

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX *poch-100i* Analyzer

Kaiser Permanente
 Medical Care Program
 California Division – South
 SCPMG Laboratory Systems
 Process Control
 Procedure

Clinical Significance

- The accurate assessment of fetal lung maturity can be extremely important in the treatment of complicated pregnancies.
- Respiratory distress syndrome (RDS) is a dire consequence of premature delivery.
- Laboratory analysis of amniotic fluid can predict susceptibility to RDS. Lamellar bodies are concentrically layered, phospholipids-filled vesicles which represent the storage form of surfactant.
- They are released by mature fetal respiratory epithelium into the amniotic fluid that is respired *in utero*.

Principle

- Lamellar body diameter (1 – 5 μm) is similar to that of small platelets. Lamellar body counts (LBCs) can be obtained rapidly with the use of the platelet channel of Sysmex *poch-100i* analyzer.
- The Sysmex *poch-100i* is a quantitative automated hematology analyzer for *in vitro* diagnostic use.
- The *poch-100i* counts the platelets (PLT) using electronic resistance detection and hydrodynamically focused technology.
- Sample is aspirated, measured to a predetermined volume, diluted at the specified ratio, then fed into each transducer.
- The transducer chamber has a minute hole called the aperture.
- Inside the detector, the sample nozzle is positioned in front of the aperture and in line with the center.
- After diluted sample is forced from the sample nozzle into the conical chamber, it is surrounded by front sheath reagent and passes through the aperture center.
- On both side of the aperture, there are the electrodes between which flows direct current.
- PLT suspended in the diluted sample pass through the aperture, causing direct current resistance to change between the electrodes.
- As direct current resistance changes, PLT volume is detected as electrical pulses.
- PLT count is calculated by counting the pulses, and a histogram is plotted by determining the pulse heights.

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

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Work place safety

- All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures.
- For standard precautions and safety practices in the laboratory; see LGM 8000, specifically, but not limited to, equipment safety, proper body mechanics, sharps exposure and proper use of personal protective equipment (PPE).
- For Universal Body Substance precautions, see LGM 8005, specifically, but not limited to, exposure to body fluids.
- For proper hand-washing, see LGM 8010, specifically, but not limited to, proper hand-washing.
- For proper infection control, see LGM 8004, specifically, but not limited to, proper use of gloves.
- For proper handling of regular and infectious waste, see LGM 8006, specifically, but not limited to proper disposal of regular and biohazardous waste.
- For proper cleaning of work area, see LGM 8007 - Cleaning Work Areas.
- For proper handling of chemicals and reagents, see the Chemical Hygiene Plan.

Clinical Decision Point

- CDP = 65,000 / μ L.
- All LBC >65,000 / μ L to be reflexed for confirmatory phospholipid analysis (LS & PG) by TLC (Thin Layer Chromatography).

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued

Specimen Requirement
 The following are the specimen requirements for the procedure.

Specimen	Required Volume	Minimum Volume
<ul style="list-style-type: none"> • Amniotic fluid • Vaginal pool without obvious mucus 	10 mL	3.0 mL

Unacceptable Specimen:
 The following amniotic fluid samples are unacceptable for Lamellar Body testing:

- Bloody (with >5% RBC)
- Mucoid & Gelled specimen
- Contaminated with Meconium
- Vaginal Pool containing obvious mucus

Materials Needed

Equipment	Supplies
<ul style="list-style-type: none"> • Sysmex poch-100i Analyzer • Vortex • Tube Mixer 	<ul style="list-style-type: none"> • Thermal Paper • Transducer brush • Phillips Screwdriver • 12 X 75 mm glass test tubes • Disposable transfer pipettes • Kimwipes • Beige adapter (for sample tubes) • Green adapter (for QC vials)

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

Controls and Calibrator The following tables list the controls and calibrator used in this procedure, their preparation, storage, and stability.

