Respiratory Virus Testing at the Clarian Virology Laboratory

Within Clarian we can now test for respiratory viral pathogens using two different methodologies:

1) The Respiratory Viral Antigen Profile (Respiratory Viral DFA) has long been available at Clarian and uses rapid fluorescence staining (DFA). This test is done by the Clinical Virology Laboratory.

2) The Respiratory Viral Panel PCR (Respiratory Viral PCR) is new to Clarian. It uses polymerase chain reaction (PCR). This test is done by the Molecular Diagnostics Laboratory.

Since there is a price difference between the tests and more importantly a difference in turnaround time, it is important that the clinician be able to order the most appropriate test for their patient.

Which Test Should I Order?

The Respiratory Viral DFA detects the presence of influenza A and B, RSV, human metapneumovirus, parainfluenza 1, 2, 3; and adenovirus in respiratory secretions or fluids. Results of the rapid DFA tests are available within several hours after the specimen is received in the laboratory. Following the rapid testing, the sample is also cultured for viruses. This viral culture may identify other potential respiratory pathogens such as parainfluenza 4, enterovirus, cytomegalovirus, rhinovirus, and herpes simplex virus 1 and 2—all of which would be missed if only the rapid antigen tests were performed. Viruses isolated in culture can be used for epidemiologic typing and susceptibility testing that will assist health care authorities in outbreak and epidemic investigations.

The Respiratory Viral PCR detects rhinovirus in addition to the eight viruses listed above for the Respiratory Viral Antigen Profile. The PCR will also subtype influenza A into H1 and H3 subtypes and RSV into A and B types. The turnaround time for this test is significantly longer than the DFA; 24-48 hours. In addition, this assay is more expensive than the DFA.

So an important question arises: which test should I order? Most patients with respiratory illnesses will not require any diagnostic testing. Most children will not require hospital admission or antiviral therapy. However, if hospitalization is needed and a decision regarding cohorting is necessary, a respiratory specimen for the Respiratory Viral DFA should be sent. If the DFA is positive, no further testing would be necessary. The DFA could also be useful in those patients in whom antiviral therapies are being considered—for influenza or for the immunocompromised host where an “experimental” antiviral agent could be utilized.

The Respiratory Viral PCR should be reserved for patients in whom the DFA is negative and in cases in which knowing if a viral pathogen is responsible for the child’s illness will significantly alter the treatment the child is receiving. While the PCR will allow for the subtyping of influenza A into H1 and H3 subtypes and the typing of RSV into A and B types, these are mostly important from an epidemiologic standpoint and will not alter patient care. Most clinicians will not routinely need this type of information to provide care to the patient with respiratory disease.

In summary, the Respiratory Viral DFA testing is adequate for most patients who require respiratory viral diagnostic testing. If this assay is positive, no further testing is necessary. The Respiratory Viral PCR should be reserved for those with negative DFA assays in whom decisions regarding antiviral therapy are being entertained, especially for the immunocompromised host or those in the intensive care unit with severe lung disease—those in whom a diagnosis of a viral infection may explain the clinical picture and the severity of the disease, and therapeutic decisions may be based on this type of information.

If you have any questions, please contact client services at 491-6000 and ask to speak to either the virology or molecular diagnostics laboratory.
Testing for H1N1 Virus

The Rapid Flu Test is a screening test for Influenza A and B, performed in emergency rooms and many physician offices. If the test is positive for Influenza B – there is no concern for Swine Flu. If positive for Influenza A, the sample will be submitted to the state lab for confirmation. Influenza A is not present in the community currently. Rapid Flu Test is less sensitive than the options below and could yield some false positive or false negative results. If the patient is symptomatic, the physician could order an Influenza Ag IF or the Respiratory Viral PCR.

Influenza Ag IF
- Costs less than PCR
- Done minimum of twice/day
- More sensitive than Rapid Flu
- Will identify Influenza A and B
- If positive for A, confirmation for H1N1 goes to state lab
- Transport media – viral transport
- TAT – 1 day

Respiratory Viral PCR
- Costs more than IF
- Done once/day
- More sensitive than both Rapid Flu and Influenza Ag IF
- Will identify different types of Influenza and subtypes h1 and h3 for humans strains. Animal h1 will be detected as Influenza A but the subtype will not be detected, making it suspicious for Swine Flu.
- If positive for A, all samples regardless of subtype will be sent to the state lab to rule out or confirm H1N1.
- Transport media – viral transport.
- TAT – 2 days

New Test: hMPV Ag IF QL

Human metapneumovirus antigen (hMPV Ag IF QL) can now be ordered individually but is also included in the respiratory viral antigen profile and the respiratory viral PCR.

