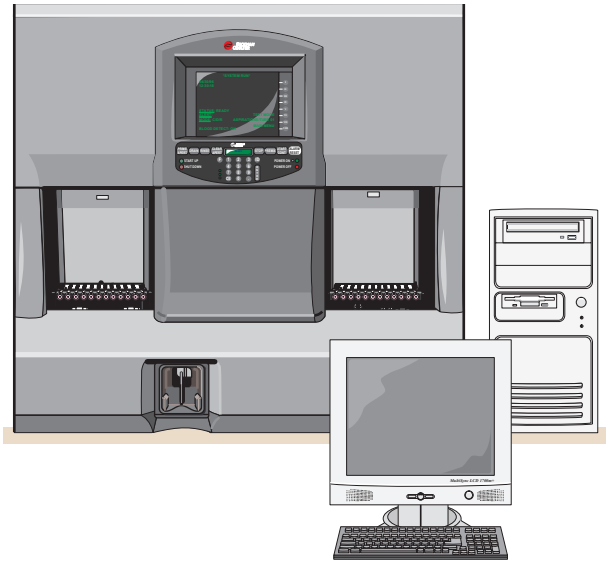
COULTER® LH Workstation
Body Fluid Application

Operator's Guide



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BECKMAN COULTER

WARNINGS AND PRECAUTIONS

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT. DO NOT ATTEMPT TO PERFORM ANY PROCEDURE BEFORE CAREFULLY READING ALL INSTRUCTIONS. ALWAYS FOLLOW PRODUCT LABELING AND MANUFACTURER'S RECOMMENDATIONS. IF IN DOUBT AS TO HOW TO PROCEED IN ANY SITUATION, CONTACT YOUR BECKMAN COULTER REPRESENTATIVE.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Can cause injury.
CAUTION - Can cause damage to the instrument.
IMPORTANT - Can cause misleading results.

BECKMAN COULTER, INC. URGES ITS CUSTOMERS TO COMPLY WITH ALL NATIONAL HEALTH AND SAFETY STANDARDS SUCH AS THE USE OF BARRIER PROTECTION. THIS MAY INCLUDE, BUT IT IS NOT LIMITED TO, PROTECTIVE EYEWEAR, GLOVES, AND SUITABLE LABORATORY ATTIRE WHEN OPERATING OR MAINTAINING THIS OR ANY OTHER AUTOMATED LABORATORY ANALYZER.

WARNING Risk of operator injury if:

- All doors, covers and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers and panels are not opened, closed, removed and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers and panels with care.
- Use the proper tools when troubleshooting.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

REVISION STATUS

Initial Issue A, 9/04
LH 700 Software Version 2B3. Manual derived from Online Help Version 2B3.042521.

Issue B, 11/06
LH 780 Software Version 1A. Manual derived from LH 780 Online Help Version1A.062781.

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LH 700 Software Version 2B3.

LH 780 Software Version 1A.

Updates were made to the company corporate address.

Note: Changes that are part of the most recent revision are indicated in text by a bar in the margin of the amended page.

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released to the Beckman Coulter website. For labeling updates, go to www.beckmancoulter.com and download the most recent manual or system help for your instrument.

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This introductory section contains the following topics:

- How to use your COULTER® LH 700 Series System hard-copy manuals
- About this manual
- Online Help System
- Conventions

HOW TO USE YOUR COULTER® LH 700 SERIES SYSTEM HARD-COPY MANUALS

Use the **Reference** manual for in-depth information about what the instrument does, the methods it uses, its specifications, and information on installation, safety and software options. The Reference manual for the LH 700 Series System is included in the online Help system; it is available in hard copy by request.

Use the **Special Procedures and Troubleshooting** manual to run calibration; to clean, replace or adjust a component on the instrument; and for troubleshooting the instrument. This document is made up of procedures from the online Help system; it is available in hard copy by request.

