

News Bulletin

May 2009

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.

- Respiratory Virus
- H1N1 Testing, BCR-ABL, EBV
- KRAS, Hgb A1c, Warfarin
- Quad Marker Screen, NBT
- DOS Changes 1
- DOS Changes 2
- DOS Changes 3
- Updated Supply Form
- Hemostasis and Thrombosis
- Normal Range Changes/Prof Testing

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.

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.

Test Information Changes—please update DOS

Acid Phos SerPI QN—Discontinued test. Order PSA.

ACTH Plasma QN—Serum, heparinized plasma, gross hemolysis, lipemic and nonfrozen samples.

Aldolase SerPI—Spin and separate ASAP. No hemolysis or plasma.

Alkaline Phos Iso SerPI—No anticoagulants containing oxalate, citrate or EDTA.

Ammonia PI QN—No hemolysis.

Amoxapin Met SerPI/Bid QN—Discontinued test

Amoxapine/Metabolite QN—New test—replacing Amoxapin Met SerPI/Bid QN

Androstenedione SerPI 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 PI 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 PI 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 SerPI QN—Performed M,Th

Calcitonin Ser QN—EDTA plasma, no gross hemolysis or lipemia.

Carbohyd Def Trans Ser QN—Discontinued Test

Carbohyd Def Transferrin—New Test—replaces Carbohyd 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 PI QN—Avoid lipemic, icteric, or hemolyzed samples.

Clomipramine/Met SerPL QN—Performed M,W,F

Coenzyme Q10 PI 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.

Cycloserine LVL QN—replacing Cycloserine Level QN—method HPLC.

D Dimer—Replaced by D-Dimer PI QN

DHEA Ser QN—Method HPLC/TDMS, Performed daily.

Factor VIII (8) Inhibitor-Porcine—Discontinued test

Febrile Antibodies Panel— Method DA/IFA/Immunodot

Folate SerPI 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 PI 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 SerPI 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 SerPI 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 SerPI QN—Green tube. Avoid use of SST or PST.

M tuberculosis DNA PCR—frozen CSF is acceptable sample type.

Metanephrines Free PI QN—Spin and separate plasma within 15 minutes of collection. Minimum volume 1.5 ml frozen plasma.

Mexilitine SerPI—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 pneumo 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 Tetrazoleum—Discontinued test. Replace by Neutrophil Oxidative Brst.

Progesterone 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.

Respiratory PCR Viral Panel—New Test—Collect in NP Swab. Send room temp.

Tau/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 SerPI QN—Avoid hemolysis.

Tumor Necrosis Fact-Alpha—Performed M,W,F

Ureaplas/Myoplas CIt—CSF, semen and urine are other acceptable sample types.

Vitamin A SerPI QN—Lavender is also an acceptable container

Vitamin B2 QN—light protect sample.

Vitamin B12 SerPI 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 SerPI/Bld QN

Warfarin SerPI/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 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!**

DATE: _____	NAME: _____	CLIENT ID# _____
CLIENT: _____		
ADDRESS: _____		
PHONE: _____	FAX: _____	

***Please indicate quantity based on unit of measure.

Collection Supplies

Tubes

- ____ 3ml Discard Tube – 100/pack
- ____ 6ml Gold With Serum Separator-100/pack
- ____ 6ml Red Vacutainer Tubes –100/pack
- ____ 6ml Gray Vacutainer Tubes – 100/pack
- ____ 4.5ml Light Green Vac Tubes100/pack
- ____ 6ml Green Na Hep Vacutainer 100/pack
- ____ 3ml Lavender Vac Tubes – 100/pack
- ____ 6ml Lavender Vacutainer Tubes –
- ____ *(Blood Bank Specimens)* - 100/pack
- ____ 4.5ml Light Blue Vac Tubes – 100/pack
- ____ 3ml Tan EDTA Vacutainer Tubes (each)
- ____ 6ml Royal Blue (K2 EDTA) (each)
- ____ 6ml Royal Blue (No Additive) (each)

****USE ONLY FOR METAL TESTS THAT REQUIRE SERUM**

- ____ 8.5 ml Yellow w/ ACD (each)
- ____ 5 ml Pearl Vacutainer Tube (each)
- ____ 6 ml No-Additive (for random urine) (ea)
- ____ Red Microtainer - 50/bag
- ____ Green Micro (Li Hep) – 50/bag
- ____ Gold Micro (SST) – 50/bag
- ____ Lavender Microtainer – 50/bag

