New Vision Medical Laboratories St. Rita's Medical Center Lima, Ohio Technical Procedure		Procedure Number: nvml.hem.043

Cytospin Preparation For Body Fluids in Hematology

This procedure is electronically produced, revised, monitored, reviewed and/or retired. For a full document history of initiation, revisions, and reviews with electronic signatures and dates, please open document in the procedure publishing software.

1. PRINCIPLE:

The Stat Spin Cytofuge uses a unique sample chamber assembly, which incorporates a plastic sample chamber, a filter card (blotter), a microscope slide, and a unique metal slide clip. When the fluid is centrifuged in the Stat Spin Cytofuge, the cells sediment onto the microscope slide as the suspension medium is simultaneously absorbed by the blotter. The result is a mono layer of preserved cells grouped within the area 6 mm in diameter on the microscope slide.

2. CLINICAL SIGNIFICANCE:

The differential results obtained from various fluid analyses are crucial for an accurate diagnosis of the disease process, or lack thereof. Please refer to the following procedures for specifics on the handling of fluid prior to making a cytospin slide: nvml.hem.020 CSF, nvml.hem.t.019 body fluid, nvml.hem.t.030 synovial fluid, nvml.hem.t.031 Eosinophil smear.

3. SPECIMEN:

A. COLLECTION AND PROCESSING:

Any body fluid can be used in the Stat Spin Cytofuge 2. Please refer to the following procedures for specifics on the handling of fluid prior to making a cytospin slide: nvml.hem.020 CSF, nvml.hem.t.019 body fluid, nvml.hem.t.030 synovial fluid, nvml.hem.t.031 Eosinophil smear. The specimen should be freshly collected and in a screw top plastic or glass container, or syringe with needle removed and cap in place.

B. REJECTION:

An unacceptable specimen would be one that is unlabeled or improperly labeled. For clotted samples or questionable samples consult with Pathologist.

C. STORAGE AND PRESERVATION:

Fluids should be processed immediately upon arrival to the lab or within two hours of collection. Fluids that have been processed are stored for several weeks in a lab refrigerator.

4. REAGENTS, STANDARDS, AND CONTROLS:

A. PREPARATION:

The approximate cell concentration of the specimen should be established prior to slide preparation for cytospin. Samples containing higher than optimal cell concentration will produce slides with cells too closely packed or overlapping. Samples containing too low a cell concentration will yield slides where cells are difficult to find, count, or examine.

To determine the amount of fluid to be used use the following guidelines:

1) **Clear fluid, 5-10 drops**
2) **Cloudy fluid,1-3 drops**
3) **Bloody fluid,5-10 drops of a 1:5 dilution**

5. EQUIPMENT:

A. INSTRUMENTS/SUPPLIES:

Stat Spin Cytofuge2
Filter Concentrators, Cytofuge
Hematology diluting fluid –stored at room temperature
Microscope slides
Microscope
Pipet
Hematology stain (Wright's stain)
Distilled water
Hyaluronidase(see synovial fluid procedure nvml.hem.t.030)

B. MICROSCOPIC EXAMINATIONS (AND REJECTIONS):

Slides may be rejected if cells are too closely packed or overlapping. Slides containing too low a cell concentration where cells are difficult to find, count, or examine.

6. PROCEDURE:

A. SPECIMEN PREPARATION:

1. LOW CELL VOLUME:

   a. Specimens received in large volumes and relatively few cells must be concentrated prior to use of the Cytospin.
   b. To sediment the cells, centrifuge the specimen at 2000 to 3000 RPM for 10-20 minutes. Avoid spinning at excessive speeds. For urine samples use the Urine select LW scientific centrifuge in the urinalysis department spin at 1800 rpm for 10 minutes.
   c. The clear supernatant above the cell button should be carefully poured off (do this step under the hood), leaving a volume of fluid approximately equal to the volume of the packed cell button.
   d. Vortex or gently agitate the tube to re-suspend the cells.
   e. Pipette appropriate volume of the concentrated sample to CytoFuge concentrators

2. HIGH CELL VOLUME:

   a. Specimens received with a cell suspension that is too high for the Cyto Spin need to be diluted.
   b. First the specimen needs to be evaluated for cell number, then diluted with Hematology diluting fluid so that the WBC count is less than 500/ul and RBC count is less than 5,000/ul.

Recommended dilutions are as follows:

WBC Count	Dilution
0-500	None
501-1000	1/2
1001-1500	1/3
1501-2000	1/4
2001-2500	1/5 ETC.

If the RBC count, which results from the above WBC dilution, is greater than 5,000/ul, calculate the further dilution necessary to bring the RBC count below 5000/ul. Use this dilution regardless of the fact that the WBC count may be very low.