Product	Preparation	Storage	Expiration
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SYSMEX SCS-1000 Calibrator Kit	Ready to Use	Store at 2-8°C before and after opening.	Unopened calibrators are stable until the expiration date shown on the vial. Once opened, the product is stable for 4 hours if returned to the refrigerator promptly after use.
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Eightcheck 3WP X-TRA Control Set	Ready to Use	Store at 2-8°C before and after opening.	Unopened controls are stable until the expiration date shown on the vial. Once opened, the product is stable for 14 days if returned to the refrigerator promptly after use.
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Amniotic Pool Positive Control	Pool previously tested amniotic fluid (AF) samples. Run the pool on poch-100. Use negative AF samples from Genetics Lab. + previously tested LBC samples and adjust the concentration to ~70,000 /µL. Aliquot 2 mL each into a screw- capped plastic tube.	Store Refrigerate At 2-10°C	Stable 6 months
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Amniotic Pool Negative Control	Pool negative AF samples from Genetics Lab to obtain a concentration of < ~3,000 /µL. Aliquot 2 mL each into a screw- capped plastic tube.	Store Frozen	Stable 6 months
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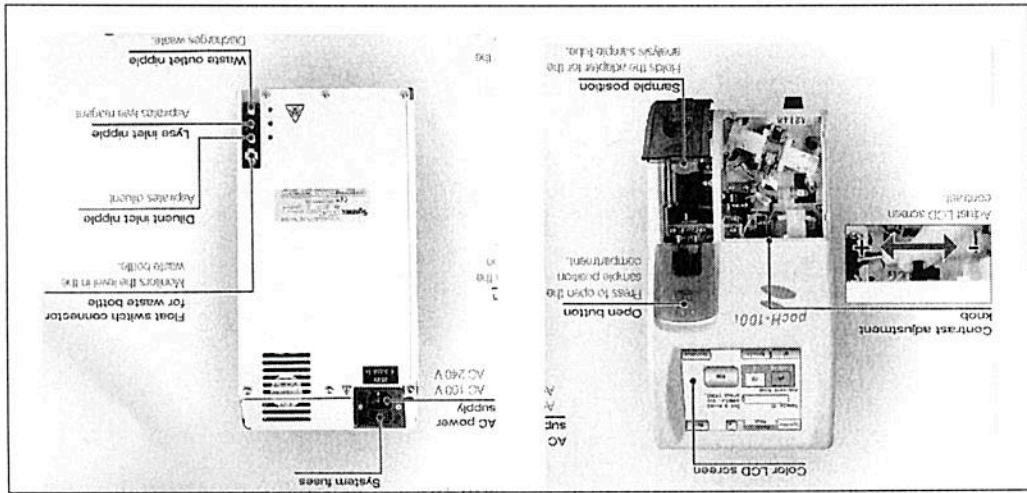
Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued

Reagents
 The following tables list the reagents used in this method, their preparation, storage, and stability.

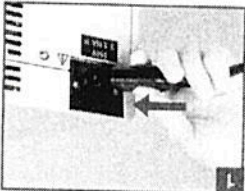
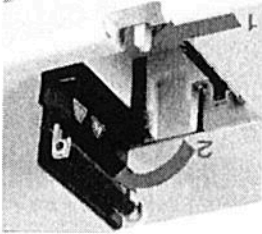
Reagent	Preparation	Storage	Expiration
poch-pack D (Diluent)	Ready to Use	Room Temp.	<ul style="list-style-type: none"> • Unopened packs are stable for 1 year. • Once opened, reagent is stable for 60 days.
poch-pack L (Lysing Reagent)	Ready to Use	Room Temp.	<ul style="list-style-type: none"> • Unopened packs are stable for 1 year. • Once opened, reagent is stable for 90 days.
Bleach (5%)	Ready to Use	Room Temp.	<ul style="list-style-type: none"> • Use fresh daily.

System Overview

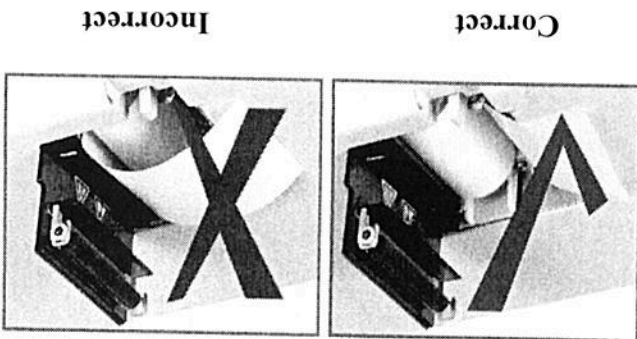
Parts of Sysmex poch-100i Analyzer



Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued

<p>Step 1</p>	<p>Action</p> <ul style="list-style-type: none"> • Verify the following before powering on: <ul style="list-style-type: none"> • Check that the power cable is connected. 
<p>2</p>	<ul style="list-style-type: none"> • Check that there is sufficient printer paper, replace if needed.  <ol style="list-style-type: none"> 1. Open the paper holder by pushing the knob. 2. Lift the printer cover.
<p>3</p>	<ul style="list-style-type: none"> • Check waste fluid in waste container, discard if needed.
<p>4</p>	<ul style="list-style-type: none"> • Check and replace reagents if needed.

