-Marie-Tooth type 1A (CMT1A)/hereditary neuropathy with liability to pressure palsies (HNPP)

Methodologies
Polymerase chain reaction, gel electrophoresis, oligo ligation assay, single nucleotide extension, fragment analysis, multiplex ligation-dependent probe amplification (MLPA)

Instrumentation
Roche MagNA Pure Compact, Roche MagNA Pure LC, ABI 9700 Thermal Cycler, ABI 3130 Genetic Analyzer
GENETICS SEQUENCING

Description
Genetic Sequencing provides sequencing for inherited diseases, as well as combined reporting of sequencing and deletion/duplication results.

Testing Areas
- Adrenoleukodystrophy, X-Linked (ABCD1) sequencing
- Alport syndrome, X-linked (COL4A5)
- ATP7A-related copper transport disorders (ATP7A)
- Beta globin (HBB) sequencing and deletion/duplication
- Beta thalassemia and hemoglobinopathies (HBB)
- Biotinidase deficiency (BTD)
- Breast and ovarian hereditary cancer syndrome (BRCA1 and BRCA2)
- CHARGE syndrome (CHD7) sequencing (also available for fetal samples)
- Citrulminemia, type I (ASS1) sequencing
- Connexin 26 (GJB2)
- Cystic fibrosis (CFTR)
- EIF2AK4-associated disorders (EIF2AK4) sequencing
- Familial adenomatous polyposis (APC) sequencing
- Familial Mediterranean fever (MEFV)
- Familial mutation, targeted Sequencing (also available for fetal samples)
- Familial transthyretin amyloidosis (TTR) sequencing
- Freeman-Sheldon syndrome (MYH3) exon 17
- Galactosemia (GALT)
- GLI3-related disorders (GLI3) Sequencing
- Hearing loss, nonsyndromic
- Hemophilia A (F8)
- Hemophilia B (F9)
- Hereditary (PRSS1)
- Hemophilia B (F9) sequencing, deletion/duplication
- Hereditary paraganglioma- pheochromocytoma (SDHB,SDHC, and SDHD)
- Juvenile polypsis/HHT (SMAD4)
- Kabuki syndrome (KMT2D) Sequencing
- Legius syndrome (SPRED1) and NF1 exon 22
- Li-Fraumeni (TP53) sequencing, deletion/duplication
- LMNA-related disorders (LMNA)
- Loeyz-Dietz syndrome (TGFBR1 and TGFBR2)
- Lynch syndrome/HNPCC (MLH1, MSH2, MSH6, and PMS2)
- Marfan syndrome, FBN1 sequencing
- MCAD deficiency (ACADM)
- Mitochondrial DNA (m.1555 and m.7445)
- Multiple endocrine neoplasia type 2 (RET) exons 10, 11, and 13–15
- Neurofibromatosis type 1 (NF1)
- Noonan syndrome (PTPN11 and SOS1)
- Pancreatitis (CTRC) sequencing
- Pancreatitis (PRSS1) sequencing
- Pancreatitis (SPINK1) sequencing
- Peutz-Jeghers syndrome (STK11)
- Primary carnitine deficiency (SLC22A5)
- Primary congenital glaucoma (CYP1B1)
- PTEN-related disorders (PTEN)
- Pulmonary arterial hypertension (BMPR2)
- RASA1-related disorders (RASA1)
- Ret syndrome (MECP2)
- SLC6A8 sequencing, deletion/ duplication
- Smith-Lemli-Opitz syndrome (DHCR7) sequencing (also available for fetal samples)
- Telangiectasia syndrome (BMP9/ GDF2) sequencing
- VLCAD deficiency (ACADVL)
- von Hippel-Lindau (VHL)

Familial mutation detection for any of the above assays is available.

Methodologies
Polymerase chain reaction, sequencing

Instrumentation
Roche MagNA Pure Compact, ABI 9700 Thermal Cycler, ABI 3730 Genetic Analyzer
GENOMICS

Description
This technical section uses massively parallel (next-generation) sequencing on DNA to identify genetic and oncologic gene variants responsible for a variety of germline and somatic diseases. Tests include aortopathy, whole exome, solid tumor mutation panel, BCR-ABL1 mutation analysis, lung mutation and translocation panel, and myeloid malignancies mutation panel.