B. CYTOSPIN PROCEDURE:

1. When a cell count analysis is ordered, a Diff slide must be prepared and read for every fluid with WBCs present. All fluid differentials must be reviewed by a pathologist.
2. Label 2 slides with specimen name, accession number and site

3. Making Cytospin slides

I. Assembly of filter concentrator

1. Unhinge plate.
2. Install sterile (flamed) slide.
3. Close unit, seal with filter concentrator clip.

II. Speed / Time Recommendations for hematology*:*

RPM RANGE	**TIME RANGE**
1600	8 minutes

III. Operation

a. Place assembled unit into the cytofuge rotor. Unit should tilt toward center of rotor. Balance with an identical unit (may be run without sample).
b. Add specimen to the bottom of the funnel (with diluent if used). Avoid getting droplets onto walls of funnel. Use care not to expose filter or slide to liquid before run. Do not overfill the unit – excess fluid will be spun out into rotor.
c. Screw lid onto rotor (finger-tight). Close centrifuge cover securely. Press START button to initiate preset run parameters.
d. When rotor stops, unlatch cover and remove rotor lid.
e. Remove Filter Concentrators while tilting the funnels forward to ensure that unabsorbed fluid, if present, does not wash cells from the slide.
For best results, remove slides immediately after spin cycle is complete.
f. Unlock the head lid and set aside.
g. Allow slides to air dry.
h. Stain with stain currently used in Hematology.

i. Count 100 cells to give a percentage of each type of WBC. Count only hematopoeitic cells, do not count cells definitely recognized as mesothelial cells, epithelial or malignant cells.
j. Record results in the LIS. All body fluid diffs shall be reviewed by the pathologist, with the exception of spinal fluid, which do not always have to be path reviewed. See nvml.hem.020 CSF. Do not release the differential results prior to pathologist review.
k. Store the fluid in refrigerator for two weeks in case additional tests are needed.
l. Retain stained slides for two weeks.

7. BACKUP FOR INOPERABLE SYSTEM

Use cytospin located in microbiology and remember to change the speed prior to centrifuging.

8. LIMITATIONS AND INTERFERRING SUBSTANCES:

The greatest limitations are due to the amount of cells present in the fluid. By using the recommended procedures and dilutions listed in this procedure, it is more likely to obtain a readable smear on the first attempt. Precipitate may be due to unclean slides, drying during the staining

9. METHOD VALIDATION:

Prior to 1992

10. REFERENCES:

1. Operator's Manual, Cytofuge2 Cytocentrifuge System, Model M801-22, 2003.
2. Henry, Clinical diagnosis and management by laboratory methods. 20th edition 2001, p. 502.
3. Kjeldsberg & Knight, Body Fluids, Laboratory examination of CSF,Seminal,Serous and synovial fluids, third edition,1993,p.321

Policy Approval:

Approved by Dr. Elsa K Malcolm - Laboratory Medical Director
3/16/2015 1:26:55 PM
Approved by Jamie S Lauf -
3/16/2015 1:45:25 PM

New Vision Medical Laboratories St. Rita's MedicalCenter Lima, Ohio Technical Procedure	New Vision Medical Laboratories	Procedure Number: nvml.ua.001b Myoglobin

This procedure is electronically produced, revised, monitored, reviewed and/or retired. For a full document history of initiation, revisions, and reviews with electronic signatures and dates, please open document in the procedure publishing software.

SUBJECT: MYOGLOBIN, URINE

1. **PRINCIPLE:** See urinalysis procedure for urine hemoglobin by dipstick.

2. **CLINICAL SIGNIFICANCE:**
Patients with urine myoglobin greater than 15 mg/L are at risk of acute renal failure. Usual results are less than 1 mg/L. Results between 1 and 15mg/L are associated with vigorous exercise, myocardial infarct, mild muscle injury and other conditions.

3. **SPECIMEN:**
Random or 24 hour urine.

4. **REAGENTS, STANDARDS, AND CONTROLS:**
See urinalysis procedure.
When necessary, the urine pH is adjusted to 8-9 with 10% Na2CO3. This solution is prepared by dissolving 10gm of Na2CO3 in 100ml di H2O.

5. **EQUIPMENT:**
Atlas or Advance.