Startup
Procedures



1. Open the paper holder by pushing the knob.
2. Lift the printer cover.

• Check that there is sufficient printer paper, replace if needed.

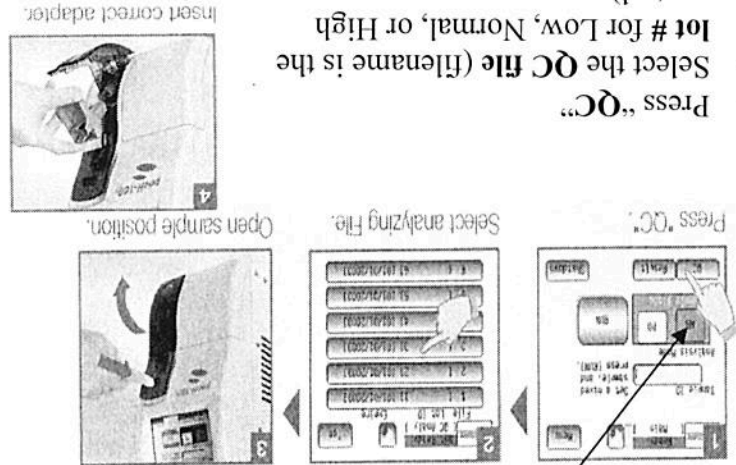
- Verify the following before powering on:
 - Check that the power cable is connected.

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

Step	Action						
1	<ul style="list-style-type: none"> • Switch power on by pressing the power switch located on the right side of the instrument. • Three automatic rinse cycles are performed and then a background check. • Should any values be out of the acceptable limit, a maximum of two extra background checks will automatically be performed by instrument 						
2	<ul style="list-style-type: none"> • Review results of background check. <table border="1" data-bbox="324 420 1055 787"> <thead> <tr> <th data-bbox="324 420 722 472">If...</th> <th data-bbox="324 472 722 525">Then...</th> </tr> </thead> <tbody> <tr> <td data-bbox="324 525 722 577">PLT count is $10 \times 10^3 /\mu\text{L}$ or less</td> <td data-bbox="324 577 722 787"> <ul style="list-style-type: none"> • print & record the result on the daily PM chart. • proceed to running controls </td> </tr> <tr> <td data-bbox="324 577 722 630">PLT count is higher than $10 \times 10^3 /\mu\text{L}$</td> <td data-bbox="324 630 722 787"> <ul style="list-style-type: none"> • perform another cycle of Auto Rinse. • if still outside the limits, refer to Section 6 page 71 of the Instruction Manual for more troubleshooting guidance • once background reading is within limits, proceed to running controls. </td> </tr> </tbody> </table>	If...	Then...	PLT count is $10 \times 10^3 /\mu\text{L}$ or less	<ul style="list-style-type: none"> • print & record the result on the daily PM chart. • proceed to running controls 	PLT count is higher than $10 \times 10^3 /\mu\text{L}$	<ul style="list-style-type: none"> • perform another cycle of Auto Rinse. • if still outside the limits, refer to Section 6 page 71 of the Instruction Manual for more troubleshooting guidance • once background reading is within limits, proceed to running controls.
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3	<ul style="list-style-type: none"> • To print results of background check (also referred to as Blank check), <ul style="list-style-type: none"> • press “Menu” • press “Str. Data” • then select the file “Blank check” • results can first be viewed on screen by using the → or ← arrow. • then press “Print” <div data-bbox="324 504 1055 787"> </div>						

Power On/
 Self Check

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued

Step	Action
1	<ul style="list-style-type: none"> • Run 1 set of EIGHTCHECK Control (Low, Normal, and High) on each day of instrument use. • Remove control vials from the refrigerator at least 15 minutes before use. • Roll 10 times, Turn upside down 10 times, then Roll again for another 10 times. • Examine vial bottom. If there is red cell pellet still formed on the bottom, then repeat the whole mixing procedure!
	<ul style="list-style-type: none"> • Include Amniotic Pool Positive & Pool Negative controls with every run of patient sample. • Negative Pool control is stored frozen. Thaw at least 30 minutes before use to bring to room temperature. • Positive pool control is stored in the refrigerator, bring to room temperature before use. • Vortex well before running.
4	<ul style="list-style-type: none"> • To run QC → from the main screen • Verify that “WB” mode is selected, if not, press “WB”  <ul style="list-style-type: none"> • Press “QC” • Select the QC file (filename is the lot # for Low, Normal, or High control). • Open the sample door (also known as sample position) and insert the green adapter

