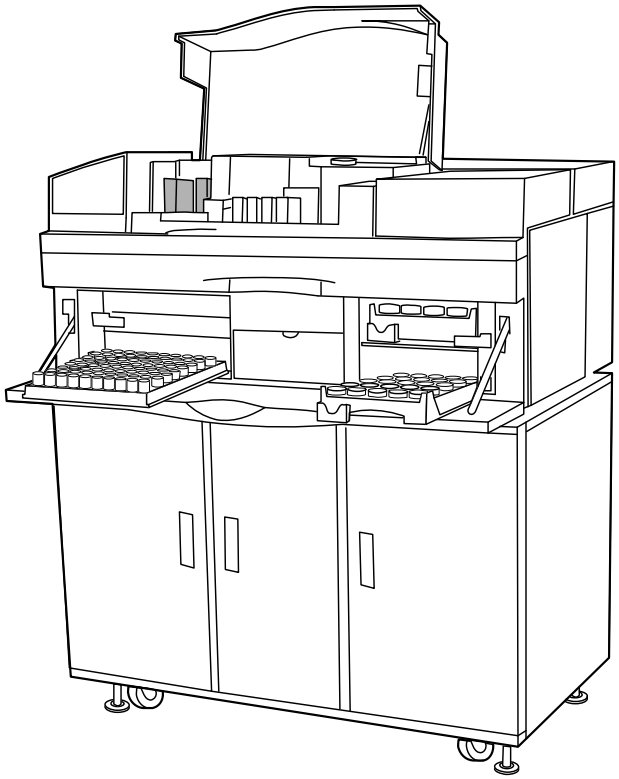
ThinPrep® 3000 Processor



Instructions for Use

INTENDED USE

The ThinPrep® 3000 Processor (TP-3000) is a device that produces cytologic preparations on glass microscope slides from gynecologic (cervical) samples, and is intended for use in cervical cytologic examinations of material collected for the ThinPrep Pap Test. TP-3000 prepared microscope slides are examined by trained cytotechnologists and pathologists for the presence of atypical cells, cervical neoplasia, including its precursor lesions (Low Grade Squamous Intraepithelial Lesions, High Grade Squamous Intraepithelial Lesions), and carcinoma as well as all other cytologic criteria as defined by *The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses*[1] (Bethesda System).

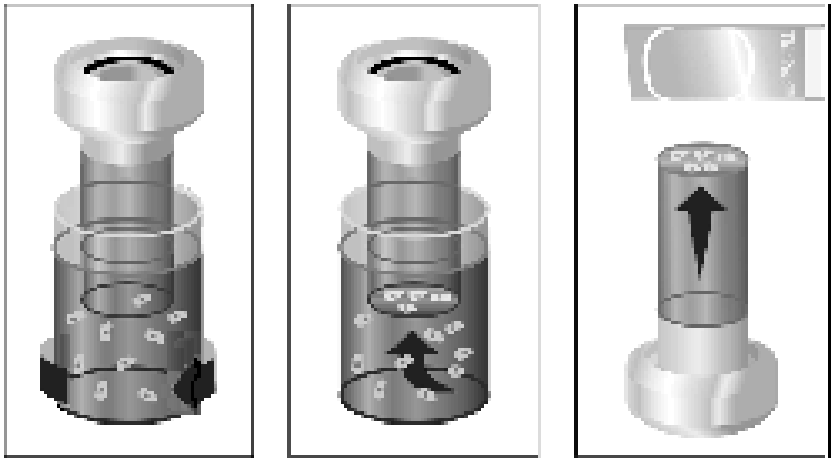
SUMMARY AND EXPLANATION OF THE SYSTEM

The ThinPrep process begins with the patient's gynecologic sample being collected by the clinician, which is then immersed and rinsed in a PreservCyt® Solution sample vial. The PreservCyt sample vial is then capped, labeled, and sent to a laboratory equipped with a TP-3000.

At the laboratory, the PreservCyt sample vial is bar-coded along with the test request form to establish a sample chain of custody and is placed into a TP-3000. A gentle dispersion step mixes the cell sample by currents in the fluid that are strong enough to separate debris and disperse mucus, but gentle enough to have no adverse effect on cell appearance.