Use the **Operator's Guide** for the day-to-day operation of your instrument. This document is made up of procedures from the online Help system; it includes Startup, running controls and samples, reviewing data, Shutdown, and the software on the Analyzer and the Workstation. This document is available in hard copy by request.

Use the **Body Fluids Application Operator's Guide** for in-depth information about processing Body Fluids with your instrument. This document is comprised of procedures, operation principles, performance characteristics, as well as specimen collection and storage. This document is available in hard copy by request.

Use the **SlideMaker Operator's Guide** for in-depth information about what the SlideMaker does, the methods it uses, its specifications, and information on installation, safety and software, as well as day-to-day operating and troubleshooting your SlideMaker. This document is made up of procedures from the online Help system; it is available in hard copy by request.

Use the **SlideStainer Operator's Guide** for the day-to-day operating and troubleshooting of your SlideStainer. This document is made up of procedures from the online Help system; it includes in-depth information about what the SlideStainer does, the methods it uses, its specifications, and information on installation, safety and software. This document is available in hard copy by request.

Use the **Host Transmission Specification** to find the information needed to program the transmission interface between the LH 700 Series System and your laboratory's host computer. This document comes with your LH 700 Series System.

See the Documentation page on the back cover of this manual for the contents of each manual. It can help you to determine quickly in which manual the information you need is located.

ABOUT THIS MANUAL

Your LH 700 Series System Operator's Guide is a source of information for the day-to-day operation of your instrument. This information is organized as follows:

- Chapter 1, System Overview
  Provides description of Intended Use, Operation Principles, Performance Characteristics as well as Known Limitations and Interfering Substances.
- Chapter 2, Sample Analysis
  Provides overview of the Body Fluids Application, sample collection and storage and the procedure for processing body fluids.
- Chapter 3, Data Review
  Provides procedures for reviewing, editing and saving results.
- Chapter 4, Troubleshooting
  Provides troubleshooting information and error recovery.
- References
- Index, hard copy only.

ONLINE HELP SYSTEM

The Workstation has a comprehensive online Help system, which includes reference information, all operating, maintenance and troubleshooting procedures. On the LH 700 Series Workstation, select  to access Help. Select  to access the tutorials.

CONVENTIONS

This document uses the following conventions:

 indicates a key on the Numeric keypad.

 indicates a key on the LH 700 Series Workstation keyboard.

 is the icon for Patient results on the LH 700 Series Workstation.

 is the icon for the Printer on the LH 700 Series Workstation.

1.1 INTENDED USE

The LH 700 Series Body Fluid Application is a procedure for obtaining in vitro quantitative determinations of leukocytes (WBC) and erythrocytes (RBC) in cerebrospinal fluid, serous fluids, and synovial fluid, using a COULTER LH 700 Series Hematology Analyzer.

Clinical Indications

Cerebrospinal Fluid (CSF)

Cerebrospinal fluid is a clear, colorless, non-cellular fluid that circulates over the brain and spinal cord. Cell enumeration is indicated to aid in the diagnosis and treatment of meningeal infections, subarachnoid hemorrhage, and central nervous system malignancies.[1]

Serous Fluids

The pericardial, peritoneal, and pleural cavities are formed by double-layered serous membranes that separate the heart, abdomen, and lung respectively from their surrounding environment. In the absence of disease, these serous membranes are separated by a minute amount of fluid that allows for movement. An accumulation of fluid between the membranes is an indication of disease. Cell enumeration is indicated to aid in the diagnosis and treatment of a number of clinical conditions, such as infections, cardiovascular disease, malignancies, pulmonary embolism, cirrhosis, and trauma.[1]

Synovial Fluid

Synovial Fluid occupies the synovial cavity to lubricate the joint space and provide nutrients to the cartilage. Cell enumeration is indicated to aid in the diagnosis and treatment of joint disease, as well as the classification of the disease as septic, inflammatory, or non-inflammatory.[1]

1.2 CONTROLS, CALIBRATOR AND REAGENTS

All stated performance characteristics in this manual are based on the use of the recommended LH 700 Series controls, calibrator and reagents. Refer to the container's label for detailed information before using the reagent.