New Test—BCR-ABL translocation quantitative detection by RT-PCR

Clinical Utility: BCR-ABL quantitative RT-PCR assay test is intended to be used for the accurate quantification of the p210 (Major breakpoint) or the p190 (minor breakpoint) BCR-ABL fusion forms at the time of diagnosis of CML or Ph+ALL, to monitor efficiency of treatment in patients with CML or Ph+ALL undergoing therapy, and for minimal residual disease (MRD) follow-up to monitor disease relapse in patients who are known to have this fusion form.

Method: The assay is performed by quantitative Reverse Transcription Polymerase Chain Reaction (qRT-PCR) on RNA sample extracted from EDTA whole blood.
Sensitivity: This test can detect the p210 or p190 BCR-ABL fusion gene transcripts to a sensitivity level of 0.001% (1 copy of BCR-ABL in 100,000 copies of ABL).
Specimen Requirements: 5 ml Lavendar (EDTA). Do not spin. Do not freeze.
Performing Lab: CPL Molecular Pathology
Performance Schedule: Once/week on Tuesday
Cerner orderable: BCR-ABL p210 QN PCR or BCR-ABL p190 QN PCR.

New Test: Epstein-Barr virus (EBV) Quantitative Test

Clinical Utility: EBV Quantitative Test is intended to be used as a prospective and diagnostic marker for the development of post-transplant lymphoproliferative disorders (PTLD), especially in EBV seronegative organ transplant recipients.
Methodology: quantitative real-time PCR.
Specimen Requirements: Peripheral blood drawn in a 6 ml EDTA tube (lavender or pearl top tube). Tubes must be centrifuged within 6 hours of collection. Centrifuge at 1600 x g for 20 minutes. Specimens should be transported refrigerated.
Performing Lab: CPL Molecular Pathology.
Performance Schedule: The test is performed M-F. Turnaround time is 24-48 hours.
New Test: KRAS gene mutation assay

Clinical Utility: KRAS gene mutation assay is intended to be used as a prognostic marker for Colorectal Cancer (CRC) and Non-Small Cell Lung Cancer (NSCLC) patients that are treated with epidermal growth factor receptor-targeted therapies.

Methodology: PCR/Shifted Termination Assay/Capillary Gel Electrophoresis and Fluorescence detection.

Specimen Requirements:
Option 1 - Formalin-fixed, Paraffin-embedded Unstained Slides: A minimum of 8 slides (plus 1 H&E) or 9 slides (w/o H&E) are required. In case of biopsy specimens (small sections), a minimum of 6 slides with three sections per slide are required. Pre-cut slides from paraffin block in 5-7 micron sections. Air dry (do not oven dry). Tissue should be well-fixed in formalin. Specimens will be rejected if an alternative fixative was used. Store specimens at room temperature (20-23.5°C). Send all slides within 5-7 days of cutting. Use cold pack for transport. Be sure cold pack is not in direct contact with specimen during transport.

Option 2 - Formalin-fixed, Paraffin-embedded Block with Corresponding H&E slide: Tissue should be well-fixed in formalin. Specimens will be rejected if an alternative fixative was used. Store specimen at room temperature (20-23.5°C). Use cold pack for transport. Be sure cold pack is not in direct contact with specimen during transport.

Performing Lab: CPL Molecular Pathology.
Performance Schedule: Once/week. Turnaround time is 7-10 business days.

New Test: Warfarin Sensitivity Assay (CYP2C9/VKORC1 genotyping)

Clinical Utility: Warfarin Sensitivity Assay is a test intended to be used for identification of patients who may require warfarin dosing adjustments including:
- patients who have previously been prescribed warfarin and have required multiple dosing adjustments to maintain the INR in the target range
- patients with a history of thrombosis or bleeding when previously taking warfarin
- patients being started on a first prescription for warfarin

Methodology: The genotyping for CYP2C9 and VKORC1 polymorphisms is performed by multiplex polymerase chain reaction (PCR) and multiplex allele-specific primer extension (ASPE) with universal tag sorting system performed on a Luminex-100 xMAP platform.

Specimen Requirements: 5 ml Lavendar (EDTA). Adult minimum volume - 2 ml WB. Pediatric minimum volume - 0.5 ml WB. Do not spin.