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

<p>Step 5</p> <ul style="list-style-type: none"> • Mix the control 10 more times then REMOVE THE CAPI! <p>Action</p> <ul style="list-style-type: none"> • Check the vial for bubbles. • Press "Run". • At the end of the run, the "Quit" button will appear on screen. • Press "Quit" to print results and to go back to main screen. 	<p>If...</p> <p>PLT count is within acceptable performance for Low, Normal, and High controls</p> <p>Control results are not acceptable</p> <p>Then...</p> <ul style="list-style-type: none"> • Proceed to running patient samples. <p>• Verify that the right QC file was selected.</p> <ul style="list-style-type: none"> • Check that there is no cell pellet on the bottom, mix the vial, then re-run control. • If still outside the limits, refer to Section 6 page 71 of the Instruction Manual for more troubleshooting guidance. • Document all problems and corrective action(s) taken on the QC/QI book. • STOP! Do not proceed to patient testing until QC is acceptable.
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Performing
 Quality Control

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

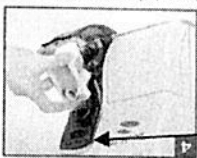

Maintaining Patient and Sample Identity

Step	Action
1	<ul style="list-style-type: none"> Check that all patient's information on the worksheet or requisition match those on sample tube(s) (Name, Accession #, MR #, gender, etc).
2	<ul style="list-style-type: none"> Always use barcode labels when labeling secondary tubes.
3	<ul style="list-style-type: none"> Use barcode scanner to scan the Accession # for sample ID when running poch 100i.

Performing Sample Analysis

Step	Action								
1	<ul style="list-style-type: none"> To run pool or patient sample → from the main screen Verify that "WB" mode is selected. Press "Sample ID" the alphanumeric keypad will appear on screen. <table border="1"> <tr> <td>If...</td> <td>Then...</td> </tr> <tr> <td>running Pool controls</td> <td>manually type in the ID (Pool).</td> </tr> <tr> <td>running patient sample</td> <td>scan the barcode ID.</td> </tr> <tr> <td></td> <td>press enter.</td> </tr> </table>	If...	Then...	running Pool controls	manually type in the ID (Pool).	running patient sample	scan the barcode ID.		press enter.
If...	Then...								
running Pool controls	manually type in the ID (Pool).								
running patient sample	scan the barcode ID.								
	press enter.								
2	<p>NOTE: Always verify that button (WB) is selected.</p>								
3	<ul style="list-style-type: none"> Transfer at least 2 mL to a 12 X 75 mm test tube. 								
4	<ul style="list-style-type: none"> If processing more than one patient sample, a Pool Negative must be analyzed after each patient to verify no carryover exhibited 								

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

Step	Action						
5	<p>The following sampling sequence <u>must be followed exactly</u></p> <ol style="list-style-type: none"> 1. Pool Positive Control (PPC). 2. Pool Negative Control (PNC). 3. Sample 1 (patient) 4. Pool Negative Control (PNC) 5. Sample 2 (patient) 6. Pool Negative Control (PNC) 7. Sample 3, (patient), etc. <p><i>Note: The pool negative sampling sequence is to ensure no carryover exhibited from previous patient or control samples</i></p>						
6	<table border="1"> <tr> <td>If...</td> <td>Then...</td> </tr> <tr> <td>PNC result is "0"</td> <td> <ul style="list-style-type: none"> • Proceed to running sample. </td> </tr> <tr> <td>PNC is giving any value</td> <td> <ul style="list-style-type: none"> • STOP! • Do not run sample, perform a "Clean Transducer" cycle. • See page 12 for stepwise procedure on How to clean the transducer. </td> </tr> </table>	If...	Then...	PNC result is "0"	<ul style="list-style-type: none"> • Proceed to running sample. 	PNC is giving any value	<ul style="list-style-type: none"> • STOP! • Do not run sample, perform a "Clean Transducer" cycle. • See page 12 for stepwise procedure on How to clean the transducer.
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PNC is giving any value	<ul style="list-style-type: none"> • STOP! • Do not run sample, perform a "Clean Transducer" cycle. • See page 12 for stepwise procedure on How to clean the transducer. 						
7	<ul style="list-style-type: none"> • Open the sample door (also known as sample position) • Insert the beige sample adapter, load sample and close door. <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>Insert the beige sample adapter</p> </div> <div style="text-align: center;">  <p>Insert sample tube and close the door.</p> </div> </div>						
8	<ul style="list-style-type: none"> • Press "Run" <p>The results will automatically print at the end of the run.</p>						

