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CLINICAL PATHOLOGY

TRANSFUSION MEDICINE SERVICE (TMS)

The Transfusion Medicine Service supports a busy, level one-trauma center, as well as active liver, cardiac, pediatric cardiac, neonatal, bone marrow transplant and hematology/oncology programs. Transfusion Medicine/Blood Bank operates 24 hours a day, 7 days a week.

TMS also supports an on site Apheresis Unit which provides therapeutic apheresis, photopheresis and peripheral blood stem cell collection. As a full service blood bank transfusion medicine department, we operate 24 hours a day, 7 days a week. We are dedicated to providing blood and blood products according to the highest standards of patient care and upholding the highest standards from all of our accrediting organizations. We also provide transfusion management support to health care providers at our institution, in the community, and throughout the Commonwealth of Virginia.

We are located on the 6th floor of the Gateway Building, at the corner of 12th and E. Marshall Street in Richmond. Patients may park at the following sites:

- Nelson Clinic,
- Parking Decks E & S.
- Randolph-Minor Parking Lot;
- limited metered on-street parking;

or at privately managed parking facilities:

- Parking Lot at 10th St between Clay and Marshall,
- Parking Lot at 11th and Broad Streets,
- Parking Lots north of the Richmond Coliseum, accessible from 5th or 7th Streets,

- Parking Lots at Jackson and 7th, accessible from 7th or Duval Streets,
- Coliseum Parking Deck, 7th Street, across from the Richmond Coliseum.

Testing [Go to Top]

Testing is performed on patient samples to assure compliance with regulatory agencies through our active Quality Assurance Program. The Quality Program monitors system essentials that assure the safety, potency, and purity of blood as defined by the:

- Food and Drug Administration (FDA)
- American Association of Blood Banks (AABB)
- College of American Pathologists (CAP)
- Center for Medicare and Medicaid Services (CMS)
- Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)

In addition to routine testing, in our special studies lab we perform complete antibody identifications on patients with routine, complex, and multiple antibodies from a diverse patient population, including sickle cell and oncology patients, and patients with warm autoantibodies.

Blood Products Available

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Blood Products which are always in stock:

- Leukoreduced packed red blood cells
- Leukoreduced platelets, whole blood derived and single donor
- Plasma, frozen
- Cryoprecipitate
- Rh immune globulin

Products made available on special request:

- Single donor platelets (SDP)
- Granulocyte concentrates, apheresis products
- Washed red blood cells
- SDP crossmatched or HLA-matched platelets when approved
- Volume-reduced random donor platelets
- CMV-negative blood products (available only for CMV-negative transplant and neonates weighing <1200 g whose mothers are CMV-negative and other patients at risk for CMV); see VCUHS Transfusion Guidelines
- Irradiated blood products (available only for bone marrow transplant patients, intrauterine exchange transfusion, congenital immune deficiency

syndromes, other patients at risk for graft-versus-host disease); see VCUHS Transfusion Guidelines

Nonemergency Ordering of Blood Products

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Informed Consent: Informed consent for transfusion must be obtained and consent form signed **prior** to transfusion of all blood and blood products.

- Obtained by MD, DO, PA, NP; witnessed
- Complete form; check "I do" vs "I do not" consent
- Required for RBC, Plasma, Cryo, Platelets
- Advised/Optional for Ivlg, Rhlg, Albumin
- Permit adequate lead time for special donations
 - Autologous donations
 - Patient selected donations (PSD)-family/friends
- Caution: form includes option "I do not consent"
 - Jehovah's witnesses

Blood products may be ordered through the CIS computer system. Certain cellular components (red blood cells and granulocytes) require that a current sample (up to 3 days old) be available so that units can be crossmatched. Other components (platelets, cryoprecipitate and plasma) require only that TM has a sample from the current admission and do not require crossmatching.

Transfusion Medicine Samples

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Both inpatients and outpatients having blood collected for transfusion must have an armband. Because of the disastrous consequences of incompatible transfusion, blood samples must be correctly labeled. The following information must be on the specimen container in order for it to be accepted by the TM department.

- Patient's name must be spelled identically to the name present on the computer order sheet or the manual requisition form.
- Chart number must be identical to chart number on the order sheet or manual requisition form.
- Address and/or social security number must be included if the patient is an outpatient and does not have a medical record number available.
- Date and time sample drawn
- Phlebotomist's initials or signature on the tube

Patient is identified and sample label is compared to identification. Sample is to be labeled at the patient bedside. Blood samples and request forms with incomplete, inconsistent, illegible, or incorrect information pertaining to patient identification **will be rejected**. Relabeling may not be performed after blood samples are received in the TM department, either by TM staff, physicians,

nurses, or members of the phlebotomy team. Specimens collected more than 8 hours before delivery to TM will be rejected. Sample labels cannot be corrected once they have been received in TM.

- "Extended life" samples may be ordered on preadmission for patients who have not been transfused or pregnant within the preceding 3 months.