1.3 OPERATION PRINCIPLES

The body fluid is aspirated into the LH 700 Series Analyzer via the manual mode and is diluted in separate WBC and RBC baths. The Coulter Method of counting cells is used to detect and measure changes in electrical resistance when a cell, suspended in a conductive diluent, passes through a small aperture. Each suspended cell acts as an insulator. As the cell passes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes, one located on each side of the aperture. The resistance generates an electrical pulse. The accumulation of electrical pulses are channelized, processed for coincidence correction, and multiplied by a calibration factor, yielding the WBC and RBC counts.

The WBC represents the TNC (total nucleated cell count) in the analysis of Body Fluids.

Additional results precision can be obtained by enabling extra digits at the Workstation.

1.4 PERFORMANCE CHARACTERISTICS

Performance Characteristics describe typical performance for an instrument that has been properly calibrated and maintained as indicated in COULTER LH 700 Series System Help.

Accuracy

WBC Accuracy (Method Comparison)

A total of 372 body fluids were processed on the COULTER LH 700 Series Hematology System and by the manual Neubauer hemacytometer counting chamber method. 152 WBC results were used for method comparison. WBC results exhibiting the following conditions were excluded.

- Reference WBC results <0.20 x 10^3 cells/µL
- Results with a Cellular Interference message
- Results that exceeded WBC linearity (+)
- Non-numeric WBC results

Fluid	N	Range of Observations	Intercept	Slope	r	r^2
Cerebrospinal	23	0.20 - 7.56	0.10	0.8904	0.9966	0.9932
Serous	82	0.20 - 34.10	0.40	0.7683	0.9461	0.8952
Synovial	47	0.25 - 47.25	1.57	0.7413	0.9142	0.8360

RBC Accuracy (Method Comparison)

A total of 372 body fluids were processed on the COULTER LH 700 Series Hematology System and by the manual Neubauer hemacytometer counting chamber method. 106 RBC results were used for method comparison. RBC results exhibiting the following conditions were excluded.

- Reference RBC <0.010 x 10^6 cells/µL
- Results that exceeded RBC linearity (+)
- Non-numeric RBC results

Fluid	N	Range of Observations	Intercept	Slope	r	r^2
Cerebrospinal	31	0.010 - 0.325	0.002	1.0549	0.9213	0.8489
Serous	43	0.010 - 2.335	0.007	1.0577	0.9783	0.9571
Synovial	32	0.010 - 6.950	0.198	0.7343	0.8168	0.6671

Carryover

High to Low Carryover

High to low carryover was evaluated by processing three consecutive high body fluid counts (H1-H3) followed by three consecutive low body fluid counts (L1-L3). Carryover is calculated as [(L1 - L3)/(H3 - L3)] x 100%.

	High H3	Low L1	Low L3	Carryover
WBC	4.97	0.28	0.25	0.64%
RBC	1.803	0.005	0.000	0.28%

Precision

WBC Precision

Precision was evaluated by processing a single body fluid 11 times. The first run in each batch was discarded. Precision statistics are presented for three levels of WBC.

Mean	N	2 SD	CV	Minimum	Maximum
0.41	10	0.04	4.44	0.39	0.45
2.13	10	0.11	2.55	1.99	2.18
14.10	10	0.10	0.37	13.99	14.15

RBC Precision

Precision was evaluated by processing a single body fluid 11 times. The first run in each batch was discarded. Precision statistics are presented for three levels of RBC.

Mean	N	2 SD	CV	Minimum	Maximum
0.015	10	0.002	6.59	0.014	0.017
0.307	10	0.005	0.89	0.303	0.312
0.988	10	0.015	0.75	0.977	1.001

Linearity

WBC Linearity

WBC linearity was evaluated by diluting a body fluid to levels approximating the linearity specification range. Refer to COULTER LH 700 Series System Help for full linear range of the WBC.