6. **PROCEDURE:**
Test must be ordered in LIS as MYO. This is a group test. The mneumonic that you will see upon resulting is UHGB3.
Test the specimen for urine hemoglobin. If the result is:
   A. Negative, use the keypad to answer UHGB3 "negative @FTNN" (Negative, further testing not necessary.) If the test is negative, no further actions are necessary.
   B. Positive, use the keypad to answer UHGB3 "positive @MYOG" (Positive, sent to reference lab for myoglobin.) The tests MYOU2 and MYOPH will be reflex ordered by the LIS when the test is answered with this result. If the urine hemoglobin is positive, the specimen must be prepared to send to ARUP laboratories by adjusting the pH in preparation for shipment.
      1.Answer 1STPH with the initial pH as measured by the urine analyzer when performing the hemoglobin test.
      2. Adjust the specimen pH to 8-9 by adding 10%Na2CO3.
      3. Answer test ADJPH with the adjusted pH value.
      4. Freeze 4.5ml adjusted pH urine in a standard ARUP transport tube. (Minimum volume 1 ml.) Please record final urine pH on label.

10% Na2CO3 is prepared by dissolving 10gm Na2CO3 in 100ml di H2O.

7. **QC PERFORMANCE POLICY:**
See urinalysis procedure.

8. **EXPECTED RESULTS:**
Usual results are less than 1 mg/L.
MYOU2 is an interfaced test. It will be answered and verified when ARUP transmits the results.

9. **LIMITATIONS AND INTERFERING SUBSTANCES:**
Myoglobin is very unstable in urine unless the pH is between 8 and 9.
More information may be found at ARUP laboratories website. Myoglobin is ARUP test #0020223.

10. **METHOD VALIDATION:**See urinalysis procedure.

11. REFERENCES: See urinalysis procedure. Also ARUP laboratory website.

Policy Approval:

Approved by Dr. Elsa K Malcolm - Laboratory Medical Director
3/16/2015 12:07:21 PM
Approved by Jamie S Lauf -
3/16/2015 12:12:32 PM

This procedure is electronically produced, revised, monitored, reviewed and/or retired. For a full document history of initiation, revisions, and reviews with electronic signatures and dates, please open document in the procedure publishing software.

SUBJECT: MASSIVE TRANSFUSION POLICY

POLICY: Massive Transfusion may be defined as an emergency situation in which a the replacement of a patients entire blood volume in 24 hours(10-12 units of packed red cells) or replacement of 50% of patients blood volume in three hours(5-6 units of packed red cells). A delay in receipt of a patient specimen may occur until the patient is "stabilized". Blood products may be issued before a specimen is received. However, only blood group O, Rh negative RBC's may be issued until the patients' blood type has been determined by the Blood Bank.

SUPPLIES:

Massive Transfusion Worksheet
"Crossmatch Not Complete" labels
Patient Identification Blood Bank band
Blank labels
Blood Bank Cooler with bag of ice
Leuko-reduced packed red cells(LRC)
Fresh Frozen Plasma(FFP)
Leuko-reduced pheresed platelet(LPH)

PROCEDURE:

A. The Blood Bank staff will be notified to begin the Massive Transfusion Policy by telephone. A PHYSICIAN MUST ORDER THIS.
   1. Call will be made to Blood Bank trauma phone at ext 9220
   2. ED responsibility is Primary nurse or Trauma Recorder
   3. OR responsibility is Primary Circulating nurse
   4. During off shifts laboratory will assign a second tech in Blood Bank for the duration of the Massive Transfusion situation.

B. The worksheet will be found in the Stat drawer.

C. The following information will be written on the worksheet:
   1. The date, time and name of ordering physician
   2. Name of patient
   3. Sex of patient
   4. Probable diagnosis

5. MR # of patient
6. Tech receiving the orders

D. Immediately prepare 5 units of O negative leuko-reduced red cells. Place bar coded label on the worksheet. Reserve segment with a bar code label. Ship units through the pneumatic tube system to the ED. Ship them two units at a time. Both the red line and the blue line can be used. The units will be placed in the ED cooler. If the patient is in OR the Colombo Surgery line may be used and four units may be sent at a time. Thaw 5 units of type AB Fresh Frozen plasma (FFP). Write the donor numbers on the worksheet. Ship them to the ordering department where the patient is located when thawed, (25 minutes). This is considered the first set. ** If units must be sent to a location other than ED, Surgery or Labor and delivery we will need to ensure they have procured the proper cooler and they are storing the products appropriately.

E. The second set contains 5 units of O negative leuko-reduced red cells and 5 units of AB FFP unless the type is known. If the type is known, use type specific leuko-reduced red cells and FFP. In addition to those, it will also contain 1 Leuko- reduced pheresed platelet (LPH). If none are available, get one from LMH or the ARC. All donor numbers will be written on the worksheet.

F. Keep those amounts ahead. (5 LRC, 5 FFP, and 1 LPH). If any of the products are used, replace it. Once the patient's type is available, switch to type specific products.