Performing Lab: CPL Molecular Pathology
Performance Schedule: The test is performed M-F and turnaround time is 24-48 hours.

Cerner orderable: Warfarin Sensitivity.

Hgb A1C HPLC Bld QN

The calculated estimated average glucose concentration is now included with the results of all Hgb A1C. The eAG will be displayed with both mg/dL and mmol/L units. This change has been made to bring our hemoglobin A1c reports into the format of the “Consensus Statement on the Worldwide Standardization of the Hemoglobin A1c Measurement”, Diabetes Care, 30, 2399-2400; 2007. The formulas are from Nathan, et al, Diabetes Care, 31, 1473 – 1478; 2008. There will be no change in the hemoglobin A1C measurements; these additional calculated results are simply additions to the hemoglobin A1C result.
New Test: Neutrophil Oxidative Burst Assay

The Neutrophil Oxidative Burst Assay is performed in the Flow Cytometry Department. This test replaces the Nitroblue Tetrazolium (NBT) test. In this assay granulocytes are stimulated with phorbol myristate acetate (PMA) and incubated in a solution of Dihydrorhodamine 123 (DHR). DHR will diffuse into the cells and will be oxidized to rhodamine 123 when the NADPH oxidase complex is activated. The red fluorescence from the rhodamine 123 will be measured on a flow cytometer. The intensity of red fluorescence from stimulated cells will be compared to the intensity of red fluorescence in unstimulated cells.

Methodology: Flow Cytometry
Source: Peripheral Blood
Collection: Notify the Flow Cytometry Department (491-6000) before drawing specimens for the Neutrophil Oxidative Burst Assay. **This test must be scheduled.** Draw two 7 ml sodium heparin tubes (dark green top tubes) from the patient and a non-related healthy control. Transport the blood immediately to CPL Flow Cytometry at ambient temperature. Blood must be drawn in the AM and received in Flow Cytometry by 11AM. **Please send directly to pneumatic tube station 949.**

Performance Schedule: Test is run on Monday – Friday. Report TAT: 1-3 days

Performance Characteristics of the assay: This test will be reported and interpreted by a pathologist.

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New Test: Quad Marker Screen

On Monday, May 18, 2009, Clarian Pathology Laboratory will begin to perform “Quad Marker” screens. After this date we will no longer be sending specimens for quad marker testing to a reference laboratory.

The “Quad Marker” test is requested during pregnancy to screen for fetal open neural tube defect, Down syndrome and Trisomy 18. The four molecules measured in the quad marker test are inhibin A, unconjugated estriol, beta subunit of human chorionic gonadotropin and alpha fetoprotein. The quad marker test identifies 80% of the affected pregnancies.

The quad marker test is performed on blood obtained between 15 weeks 0 days and 21 weeks 6 days gestation. The blood must be sent to Clarian Pathology Laboratory along with a completed requisition. Information from the requisition is added to the results of the four quad marker tests to identify women at risk of having an affected child. Results will be reported as positive or negative, along with the relative risk for each condition.

The quad marker test will be performed daily, Monday thru Friday, with a turn around time of one to three days. Recalculations will be available Monday thru Friday 07:00 – 3:30pm by paging 312-6909. Specimen Requirements: 5 mL Gold tube (Serum only); Specimen must be accompanied by a completed requisition.

For any questions regarding methodology and interpretations, please contact Dr. Ken Ryder, Director of Laboratories, Clarian Pathology Laboratory at 491-6630. All other inquiries such as specimen requirements and test availability call Client Services at 491-6000.

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Test Information Changes—please update DOS

**Acid Phos SerPl QN**—Discontinued test. Order PSA.
**ACTH Plasma QN**—Serum, heparinized plasma, gross hemolysis, lipemic and nonfrozen samples.
**Aldolase SerPl**—Spin and separate ASAP. No hemolysis or plasma.
**Alkaline Phos Iso SerPl**—No anticoagulants containing oxalate, citrate or EDTA.
**Ammonia Pl QN**—No hemolysis.
**Amoxapin Met SerPl/Bld QN**—Discontinued test
**Amoxapine/Metabolite QN**—New test—replacing Amoxapin Met SerPl/Bld QN
**Androstenedione SerPl QN**—Preferred tube Gold, other acceptable type include Green, Lt Green, or Lavender. Method—HPLC/TDMS, collect sample between 6-10 am. Minimum volume 0.15 ml ser/plas.
**Androstenedione 0-6 mo**—Preferred tube Red. EDTA plasma acceptable, 0.2 ml minimum volume.
**aPTT Pl QL**—name changed to aPTT PI QN
**Arbovirus Pnl IgG Ser Ttr**—Method IFA/ELISA. Minimum volume—1.5 ml serum
**B pertussis IgG/IgA Ser**—Minimum volume—0.2 ml serum, TAT 2-9 days
Test Information Changes—Cont’d