 These samples are good for 14 days if patient has no atypical antibodies.
- Type Confirmation (2nd sample): To help ensure patient safety, all patients that do not have an historic blood type on record with the blood bank, will require a second patient's type be performed on a sample that was collected independently of the original sample.

For elective surgery, crossmatched blood will be set up according to the Maximum Surgical Blood Order Schedule through the CIS ordering pathway under Transfusion Medicine. Samples for inpatients must be ordered by 8 PM the day prior to surgery.

Release of blood components may be accomplished by computer release or by sending a blue release slip to TM. Orders picked up in person will only be released in exchange for a blue release slip or computer release slip. **Note:** Pharmacy is the main dispensing location of albumin or plasma protein fraction.

Emergency Ordering of Blood Products

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In very urgent situations, blood can be issued immediately. This can be accomplished through the CIS computer by ordering emergency release blood. The computer then asks whether group-specific or emergency group O blood should be released. If a sample has been sent to TM earlier during the patient's current hospital admission, group-specific blood should be ordered. If the patient has no sample in TM, only emergency group O blood can be ordered. If at all possible, a pretransfusion sample should be drawn and sent to TM so that the patient can be switched to group-specific blood. This helps conserve scarce units of group O blood. A phone call should be made to TM to apprise them of the urgency of the situation and to inform them as to anticipated use of blood products.

Other Services Provided by Transfusion Medicine: Therapeutic Apheresis Unit

The **Apheresis Unit** is an inpatient and outpatient unit providing therapeutic apheresis procedures to adults and children. The Apheresis Unit is open Monday-Friday, 8 AM to 5 PM. Apheresis staff are available 24 hours, 7 days a week for emergency procedures. Services are available by consultation with the TM physicians at 804-828-0093. Afterhours contact TM at 828-0256 for Pathology attending physician name and contact information..

Apheresis Services include:

- Erythropheresis (red cells)
- Leukopheresis (white cells)
- Platelet pheresis (platelets)
- Plasmapheresis (plasma)
- Photopheresis (white cells exposed to UV light)
- Peripheral blood stem cell collection

Outpatient transfusions can be scheduled by calling 828-0093, and require prior approval by a TM physician. Appointments are needed with at least 24 hours notice if possible. Referring physicians must provide:

- Written order for transfusion
- Signed transfusion consent
- Brief recent medical history or clinic visit note
- Current lab work and medication list
- Sample to Blood Bank with Type and Crossmatch order
- Insurance information/authorization and referral as needed.

Outpatient therapeutic phlebotomies are performed on outpatients with disorders such as hemachromatosis, porphyria, and polycythemia. These procedures can be scheduled depending on patient status and space availability in the unit.

Contact the Apheresis Unit (828-0093) to schedule patients and provide:

- Physician's written order for phlebotomy, to include goals of therapy
- Recent medical history and
- Physical or clinic visit notes including current labs
- Insurance information/authorization and referral as needed

Scheduling [Go to Top]

To schedule a TM procedure, please call (804) 828-0093. Twenty-four hours notice is necessary for some procedures. Please provide appropriate insurance authorization and referral. Please provide at least 24-hour notice if unable to keep an appointment. Fees will be charged for appointments not cancelled.

VCUHS TRANSFUSION GUIDELINES (Revised July 2008) [Go to Top]

Blood Product	Dose	Response	Guidelines
Packed RBC	Adult: 1 unit	1 g/dL increase Hb	Hb <8 g/dL
	Neonatal: 5-15 mL/kg	3% increase in Hct	Need to increase O ₂ carrying capacity Blood loss >30%
	Adult: >3 x 10 ¹¹ platelets; Pool random donors (RDP) vs single donor apheresis (SD) Neonatal: 10 mL/kg	Increase in count 30-60,000µL/dose Assay 10 min to 1 h post transfusion	Plt <10-20,000 µL Plt <50,000 with bleeding or invasive procedure Plt <100,000 CNS surgery Platelet dysfunction with bleeding
	Warfarin reversal 5-8 mL/kg Factor replacement 10-15 mL/kg Adult: 2-4 units Neonatal: 10-15 mL/kg	Decrease in PT or INR Replace coagulation factors	PT > 1.5 times the upper limit of normal or the midpoint of normal range; aPTT > 1.5 times the upper limit of normal with bleeding or invasive procedure. Factor deficiency ONLY if no concentrate available
	Adult: Typical dose 10 units Neonatal: 1 unit/10 kg	Increase in fibrinogen Increase vWF (von Willebrand factor) Increase factor VIII Increase factor XIII	Fibrinogen <100mg/dL von Willebrand disease if other safer products not available Uremic platelet dysfunction with bleeding
Risk/unit by serology: HBV 1:208-488,000; HTLV I/II: 1:641,000.			

Blood Product Dose	Response	Guidelines
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Risk/unit by Nucleic Acid Testing (NAT) and serology combined HCV 1:1,600,000 HIV 1:1,900,000, HBV NAT: has not demonstrated a decreased risk from serologic testing as listed above.