G. The physician must still sign the Emergency Blood Release Form.

H. On the Worksheet list the donor #, time of issue, who you issued the unit to, product, and location

I. Downtime Transfusion Records are not used. The worksheet will be filled in with product information. This will be copied and sent with the units. The nurse will fill in the information for each unit, time started and stopped, nurse's signature, whether there was a reaction, and amount given.

J. The blood bank will print a transfusion record on the REC Report printer as time permits to enter the issue in the computer.

K. When a patient receives 10 units of blood in 24 hours or 5-6 units within three hours, certain lab tests should be considered. These include a Protime, a PTT, a platelet count, and a fibrinogen.

1. FFP should be recommended if the INR is >1.7 or the PTT is >45.0.
2. Platelets should be considered if there is active bleeding and the platelet count drops below 100,000 or less than 50,000 for non-active bleeding.
3. Cryoprecipitate: should be recommended if the fibrinogen is <100mg/dl.

L. The results of the lab test will be compiled by Blood Bank. If the results meet any of the thresholds stated above, the BB will notify the

pathologist.

M. The pathologist will confer with the primary physician to determine if the replacement therapy is needed.

REFERENCES:

1.Massive Transfusion in Trauma Guidelines. American College of Surgeons Trauma Quality Improvement Program. 2013

2. Resources for Optimal Care of the Injured Patient. Committee on Trauma - American College of Surgeons © 2014.

3. TQIP: Best Practice Lectures – Massive Transfusion. American College of Surgeons ©2013.

St. Rita's Medical Center
Lima, OH

MASSIVE TRANSFUSION WORKSHEET
4256788

Patient's Name_____ Sex_____ Diagnosis_____

Ordering Physician _____ MR Number_____Date_____ Time_____ Tech_____

Donor #	Product	Nurse Signature	Start Time	Stop Time	Ward	Reaction	Amt given
	1-LRC				ED /OR	Y / N	
	2-LRC				ED /OR	Y / N	
	3-LRC				ED /OR	Y / N	
	4-LRC				ED /OR	Y / N	
	5-LRC				ED /OR	Y / N	
	1-FFP				ED /OR	Y / N	
	2-FFP				ED /OR	Y / N	
	3-FFP				ED /OR	Y / N	
	4-FFP				ED /OR	Y / N	
	5-FFP				ED /OR	Y / N	
	1-LPH				ED /OR	Y / N	

BLOOD BANK-Fill out paper, copy and send with blood product
NURSING-Fill out section for each unit transfused; copy; return to blood bank g:\formsbb\special\massive version 1.0 Effective 3.16.2009

Original – Blood Bank Copy – Chart

Policy Approval:

Approved by Samuel A Schroeder -
3/4/2015 12:27:31 PM
Approved by Thomas J Geis - Operations Manager NVML
3/4/2015 1:21:15 PM
Approved by Dr. Elsa K Malcolm - Laboratory Medical Director
3/5/2015 9:53:59 AM
Approved by Michael T Sheehan - Trauma Services Medical Director
3/9/2015 12:05:52 PM
Approved by Dr. Elsa K Malcolm - Laboratory Medical Director
3/16/2015 1:35:02 PM
Approved by Dr. Matt T Kuhn - Blood Bank Director
3/17/2015 11:20:38 AM

New Vision Medical Laboratories St. Rita's Medical Center Lima, Ohio Technical Procedure		Procedure Number: Procalcitonin Nvml.chem.t.382 Procalcitonin

This procedure is electronically produced, revised, monitored, reviewed and/or retired. For a full document history of initiation, revisions, and reviews with electronic signatures and dates, please open document in the procedure publishing software.

SUBJECT: PROCALCITONIN

1. PRINCIPLE:

The assay principle combines a one-step immunoassay sandwich method with a final fluorescent detection (ELFA).

The solid phase receptacle (SPR), serves as the solid phase as well as the pipetting device. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.

All of the assay steps are performed by the instrument. The sample is transferred into the wells containing anti-procalcitonin antibodies labeled with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in an out of the SPR several times. This operation enables the antigen to bind with the immunoglobulins fixed to the interior wall of SPR and the conjugate to form a sandwich. Unbound compounds are eliminated during the washing steps.

Two detection steps are performed successively. During each step, the substrate (4-Methyl-umbellifery phosphate) is cycled in and out of the SPR. The conjugated enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone). The fluorescence of which is measured at 450 nm. The intensity is proportional the concentration of the antigen.

At hew end of the assay, results are calculated by the instrument in relation to two calibration curves corresponding to the two detection steps. A fluorescence threshold value determines the calibration curve to be used for each sample. These results are then displayed.