The cells are then captured on a Gynecological ThinPrep Pap Test Filter that is specifically designed to collect cells. The TP-3000 constantly monitors the rate of flow through the ThinPrep Pap Test Filter during the collection process in order to prevent the cellular presentation from being too scant or too dense. The TP-3000 will label the glass slide with the sample identification number read from the bar-code on the sample vial. A thin layer of cells is then transferred to a glass slide in a 20 mm-diameter circle. The slide is completed when its cells are fixed in place by a fixative solution (CellFyx™ Solution) that is applied automatically by the processor.

The ThinPrep Pap Test Slide Preparation Process



1. Dispersion **2. Cell Collection** **3. Cell Transfer**

(1) Dispersion
The cell sample is mixed by currents created in the preservation fluid that are strong enough to separate debris and disperse mucus, but gentle enough to have no adverse effect on cell appearance.

(2) Cell Collection
A gentle vacuum is applied to the ThinPrep Pap Test Filter to collect cells.

(3) Cell Transfer
The ThinPrep Pap Test Filter is gently pressed against the ThinPrep Microscope Slide. Positive pressure applied to the inside of the filter assists in transferring the cells from the filter membrane to the surface of the slide.

As with conventional Pap smears, slides prepared with the TP-3000 are examined in the context of the patient's clinical history and information provided by other diagnostic procedures such as colposcopy, biopsy, and human papillomavirus (HPV) testing, to determine patient management.

The PreservCyt® Solution component of the ThinPrep 2000 System is an alternative collection and transport medium for gynecologic specimens tested with the Cervista® HPV HR Test, the Cervista® HPV 16/18 Test, the Roche cobas® HPV Test and the Digene Hybrid Capture™ System HPV DNA. Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens for use in those systems.

The PreservCyt Solution component of the ThinPrep 2000 System is an alternative collection and transport medium for gynecologic specimens tested with the Hologic APTIMA COMBO 2® CT/NG Assays, the Hologic APTIMA® Trichomonas vaginalis Assay, and the BD ProbeTec™ CT Q^{x} Amplified DNA Assay. Refer to the respective manufacturer's package inserts for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens for use in those systems.

The PreservCyt Solution component of the ThinPrep 2000 System is also an alternative collection and transport medium for gynecologic specimens tested with the Roche Diagnostics COBAS AMPLICOR™ CT/NG assay. Refer to Hologic's labeling (Document #MAN-02063-001) for instructions for using PreservCyt Solution for collection, transport, storage, and preparation of specimens and to the Roche Diagnostics COBAS AMPLICOR CT/NG package insert for instructions for use of that system.

LIMITATIONS

- Gynecologic samples collected for the TP-3000 should be collected using a broom-type or endocervical brush/plastic spatula combination collection devices. Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.
- Preparation of slides on the TP-3000 should be performed only by personnel who have been trained by Hologic or by organizations or individuals designated by Hologic.
- The staining procedure using the CellFyx® Fixative Solution has been demonstrated for Papanicolaou stain only.
- Evaluation of slides prepared on the TP-3000 should be performed only by cytotechnologists and pathologists who have been trained to evaluate ThinPrep Pap Test slides by Hologic or by organizations or individuals designated by Hologic.
- Supplies used for TP-3000 gynecologic slide preparations are those designed by Hologic specifically for use on the instrument. These supplies include PreservCyt® Solution vials for use with the ThinPrep Pap Test, ThinPrep Pap Test Filters, ThinPrep Microscope Slides, and CellFyx Fixative Solution. For proper performance of the system these supplies cannot be substituted. After use, supplies should be disposed of in accordance with local, state, and federal regulations.
- All supplies, with the exception of CellFyx Fixative Solution, are single-use disposable items and cannot be reused.
- The performance of HPV DNA and CT/NG testing on reprocessed sample vials has not been evaluated.

CONTRAINDICATIONS

- *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing using the Roche Diagnostics COBAS AMPLICOR and Gen-Probe APTIMA COMBO 2® CT/NG assays should not be performed on a sample that has already been processed using the ThinPrep 3000 processor.

WARNINGS

- For In Vitro Diagnostic Use.
- Danger. PreservCyt Solution contains methanol. Toxic if swallowed. Toxic if inhaled. Causes organ damage. Keep away from heat, sparks, open flames and hot surfaces. Other solutions must not be substituted for PreservCyt Solution. PreservCyt Solution should be stored and disposed of in accordance with local, state, and federal regulations.