Risk of West Nile Virus varies by year, location, and season; testing by NAT. Risk of Chagas: Dependent on geographic location, testing by ELISA and positives confirmed by RIPA.

CMV SERONEGATIVE COMPONENTS

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- Reduce exposure to Cytomegalovirus (CMV).
- Donor serum screened for CMV antibodies.
- Determine patient CMV immune status-order titer.

Indications:

- 1. CMV seronegative BMT and PBSC transplant candidates and recipients
- 2. Infants <4 months of age
- 3. Intrauterine transfusions
- 4. Congenital immunodeficiencies
- 5. CMV seronegative children receiving CMV seronegative solid organ transplants
- 6. HIV positive patients who are also CMV seronegative
- 7. Seronegative pregnant women.

Alternative = leukoreduced components

Considered CMV "safe" equivalent. White cells which harbor CMV are removed.

SICKLEDEX NEGATIVE RED CELLS

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Prevent the transfusion of abnormal Hgb S.

Indications:

- 1. Neonates <4 months
- 2. Patients with sickle cell disease

Premedication: Acetaminophen / Benadryl® Caution

Premedication should be given only when indicated, not as a routine for all patients. Premedication may mask symptoms such as fever which is the first indication of an acute hemolytic transfusion reaction.

Informed Transfusion Consent

- Obtained by MD, DO, PA, NP; witnessed
- · Complete form; check "I do" vs "I do not" consent
- Required for RBC, FFP, Cryo, Platelets
- Permit adequate lead time for special donations
- · Autologous donations
- Patient selected donations (PSD)-family/friends
- Caution: Form includes option "I do not consent" (Jehovah's witnesses)

For more information, please call Transfusion Medicine at 828-0256.

LEUKOREDUCED COMPONENTS

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All blood products at VCUHS are prestorage leukoreduced. Products still require a standard blood administration set. Evidence based indications are listed below as a reference.

Reduces incidence:

- 1. HLA alloimmunization/plt refractoriness
- 2. Febrile transfusion reactions, recurrent
- 3. CMV transmission = **CMV "safe equivalent"

Indications:

- 1. Hematologic malignancies
- 2. BM or PBSC transplant recipients/candidates
- 3. Patients w/history of multiple febrile reactions
- 4. Chronically transfused patients (ie. Sickle Cell disease)
- 5. Patients receiving multiple rounds chemotherapy
- 6. Living liver donor
- 7. Patients on cardiac bypass
- 8. Patients undergoing cardiac transplant
- 9. Cardiac patients on LVAD or mechanical heart

IRRADIATED COMPONENTS

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- Prevents transfusion associated graft-vs-host disease (GVHD).
- Fatal complication-need to prevent, no cure;
- Indicated for immunocompromised recipients;
- Prevents immunocompetent donor T-cell replication.

Notify TM to flag patient-irradiated products.

Required for cellular products, not plasma.

^{**}Do **not** use bedside LR filters with LR products.

Indications:

- 1. BM or PBSC transplant recipient
- 2. Hematologic malignancies
- 3. High dose chemotherapy and/or radiation therapy with bone marrow suppression
- 4. Congenital immunodeficiencies
- 5. HLA-crossmatched platelets
- 6. Patient selected donation (PSD)
- 7. Intrauterine transfusions
- 8. Infants who received intrauterine transfusion
- 9. Infants <1 year

For more information, please call Transfusion Medicine at 828-0256.

TRANSFUSION REACTIONS (Revised July 2008)

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Clinical response for all reactions:

- 1. STOP TRANSFUSION / check patient ID against bag / keep I.V. open with 0.9% NaCl / document vital signs.
- 2. Notify physician / document decision process in medical record.
- 3. Order transfusion reaction work up and notify Transfusion Medicine (TM).
- 4. Send a pink/purple (EDTA) top tube and remaining unit with any attached tubing to TM (for mild allergic reaction, see below).

Reaction Type	Signs and Symptoms	Etiology	Clinical Action
Allergic (mild)	Pruritus, hives, limited to small area	Antibodies to transfused plasma proteins	Administer antihistamines. Resume transfusion if improved. Notify TM; no samples necessary. If no improvement in 30 minutes treat as moderate to severe. Do not use unit of blood.
Allergic (moderate to severe)	Generalized hives, bronchospasm and dyspnea, abdominal pain, hypotension, nausea, anaphylaxis	Antibodies to plasma proteins usually IgE; can be IgA	Administer antihistamines, epinephrine, vasopressors, and corticosteroids as