2. CLINICAL SIGNIFICANCE:

Procalcitonin is the prohormone of calcitonin. Whereas, calcitonin is produced only in the C cells of the thyroid gland as a result of hormonal stimulus, procalcitonin is secreated, by different types of cells from numerous organs in response to pro-inflammatory stimulation, particularly from bacterial stimulation. Depending on the clinical background, a PCT concentration of 0.1 ng/ml can indicate clinically relevant bacterial infection requiring antibiotic treatment. At a concentration of >0.5 ng/ml, a patient should be considered at risk of developing severe sepsis or septic shock.

Sepsis is an excessive reaction of the immune system and coagulation system to and infection. The diagnosis and monitoring of infected patients are a major problem for physicians. It has been proven that PCT levels increase precociously, specifically in patients with bacterial infections. PCY is therefore an important marked enabling specific differentiation between a bacterial infection and other causes of inflammatory reactions. Moreover, the resorption of the septic infection is accompanied by a decrease in the PCT concentration which returns to normal with a half-life of 24 hours.

In certain situations (newborns, polytrauma, burns, major surgery, prolonged or severe cardiogenic shock, ect.) PCT elevations may be independent of any infectious aggression. The return to normal is usually rapid. Viral infections, allergies, autoimmune diseases and graft rejections do not lead to a significant increase in PCT. A localized bacterial infection can lead to moderate increase in PCT levels.
The evaluation of theVidas BRAHMS PCT assay results must always be performed taking into consideration the patient's history and the results of any other tests performed.

3. SPECIMEN:

A. COLLECTION AND PROCESSING:

Acceptable samples are serum and lithium heparin plasma. Minimum amount of sample needed is 250 ul. for one run.

B. REJECTION:

EDTA samples are not to be used. Hemolyzed sample should be recollected unless no other sample can be provided. Results are not effected by hemolysis up to a concentration of 347 umol/L.

C. STORAGE AND PRESERVATION:

Serum or plasma samples can be stored at 2-8° C for up to 48 hours. Frozen for 6 months at -25C. Room temperature sample are stable for 8 hours after collection.

4. REAGENTS, STANDARDS, AND CONTROLS:

A. PREPARATION:

The reagents for the test are in the form of a kit. The "PCT" strip and the "PCT" SPR are ready for immediate use. The Calibrators provided are, 2 levels (S1 & S2). Reconstitute with 2 ml. of dH2O and wait for 5-10 minutes. Aliquot the unused portion of the bottle into tubes with 0.5 ml per tube and freeze. Calibration in duplicate requires 400 uL. The controls provided are 2 levels (C1 & C2). Reconstitute with 2 ml. of dH2O and wait 5-10 minutes. The controls are stable 8 hours at room temperature. Any remaining control needs to be aliquoted and frozen. Deliver 225 uL to each tube of control to be frozen. Testing required 200 uL for analysis. Make 8 aliquots for each 2 ml bottle of control.

B. CONTROL PROCEDURE:

Two levels of control must be performed each day patient testing occurs. Run both C1 & C2.

5. EQUIPMENT:

A. INSTRUMENTS: Mini Vidas

B. MICROSCOPIC EXAMINATIONS (AND REJECTIONS): N/

Not Applicable

6. PROCEDURE:

A. PERFORMANCE:

Prior to any patient testing, the master lot information for the reagent lot must be entered into the Mini Vidas by use of the MLE data card. Print and save the mini Vidas Report provided by the instrument when successfully completed.

Perform the calibration of the new lot running the calibrators provided in duplicate. Save this calibration report provided by the Vidas for test history. When entering calibration samples into the Vidas, select S1 for level 1, S2 for level 2.

Perform the controls after a successful calibration to ensure proper test performance. Perform the Quality Control in

duplicate when a new lot of procalcitonin kit is opened prior ro be put into use. Acceptable control ranges will print on the mini Vidas calibration report. Use these ranges to evaluate test performance. Enter these Quality Control results into the LIS QC program. When entering control information into the Vidas, select C1 for Control 1 and C2 or Control 2

PATIENT TESTING:

Remove one (SPR) and one reagent strip for each patient, control or calibrator needed. Use these reagents immediately when removed from the refrigerator. Place the SPR into the analyzer. Label each reagent strip with the sample identifier and pipet 200 ul into each of the reagent strips. Place the sample in the first well of the strip. Place these strips on the analyzer and then properly program the Vidas for each sample. Press start when done programing. One can use either side A or side B on the Vidas.

The printed report from the Vidas will identify each sample ID and position on the analyzer. The result will printed in bold letters. Report these results if QC is acceptable and no error codes exist.

Dispose of the used strips and SPR into a biohazard container.