Dilution	Expected Count	Actual Count
1:32	0.11	0.22
1:16	0.22	0.31
1:8	0.45	0.59
1:4	0.89	1.01
1:2	1.78	1.96
Undiluted	3.57	3.57

r^2	Slope	Intercept
0.9985	0.9748	0.1338

RBC Linearity

RBC linearity was evaluated by diluting a body fluid to levels approximating the linearity specification range. Refer to COULTER LH 700 Series System Help for full linear range of the RBC.

Dilution	Expected Count	Actual Count
1:32	0.004	0.004
1:16	0.008	0.008
1:8	0.016	0.017
1:4	0.032	0.031
1:2	0.065	0.062
Undiluted	0.129	0.129

r^2	Slope	Intercept
0.9995	0.9989	0.0007

Normal Reference Ranges

Reportable body fluid results obtained from the COULTER LH 700 Series Hematology System may exceed commonly accepted normal reference ranges for all body fluids. Results should always be interpreted in light of the total clinical presentation of the patient, including clinical history, data from additional tests, and other appropriate information.

Cerebrospinal Fluid

The inability to collect cerebrospinal fluid specimens in the normal, non-diseased population limits the ability to determine reference ranges. Literature[1] suggests the following normal reference ranges.

- WBC 0 - 5 cells/µL in adults
- WBC 0 - 30 cells/µL in children less than 1 year of age
- WBC 0 - 20 cells/µL in children 1 to 4 years of age
- WBC 0 - 10 cells/µL in children 5 years of age to puberty
- RBC none to few

Serous Fluids

The accumulation of fluid in a serous cavity is an indication of a disease state. The normal, non-diseased population has no fluid accumulation. Therefore, there are no normal reference ranges for serous fluids. However, the number of cells present in a serous fluid are used to aid in the classification, diagnosis and treatment of disease.[1]

Synovial Fluid

The inability to collect synovial fluid specimens in the normal, non-diseased population limits the ability to determine reference ranges. Literature[1] suggests the following normal reference ranges.

- WBC 0 - 150 cells/µL
- RBC none

1.5 KNOWN LIMITATIONS AND INTERFERING SUBSTANCES

Limitations concerning sample collection, storage, mixing and clotted specimens can be found in Heading 2.2, SPECIMEN COLLECTION AND STORAGE. See below for those specific to Body Fluids Application.

Parameter	Description
WBC	NRBCs, giant platelets, platelet clumps, malarial parasites, precipitated elevated proteins, cryoglobulin, microlymphoblasts, very small lymphocytes, fragmented white cells, agglutinated white cells, lyse resistant red cells, unlysed particles >35 fL in size.
RBC	Very high WBC count, high concentration of very large platelets, auto-agglutination.

All Fluids

- Clotted specimens may lead to misleading or erroneous results. Follow standard laboratory operating procedure for inspecting specimens for clots.
- Improperly mixed specimens may lead to misleading or erroneous results.
- Cellular debris may lead to misleading or erroneous results.

- Results should be interpreted in light of the total clinical presentation of the patient, including clinical history, data from additional tests, smear review, and other appropriate information.

Cerebrospinal Fluid

- The low levels of albumin and lipids in cerebrospinal fluid may accelerate cell lysis, leading to decreased manual counts and an apparent lack of correlation.[2]
- Delays in processing may lead to misleading or erroneous results. Refer to Heading 2.2, SPECIMEN COLLECTION AND STORAGE.

Synovial Fluid

- Fat globules may lead to misleading or erroneous results.
- Crystals may lead to misleading or erroneous results.
- Highly viscous synovial fluids may trap cells leading to misleading or erroneous results.
- Delays in processing may lead to misleading or erroneous results. Refer to Heading 2.2, SPECIMEN COLLECTION AND STORAGE.