Reaction Type	Signs and Symptoms	Etiology	Clinical Action
			needed. Do not use unit of blood.
Febrile non- hemolytic	Temp >1°C or 2°F, chills, rigors, anxiety	Cytokines released from WBC	Mild: Administer antipyretics as needed Recurrent or severe reactions, require consultation with Transfusion Medicine attending physician *May occur after transfusion complete
Acute hemolytic	Hemoglobinemia / - uria, fever, chills, anxiety, shock, flank pain, chest pain, unexplained bleeding, cardiac arrest	Intravascular hemolysis usually due to ABO incompatibility; check for patient ID, clerical error	Treat shock with vasopressors; maintain airway; increase renal blood flow; administer fluids and maintain brisk diuresis; monitor for acute renal failure. If DIC is present, consider heparin. Administer blood products as needed after etiology is clear.
Septic	Rise of ≥2°C or 3°F; sudden hypotension or hypertension, shock	Bacteria in donor bag Risk previously greater for platelets vs. RBC; platelets now screened for pathogens by culture or pH changes	Send bag to transfusion medicine. Order blood culture on patient as needed. Pressor support if necessary. Broad spectrum antibiotics.
TRALI- Transfusion Related Acute Lung Injury	Acute respiratory distress usually within 1-2 hours of transfusion. Non-cardiogenic pulmonary	Usually donor HLA antibodies from transfused plasma. Recipient has corresponding	Respiratory support! Most will resolve within 24-96 hours. Steroids, diuretics; no known benefit.

Specific Guidelines for Laboratory Services

Reaction Type	Signs and Symptoms	Etiology	Clinical Action
	to diuretic; diagnosis of exclusion. One of the leading causes of death due to transfusion reported to	antigens; get pulmonary neutrophil activation that results in extravasation of fluid into air spaces.	

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COAGULATION STUDIES

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The Coagulation Studies laboratory service offers a comprehensive menu of tests that may be used in the evaluation of both bleeding and clotting disorders. Specific analytes are available for the assessment of all coagulation factors and for the diagnosis and monitoring of factor deficiencies, including von Willebrand disorders. Platelet function assays and studies may be obtained to specifically help assess platelet function in coagulopathies or to assess the adequacy of salicylate or other antiplatelet agents. Refer to the specific test listing in this catalog or contact the laboratory at 828-7284 for details Special procedures must be scheduled with the Coagulation Laboratory prior to ordering testing.

HEMATOPATHOLOGY

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Blood, Bone Marrow Biopsy, and Lymph Node Examination

The Hematopathology Service provides extensive diagnostic services for interpretation of blood, bone marrow, and lymph node tissue, including evaluation of anemia, lymphoma, metastatic tumor, and infectious disease. Extensive testing is available, including cytochemistry stains, flow cytometric analysis, immunohistochemistry stains, DNA cell cycle and ploidy studies, molecular biologic examination for the presence of gene alterations (through Clinical Molecular Biology), chromosome karyotyping (through the Department of Human Genetics), and microbiologic culture (through Clinical Microbiology). Refer to the specific test listing in this catalog or contact the Bone Marrow Laboratory or faculty for more details and to schedule services.

IMMUNOLOGY

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The Immunology laboratory provides the following services:

Flow Cytometry: The Flow Cytometry laboratory is staffed 7 days per week from 8:30am-5:00pm. Testing is provided in the following areas: immunophenotyping for the diagnosis of leukemia and lymphoma, CD3,4,8 panels for the monitoring of HIV, and lymphocyte enumeration.

Autoimmune Serology: Testing is performed in this section of the laboratory Monday- Friday; 7:30am-5:00pm. The laboratory provides serologic screening and identification of antibodies associated with autoimmune diseases.

Infectious Disease Serology: The laboratory provides serologic tests for the evaluation of infectious diseases and/or immune status. RPR testing is performed 7 days per week on dayshift. Other testing is provided Monday-Friday; 7:30am-5:00pm.

Protein Electrophoresis: Full service protein electrophoresis is performed Monday- Friday; 7:30am-5:00pm. Routine testing includes: quantitation of serum and urine protein fractions; Immunofixation Electrophoresis of gamma globulins in serum, urine or cryoprecipitate; detection of Tau (Beta-2) Transferrin in body fluids; and high resolution gel detection of Oligoclonal banding in CSF.

Allergy: Allergy testing is performed daily, Monday- Friday; 7:30am-5:00pm. Using Specific IgE testing for a broad range of allergens, including those commonly found in foods, pollens, molds, animal dander, and insect venom. Test results provide a semi-quantitative level of circulating IgE antibody specific for a particular allergen.

MICROBIOLOGY

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When ordering cultures to diagnose an infectious disease, please be aware that routine cultures are designed to detect only bacteria, not other types of microorganisms. When mycobacteria, fungi, viruses, or parasites are part of the differential diagnosis, please order the additional tests necessary to detect these organisms. In addition, certain bacteria with special growth requirements (eg, *Legionella*, *Bordetella*, etc) will also not be detected by routine bacterial cultures. Consult specific tests in this handbook to determine which test to order for a specific organism.

Please contact the laboratory if you have questions regarding detection of particular organisms, appropriate specimen collection, or test availability.