PRECAUTIONS

- A TP-3000 generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the Operator's Manual, may cause interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case, the user will be required to correct the interference at his/her own expense.
- PreservCyt Solution *with* cytologic sample intended for ThinPrep Pap testing must be stored between 15°C (59°F) and 30°C (86°F) and tested within 6 weeks of collection.
- PreservCyt Solution *with* cytologic sample intended for CT/NG testing using the Roche Diagnostics COBAS AMPLICOR CT/NG test must be stored between 4°C (39°F) and 25°C (77°F) and tested within 6 weeks of collection.
- Excessively bloody samples may result in a higher unsatisfactory[1] rate.

- PreservCyt Solution was challenged with a variety of microbial and viral organisms. The following table presents the starting concentrations of viable organisms, and the number of viable organisms found after 15 minutes in the PreservCyt solution. The log reduction of viable organisms is also presented. As with all laboratory procedures, universal precautions should be followed.

Organism	Initial Concentration	Log Reduction after 15 min.
Candida albicans	5.5×10^5 CFU/mL	>4.7
Aspergillus niger*	4.8×10^5 CFU/mL	2.7
Escherichia coli	2.8×10^5 CFU/mL	>4.4
Staphylococcus aureus	2.3×10^5 CFU/mL	>4.4
Pseudomonas aeruginosa	2.5×10^5 CFU/mL	>4.4
Mycobacterium tuberculosis**	9.4×10^5 CFU/mL	4.9
Rabbitpox virus	6.0×10^6 PFU/mL	5.5***
HIV-1	$1.0 \times 10^{7.5}$ $TCID_{50}$/mL	7.0***

* After 1 hour >4.7 log reduction
** After 1 hour >5.7 log reduction
*** Data is for 5 minutes

PERFORMANCE CHARACTERISTICS: REPORT OF CLINICAL STUDIES

A prospective multi-center clinical study was conducted at three sites to evaluate the performance of the TP-3000 in direct comparison to the ThinPrep® 2000 Processor (TP-2000). The objective of this clinical study was to demonstrate that gynecologic specimens prepared using both instruments were equivalent when used for the detection of atypical cells and cervical cancer or its precursor lesions in a variety of patient populations. In addition, an assessment of specimen adequacy was performed.

The initial clinical study protocol was a single-masked, direct-to-vial, matched-pair study, for which the order of preparation for each instrument was randomized. At the laboratory, the PreservCyt sample vial was placed into both a TP-3000 and a TP-2000 and two slides were prepared (one per instrument) from the patient's sample. All slides were examined and diagnosed independently. The same cytotechnologist and pathologist (if referred) reviewed each matched-paired slide set. To minimize slide recognition bias there was a minimum one-day lag between the cytotechnologist and pathologist review of all slides from a matched-pair set. Reporting forms containing patient history as well as a checklist of all possible categories of the Bethesda System were used to record the results of the screening. A panel of three independent pathologists adjudicated all discordant cases (a one-grade or higher cytologic difference) in a masked fashion to determine a consensus diagnosis.

LABORATORY AND PATIENT CHARACTERISTICS

The cytology laboratories participating in the study were comprised of one referral center (designated as S1), one screening/referral center (designated as S2) and one screening center (designated as S3).

The screening center in the study served patient populations (screening populations) with rates of abnormality (Low-grade Squamous Intraepithelial Lesion [LSIL] and more severe lesions) similar to the United States average of less than 5%.[3] The referral center in the study served a high risk referral patient population (referral populations) characterized by high rates (>10%) of cervical abnormality. The screening/referral center's abnormality rate was a combination of the two previously mentioned rates. Table 1 describes the laboratories and the patient populations.

Table 1: Site Characteristics

	Laboratory Characteristics			Clinical Study Demographics			
Site	**Type of Patient Population**	**Laboratory Volume - Smears per Year**	**Cases**	**Patient Age Range**	**Post Menopausal %**	**Previous Abnormal Pap Smear %**	**Con-current Infection %**
S1	Referral	44,709	1188	18-85	11.8	51.8	35.2
S2	Screening/Referral	62,195	1141	18-77	6.0	21.8	15.1
S3	Screening	90,639	1198	18-82	12.5	22.7	10.2

Cases with patient's age less than 18 years or patients with a hysterectomy were excluded from this analysis.

CLINICAL STUDY RESULTS

The diagnostic classes of the Bethesda System are used to present the comparison between the TP-3000 and TP-2000 findings from all of the clinical trial sites.