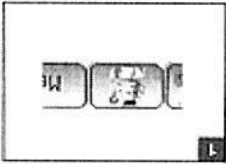
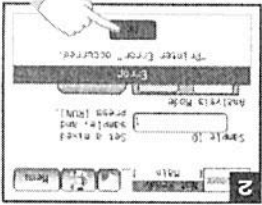
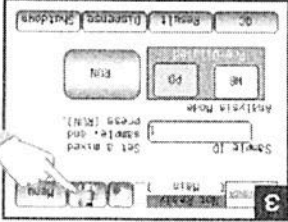
Push the top part to open the door

Performing Sample Analysis, continued

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

Step	1	<ul style="list-style-type: none"> From Main screen at the "Ready" status, 1. press "Menu", 2. press "Maint.", 3. select "Clean Transducer"
Step	2	<ul style="list-style-type: none"> Fill 12 x 75 mm test tube with concentrated bleach. Push the sample door to open the sample position. Place the tube with bleach on the beige adapter. Press "Execute"

How to
 Perform Clean
 Transducer

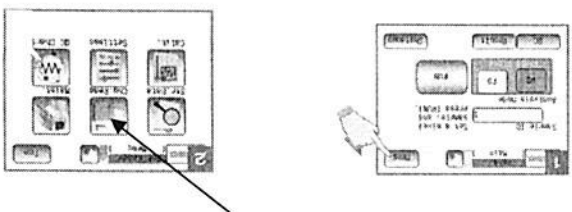
Step	1	<ul style="list-style-type: none"> When an error occurs, <ul style="list-style-type: none"> Alarm will sound Alarm button will flash.
Action		
Step	2	<ul style="list-style-type: none"> Error message(s) will appear on screen. In case of multiple errors, they will be displayed on screen ranked by importance. Press the "OK" button on error message screen to stop the alarm and to close error dialog.
Action		<ul style="list-style-type: none"> Press the HELP button (also called alarm button). This will show on screen the kind of error that had occurred. Press "Detail" to see instructions on how to fix the error.
Step	3	<ul style="list-style-type: none"> Press the HELP button (also called alarm button). This will show on screen the kind of error that had occurred. Press "Detail" to see instructions on how to fix the error.
Action		 

How to fix
 Error
 Messages

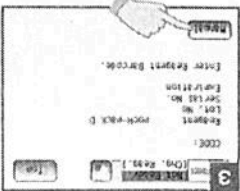

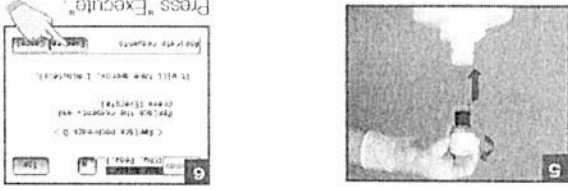
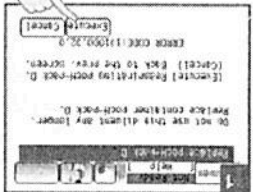
Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

How to fix
Error Messages,
continued

Step	Action
4	<ul style="list-style-type: none"> Refer to Page 67 (Chapter 6) of the Instructions Manual for more troubleshooting guidance.
5	<ul style="list-style-type: none"> If unable to solve the problem, call 1(866)-8SYSMEX for technical assistance.
6	<ul style="list-style-type: none"> NOTE: In case of power failure during operation, turn the main power switch OFF.

Step	Action												
1	<ul style="list-style-type: none"> Changing reagent from Main screen at the "Ready" status, <ul style="list-style-type: none"> press "Menu", press "Chg. Reag" 												
2	<ul style="list-style-type: none"> The reagent screen will appear, (for example): <table border="1" data-bbox="324 661 1055 819"> <thead> <tr> <th>Expiration</th> <th>Lot. No.</th> <th>poch-pack D</th> <th>poch-pack L</th> </tr> </thead> <tbody> <tr> <td>07/14/2010</td> <td>A8073</td> <td>poch-pack D</td> <td>poch-pack L</td> </tr> <tr> <td>12/18/2009</td> <td>A8014</td> <td>poch-pack L</td> <td></td> </tr> </tbody> </table>	Expiration	Lot. No.	poch-pack D	poch-pack L	07/14/2010	A8073	poch-pack D	poch-pack L	12/18/2009	A8014	poch-pack L	
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07/14/2010	A8073	poch-pack D	poch-pack L										
12/18/2009	A8014	poch-pack L											
3	<ul style="list-style-type: none"> Choose the reagent to replace <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 5px;">poch-pack D</div> <div style="border: 1px solid black; padding: 5px;">poch-pack L</div> <div style="border: 1px solid black; padding: 5px;">Reag. Log</div> </div> <ul style="list-style-type: none"> Press the appropriate button for the reagent pack to replace. 												