B pertussis IgM Ser QL—Minimum volume—0.1 ml serum, TAT 2-9 days
Bladder Tumor Ag Ur QL—Discontinued test
Bladder Tumor Associated Ag QL—New test replacing Bladder Tumor Ag Ur QL
BNP Pl QN—Avoid severe hemolysis.
Bone Specific Alk Phos Ser—Preferred tube Gold. Lt Green or Green acceptable. Minimum vol—0.5 ml ser/plas
Bupropion SerPl QN—Performed M,Th
Calcitonin Ser QN—EDTA plasma, no gross hemolysis or lipemia.
Carbohydr Def Trans Ser QN—Discontinued Test
Carbohydr Def Transferrin—New Test replaces Carbohydr Def Trans Ser QN
Chlamydia PCR—Refrigerate swab samples if they cannot be delivered to lab within 1 hr of collection. Swabs with wooden shafts are unacceptable. Thin preps are stored room temp. Ship room temp.
CK-MB Mass Pl QN—Avoid severe hemolysis.
Clomipramine/Met SerPl QN—Performed M,W,F
Coenzyme Q10 Pl QN—minimum volume is 1.5 ml frozen plasma
Copper Liver Tissue—New Test replaces Copper Liver Tissue QN
Copper Liver Tissue QN—Discontinued test.
Cortisol 0-6 months—Discontinued test.
Cyclosporine LVL QN—replacing Cyclosporine Level QN—method HPLC.
D Dimer—Replaced by D-Dimer Pl QN
DHEA Ser QN—Method HPLC/TDMS, Performed daily.
Factor VIII (8) Inhibitor-Porcine—Discontinued test
Febrile Antibodies Panel—Method DA/IFA/Immunodot
Folate SerPl QN—overnight fasting preferred
Gastrin Ser QN—Spin and separate within 1 hour of collection. No plasma, hemolysis or lipemia.
GC PCR—Refrigerate swab samples if they cannot be delivered to lab within 1 hr of collection. Swabs with wooden shafts are unacceptable. Thin preps are stored room temp. Ship room temp.
GC+Chlamydia PCR—Refrigerate swab samples if they cannot be delivered to lab within 1 hr of collection. Swabs with wooden shafts are unacceptable. Thin preps are stored room temp. Ship room temp.
Growth Hormone—No gross hemolysis or lipemic samples.
Growth Hormone 0, 30, 60, 90 or 120 Minutes—No gross hemolysis or lipemic samples.
Hantavirus IgG Ser QL—TAT varies, minimum volume 1.5 ml serum
Hantavirus IgM Ser QL—TAT varies, minimum volume 1.5 ml serum
HCV Genotype SerPI—Minimum volume 1 ml plasma
Hepatitis C PCR QN—Minimum volume 1 ml plasma
Hepatitis B DNA Pl QN PCR—Minimum volume 1 ml plasma
Hemoglobin Electrophoresis Bld QN—Lavender preferred, Green Na Heparin acceptable
Hepatitis B Hybrid Capture—Discontinued test
hMPV Ag IF QL—New test.
Hydrogen Breath Test—Discontinued Test
IAT MTS—Discontinued test
Indirect Antiglobulin Test—New test replacing IAT MTS—this is the indirect coombs test
IBD Diag Sys Ser QN—Discontinued test
ICG SerPl QN—Ship refrigerated. No hemolysis.
IGF-1 Ser QN—No plasma, gross hemolysis or lipemia.
IGF Binding Prot 3 Ser QN—No plasma, gross hemolysis or lipemia.
Intact HCG Ser QN—Method—Chemiluminescence, Performed Daily, D,E,N. TAT—2-4 hrs.
Itraconazole SerPl QN—ship frozen ser/plas.
LD CSF QN—Send room temp. Do not refrigerate or freeze.
LDH Fld QN—Do not refrigerate or freeze. Ship room temp.
Lidocaine SerPl QN—Green tube. Avoid use of SST or PST.
M tuberculosis DNA PCR—frozen CSF is acceptable sample type.
Metanephrines Free Pl QN—Spin and separate plasma within 15 minutes of collection. Minimum volume 1.5 ml frozen plasma.
Mexilithine SerPl—Performed M,W,F
Test Information Changes—Cont’d