Testing Areas

Genetic Tests
- Aortopathy panel, sequencing and deletion/duplication, 21 genes
- Breast and ovarian hereditary cancer panel, sequencing and deletion/duplication, 20 genes
- Charcot-Marie-Tooth (CMT) and related hereditary neuropathies panel, sequencing
- Cobalamin/propionate/homocysteine metabolism related Disorders panel, 25 genes
- Duchenne muscular dystrophy (DMD)
- Exome sequencing with symptom-guided analysis: both individual and familial
- Expanded hearing loss panel, sequencing (56 Genes) and deletion/duplication (53 Genes)
- Hereditary hemolytic anemia sequencing, 28 genes
- Holoprosencephaly panel, nonsyndromic, sequencing and deletion/duplication, 11 genes
- Mitochondrial disorders panel (mtDNA by sequencing and deletion/duplication, 121 nuclear genes by sequencing, 119 nuclear genes by deletion/duplication)
- Mitochondrial disorders (mtDNA), sequencing
- Multiple epiphyseal dysplasia panel, sequencing and deletion/duplication, 6 genes
- Non-invasive prenatal testing for fetal aneuploidy
- Noonan spectrum disorders panel, 15 genes
- Periodic fever syndromes panel, sequencing (7 genes) and deletion/duplication, 6 genes
- Primary antibody deficiency panel, sequencing (35 genes) and deletion/duplication (26 genes)
- Retinitis pigmentosa/leber congenital amaurosis panel, sequencing and deletion/duplication, 53 genes
- Skeletal dysplasia panel, sequencing (39 genes) and deletion/duplication (36 genes)
- Vascular malformations panel, sequencing and deletion/duplication, 14 genes

Hereditary Cancers
- Central nervous system hereditary cancer panel, 15 genes
- Gastrointestinal hereditary cancer panel, 16 genes
- Renal hereditary cancer panel, 15 genes

Oncology Tests
- BCR-ABL1 mutation analysis
- Solid tumor mutation panel
- Myeloid malignancies mutation panel

Methodologies
SureSelect and Nimblegen captures, custom NGS library preps, massively parallel sequencing, Agilent CGH microarray

Instrumentation
Agilent Bravo Option A, Beckman-Coulter SPRI-TE, Life Technologies Ion Torrent, Illumina HiSeq, Illumina MiSeq, Illumina NextSeq
HEMATOLOGIC FLOW CYTOMETRY

Description
Hematologic Flow Cytometry performs immunophenotyping of cells that assists in the determination of leukemia and lymphoma. The lab can perform this assay on various types of specimens, such as blood or tissue. This section also performs circulating tumor cell testing to help monitor patients with metastatic breast, prostate, and colon cancers.

Testing Areas
• B-cell CD20 expression: monitoring the effectiveness of monoclonal antibody-based therapies targeted against the CD20 antigen
• CTC count: detection of circulating tumor cells in metastatic carcinoma (prostate, breast, and colon)
• Leukemia/lymphoma: whole blood, bone marrow, and miscellaneous tissues and fluids
• T-Cell Clonality by Flow Cytometry Analysis of TCR V-Beta: diagnostic indicator of T-cell lymphoproliferative disorders

Methodologies
Flow cytometry, immunomagnetic separation, fluorescent antibody staining

Instrumentation
Flow cytometers (FC500 cytometers by Beckman Coulter), Janssen (Johnson & Johnson), Autoprep, CellTracks Analyzer II

SPECIAL HEMATOLOGY

Description
Special Hematology performs testing that assists in the determination of various hematologic disorders.

Testing Areas
• Complete bone marrow workup with comprehensive report
• Bone marrow differentials and peripheral blood smear interpretation
• Cytochemical stains (i.e., LAP, NSE, and MPO) on blood or bone marrow
• Hemoglobin evaluation using HPLC (HGB EL and HB CASCADE), electrophoresis and sickle solubility
• Red blood cell disorder testing (osmotic fragility, Heinz body staining, unstable hemoglobin testing, carboxyhemoglobin testing)

Methodologies
Cytochemical staining, HPLC (High Performance Liquid Chromatography), Hemoglobin Electrophoresis, CO-Oximetry, Spectrophotometry, RBC Solubility, Supravital Stain

Instrumentation
Bio-Rad Varriant II (HPLC), SEBIA CAPILLARYS 2 Flex Piercing Analyzer, Radiometer ABL800 FLEX
HISTOLOGY

Description
Histology performs processing, embedding, cutting, and staining of biopsies and larger surgical specimens for final microscopic interpretation by a pathologist. Support for other areas, such as cytopathology, hematopathology, immunohistochemistry, molecular oncology, fragment analysis, and flow cytometry, is a key aspect of Histology’s daily routine.