Bacteriology Cultures

Routine bacterial cultures detect aerobic and facultative anaerobic bacteria. Susceptibility tests are routinely performed where appropriate.

Isolates of staphylococci will be routinely reported as *Staphylococcus aureus* or as coagulase-negative staphylococci from all specimens except urines. Coagulase-negative staphylococci isolated from urine will be further tested to rule out *Staphylococcus saprophyticus* if the colony count is significant (eg, >100,000 CFU/mL in a clean catch urine).

If an anaerobic infection is suspected, please refer to the Microbiology Specimen Collection section of this catalog for appropriate specimen collection. Susceptibility tests are routinely performed by E-test on significant anaerobic isolates. Specimens contaminated with normal flora will **not** be cultured for anaerobic bacteria because they predictably yield numerous isolates of doubtful clinical significance, and the laboratory results will mislead the clinician as well as waste laboratory resources.

Mycobacterial Cultures

If a mycobacterial infection is suspected, a specific request for AFB (ie, mycobacterial) culture must be made. Culture for other types of organisms can be done on the same specimen but must be specifically requested on the appropriate requisition. A sufficient volume of specimen is required to detect mycobacteria; swabs are unacceptable.

Mycobacterial smear results are routinely provided within approximately 24 hours of specimen receipt. Growth is detected using both conventional and broth culture methods. Rapid identification of isolates is made using DNA probes for *Mycobacterium tuberculosis* complex, *Mycobacterium avium* complex, *Mycobacterium kansasii*, and *Mycobacterium gordonae*. Standard biochemical identification methods are required to identify some mycobacteria species, and may require 2-4 weeks to complete after the organism is isolated. If *M. tuberculosis* is isolated for the first time, primary drug susceptibilities will be performed by the Division of Consolidated Laboratories.

Fungal Cultures

If a fungal infection is suspected, a specific request for fungal (mycology) culture must be made. Record the specific site of the specimen so that the laboratory has sufficient information to determine if special processing or culture techniques are required to recover the suspected organism. If skin lesions are submitted for culture, state on the requisition/transmittal form whether a dermatophyte or a deeper skin infection is suspected. If a specific etiologic agent is suspected, please record on the requisition/transmittal form. See the Microbiology Specimen Collection section of this catalog and specific instructions under Fungal Culture tests for details of specimen collection.

Parasitology Examination

See "Intestinal Parasitology Examination" under the Microbiology Specimen Collection section of this catalog or specific parasitology tests for details of specimen collection.

Viral Cultures and Examinations

If a viral infection is suspected, a specific test for this type of culture (see Virus Culture) must be made. Collect specimens as soon as possible after onset of illness, preferably on day 1 but at least by day 3. When collecting specimens for virus culture, record the specific site of the specimen on the requisition/transmittal slip so that the laboratory has sufficient information to determine which culture techniques are required. For details of specimen collection, see the Virology Specimen Collection section of this catalog.

Culture for viral respiratory illnesses may be ordered year-round. Virus culture of respiratory specimens detects influenza A and B, respiratory syncytial virus

(RSV), parainfluenza viruses 1, 2 and 3, and human metapneumovirus. Direct testing for influenza A and B and RSV will be available once any one of these agents is detected in culture during viral respiratory season. Results of direct detection testing for these 3 viruses will be available 7 days a week during the respiratory season.

Please contact the laboratory if you have questions regarding appropriate specimens, specimen collection, or test availability.

Microbiology Consultations

The Microbiology and Immunology faculty are available for consultations involving interpretation of laboratory tests or for analytical problems related to a specific patient's care. Contact the clinical laboratory at 628-4000 or faculty for more information.

MOLECULAR DIAGNOSTICS

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The Division of Molecular Diagnostics uses progressive technologies and procedures to evaluate infectious disease, inherited disorders, oncogene copy number, and other gene abnormalities. The use of PCR, DNA hybridization, RFLP, and blotting techniques are available, as are specific studies in T- and B-cell receptor/gene rearrangement assays, HIV quantitation and genotyping, HCV quantitation and genotyping, HSV, BK Virus, CMV quantitation, fragile X, t(9;22) quantitation and t(14;18) translocations, hematopathological disorders, human identity testing, B- and T-cell monoclonality by PCR tests for diagnosis and treatment of possible lymphomas; Factor V Leiden, Factor II (prothrombin) G20210A for hypercoagulopathies, pulmonary embolisms and related conditions, and other assays. Please see our listing of tests. Additional assays are always in development.

Refer to specific test listings in this directory or contact the Molecular Diagnostics laboratory at 804-828-9564 for more information.

CYTOGENETICS

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The Cytogenetics Diagnostic Laboratory is a full service facility that offers "state-of-the-art" cytogenetic testing to health care providers from central Virginia and across the United States. The tests offered include chromosome studies from specimens of: peripheral blood; bone marrow; amniocytes; chorionic villi; spontaneous miscarriages; solid tumors; and histology preparations.