MBC—Discontinued test.
MIC - Discontinued test.
MIC - Discontinued test.
MID MBD—Discontinued test.
Microalbumin/Crt Tm QN—No bloody urine. Do not freeze.
Mycoplasma pneu mo Cult—Discontinued test—Please order Mycoplasma pneumoniae by PCR.
Myoglobin Ser QN—No gross hemolysis.
Neutrophil Oxidative Burst—Discontinued test
Neutrophil Oxidative Burst—New test to replace Neutrophil Oxidative Burst
Nitroblue Tetroxidoleum—Discontinued test. Replace by Neutrophil Oxidative Brst.
Progeste rone Ser QN—Avoid grossly lipemic samples.
PTH-Related Protein PI QN—Special collection tube is no longer acceptable. Collect in Green Na Heparin tube. Send 0.5 ml plasma at room temp. Minimum volume is 0.3 ml plasma.
Renin PI QN—Spin, separate and freeze within 6 hrs of collection. No hemolysis. Avoid lipemic, icteric or citrated samples.
Retic—Stability: Room Temp 8 hrs; Refrigerated 72 hrs. Ship refrigerated.
Tαu/AB42 CSF Level—Transfer CSF from CSF tube into polypropylene transfer tube. Polystyrene and glass are not acceptable.
Testosterone F+T Female/Children—Method HPLC/TDMS/ECIA, minimum volume 0.4 ml ser/plas, preferred tube is Gold, Green (Heparin) and Lavender (EDTA) are acceptable containers.
Thyroglobulin Ab QN—No gross hemolysis or lipemic samples.
TSH 3rd Gen SerPl QN—Avoid hemolysis.
Tumor Necrosis Fact-Alpha—Performed M,W,F
Ureaplas/Mycoplas Clt—CSF, semen and urine are other acceptable sample types.
Vitamin A SerPl QN—Lavender is also an acceptable container
Vitamin B2 QN—Light protect sample.
Vitamin B12 SerPl QN—Avoid hemolysis.
von Willebrand Factor Activity—replaced by new orderable, vWF Activity Screen.
vWF Activity Screen—New Test replacing von Willebrand Factor Activity.
vWF Collagen Binding Assay—New Test
Warfarin QN—New Test—replacing Warfarin SerPl/Bld QN
Warfarin SerPl/Bld QN—Discontinued Test
Warfarin Sensitivity—New Test—5 ml Lavender. DO NOT SPIN. No heparin or clotted samples. Adult minimum volume - 2 ml WB. Pediatric minimum volume - 0.5 ml WB. Ship within 48 hours. Performed daily, M-F.

ATTENTION:

• **Swabs for Rapid Strep Test** interfere with routine Strep Culture. You must collect a back up swab that can be used for a culture when performing Rapid Strep Test.

• **Swabs with wooden shafts** are NOT ACCEPTABLE for GC PCR, Chlamydia PCR and GC/Chlamydia PCR.

• Samples for GC PCR, Chlamydia PCR and GC/Chlamydia PCR submitted in ProbeTek tubes cannot be performed at CPL. They will be have to be sent to an outside reference laboratory which will result in delayed turn around time.

• **Samples for Isoelectric Focusing QL** for Oligoclonal Bands must include BOTH CSF and Serum. Please make sure that the serum is transported with the CSF.

• **Please note different supplies available for Urinalysis on the newest client supply form.** If you do not routinely need the grey urine culture tube, then please order for UA only.

  ___ Urine UA/C&S Collection/Transport Kit includes cup, wipe, yellow & grey tubes (50/Box) or (each)
  ___ Urine UA only Collection/Transport Kit includes cup and yellow tube (50/Box) or (each)
  ___ Urine C/S – Grey Urine Tube (each)
**Client Supply Order Form**

**FAX to 317-491-6001**

**We can ONLY supply what is needed for the actual amount of work that you send to one of our Clarian Health laboratories. It is a violation of our compliance policy and the Office of the Inspector General for us to provide supplies to clients who do not comply with this criterion. PLEASE USE CLIENT NUMBER!**

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<tr>
<th>DATE:</th>
<th>NAME:</th>
<th>CLIENT ID#</th>
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**Please indicate quantity based on unit of measure.**