Testing Areas
• Kidney-biopsy procedures
• More than 35 special histochemical stains available
• Routine tissue processing

Methodologies
Rapid and traditional processing, paraffin embedding, microtomy of paraffin blocks, regressive H&E staining, multiple special stains

Instrumentation
Peloris rapid tissue processor, Tissue-Tek VIP 6 tissue processor, Tissue-Tek Prisma stainer and coverslipper, Ventana Nexus and Benchmark special stain modules

IMMUNOHISTOCHEMISTRY

Description
Immunohistochemistry performs a wide variety of immunologic stains on formalin-fixed, paraffin-embedded tissues for consultative cases and technical-only submissions. Molecular testing is performed for several cancer-related illnesses on solid tumor specimens; other testing is helpful in the diagnosis of renal pathologic disorders.

Testing Areas
• More than 175 immunohistochemistry markers, including hematopoietic and solid tumor markers, as well as a full complement of breast tumor markers, primarily on paraffin-block sections
• In situ hybridization on paraffin-block sections for HPV, EBV, KAPPA, and LAMBDA
• Fluorescent in situ hybridization on paraffin sections for breast carcinoma (HER-2/neu), oligodendrogloma (1p19q), synovial sarcoma (SYT), N-myc, EGFR, mantle-cell lymphoma (IgH-CCND1), and Ewing sarcoma (EWSR1), as well as others
• Immunofluorescent and enzymatic staining on frozen sections from kidney

Methodologies
Immunohistochemistry (automated and manual), in situ hybridization, fluorescent in situ hybridization, immunofluorescent antibody staining (automated and manual)

Instrumentation
Ventana BenchMark ULTRA, Dako Autostainer, Vysis/Abbott VP2000, Abbott Thermobrite, Aperio ScanScope Imaging System
## MOLECULAR GENETICS

### Description
This technical section performs analysis for inherited disorders such as factor V Leiden, prothrombin, MTHFR, hemochromatosis, fragile X syndrome, APOE, MCAD, and pharmacogenetics testing.