In addition to standard chromosome analysis techniques, the cytogenetics laboratory offers molecular cytogenetic evaluations using fluorescence *in situ* hybridization (FISH) methods. The tests performed include (but are not limited to):

- FISH to assess over 42 conditions including those for microdeletions; leukemia; solid tumors; and subtelomeric probes (ToTel Vision). Given its strong history of high quality FISH, it was selected as one of 42 centers worldwide that participated in the VYSIS clinical trial that led to FDA approval of the AneuVysion probe set.
- **Spectral Karyotyping (SKY)** for evaluation of constitutional, prenatal, leukemia, solid tumor and research cell lines. The facility is a referral site for SKY analysis of cases, nationwide.

In addition to providing top quality diagnostic care, the cytogenetics laboratory has also been an active training site for clinical cytogeneticists. In fact, the number of American Board of Medical Genetics certified cytogeneticists who have been trained in the Department of Human Genetics at Virginia Commonwealth University accounts for approximately 10% of the total number of cytogeneticists who have obtained board certification since 1991.

TOXICOLOGY

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Therapeutic Drug Monitoring — Drug Concentrations

A large number of quantitative determinations of therapeutic drugs are available through the Toxicology Laboratory. Please see individual test listings on this website for details or contact the laboratory to determine if analysis of a drug is feasible. Typically, drug concentrations are obtained to aid in the monitoring of the treatment of various disorders. They are also obtained due to indications of suspected toxicity, suspected noncompliance, and/or suspected drug-drug interactions. The specific requirements for the proper collection and use of drug concentrations make it necessary that timing of the collection and drug dosage be controlled.

Drug concentration determinations should be performed only when there is appropriate indication for this information and with consideration of the following pharmacokinetic principles. Drug concentrations are typically drawn after steady-state has been reached (i.e., 4-5 half-lives of dosing, or after a loading dose and once maintenance dosing has been instituted).

- Trough concentrations (drawn just before the next dose) are recommended for most orally administered drugs.
- Peak concentrations (drawn just after a dose) are recommended for use only with I.V. administered medications where the "peak" can be specifically defined.

Individual pharmacokinetic information may be obtained using the collection of serial drug concentrations in a controlled fashion. Please contact the Pharmacokinetic Dosing Service or the laboratory for more details.

Emergency Toxicology / Forensic Toxicology

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Emergency Toxicology deals with the isolation and identification of drugs and/or other intoxicants in man. Such testing may assist Emergency Department physicians in the diagnosis, treatment, and/or prognosis of the poisoned patient. The common types of clinical presentations which may require toxicological laboratory analysis are as follows:

- Acute overdose of a drug or toxic substance (accidental or suicide)
- Rule out drug toxicity as the cause of coma or mental status changes
- Suspected substance abuse of illicit drugs
- Suspected toxicity from therapeutic administration of drugs or substances
- Environmental or occupational exposure to toxic substances
- Workplace substance screening
- Forensic analysis or drug substance toxicity

The Clinical and Forensic Toxicology Laboratories of the Department of Pathology have extensive resources to provide a wide range of specialty drug testing. Consultations with the laboratory personnel concerning the specific types of analysis required in any specific patient are available. However, the following is a summary of the toxicology testing that is routinely available in the laboratory.

Drug Screen — **General Unknown, Urine:** Includes testing for a wide variety of drugs using immunoassays, gas chromatography, GC/MS, and salicylate spot test. Used primarily to help in the assessment of drug overdoses or to rule out drug toxicity or to be used in patient compliance testing.

Drug Screen — **Drugs of Abuse (DAU), Urine:** Includes immunoassay testing for amphetamines, barbiturates, benzodiazepine, opiates, cocaine, and PCP drug groups or specific drugs. Used primarily to help in the assessment of substance abuse by patients or other persons.

Drug Screen — **Specific, Urine, or Blood:** Includes any one or combinations of immunoassay testing for amphetamines, barbiturates, benzodiazepine, cocaine, methadone, opiates, PCP, propoxyphene, and THC drug groups or specific drugs.

Drug Screen — **General, Gastric:** Similar to the urine screen, but is primarily used to assess acute overdose cases where gastric lavage has been performed.

Volatile Screen, Urine, or Serum: Includes testing for ethanol, isopropanol, methanol, and acetone by gas chromatography. Used in the assessment of acute toxicity.

Specific Analyses: Numerous analyses are available for the quantitative determination of drugs or toxic substances (i.e., volatile screens, therapeutic drug

concentrations, heavy metal screens, tricyclic antidepressant concentrations). In addition, testing using more sophisticated techniques such as GC/MS is available if required. Typically, blood is the specimen of choice for quantitative determinations, but urine may be helpful in some cases. Refer to the specific test listing on this website or contact the laboratory or faculty for more information. Urine is the specimen of choice for qualitative determinations when testing for compliance, due to longer detection times in urine.