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<thead>
<tr>
<th>Collection Supplies</th>
<th>PAP Supplies</th>
<th>MISCELLANEOUS Supplies</th>
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<tr>
<td>Tubes</td>
<td>Thin Prep Kits</td>
<td>Urine UA/C&amp;S Collection/Transport Kit</td>
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<td>(Brushes, Vial, Swabs) - 25/tray</td>
<td>includes cup, wipe, yellow &amp; grey tubes (50/box) or (each)</td>
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<td>Brooms for Thin Prep - 50/tray</td>
<td>Urine UA only Collection/Transport Kit includes cap and yellow tube (50/box) or (each)</td>
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<td>Pap Smear Kits (Pap Packs) - 25/box</td>
<td>Urine C/S - Grey Urine Tube (each)</td>
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<td>Pap Smear Fixative Spray (each)</td>
<td>Urine Cup w/Temp Strip -100/pack</td>
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<td>Pap Smear Empty Transport Cont. -25</td>
<td>Black screw cap tubes (500mL) (each)</td>
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<td>Alcohol tubes (each)</td>
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<td>Fetal Fibronectin kits (box of 8)</td>
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<td>Glucose 50 Grams 6/pack</td>
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<td>Red Microtainer - 50/bag</td>
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<td>Gold Micro (SST) - 50/bag</td>
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<td>Lavender Microtainer - 50/bag</td>
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<td>Vacutainer Needles, 21g 1/2 - 100/box</td>
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<td>Vacutainer Needle Safety Holders - 25/pack</td>
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<td>Tourniquets - 100/box</td>
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<td>Labels, 2 part Barcode - Manifest</td>
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**Requisitions & Forms**

- Custom Reqs (ea)

- (Attach copy of your custom requisition)
- Lab Reqs (ea)
- Pap GYN Reqs (ea)
- Non-Gyn Reqs (ea)
- Surg Path Reqs (ea)
- Allergy Reqs (ea)
- FLM/LS Reqs (ea)
- Flow Cytometry Reqs (ea)
- Quad Marker Reqs
- Triple Marker Reqs
- DemPath Reqs (ea)
- GI Path Reqs (ea)
- Liver Path Reqs (ea)
- Neopath Reqs (ea)
- Ophthalmic Path Reqs (ea)
- Renal Path Reqs (ea)
- Urologic Path (ea)
- ABN Forms English (each)
- ABN Forms Spanish (each)

**Micro Supplies**

- Anaerobe Transpo Media (Port-A-Cult) (each)
- BHI Agar
- Blood Agar
- Blood Cx bottle, aerobic (ea)
- Blood Cx bottle, anaerobic (ea)
- Blood Cx bottle, pediatric (ea)
- Blood Cx, TB (AFB) (SFS tubes) (each)
- Chocolate Agar
- Catheter Swabs (Routine) (50/pkg)
- Eye/Bordetella Cx (Amies Culturette) (ea)
- Fungal Bio/BM Cx (Isolator) (ea)
- QC Culture Kits (each)
- GC/Chlam PCR (DNA Probe M&F) (ea)
- Herpes Cx (Viral Transport Media) (each)
- H. pylori screen (CLO Test) (each)
- Para Pak for E+P (O & P) Kits (each)
- Sabouraud Agar
- Stool Culture (Carey Blair Media) (each)
- Viral Cx (Viral Transport Media) (each)
- Other

**Bags**

- Plastic Bio-Hazard Bags - 50/pack
- STAT Bio-Hazard Bags - 100/pack
- 13 x 18 bags ( urine jugs) (each)
- Brown paper large ( urine jugs) (each)

3/19/2009
Add Test Comment:
Double spin and freeze plasma within 4 hrs of collection: Spin at 3000rpm for 15 min. Place top 2/3 of plasma in aliquot tube and spin aliquot at 3000 rpm for 15 min. Take top 2/3 of 2nd spin and put in another aliquot tube. Mark tube ‘plasma’. Freeze immediately. Send frozen plate-let poor plasma.