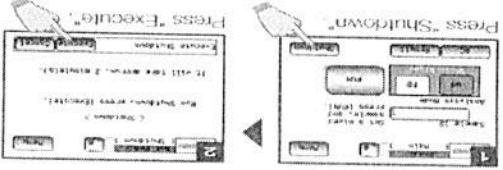
Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued

Step	Action
4	<ul style="list-style-type: none"> • The screen below opens up.  <ul style="list-style-type: none"> • Reagent lot & exp. date can be entered manually or by scanning the reagent barcode. • Scan the reagent barcode, the lot # & exp. date will automatically register on screen.
5	<ul style="list-style-type: none"> • Press "OK" to confirm the Lot # & exp. date. 
6	<ul style="list-style-type: none"> • Insert the container spout into the new bottle. • Tighten the cap then press "Execute". 
7	<ul style="list-style-type: none"> • If the reagent runs out in the middle of run, an error message will appear on screen prompting the operator to replace the depleted reagent. • Press "Execute" • Follow steps 4-6 above. 

How to Replace
 Reagents,
 continued

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued

Performing Daily Shutdown Procedure

Step	Action
1	<ul style="list-style-type: none"> It is very important to perform shutdown procedure at the end of the day to remove deposits in the tubing. Deposits in the instrument tubing can cause incorrect results or it may damage the instrument.
2	<ul style="list-style-type: none"> Run concentrated bleach as sample to clean the transducer of residual protein.
3	<ul style="list-style-type: none"> Perform shutdown cycle, from Main screen at the "Ready" status, <ul style="list-style-type: none"> press "Shutdown". press "Execute". 
4	<ul style="list-style-type: none"> After the shutdown cycle (2 minutes), turn OFF the instrument.

Reporting/ Results Interpretation

Step	Action						
1	<ul style="list-style-type: none"> Lamellar Body Counts are read as PLT on <i>poch-100i</i>. <table border="1" data-bbox="324 231 1071 546"> <thead> <tr> <th>If...</th> <th>Then...</th> </tr> </thead> <tbody> <tr> <td>PLT count is $\geq 65 \times 10^3/\mu\text{L}$</td> <td> <ul style="list-style-type: none"> Release in LMS, it will be reported as MATURE. </td> </tr> <tr> <td>PLT count is $< 65 \times 10^3/\mu\text{L}$</td> <td> <ul style="list-style-type: none"> Release in LMS, it will reflex to L/S & PG confirmation by TLC. </td> </tr> </tbody> </table> 	If...	Then...	PLT count is $\geq 65 \times 10^3/\mu\text{L}$	<ul style="list-style-type: none"> Release in LMS, it will be reported as MATURE. 	PLT count is $< 65 \times 10^3/\mu\text{L}$	<ul style="list-style-type: none"> Release in LMS, it will reflex to L/S & PG confirmation by TLC.
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Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued


How to Calibrate

Step	Action
1	<ul style="list-style-type: none"> • Calibration interval on <i>poch-100i</i> is every 6 months.
2	<ul style="list-style-type: none"> • The calibration is always performed in the "WB" mode. • The type of calibration performed is "Calibrator calibration for whole blood (WB) mode" page 65, <i>instructions manual</i>.
3	<ul style="list-style-type: none"> • A precision check is performed prior to calibration. • When performing this calibration, the first analysis data is not included in the calculation. • It is overwritten by the second analysis data.
4	<ul style="list-style-type: none"> • If an error occurs during precision check analysis or calibrator analysis, an alarm sounds and an error dialog appears • The results of the analysis where the error occurred are displayed in reverse video, as "--.-"; • Press "OK" to close the error dialog, then press "Run" again.
5	<ul style="list-style-type: none"> • Take out the calibrator from refrigerator at least 30 minutes before use to warm the vial to room temperature. • Mix each vial by gentle end-to-end inversion until the cell button in the bottom of the vial is completely suspended. • Allow the vial to rest on flat surface 15 seconds prior to analysis to allow for the dispersion of micro-bubbles.
6	<ul style="list-style-type: none"> • From Main screen, <ul style="list-style-type: none"> • press "Menu" • press "Calib" • select "Calibrator (WB)"
7	<ul style="list-style-type: none"> • Insert the green adapter into the sample position then load the calibrator vial.
8	<ul style="list-style-type: none"> • Press "Run", let the analysis finish; then repeat this step 10 more times. • This step should be performed a total of 11 times for precision check.
9	<ul style="list-style-type: none"> • After the completion of precision check, <ul style="list-style-type: none"> • press "Next" • press "Quit"