2.1 BODY FLUIDS APPLICATION OVERVIEW

The Body Fluids Application provides analysis of cerebrospinal fluid, serous fluids (pleural, peritoneal, pericardial) and hyaluronidase-treated synovial fluids. The application is accessed similar to the predilute sample function on the LH 700 Series System:

- Body fluid analysis defaults to the CBC mode.
- Samples must be analyzed in the Manual mode.
- No Primary mode analysis available.
- When Body Fluids mode is selected, Predilute mode is not available.
- Selection of Body Fluids mode applies to only one sample at a time.

In Body Fluid analysis, there are differences in flagging and result reporting compared to whole blood. Only WBC and RBC results are reported. All other parameters and associated graphics are suppressed. Most differences reflect the notification that the sample is a body fluid and should be handled differently than whole blood samples.

Flagging differences include:

- No high and low flagging of results.
- No Definitive messages are reported.
- No Decision rules are applicable.
- No Delta check available.
- No Autovalidation of results. Results must be manually validated.
- Only the Cellular Interference Suspect message is reported.

Reporting differences include:

- Body fluid results are not collated with other samples of the same patient ID.
- The patient screen displays CBC: BF.
- The patient report footer displays “BODY FLUID”.
- Body fluid results are excluded from patient history statistics on the patient history screen.
- Body fluid results are excluded from XB.
- The comment 'TNC=WBC' is displayed in the comment field of the patient test screen.
- With transmissions to host for body fluid runs, the field tag BODF states 'Body Fluid'.
- Pending test request in the ToDo list will be ignored when a Body Fluid is run.

2.2 SPECIMEN COLLECTION AND STORAGE

Sample Collection

Anticoagulants

Cell counts can be performed on non-anticoagulated specimens as well as those containing dipotassium or tripotassium EDTA or heparin per standard laboratory operating procedure.

Required Sample Volume

Minimum required volume for aspiration is 200 µL.

Sample Preparation

To reduce viscosity, synovial fluids should be pretreated with hyaluronidase[1], per standard laboratory operating procedures.

- Pretreat synovial fluid with bovine hyaluronidase before running on the instrument. Add synovial fluid to a pre-dispensed tube of hyaluronidase in the ratio of 1.0 mL of synovial fluid to 5 mg of hyaluronidase. Mix for 5 minutes.

WARNING Handle hyaluronidase under a hood and avoid contact and inhalation. Use barrier protection in accordance with your national health and safety standards and your specific laboratory procedures. Refer to the MSDS sheet for complete information about this chemical.

Sample Stability and Storage

- Cerebrospinal fluid should be processed within 2 hours after collection when stored at ambient temperature.[2] Refrigeration at 4°C may help to retard cell destruction.
- Synovial fluid should be processed within 8 hours after collection and storage at ambient temperature.[1, 4] Refrigeration at 4°C may help to maintain morphologic features.
- Serous fluids should be processed within 8 hours after collection and storage at ambient temperature. Refrigeration at 4°C may help to retard cell destruction.

Specimen Type

The following specimen types are supported by the Body Fluids Application:

- Cerebrospinal fluids (CSF)
- Serous Fluids (pleural, pericardial, peritoneal, peritoneal lavage, and peritoneal dialysate)
- Synovial fluid.

2.3 PROCESSING BODY FLUIDS IN THE MANUAL MODE

IMPORTANT Risk of erroneous results can occur if Body Fluid samples are not run in the manual Body Fluid mode.

Refer to the COULTER LH 700 Series System Help for reagent, control, and calibrator information as well as procedures relative to instrument startup, shutdown, quality control, calibration, and maintenance information.

1. Ensure the specimen has been properly collected and sufficient volume is available. Approximately 200 µL is necessary for processing in the Manual mode.

IMPORTANT Misleading results can occur if specimens contain clots. Inspect specimens for clots and use good laboratory practices for verifying results to ensure you do not report misleading results.

IMPORTANT Synovial fluids should be pretreated with hyaluronidase[1] to reduce viscosity. Follow your standard operating procedures for pretreatment.