### Testing Areas

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achondroplasia (FGFR3)</td>
<td>2 mutations</td>
</tr>
<tr>
<td>Alpha-1-antiprypsin (SERPINA1)</td>
<td>2 mutations</td>
</tr>
<tr>
<td>Alport syndrome, X-linked (COL4A5)</td>
<td>3 mutations</td>
</tr>
<tr>
<td>Angelman syndrome and Prader-Willi syndrome by methylation</td>
<td>(also available for fetal samples)</td>
</tr>
<tr>
<td>Anklosing spondylitis (HLA-B27)</td>
<td>genotyping</td>
</tr>
<tr>
<td>Apolipoprotein B (APOB) mutation</td>
<td></td>
</tr>
<tr>
<td>Apolipoprotein E (APOE) genotyping</td>
<td>Alzheimer disease risk</td>
</tr>
<tr>
<td>Apolipoprotein E (APOE) genotyping, cardiovascular risk</td>
<td></td>
</tr>
<tr>
<td>Ashkenazi Jewish diseases, 16 genes, ABCC8-related hyperinsulinism, glycogen storage disease type 1A, Joubert syndrome type 2, lipoamide dehydrogenase deficiency (DLD), maple syrup urine disease type 1B, NEB-related nemaline myopathy (NEB), Usher syndrome type 1F, Usher syndrome type 3</td>
<td></td>
</tr>
<tr>
<td>Beta-2-adrenergic receptor (ADBR2) haplotyping</td>
<td></td>
</tr>
<tr>
<td>Celiac disease (HLA-DQA1<em>05, HLA-DQB1</em>02, and HLA-DQB1*03:02) genotyping</td>
<td></td>
</tr>
<tr>
<td>Chronic granulomatous disease (CYBB gene scanning and NCF1 exon 2 GT deletion) with reflex to CYBB sequencing</td>
<td></td>
</tr>
<tr>
<td>Chronic granulomatous disease (NCF1) exon 2 GT deletion</td>
<td></td>
</tr>
<tr>
<td>Chronic granulomatous disease, X-linked (CYBB) gene scanning with reflex to sequencing</td>
<td></td>
</tr>
<tr>
<td>Cystic fibrosis (CFTR) 165 pathogenic variants (also available for fetal samples)</td>
<td></td>
</tr>
<tr>
<td>Cytochrome P450 2C19, CYP2C19, 9 variants</td>
<td></td>
</tr>
<tr>
<td>Cytochrome P450 2C9, CYP2C9, 2 variants</td>
<td></td>
</tr>
<tr>
<td>Cytochrome P450 2D6 (CYP2D6), 14 variants and gene duplication</td>
<td></td>
</tr>
<tr>
<td>Cytochrome P450 3A5, CYP3A5, 2 variants</td>
<td></td>
</tr>
<tr>
<td>Cytochrome P450 genotype panel</td>
<td></td>
</tr>
<tr>
<td>Factor V Leiden (F5) 506G mutation</td>
<td></td>
</tr>
<tr>
<td>Factor XIII (F13A1) V34L variant</td>
<td></td>
</tr>
<tr>
<td>Filaggrin (FLG) 2 mutations</td>
<td></td>
</tr>
<tr>
<td>Glucose-6-phosphate dehydrogenase (G6PD) 2 mutations</td>
<td></td>
</tr>
<tr>
<td>Hemochromatosis (HFE) 3 mutations</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin lepore (HBD/HBB fusion) 3 mutations</td>
<td></td>
</tr>
<tr>
<td>HLA-B*5701 genotyping</td>
<td></td>
</tr>
<tr>
<td>Hypochondroplasia (FGFR3) 1 mutation</td>
<td></td>
</tr>
<tr>
<td>Kell K/k antigen (KEL) genotyping</td>
<td></td>
</tr>
<tr>
<td>Macular degeneration, age-related, 2 markers</td>
<td></td>
</tr>
<tr>
<td>Medium-chain acyl-CoA-dehydrogenase (ACADM) 2 mutations</td>
<td></td>
</tr>
<tr>
<td>Methylenetetrahydrofolate reductase (MTHFR) 2 mutations</td>
<td></td>
</tr>
<tr>
<td>Narcolepsy (HLA-DQB1*06:02) genotyping</td>
<td></td>
</tr>
<tr>
<td>Opioid receptor, μ (OPRM1) genotype, 1 variant</td>
<td></td>
</tr>
<tr>
<td>Platelet antigen panel (1,2,3,4,5,6, and 15)</td>
<td></td>
</tr>
<tr>
<td>Plasminogen activator inhibitor-1 (PAI-1) (SERPINE1) genotyping</td>
<td></td>
</tr>
<tr>
<td>Prothrombin (F2) G20210A mutation</td>
<td></td>
</tr>
<tr>
<td>Rh Cc antigen (RHCE) genotyping</td>
<td></td>
</tr>
<tr>
<td>RhD antigen (RhD) genotyping</td>
<td></td>
</tr>
<tr>
<td>RhEe antigen (RHCE) genotyping</td>
<td></td>
</tr>
<tr>
<td>Statin Sensitivity (SLCO1B1), 1 variant</td>
<td></td>
</tr>
<tr>
<td>Thiopurine methyltransferase (TPMT) genotyping, 4 variants</td>
<td></td>
</tr>
<tr>
<td>Warfarin sensitivity (CYP2C9 and VKORC1) 3 mutations</td>
<td></td>
</tr>
<tr>
<td>Y chromosome microdeletion</td>
<td></td>
</tr>
</tbody>
</table>

### Methodologies
DNA extraction, PCR, high-resolution melt analysis, ASPE, multiplex polymerase chain reaction and detection primer extension, gel electrophoresis

### Instrumentation
Roche: Light Cycler, LC480, MagnaPure, AutoGenomics: Infinity and Infinity Plus, Biofire: Light Scanner 96, Light Scanner 32, GenMarkDx: E-Sensor, QuantStudio
MOLECULAR ONCOLOGY