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

Step	Action
10	<ul style="list-style-type: none"> The calibration screen opens up. Manually enter the target values listed on calibrator insert and verify that they are correct press "Enter" press "Next" press "OK"
11	<ul style="list-style-type: none"> Press "Run", let the analysis finish; then repeat this step 5 more times. This step should be performed a total of 6 times to obtain required calibration data.
12	<ul style="list-style-type: none"> After analysis, press "Next". The calibration results show on screen.
13	<ul style="list-style-type: none"> Press "Quit" to update calibration value and calibration history.
14	<ul style="list-style-type: none"> Document calibration on calibration log, CLS initials & date.

How to
 Calibrate,
 continued

Step	Action
1	<ul style="list-style-type: none"> Image below shows an example result of calibration run.  <p>Press "Quit" to update calibration value and calibration history.</p>

Reviewing
 Calibration
 Results

**Procedure for Lamellar Body Counts in Amniotic Fluid On
 SYSMEX poch-100 Analyzer, continued**

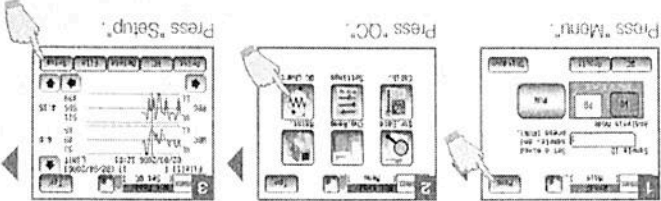
**Reviewing
 Calibration
 Results,
 continued**

2	<ul style="list-style-type: none"> • Explanation of displayed items on calibration result screen.
Range V.	<ul style="list-style-type: none"> • The highest value minus the lowest value within five consecutive analysis. •
MaxRange	<ul style="list-style-type: none"> • The maximum Range Value allowed.
Mean V.	<ul style="list-style-type: none"> • Mean value of five consecutive analysis results.
Delta %	<ul style="list-style-type: none"> • $\frac{\text{Assay Target} - \text{Mean Value}}{\text{Mean Value}} \times 100$ (this is automatically calculated and displayed).
ACPT LMT	<ul style="list-style-type: none"> • Maximum Upper Limit of Delta Percent (%).
SERV LMT	<ul style="list-style-type: none"> • If the Delta Percent exceeds this limit, technical assistance may be necessary and instrument system needs service.
Current	<ul style="list-style-type: none"> • Current calibration value which was obtained in the previous calibration procedure.
New	<ul style="list-style-type: none"> • New calibration value calculated from the calibrator analysis.

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100 Analyzer, continued

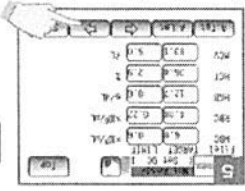
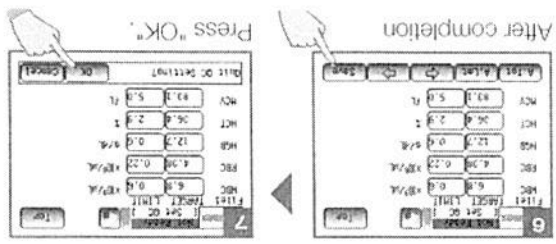
<p>Step 3</p>	<p>• Table below shows how the calibration data is used by the system.</p> <table border="1"> <tr> <td data-bbox="732 1591 1084 1713"> <p>If...</p> <ul style="list-style-type: none"> • Delta % is within ACP T LMT • Calibration factor will not be changed, i.e. instrument will continue using the "Current" calibration value. </td> <td data-bbox="225 1402 732 1591"> <ul style="list-style-type: none"> • The "New" calibration value will become the "Current" calibration value. </td> </tr> <tr> <td data-bbox="732 1287 1084 1402"> <ul style="list-style-type: none"> • The "New" calibration value will become the "Current" calibration value. </td> <td data-bbox="225 1171 732 1287"> <ul style="list-style-type: none"> • The "New" calibration value will become the "Current" calibration value. </td> </tr> <tr> <td data-bbox="732 1056 1084 1171"> <ul style="list-style-type: none"> • Delta % > MaxRange </td> <td data-bbox="225 961 732 1056"> <ul style="list-style-type: none"> • Calibration will not be allowed. • Instrument needs service. • Call 1(866)-8SYSMEX for technical assistance. </td> </tr> </table>	<p>If...</p> <ul style="list-style-type: none"> • Delta % is within ACP T LMT • Calibration factor will not be changed, i.e. instrument will continue using the "Current" calibration value. 	<ul style="list-style-type: none"> • The "New" calibration value will become the "Current" calibration value. 	<ul style="list-style-type: none"> • The "New" calibration value will become the "Current" calibration value. 	<ul style="list-style-type: none"> • The "New" calibration value will become the "Current" calibration value. 	<ul style="list-style-type: none"> • Delta % > MaxRange 	<ul style="list-style-type: none"> • Calibration will not be allowed. • Instrument needs service. • Call 1(866)-8SYSMEX for technical assistance.
<p>If...</p> <ul style="list-style-type: none"> • Delta % is within ACP T LMT • Calibration factor will not be changed, i.e. instrument will continue using the "Current" calibration value. 	<ul style="list-style-type: none"> • The "New" calibration value will become the "Current" calibration value. 						
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<ul style="list-style-type: none"> • Delta % > MaxRange 	<ul style="list-style-type: none"> • Calibration will not be allowed. • Instrument needs service. • Call 1(866)-8SYSMEX for technical assistance. 						
<p>4</p>	<ul style="list-style-type: none"> • "NEW" calibration value = (Target/Mean V.) x Current (automatically calculated & stored by instrument) 						