B. CALCULATIONS: None

C. INTERPRETATION OF RESULTS:

Procalcitonin is available to aid in the assessment of bacterial infections and promote antimicrobial stewardship. Thirty to fifty percent of inpatient antimicrobial use is inappropriate causing drug toxicity, drug resistance and C. difficile colitis. Procalcitonin is a dynamic biomarker of bacterial infection and a useful adjunct to assess bacterial infection and response to antimicrobial therapy. The serum concentrations are elevated in clinically relevant bacterial infections and rise with increasing severity of disease or decline with response to treatment. Therefore serial measurements are suggested for greatest utility. However, as an expression of individually different immune responses and different clinical situations, the same focus of infection may be associated with varying individual elevations in PCT concentrations.

PCT levels may not always be elevated because of bacterial infection. Other things which may elevate PCT include:

A. Neonates < 48 hours of life

B. Within the first days of a major trauma, major surgical intervention, severe burns, treatment with OKT3 antibodies and other drugs stimulating the release of pro-inflammatory cytokines

C. Patients with invasive fungal infections and acute attacks of plasmodium falciparum malaria

D. Patients with prolonged or severe cardiogenic shock, prolonged severe organ perfusion abnormalities, small cell lung cancer, medullary C-cell carcinoma of the thyroid

Low PCT levels do no exclude a bacterial infection. Low levels may be seen early in the course of infection as well as in localized infections and in sub-acute endocarditis. This is why using serial PCT levels as well as clinical suspicion should drive treatment.

Clinicians should always use PCT results <u>in conjunction</u> with other patient characteristics, including laboratory values and signs and symptoms within each patient's present clinical context to determine antimicrobial therapy.

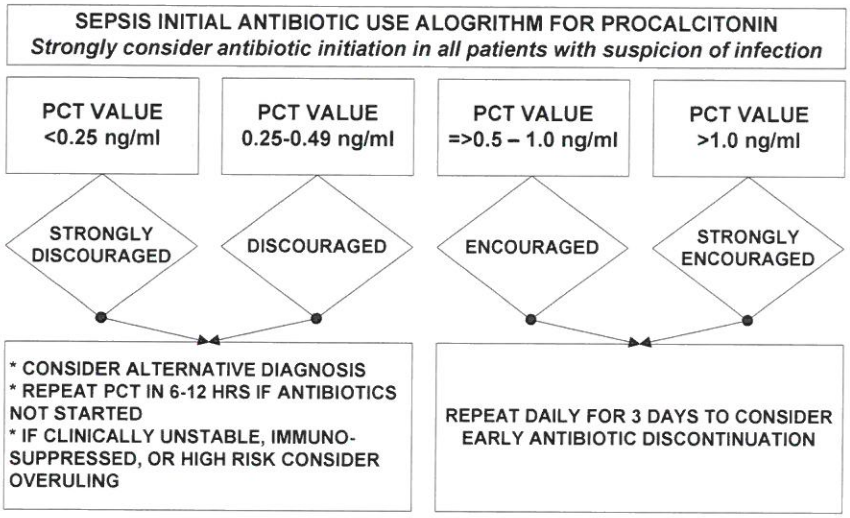
<u>CarePath Procalcitonin (PCT) Labtest # 6142</u>
<u>Normal Reference Range</u>: 0.05-0.09 ng/ml (i.e. <0.1 ng/ml)

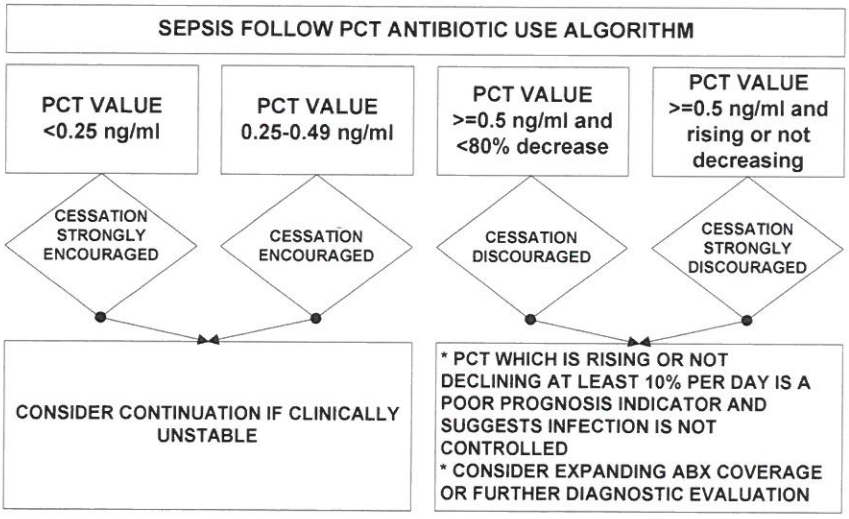
<u>Suspected Lower Respiratory Tract Infections</u>