Forensic Toxicology

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Chain-of-Custody Protocol and Specimen Collection: Use of chain-of-custody is a legal protocol describing the documentation of specimen transfer from the time of collection until final disposition of the sample. The chain-of-custody protocol is a clerical and custodial service offered by the laboratory to document specimen transfer and provide for extended specimen storage. A written record of specimen transfer, from donor, to analyst, to storage and disposal, is maintained on all specimens covered by chain-of-custody. All drug screens, blood alcohols, or any other tests having medico-legal significance should be accompanied by chain-of-custody and a written release form.

Forensic Testing

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Workplace Drug Testing: Urine samples collected under chain-of-custody procedures. Minimum sample volume: 30 ml preferred. Tests include an initial immunoassay screen, urine adulteration testing, and GC/MS confirmation of all positives.

- **Non-DOT Panel 5** (similar to SAMSHA / NIDA 5 Panel), #3985. Includes: Amphetamines, cocaine metabolite, opiates, phencyclidine, THC50.
- **Non-DOT Panel 7**, #3987. Includes: Amphetamines, barbiturates, benzodiazepines, cocaine metabolite, opiates, phencyclidine, THC50.
- **Non-DOT Panel 9**, #3989. Includes: Amphetamines, barbiturates, benzodiazepines, cocaine metabolite, methadone, opiates, phencyclidine, propoxyphene, THC50.
- **GC / MS Confirmation**. The laboratory is capable of providing GC/MS confirmation of other drugs that may be specifically requested from samples maintained under chain-of-custody.

Postmortem Drug Testing: The laboratory is capable of providing identification and quantitation of various drugs present in postmortem samples. Please contact the laboratory for specific testing requirements.

Special Studies: The Toxicology Laboratory and personnel are capable of developing and implementing new toxicology assays that may be used for patient

care. New procedures described in the literature are continuously evaluated for possible implementation; however, specific analyses may also be developed in consultation with the Pathology faculty. These analyses may be for use in both clinical and research applications. Contact Laboratory Administration for details.

Consultations: The interpretation of several toxicology analyses is routinely performed by the Toxicology Laboratory house staff or faculty (i.e., GC, HPLC, LCMS, or GC/MS procedures, toxicology exams, etc). The faculty is also available for consultations involving interpretation of laboratory tests or for analytical problems related to a specific patient's care. Contact the laboratory for more information.

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ANATOMIC PATHOLOGY

AUTOPSY SERVICES

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A routine autopsy includes examination of the thorax, abdomen, pelvis, and central nervous system. A routine autopsy in no way precludes an open casket funeral. If special procedures are indicated or portions of the examination are forbidden by the next-of-kin, it should be clearly indicated on the Autopsy Permit. Hospital autopsies are performed at the VCUHS facilities in B2-018 Sanger Hall. Students and medical care personnel associated with a case are encouraged to attend the autopsy. Medical Examiner autopsies are performed by order of the Medical Examiner in their facilities.

Hours of Service

Most autopsies are performed Monday through Friday between 8 AM and 3 PM and on Saturdays from 8 AM to noon; Sundays and Holidays only under special circumstances. When the chart, a valid permit, and the body are all received by the Pathology Department, the postmortem examination will be done. In most cases, if the permit is received after the cutoff time, the autopsy will be performed the following working day. The body is usually released to the mortician within 48 hours of the time of receiving the valid permit.

If tissue is needed immediately for cultures, chromosome studies, or chemical studies, or if the body must be transported quickly, the autopsy may be performed during evening or night hours. Contact the Autopsy Service or Anatomic Pathology resident "on call" if this service is needed.

Autopsy Permit: Who Gives Permission/Authorization

Permission to perform an autopsy must be obtained from the proper relative or authority.

Guidelines, as established by Virginia Code §54-325.8 are as follows:

§54-325.8 Persons who may authorize postmortem examination of decedent's body.

Any of the following persons, in order of priority stated, may authorize and consent to a postmortem examination and autopsy on a decedent's body for the purpose of determining the cause of death of the decedent, for the advancement of medical or dental education and research, or for the general advancement of medical or dental science, if: 1) no person in a higher class exists or no person in a higher class is available at the time authorization or consent is given, 2) there is

no actual notice of contrary indications by the decedent, and 3) there is no actual notice of opposition by a member of the same or prior class.

The order of priority shall be as follows: 1) the spouse, 2) an adult son or daughter, 3) either parent, 4) an adult brother or sister, 5) a guardian of the person of the decedent at the time of his death, or 6) any other person authorized or under legal obligation to dispose of the body.

If the physician or surgeon has actual notice of contrary indications by the decedent or of opposition to an autopsy by a member of the same or a prior class, the autopsy shall not be performed. **The persons authorized herein may authorize or consent to the autopsy after death or before death**.

In cases of death where official inquiry is authorized or required by law, the provisions of Article 1 (§32.1-277 et seq) of Chapter 8 of Title 32.1 shall apply. If at the time of death, a postmortem examination is authorized or required by law, any prior authorization or consent pursuant to this section shall not be valid unless the body is released by the Chief Medical Examiner or one of his assistants.