2. Cycle a diluent blank prior to analyzing a body fluid specimen. If the WBC and RBC results are above the acceptable background limits, repeat the diluent blank.
3. On the Command Center, select **AUTOANALYSIS** as the process type; and enable the Body Fluid (CBC) check box ( ).

Note: The Body Fluids check box can be enabled with any process type controlled by the Workstation prior to the sample run.

IMPORTANT If the probe is stuck in the IN position after you entered the patient ID, you can discard that ID only by resetting the Analyzer.

4. Enter the sample ID via the numeric keypad or handheld scanner.

Note: If results are not received at the workstation within approximately 2 minutes, the body fluid function is disabled.

5. Mix the sample well.
6. Aspirate the sample.

   Review the sample results at the Workstation, refer to Reviewing Sample Results for detailed instructions.

   Note: Review those Flags, Codes and Suspect/Definitive Messages related to Body Fluids from the Body Fluids: Data Review help topic.

ATTENTION:
Do not report the WBC if ≤0.20 x 10^3 cell/µL. Obtain WBC by an alternate method.
Do not report the RBC if ≤0.010 x 10^6 cell/µL. Obtain RBC by an alternate method.

3.1 DATA REVIEW

Refer to the LH 700 Series System Help for detailed instructions for reviewing sample results.

Flags and Codes

Refer to the LH 700 Series System Help for detailed instructions regarding Flags and Codes. There are no body fluid-specific flags or codes, whole blood flags and codes are used as appropriate.

Flags

In addition to the functionality of the R Flag for whole blood, Body Fluid specific flagging appears below:

R Results are equal to or below the reportable range. Follow your laboratory's policies for reviewing the sample.

Codes

Refer to the LH 700 Series System Help for detailed instructions regarding Flags and Codes. There are no body fluid-specific flags or codes, whole blood flags and codes are used as appropriate.

Suspect Messages

The only Suspect Message used by the Body Fluids Application is Cellular Interference as defined below:

MESSAGE	NOTES	SOURCE
Cellular Interference	WBC histogram pattern consistent with interference at the 35 fL region. When the separation between the WBC populations is poorly defined on the histogram, WBC correction will be performed and the corrected WBC will have an R flag.	CBC

Abnormalities should be confirmed by microscopic review.

IMPORTANT No other suspect messages are enabled or applicable to Body Fluid analysis.

3.2 REPORTS

Report Format for Body Fluids Application

The Body Fluids Application uses any LH 700 Series Report Format (chartable or in-lab). Body Fluids mode is indicated next to the test type and a comment appears in the Comments field.

Report Comments

The following comment appears in the Comments field when using Body Fluids mode: TNC = WBC.

Printed Report Footer

The following footer will appear for any Body Fluid reports:

This footer	Means This
Body Fluid	Indicates that this test was run with the Body Fluids mode ON.

Note: All report formats support A4 and US letter paper sizes.

4.1 HAZARDS

Refer to the LH 700 Series System help topics: Special Notices to Operators and Hazards for additional notices, warnings and precautions.

IMPORTANT Patient samples may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.

4.2 ERROR MESSAGES

Refer to the LH 700 Series Message List help topic for detailed instruction regarding acknowledging error messages.

Message Description

This message displays when a body fluid type is processed in automatic sampling mode rather than manual mode.

Current System Status

- This message appears in the Event log.
- System Status is READY.
-  appears on the Command Center.
- Sample results are not stored and the system stops processing.

What To Do

Rerun the sample in the manual aspiration mode.

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2. Steele R, Marmer D, O'Brien M, Tyson S, Steele C. Leukocyte survival in cerebrospinal fluid. *J Clin Micro*, 198; 23:965-966.
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The information in the Reference manual, Operator's Guide, Special Procedures and Troubleshooting manual, SlideMaker Operator's Guide and the SlideStainer Operator's Guide comes from the Online Help System.

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