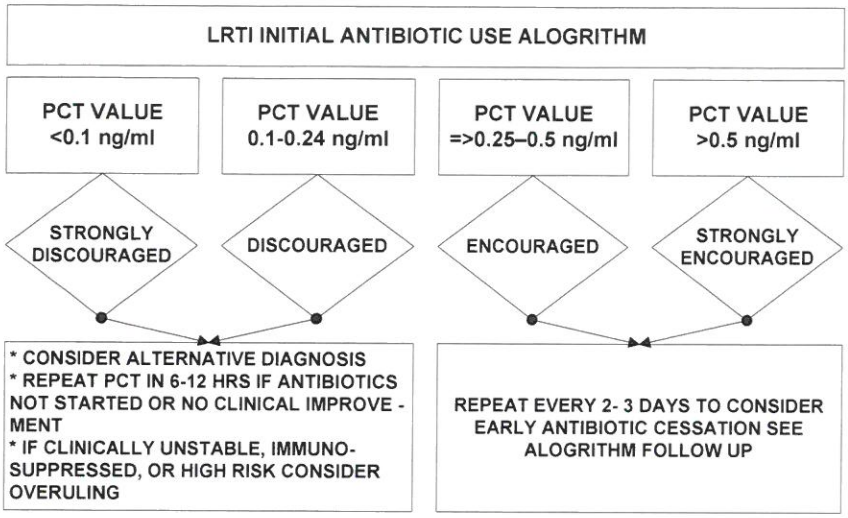
0.1-0.49 ng/ml - Low likelihood of bacterial infection: Antibiotics discouraged
>= 0.25 ng/ml -Increased likelihood of bacterial infection: Antibiotics encouraged

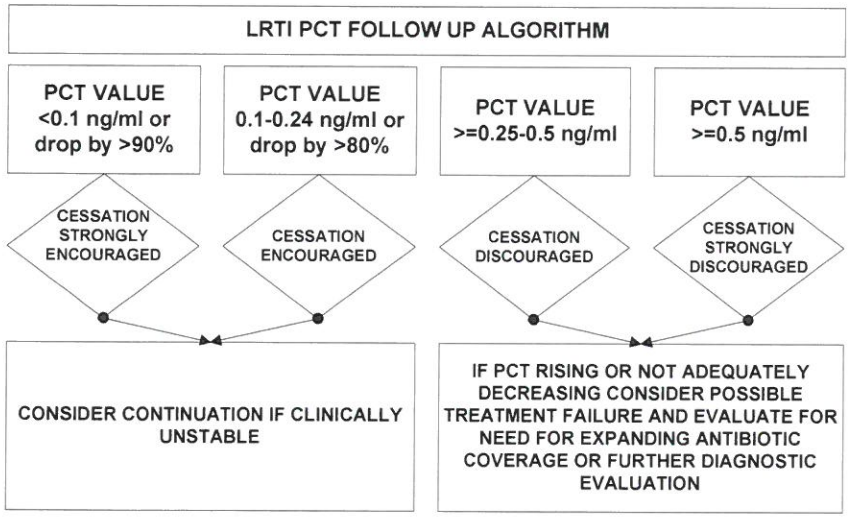
Suspected Sepsis: Strongly Consider antibiotics in all unstable patients
0.1- 0.49 ng/ml - Low likelihood of sepsis: Antibiotics discouraged
>= 0.5 ng/ml - Increased likelihood sepsis: Antibiotics encouraged
>2.0 ng/ml - High Risk of sepsis/shock: Antibiotics strongly encouraged

If antibiotics are administered, repeat procalcitonin testing should be obtained every 2-3 days to consider early antibiotic cessation. PCT is a dynamic biomarker and most useful when trends are analyzed over time in accompaniment with other clinical data. Interpretation should be based upon clinical context and algorithms. See below algorithms for initial and serial PCT measurements for sepsis and lower respiratory tract infections.