A surgeon or physician acting in accordance with the terms of this section shall not have any liability, civil or criminal, for the performance of the autopsy. (Code 1950, §32-364.4:1; 1973, c. 357; 1979, c. 720; 1986, c. 237).

Autopsy Permit: Filling in the Form

These must be filled out completely, signed by the next-of-kin, and witnessed. Witnessed telephone consent is legal but follow-up written or telegraph/fax is encouraged.

SURGICAL PATHOLOGY AND CYTOPATHOLOGY [Go to Top]

Requests for Surgical Pathology and Cytopathology examinations and consultations are made by completely filling out a Surgical Pathology or Cytopathology form and submitting this form along with the patient's specimen(s) for examination. As with other test requests, critical items of information are required to accompany each specimen. These include:

- patient's name, hospital number, account number, birth date, sex (this information must be on the requisition and all specimen containers)
- specific source of each specimen and operation performed
- pertinent clinical information should include preop and postop diagnosis;
 additional information is always encouraged; ICD-9 code is required
- attending physician and operating physician if different from attending; referring physician

Fine Needle Aspiration Service

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This diagnostic service is provided for both inpatients and outpatients. Fine needle aspirations can be requested by calling the Cytopathology Laboratory at 828-9739. For FNAs requiring radiologic guidance (CT, ultrasound, or endoscopy), call ahead 1-2 hours to alert the laboratory and provide patient information. A second telephone call is necessary once the radiologist has positioned the needle. Outpatients for fine needle aspiration can be scheduled at VCUHS by calling Anatomic Pathology.

The use of FNAs is specifically helpful for the rapid and cost-effective diagnosis of lesions that are accessible by the needle aspiration technique. Problems such as breast lumps, thyroid nodules, lymph node enlargements, and abdominal or chest masses can be commonly resolved through the use of aspiration cytology examination. Contact the Cytopathology Laboratory for more information and specific indications and contraindications for this procedure.

Intraoperative Consultation Requests

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Request for intraoperative consultations are performed as needed by direct request from the operating rooms or Ambulatory Care by contacting surgical Pathology by intercom from the main operating rooms or by phone from Ambulatory Care (direct line: 828-0291). Pathologists are routinely available to perform intraoperative consultations Monday through Friday, from 8 AM – 5 PM. Consultations requested outside these hours should be arranged by contacting the surgical pathology resident on call. This listing is available at main control in the main operating rooms, and there is a pager number as well as home phone number.

For all requests a Surgical Pathology accession form must be completed with all appropriate information, including identification of the patient and the specimen, the appropriate clinical information, and the question the surgeon wants answered. The requisition and the specimen should be promptly delivered to the Surgical Pathology accession area, 6th floor Gateway Building. The pathologist will give a report to the operating surgeon by intercom in the case of the main operating rooms and by phone in the case of Ambulatory Surgery. The findings will be incorporated into the final surgical pathology report. Intraoperative consultation should only be requested where a definite therapeutic decision is to be based on the results, not for curiosity or to provide family members of the patient with a quick diagnosis.

Review of Previous Pathology Materials

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Requests for a review of a patient's previous tissue or cytology examinations can be made by completing and submitting a surgical or cytology requisition form and forwarding that form with the patient's previous materials to the Archival Office located on 6th floor, Gateway Building. The requisition form <u>must</u> include: patient's name, patient's medical record number, patient's referring physician (must be a VCUHS <u>attending</u>), and an ICD-9 code. Incomplete forms will result in the return of the materials to the referring physician. If there are any questions regarding acquisition of the form, please contact the Archival Office. The materials should include a copy of the original pathology report, microscopic slides, and/or blocks. These materials will be reviewed and a pathology report will be generated. It is hospital policy that this review be carried out prior to any major therapy to be undertaken at VCUHS, unless part of this review process will be promptly returned to their origin after the case is completed, except for representative slides if the patient is to be treated and followed by physicians at VCUHS.

Ancillary Testing: Immunohistochemistry, Hormone Receptor Assays, In Situ Hybridization, Immunofluorescence, and Electron Microscopy

Requests for specific ancillary tests on pathology tissues should be made directly with the pathologist responsible for the tissue examination. Typically these studies are initiated by the pathologist responsible for the tissue examination to help them properly complete the diagnostic report on the submitted tissue.

Please send ancillary test requests to the Anatomic Pathology receiving area located on the 6th floor, Gateway Building. Hours of operation are 8 AM – 5 PM, Monday through Friday. After hours the specimens are to be delivered to the Clinical Support Central Receiving Area on the 6th floor of Clinical Support Center. Clinical history is required for all patient samples. For neuropathology specimens, bone tumors, or consults, the radiology report and films are also requested. Consult material should be accompanied by any associated pathology report(s) including any preliminary reports, H & E slide and paraffin block where applicable.

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