Add Test Comment:
Spin and separate within 2 hours of collection.
Albumin SerPl QN
Alkaline Phos serPl QN
Alpha-1-Antitrypsin
Amylase SerPl QN
ASO
AST SerPl QN
Barbiturates Scn SerPl QL
Benzodiaz Scn SerPl QN
Bilirubin Direct SerPl QN
Bilirubin Total SerPl QN
BUN SerPl QN
BUN Post SerPl QN
BUN Pre SerPl QN
C3 Complement Ser QN
C4 Complement Ser QN
Caffeine SerPl QN
Calcium Total SerPl QN
Carbamazepine SerPl QN
Ceruloplasmin
CO2 SerPl QN
Chloride SerPl QN
Cholesterol SerPl QN
CK SerPl QN
Creatinine SerPl QN
CRP SerPl QN
CRP High Sensitiv SerPl QN
Digoxin SerPl QN
Ethanol Pl QN
Free Light Chains Ser QN
GGT SerPl QN
Gentamicin Post SerPl QN
Gentamicin Pre SerPl QN
Gentamicin Ran SerPl QN
Haptoglobin Ser QN
HDL SerPl QN
IgA Ser QN
IgG Ser QN
IgM Ser QN
Immunoglobulin Profile
Iron SerPl QN
Iron TIBC Profile
LDH SerPl QN
LDL Measured SerPl QN
Lipase SerPl QN
Minimum Processed Volume:
APC Resistance—0.5 ml plasma
AT-III AG—0.5 ml plasma
Chromogenic Factor X Assay—0.5 ml plasma
 DRVVT—0.5 ml plasma
Heparin Level—0.5 ml plasma
Plasminogen Inhib-1 Activity—0.5 ml plasma
Plasminogen Inhib-1 Antigen—0.5 ml plasma
Protein C Activity—0.5 ml plasma
Protein C Antigen—0.5 ml plasma
Protein S Clottable—0.5 ml plasma
Protein S Antigen—0.5 ml plasma
Protein S Antigen Free—0.5 ml plasma
Reptilase Clotting Time—1.0 ml plasma
STALA— 0.5 ml plasma
vWF Activity Screen—0.5 ml plasma
Von Willebrand Factor Antigen—0.5 ml plasma
VW Multimeric Factor Pl
In order to produce valid results for all hemostasis/thrombosis testing, routine and special, specimen integrity is crucial and must be maintained. All specimens sent for testing must be collected and shipped in the following manner:

- Obtain venous blood by clean venipuncture. Avoid slow flowing draws and/or traumatic venipunctures as either of these may result in an activated or clotted sample. Do not use needles smaller than 23 gauge.

- Always draw a discard tube (clear plastic or light blue, 3.2% sodium citrate tube preferred) before drawing coagulation specimens in light blue vacuum tubes (3.2% buffered sodium citrate). NOTE: Reference ranges have been established using 3.2% buffered sodium citrate. When using a winged collection set for venipuncture and a coagulation (3.2% citrate) tube is the first specimen tube to be drawn, a discard tube must be drawn to fill the blood collection set tubing’s “dead space” with blood but the discard tube does not need to be completely filled. This important step will ensure maintenance of the proper blood to anticoagulant ratio of the blood sample. Noncompliance will result in an under-filled coagulation tube, which can result in falsely prolonged coagulation results. The discard tube can be a second light blue coagulation tube.

- Always draw a discard tube, regardless of the blood collection system used, (clear plastic or light blue, 3.2% sodium citrate tube preferred). NOTE: This reflects a change in NCCLS recommended order of draw, NCCLS H3-A5, Vol 23, No 32, 8.10.2 ) before drawing coagulation specimens in light blue vacuum tubes (3.2% buffered sodium citrate). NOTE: Reference ranges have been established using 3.2% buffered sodium citrate.

- Withdrawing blood from intravenous lines or indwelling catheters should be avoided if at all possible. Frequently, heparin flushes are used to maintain patency in catheters and lines. If not properly cleared of heparin before drawing blood from lines, the results of coagulation studies such as the Prothrombin Time, aPTT, Thrombin Time, dRVVT, APCR and aPTT bases Protein S Assays can be FALSELY PROLONGED. When obtaining samples for hemostasis studies from indwelling lines that may contain heparin, the line must be flushed with 5mL of saline and the first 5mL of blood drawn must be discarded before the tube that will be used for hemostasis tests is filled.

- Fill light blue top tubes as far as the vacuum will allow, an exact ratio of 9 parts blood to one part anticoagulant must be maintained, and mix by gentle inversion. Samples with less than 90% fill must be redrawn. Failure to maintain an exact 9:1 ratio will interfere with accurate results. Patients with hematocrits greater than 55% must be drawn in a “corrected” 3.2% sodium citrate tube. This is a tube with a portion of anticoagulant removed to compensate for the increased hematocrit but still maintains 9:1 ratio. To calculate the amount of anticoagulant to remain in the tube, see the formula below.
  