Misc

- ____ Vacutainer Needles, 21g 1 ½ -100/box
- ____ Vacutainer Needle Safety Holders-25/pack
- ____ Butterfly 21g needles 50/pack
- ____ Butterfly 23g needles 50/pack
- ____ Butterfly Holder 250/bag
- ____ Tourniquets – 100/box

Power Chart Clients ONLY

- ____ Toner, H-P Laser jet 4200 (each)
- ____ Toner, H-P Laser jet 4250 (each)
- ____ Paper, 8.5x11 Printer (each)
- ____ Labels, 1 part Zebra (77001) (each)
- ____ Labels, 2 part Barcode - Manifest

Labels

- ____ Labels, 2-part Barcode (transfer list)

PAP Supplies

- ____ Thin Prep Kits
(Brushes, Vial, Spatula)-25/tray
- ____ Brooms for Thin Preps - 50/pack
- ____ Pap Smear Kits (Pap Packs) - 25/box
- ____ Pap Smear Fixative Spray (each)
- ____ Pap Smear Empty Transport Cont.-25

Pathology Supplies

- ____ Renal Biopsy Specimen Kits (each)
- ____ Dermatology Submission Supplies (ea)
- ____ DermPath Immunofloures Supplies(ea)
- ____ Prostate Biopsy Kits – 6 bottles (each)
- ____ Prostate Biopsy Kits – 12 bottles (each)
- ____ Formalin (30 ml) – 25/tray

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
- ____ DermPath Reqs(ea)
- ____ GI Path Reqs(ea)
- ____ Liver Path Reqs(ea)
- ____ Neuropath Reqs (ea)
- ____ Ophthalmic Path Reqs (ea)
- ____ Renal Path Reqs(ea)
- ____ Urologic Path (ea)
- ____ ABN Forms English (each)
- ____ ABN Forms Spanish (each)

MISCELLANEOUS Supplies

- ____ 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)
- ____ 24/hr Urine Jugs (each)
- ____ Urine Cup w/ Temp Strip -100/pack
- ____ Black screw cap tubes (for fluids) (each)
- ____ Aliquot tubes (each)
- ____ Fetal Fibronectin Kits (box of 8)
- ____ Glucola 50 Grams 6/pack
- ____ Glucola 75 Grams 6/pack
- ____ Glucola 100 Grams 6/pack
- ____ Salivary Cortisol Kits (each)
- ____ Sterile Cup (each)

Micro Supplies

- ____ Anaerobe Transp 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) (SPS tubes) (each)
- ____ Chocolate Agar
- ____ Culturette Swabs (**Routine**) (50/pkg)
- ____ Eye/Bordetella Cx(Amies Culturette (ea)
- ____ Fungus Bld/BM Cx (Isolator) (each)
- ____ GC Culture Kits (each)
- ____ GC/Chlam PCR (DNA Probe M&F)(ea)
- ____ Herpes Cx (Viral Transport Media) (each)
- ____ H. pylori screen (CLOE 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)

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 platelet poor plasma.

aPTT
 APC Resistance
 AT-III AG
 AT III Functional
 Chromogenic Factor X Assay
 CRRT aPTT
 D-Dimer PI QN
 DRVVT
 Factor II (2) Assay
 Factor V (5) Assay
 Factor VII (7) Assay
 Factor VIII (8) Assay
 Factor IX (9) Assay
 Factor X (10) Assay
 Factor XI (11) Assay
 Factor XII (12) Assay
 Factor XIII (13) Assay
 Factor V (5) Inhibitor Assay
 Factor VIII (8) Inhibitor Assay
 Factor VIII (8) Inhibitor-Porcine
 Factor IX (9) Inhibitor Assay
 Fibrinogen Ag
 Heparin Level
 Heparin Induced Ab
 Mixing Studies
 Plasminogen Inhib-1 Activity
 Plasminogen Inhib-1 Antigen
 Protein C Activity
 Protein C Antigen
 Protein S Clottable
 Protein S Antigen
 Protein S Antigen Free
 Reptilase Clotting Time
 STALA
 Thrombin-Antithrombin
 Thrombin Time
 Tissue Plasminogen Activator Ag
 vWF Activity Screen
 Von Willebrand Factor Antigen
 VW Multimeric Factor PI

Add Test Comment:

Spin and separate within 2 hours of collection.