Description
This technical section primarily uses traditional PCR, real-time PCR, sequencing, pyrosequencing, digital droplet PCR, mass spectrometry, and gel and capillary electrophoresis on DNA and RNA to identify chromosome translocations and gene rearrangements for the detection of a variety of leukemias, lymphomas, and solid tumors. Tests include BCR-ABL1, JAK2, JAK2 exon 12 and MPL, T and B cells, GIST, PML quant, KIT mutations, CEBPA, WT1 for AML, IDH1/2, Epi proColon (Septin 9 methylation), BRAF, KRAS, NRAS, PIK3CA, MGMT, EGFR, MLH1, and many other condition-specific translocations and mutations.

Testing Areas
- Leukemia and lymphomas of B and T cells using PCR, and capillary electrophoresis
- Qualitative and/or quantitative JAK2 V617F, and JAK2 exon 12, CALR and MPL for myeloproliferative disorders
- Qualitative and quantitative testing for BCR-ABL1 t(9;22)
- Solid tumor mutation detection for diagnostic and therapeutic purposes

Methodologies
PCR, real-time PCR, capillary electrophoresis, Sanger sequencing, mass spectrometry, digital droplet PCR, and pyrosequencing

Instrumentation
- Extractions: Promega Maxwell
- Reverse transcription or amplification: ABI 9700 thermocyclers, ABI Veriti Dx thermocyclers
- Detection: ABI 7500 Fast Dx, Raindance RainDrop Plus, QIAGEN QIAxcel, Alphalnnotech Alpha Imager, ABI 3500, Roche LC480, QIAGEN PyroMark Q24, and Sequenom MassARRAY

SUPPLEMENTAL NEWBORN SCREENING

Description
This lab works in conjunction with the Utah Department of Health to provide newborn screening by tandem mass spectrometry for more than 30 disorders. The Supplemental Newborn Screening Lab screens for amino acid disorders, fatty-acid oxidation disorders, and organic acid disorders. The birth rate in Utah is greater than 50,000 babies per year. Two specimens are collected for newborn screening, one at approximately 48 hours after birth and a second between 7 and 28 days after birth.

Methodologies
LC-MS/MS

Instrumentation
LC-MS/MS
RESEARCH AND DEVELOPMENT

Description
Research and Development actively works on more than 100 projects, approximately 80 of which are in preliminary work-up, with another 80 in the queue awaiting resources. R&D projects arise because of new technology, new applications for an existing assay, or discontinuation of an assay due to enhancements or extinction. Each project focuses on three major areas:

• Medical value to the patient
• Economic value to ARUP
• Academic value to the institute and faculty

Current R&D projects include those that are directed toward molecular and genetic testing and simultaneous multi-analyte detection. Technologies actively being pursued include next-generation sequencing, molecular arrays and proteomics, LC-tandem mass spectrometry. All R&D personnel reside in one general lab area and clean and dirty labs are isolated to prevent nucleic acid contamination during critical assay development.

SPECIALIZED TECHNOLOGIES AND MANUFACTURING

CLINICAL RESEARCH AND STUDIES (CRS)

Description
ARUP’s Clinical Research & Studies (CRS) Department facilitates requests to perform study testing. Studies are evaluated based on criteria required for the performance of the study (such as regulatory requirements), internal operational logistics, and capacity to successfully perform the study, as well as academic opportunities for ARUP’s medical directors.

• Academic opportunity
• Research feasibility
• Study compatibility
• Study negotiations

QUALITY ASSURANCE (STM-QA)

Description
ARUP’s STM-QA provides quality practices oversight for the Specialized Technology & Manufacturing (STM) Group. The STM Group consists of the STM-QA, Reagent Laboratory, Corporate Laboratory Glassware Washroom, Technology Transfer, and Clinical Research & Studies (CRS) departments. In addition to maintaining proper documentation and operating procedures, the STM-QA Department provides water-quality testing for ARUP’s clinical sections and acts as an independent evaluator of Reagent Laboratory manufactured products and processes.