LRTI INITIAL ANTIBIOTIC USE ALOGRITHM
PCT VALUE <0.1 ng/ml
PCT VALUE 0.1-0.24 ng/ml
PCT VALUE =>0.25–0.5 ng/ml
PCT VALUE >0.5 ng/ml
STRONGLY DISCOURAGED
DISCOURAGED
ENCOURAGED
STRONGLY ENCOURAGED
* CONSIDER ALTERNATIVE DIAGNOSIS
* REPEAT PCT IN 6-12 HRS IF ANTIBIOTICS NOT STARTED OR NO CLINICAL IMPROVE - MENT
* IF CLINICALLY UNSTABLE, IMMUNO-SUPPRESSED, OR HIGH RISK CONSIDER OVERULING
REPEAT EVERY 2- 3 DAYS TO CONSIDER EARLY ANTIBIOTIC CESSATION SEE ALOGRITHM FOLLOW UP


LRTI PCT FOLLOW UP ALGORITHM
PCT VALUE <0.1 ng/ml or drop by >90%
PCT VALUE 0.1-0.24 ng/ml or drop by >80%
PCT VALUE >=0.25-0.5 ng/ml
PCT VALUE >=0.5 ng/ml
CESSATION STRONGLY ENCOURAGED
CESSATION ENCOURAGED
CESSATION DISCOURAGED
CESSATION STRONGLY DISCOURAGED
CONSIDER CONTINUATION IF CLINICALLY UNSTABLE
IF PCT RISING OR NOT ADEQUATELY DECREASING CONSIDER POSSIBLE TREATMENT FAILURE AND EVALUATE FOR NEED FOR EXPANDING ANTIBIOTIC COVERAGE OR FURTHER DIAGNOSTIC EVALUATION

7. **QC PERFORMANCE POLICY:**
   A. CALIBRATION AND CALIBRATION VERIFICATION

   Perform every six months using AUDIT Microcontrols Linearity / Calibration Verification material

   B. FAILURE/REMEDIAL ACTION:
   Unacceptable QC results should be entered in to the computer along with appropriate actions taken.
   2. Various corrective actions include:
      a. Check reagent expiration dates and check for proper storage conditions.
      b. Rerun QC (use same reagent).
      c. Calibrate and run freshest control material
      d. Open new reagent and run qc
      e. Call hotline for assistance and document actions taken
      f. Inform a Technical Specialist

8. **EXPECTED RESULTS:**
   A. ANALYTICAL MEASUREMENT RANGE: <0.05 – 200 ng/ml. No dilutions to be performed.

   CLINICAL REPORTABLE RANGE: <0.05 – 200 ng/ml

   B. REFERENCE RANGE: <0.05 – 0.09
   Results of 0.10 or high will flag as HIGH in the LIS.

   C. CRITICALVALUES: None Stated

9. **REPORTING RESULTS:**
   A. NORMAL VALUES: ≤ 0.05 – 0.09 ng/ml

   B. CRITICAL VALUES: None Stated

10. **PROCEDURAL NOTES:**
    A. BACKUP FOR INOPERABLE SYSTEM
    Send to ARUP for testing.

    B. REFERAL OF SPECIMENS: N/A

C. SUBMISSION/HANDLING OF REFERRAL SPECIMENS:

Separate serum or plasma from the cells within 2 hours. Refrigerate the sample. Stable 5 days at 2-8°C

11. LIMITATIONS AND INTERFERRING SUBSTANCES:

The following compounds do not affect procalcitonin at tested concentrations:

Protein	Human calcitonin
Human Katacalcin	Human a-CRGP
Human b-CRGP	Imipenem
Cetotaxime	Vancomycin
Dopamine	Noradrenalin
Dobutamine	Heparin
Furosemide	

12. METHOD VALIDATION:

- This test was validated by means of startup studies (on file). Subsequent validation is by virtue of QC and CAP surveys and linearity materials.

References:

1.http://www.nebraskamed.com/app_files/pdf/careers/education-programs/asp/pct-slides.pdf
2.Prkno Anna, Wacker Christina, Brunkhorst Frank M, and Schlattmann Peter. Procalcitonin-guided therapy in intensive care unit patients with severe sepsis and septic shock- a systemic review and meta-analysis. *Critical Care* 2013, 17:R291
3.Schuetz Philipp, Amin Devendra and Greenwald Jeffrey. Role of Procalcitonin in Managing Adult Patients with Respiratory Tract Infections. *Chest* 2012; 141; 1063-1073.
4.Fouschee Jaime, Hope Nancy and Grace Edward. Applying biomarkers to clinical practice: a guide for utilizing procalcitonin assays. *J of Antimicrob Chemother* 2012;67:2560-2569.
5.Hohn A, Schroeder S, Gehrt A, Bernhardt K, Bein B, Wegscheider K, and Hochreiter M. Procalcitonin-guided algorithm to reduce length of antibiotic therapy in patients with severe sepsis and septic shock. *BMC Infectious Diseases* 2013, 13:158.
6. Vidas B-R-A-H-M-S PCT product insert. 30 450-01. Vidas analyzer operator's manual.