Reviewing
 Calibration
 Results,
continued

<p>Step 1</p>	<p>Action</p> <ul style="list-style-type: none"> • To setup QC file, from Main screen, press "Menu"; • press "Chg. Reag"; • press "Setup"; 
<p>2</p>	<ul style="list-style-type: none"> • Scan the barcode label for the Lot #. (the first set of barcodes on top of the QC package insert-refer to step 3). • Expiration date has to be manually entered.

How to Setup
 QC File

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued

Step	4	<p>Action</p> <ul style="list-style-type: none"> • Press → to go to the next 5 QC file setting screens. • Scan all 19 barcode labels for each level (Low, Normal, and High). 	How to Setup QC File, <i>continued</i>
5	<ul style="list-style-type: none"> • Once all the parameter have been entered/ scanned, 	<ul style="list-style-type: none"> • press "Save" • press "OK" 	

Step	1	<p>Action</p> <ul style="list-style-type: none"> • When calculating ranges for new lot of whole blood controls or new batch of amniotic pool positive control, use the same historical SD & CV as the Regional Reference Laboratory. 	Quality Control Evaluation
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Step	1	<p>Action</p> <ul style="list-style-type: none"> • For sub-optimal samples that are unacceptable for Lamellar Body Count obtain L/S& PG order and send specimen to the Regional reference laboratory for L/S & PG detection by TLC. 	Notes and Limitations
2	<ul style="list-style-type: none"> • If the AF hematocrit (HCT) exceeds 1%, reflex the specimen for L/S & PG detection by TLC. 		

Procedure for Lamellar Body Counts in Amniotic Fluid On SYSMEX poch-100i Analyzer, continued

Step	Action
1	<ul style="list-style-type: none"> In the event of instrument malfunction and the problem could not be resolved, <u>samples should be sent straight for L/S & PG</u> <i>Detection by TLC.</i>

Alternate Method

Non-Controlled Documents

The following non-controlled documents support this procedure.

Reference	
Non-controlled	SYSMEX poch-100i Analyzer, Instructions 2005-2006
Non-controlled	SYSMEX package inserts (reagents, calibrators, controls)
Non-controlled	Preventive Maintenance for poch-100i Analyzer
Non-controlled	Lamellar Body Count Inventory
Non-controlled	Calibration Log
Non-controlled	Operator Training Checklist

Controlled documents

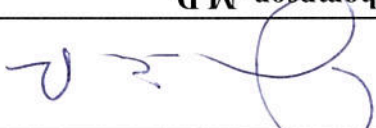

Title	
LGM8000	Standard precautions and safety practices in the laboratory
LGM8005	Universal Body Substance precautions
LGM8010	Proper hand-washing
LGM8006	Infection Control
LGM8007	Cleaning Work Areas
LGM8012	Proper storage and disposal of chemical hazardous waste

Author

M Toprakci

**Procedure for Lamellar cody Counts in Amniotic Fluid on
 SYSMEX poch-100i Analyzer**

Reviewed and approved by:

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Continued on next page

Procedure for Lamellar cody Counts in Amniotic Fluid on
SYSTEMX poch-100i Analyzer, Continued

Document History Page

Effective Date:

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Signature responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change implemented
New		10/29/12	<i>[Signature]</i> 12/14/12	<i>[Signature]</i> 12/14/12	