• Compliance evaluation
• Corporate quality-indicator tracking
• Documentation and procedures
• Product monitoring
• Water testing
REAGENT AND CELL CULTURE LABORATORIES

Description
ARUP’s Reagent and Cell Culture laboratories provide in-house manufactured products required by the clinical sections for patient testing. Many of the products made in the Reagent and Cell Culture labs are not commercially available, allowing ARUP to provide esoteric testing to improve patient care.

Product lines include:

• Assay controls/calibrators
• Diagnostic ELISA and enzymatic kits
• Electrophoresis gels
• Mammalian cells
• Microbiological agars and broths
• Reagent manufacturing
• Specimen-collection kits

TECHNOLOGY TRANSFER

Description
ARUP’s Technology Transfer provides a bridge between R&D efforts and the clinical testing sections. Individuals within this department are specialized in various disciplines in order to provide a focus for implementation of assays and new platforms into the testing sections. Technology Transfer also provides validation expertise for new instrumentation and quick response troubleshooting for assays that may be experiencing complications. It also provides a focal point for preparing submission packets to the New York State Department of Health.
AUTOMATED SPECIMEN MANAGEMENT (ASM)

**Description**
Automated Specimen Management operates the pre-analytical sorting and post-analytical storage functions.

- APX software drives the track and, in conjunction with ARUP’s Expert Specimen Processing (ESP) software, determines the routing for specimens.
- Automated specimen delivery systems transport specimens to predetermined sorters and, upon test completion, send them back to storage.
- The automated track handles approximately 30,000 to 40,000 specimens each day.
- Eight lane sorters have 32 lanes each and sort specimens by lab, instrument, or assay.
- Three automated sorters route specimens for storage or for specimen retrieval from storage.
- ARUP recently added a third storage device created by ATS, which has the ability to store an additional 4,000 specimens per hour.
- Two Motoman robots are used for automated thawing and mixing of Core Lab specimens.

ARUP is one of the most automated laboratories in the United States. The 1,100-foot transport and sorting system with a capacity of 8,000 specimens per hour is a key element of our system. Equally important are three automated sorters that load specimens into storage trays and a two-story automated storage and retrieval system (AS/RS) housed in the world’s largest clinical laboratory freezer. The AS/RS capacity exceeds 2.3 million specimens, and individual specimens are robotically retrieved in less than 2.5 minutes. ARUP has also installed the first automated thawing and mixing workcells. These workcells thaw and mix frozen specimens on the transport system at a rate of more than 1,000 per hour, thus reducing pre-analytical preparation time. ARUP is committed to developing cutting-edge automation that improves the overall quality of testing and reduces turnaround time.

INFECTIOUS DISEASE PROCESSING

**Description**
- Processes more than 100,000 samples per month for Virology, Bacteriology, Special Microbiology, Parasitology and Fecal Testing, Infectious Diseases Rapid Testing, Microbial Amplified Detection, Molecular Infectious Disease, Molecular Hepatitis/Retrovirus, and Sequencing Infectious Disease laboratories.
- Provides client education and training in specimen collection and submission requirements for both hospital and reference laboratory clients.
- Provides exception handling for all Infectious Disease laboratories.
- Provides support services for the Infectious Disease technical sections (i.e., Exception Handling, Specimen Receiving, and Client Services).
- Triages communications between internal and client-based technical sections.
- Triages samples and evaluates specimen acceptability.
INTEGRATED ONCOLOGY AND GENETICS SERVICES

Description
- Processes more than 7,000 samples per month for Anatomic Pathology, Biochemical Genetics, Cytogenetics and Genomic Microarray, Cytopathology, Fragment Analysis, Genetics Sequencing, Genomics, Hematologic Flow Cytometry, Histology, Immunohistochemistry, Molecular Genetics, Molecular Oncology, Special Genetics, Special Hematology and Supplemental Newborn Screening laboratories.
- Provides client education and training in specimen collection and submission requirements for both hospital and reference laboratory clients.
- Manages international requests for genetics and oncology testing.
- Provides exception handling for select Integrated Oncology and Genetics laboratories.
- Provides support services for the Integrated Oncology and Genetics technical sections (i.e., Exception Handling, Specimen Receiving, and Client Services).
- Triage communications between internal and client-based technical sections.
- Triage samples and evaluates specimen acceptability.