  - Formula for adjustment of 3.2% sodium citrate in tube,
  
  \[
  X = N (100 - hct) 
  \]

- In order to produce accurate and valid results, all specimens must be “platelet free”(<5000/uL) before freezing for shipment. This residual count can be obtained by “double-spinning” the sample.
  
  - Centrifuge the specimen at no less than 1500 x g for 15 minutes (or at a speed and time required to consistently produce platelet-poor plasma, <10,000/uL) within 1 hour of blood draw.
  
  - Immediately remove only the top two-thirds of the platelet-poor plasma from the sample using a plastic transfer pipette (use of glass transfer pipettes may result in activation and/or clotting of the plasma). Place the plasma in a properly labeled plastic vial.
  
  - Re-spin this plasma at 1500 X g for 15 minutes. Remove the top two-thirds of the “platelet-free” plasma with a plastic transfer pipette being careful not to disturb any cell button at the bottom of the tube. Place this plasma in a properly labeled plastic vial and clearly mark the vials contents as PLASMA. Glass vials will be rejected. Hemolyzed samples will be rejected. Each assay requested must be submitted in a separate vial.

- Ship samples in a Styrofoam container with five pounds of block dry ice.

Some assays may be performed on a priority basis if a medical emergency exists. Contact the Hemostasis/Thrombosis Laboratory to make arrangements. Please call 317-491-6000. Hours: M-F, 7AM - 4PM.

All requests for coagulation assays must include a brief patient history and pertinent clinical information (i.e., medications, blood products, etc.). NOTE: Samples containing heparin must not be used for coagulation testing. If possible, stop heparin therapy before the draw to avoid contamination. Heparin interferes with most clotting assays.

Coagulation interpretation available. Contact the Hemostasis/Thrombosis Laboratory at 317-491-6000.
### Reference Range Changes

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Male or All</th>
<th>Female</th>
<th>Critical</th>
<th>Units</th>
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<tbody>
<tr>
<td>AT III Functional</td>
<td>86-118</td>
<td></td>
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<td>%</td>
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<td>AT-III AG</td>
<td>78-131</td>
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<td>%</td>
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<tr>
<td>D-Dimer</td>
<td>&lt;292</td>
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<td>Ng/mL</td>
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<tr>
<td>Factor II (2) Assay</td>
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<td>Factor IX (9) Assay</td>
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<td>Factor V (5) Assay</td>
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<td>Factor VII (7) Assay</td>
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<td>Factor VIII(8) - Assay</td>
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<td>Factor XI(11) Assay</td>
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<td>Factor XII(12) Assay</td>
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<td>Fibrinogen</td>
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<td>&lt; 70</td>
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<td>Heparin Induced Ab</td>
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<td>Protein C Functional (Activity)</td>
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<td>Protein S Antigen Free</td>
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<td>Reptilase Clotting Time</td>
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<td>Vancomycin, Pre</td>
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<tr>
<td>von Willebrand Factor Act Scr</td>
<td>40-126% Non O; 49-163% Type O</td>
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<tr>
<td>von Willebrand Factor Antigen</td>
<td>42-141% Non O; 66-176% Type O</td>
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</tbody>
</table>

### Reporting Units for Viral Load Testing

Clarian Molecular Pathology reports plasma viral load for HBV, HCV, CMV, and HIV results in either “copies per milliliter (mL)” or “IU per milliliter (mL).” Starting soon results will also be expressed in scientific notation (log 10). Units will be Log copies/mL and Log IU/mL depending the target virus. This additional information is being added to aid physicians in determining when changes in viral load represent a significant change.

### Proficiency Testing (PT)

Debbie Walters, Regulatory Specialist

The Centers for Medicare & Medicaid Services (CMS) has recently sent a memo to non-waived laboratories to encourage them to review various items to ensure compliance with CLIA regulations. These include:

1. Examine internal processes to ensure maximum integrity of the PT process in their lab;
2. Promote lab-wide employee training in the CLIA requirements to process PT samples in the same manner as patient specimens;
3. Avoid any inter-laboratory communications regarding PT samples during the PT event; and
4. Promote lab awareness that PT samples or parts of samples should never be referred to another lab for any reason.

If a reference laboratory receives PT samples or parts of samples from another laboratory, the reference laboratory has to notify their inspection agency or State agency inspectors to report the occurrence (but the reference lab will not test the samples).

More information can be found at [http://www.cms.hhs.gov/CLIA](http://www.cms.hhs.gov/CLIA)