Albumin SerPI QN
 Alkaline Phos serPI QN
 Alpha-1-Antitrypsin
 Amylase SerPI QN
 ASO
 AST SerPI QN
 Barbiturates Scn SerPI QL
 Benzodiaz Scn SerPI QN
 Bilirubin Direct SerPI QN
 Bilirubin Total SerPI QN
 BUN SerPI QN
 BUN Post SerPI QN
 BUN Pre SerPI QN
 C3 Complement Ser QN
 C4 Complement Ser QN
 Caffeine SerPI QN
 Calcium Total SerPI QN
 Carbamazepine SErPI QN
 Ceruloplasmin
 CO2 SerPI QN
 Chloride SerPI QN
 Cholesterol SerPI QN
 CK SerPI QN
 Creatinine SerPI QN
 CRP SerPL QN
 CRP High Sensitiv SerPI QN
 Digoxin SerPI QN
 Ethanol PI QN
 Free Light Chains Ser QN
 GGT SerPL QN
 Gentamicin Post SerPI QN
 Gentamicin Pre SerPI QN
 Gentamicin Ran SerPI QN
 Haptoglobin Ser QN
 HDL SerPI QN
 IgA Ser QN
 IgG Ser QN
 IgM Ser QN
 Immunoglobulin Profile
 Iron SerPI QN
 Iron TIBC Profile
 LDH SerPI QN
 LDL Measured SerPI QN
 Lipase SerPI QN

Add Test Comment:

Spin and separate within 2 hours of collection.

Lithium SerPI QN
 Magnesium SerPI QN
 Phenytoin SerPI QN
 Phosphorus SerPI QN
 Potassium SerPI QN
 Prealbumin Ser QN
 Pseudochol Pheno SerPI QN
 RF QN
 Salicylate SerPI QN
 Sodium SerPI QN
 Theophylline SerPI QN
 Total Protein SerPI QN
 Transferrin Ser QN
 Tricyclic Antid SerPI QN
 Triglyceride SerPI QN
 Troponin I PI QN
 Uric Acid SerPI QN
 Valproic Acid SerPI QN
 Vancomycin Post SerPI QN
 Vancomycin Pre SerPI QN
 Vancomycin Ran SerPI 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

General Guidelines for Hemostasis and Thrombosis

Specimen Collection Instructions: Hemostasis/Thrombosis Testing-Plasma Samples

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,
$$X = \text{amount of anticoagulant to remain in the tube:}$$
$$N = 0.5, 0.3, 0.2 \text{ mL of anticoagulant}$$
$$X = \frac{N(100 - \text{hct})}{55}$$
- 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 vial contents as PLASMA. **Glass vials will be rejected. Hemolyzed samples will be rejected.**
 - Quick-freeze the samples using a -70C freezer or a dry ice and methanol bath. **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

Test Name	Male or All	Female	Critical	Units
AT III Functional	86-118			%
AT-III AG	78-131			%
D-Dimer	<292			Ng/mL DDU
Factor II (2)Assay	79-138			%
Factor IX (9)Assay	65-150			%
Factor V (5)Assay	77-146			%
Factor VII (7)Assay	58-133			%
Factor VIII(8)-Assay	50-150			%
Factor X(10) Assay	77-151			%
Factor XI(11) Assay	65-150			%
Factor XII(12) Assay	50-150			%
Fibrinogen	193-489		< 70	mg/dL
Heparin Induced Ab	<0.400			OD
Protein C Functional (Activity)	80-138			%
Protein S Antigen	60-140			%
Protein S Antigen Free	68-147			%
Protein S Clottable (Functional)	80-153			%
Reptilase Clotting Time	14.5-20.3			sec
T4 Free Direct SerPI QN	0.6-1.5			ng/dL
Thrombin Time	10.8-17.7			sec
Vancomycin, Pre	10-15			mcg/mL
von Willebrand Factor Act Scr	40-126% Type O; 49-163% Non O			%
von Willebrand Factor Antigen	42-141% Type O; 66-176% Non O			%

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>