SPECIMEN PROCESSING

Description
- Handles pre-analytical laboratory functions, including specimen integrity checking, order matching, and labeling.
- Edits manual test request forms.
- Processes all inbound samples from national clients, along with many more from our local clients and University of Utah clinics.
- Labels specimens and routes them to the technical sections via the automated track and manual sorting systems.
- Manifests shipments (tracks bags and samples sent by clients and records any shipping violations) in Expert Specimen Processing (ESP) shipment tracking.
- Matches specimens to paperwork and orders in system.
- Processes specimens in ESP accessioning.
- Records specimen information (type, temperature, and number submitted).
- Reviews remote-collect and central-collect pending lists.
- Scans all paperwork into Image Management System (IMS).
- Submits questionable specimens (situations, paperwork, etc.) to Exception Handling for client clarification and notification.
- Processes approximately 35,000 to 40,000 specimens per day.
- Provides internal customer service and support when labeling or processing questions arise within the lab sections.
- Provides complete inbound and assigned tracking for inbound packages received via many carriers including Delta, American Airlines, FedEx, etc.

ARUP utilizes ESP software that interfaces with the automated track and sorting systems, as well as additional enhanced specimen tracking applications including ESP Inquiry and ESP Checkout. The department has more than 120 workstations and more than 400 staff members working around the clock. Approximately 90 percent of all orders received in Specimen Processing are electronically transmitted via client interfaces.
BLOOD SERVICES

Description
ARUP Blood Services is the sole provider of blood products to University of Utah Health Care, (including University Hospital, Huntsman Cancer Hospital, University Orthopedic Center, and South Jordan Health Center), as well as Primary Children’s Hospital and Shriners Hospital for Children. These hospitals use approximately 25 percent of the blood transfused in Utah. ARUP Blood Services travels all over the state each day and collects approximately 1,800 red blood cell units and 600 platelet units per month. In all, nearly 7,000 patients receive transfusions from blood products collected and processed by ARUP Blood Services each year. Blood Services also provides therapeutic procedures at the hospitals, including exchanges of platelets, white and red blood cells, and plasma.

IMMUNOHEMATOLOGY REFERENCE LABORATORY (IRL)

Description
The AABB-accredited Immunohematology Reference Laboratory is a member of the American Rare Donor Program.

Testing Areas
- ABO Rh blood grouping and discrepancies
- Antigen screening of RBC donor units
- Antibody elution and adsorption
- Direct and indirect antiglobulin testing
- Donath-Landsteiner testing
- Extended red cell antigen typing
- Isohemagglutinin titers
- Red cell antibody identification
- Red cell antibody titers

Methodologies
Hemagglutination, solid-phase red cell adherence

Instrumentation
Immucor Galileo Echo automated platform

TRANSFUSION SERVICES

Description
The Transfusion Services Laboratory provides full transfusion services for University of Utah Health Care (including University Hospital, Huntsman Cancer Hospital, University Orthopedic Center, and South Jordan Health Center), along with Primary Children’s Hospital and Shriners Hospital for Children.

Testing Areas
- Antibody identification
- Blood grouping
- Compatibility testing
- Component modification
- Other testing for all patients receiving blood products at these institutions

Methodologies
Hemagglutination, solid-phase red cell adherence

Instrumentation
Immucor Neo, Galileo Echo automated platform
UNIVERSITY HOSPITALS AND CLINICS, CLINICAL LAB

The Phlebotomy Department provides phlebotomy services for inpatient units and outpatient clinics at the Huntsman Cancer Hospital, University of Utah Hospital, University of Utah Neuropsychiatric Institute, and Madsen Clinic. The Support Services Department encompasses client services, exception handling, and specimen processing for these same organizations. In addition, Phlebotomy and Support Services collects, processes, and ships numerous clinical research specimens.

The University Clinical Laboratories provides routine testing for the Huntsman Cancer Hospital, University of Utah Hospital, South Jordan Clinic, and Redwood Clinic.

Testing Areas
- Hematology
- Chemistry
- Coagulation
- Urinalysis
- Therapeutic drug monitoring

CLIENT COMMITMENT

CLIENT COMMITMENT STATEMENT

ARUP supports our clients’ success by providing excellence and consistency in our delivery of services, sharing knowledge, and developing progressive laboratory technology.