Three independent pathologists served as an adjudication panel for the three clinical sites. The panel reviewed all discordant cases (a one-grade or higher cytologic difference) for descriptive diagnosis and specimen adequacy. Since a true reference cannot be determined in such studies and therefore true sensitivity cannot be calculated, the use of an independent adjudicated review provides an alternative to histologic confirmation by biopsy or human papillomavirus (HPV) testing as a means for determining the reference diagnosis. Consensus was determined when a minimum of 2 out of 3 independent pathologists rendered an equivalent diagnosis. If a majority vote could not be obtained, a consensus was achieved during a review by all three pathologists at a multi-headed scope.

Table 2 shows the unadjudicated descriptive diagnosis results from all sites for the TP-3000 and TP-2000. Of the 3,527 total patients enrolled in the study, 3,224 were included in the descriptive diagnosis analysis after all data integrity sorting was applied.

Few cases of cervical cancer were represented in the clinical study, as is typical in the United States patient population.[4]

Table 2: Unadjudicated 7 x 7 Classification Table, All Categories

		TP-3000							
		NEG	**ASCUS**	**AGUS**	**LSIL**	**HSIL**	**SQ CA**	**GL CA**	**TOTAL**
TP-2000	**NEG**	**2570**	104	6	26	3	0	0	2709
	ASCUS	119	**90**	0	23	6	0	0	238
	AGUS	4	1	**0**	0	0	0	0	5
	LSIL	17	29	1	**132**	10	0	0	189
	HSIL	0	10	0	17	**54**	0	0	81
	SQ CA	0	0	0	0	0	**2**	0	2
	GL CA	0	0	0	0	0	0	**0**	0
	TOTAL	2710	234	7	198	73	2	0	**3224**

Abbreviations for Diagnoses*: **NEG** = Normal or negative, **ASCUS** = Atypical Squamous Cells of Undetermined Significance, **AGUS** = Atypical Glandular Cells of Undetermined Significance, **LSIL** = Low-grade Squamous Intraepithelial Lesion, **HSIL** = High-grade Squamous Intraepithelial Lesion, **SQ CA** = Squamous Cell Carcinoma, **GL CA** = Glandular Cell Adenocarcinoma*

Tables 3 - 9 show the adjudicated descriptive diagnosis results from all sites for the TP-3000 and TP-2000.

Table 3: Adjudicated 7 x 7 Diagnostic Classification Table, All Categories (Includes adjudicated cases only)

		TP-3000							
		NEG	**ASCUS**	**AGUS**	**LSIL**	**HSIL**	**SQ CA**	**GL CA**	**TOTAL**
TP-2000	**NEG**	**258**	25	0	5	1	0	0	289
	ASCUS	29	**11**	0	11	0	0	0	51
	AGUS	0	0	**0**	0	0	0	0	0
	LSIL	6	9	0	**10**	2	0	0	27
	HSIL	1	2	0	3	**3**	0	0	9
	SQ CA	0	0	0	0	0	**0**	0	0
	GL CA	0	0	0	0	0	0	**0**	0
	TOTAL	294	47	0	29	6	0	0	**376**

Abbreviations for Diagnoses*: **NEG** = Normal or negative, **ASCUS** = Atypical Squamous Cells of Undetermined Significance, **AGUS** = Atypical Glandular Cells of Undetermined Significance, **LSIL** = Low-grade Squamous Intraepithelial Lesion, **HSIL** = High-grade Squamous Intraepithelial Lesion, **SQ CA** = Squamous Cell Carcinoma, **GL CA** = Glandular Cell Adenocarcinoma*

The diagnostic data analysis from all sites is summarized in Table 4 for adjudicated cytologic results of LSIL+.

Table 4: Adjudicated Two-Category Diagnostic Classification Table, LSIL and More Severe Lesions (Includes adjudicated cases only)

		TP-3000		
		NEG/ASCUS/ AGUS	**LSIL+**	**TOTAL**
TP-2000	**NEG/ASCUS/AGUS**	**323**	**17**	**340**
	LSIL+	**18**	**18**	**36**
	TOTAL	**341**	**35**	**376**

The diagnostic data analysis from each site is summarized in Table 5 for adjudicated cytologic results of LSIL+. When the p-value is significant ($p < 0.05$), the method favored is indicated in the tables.

Table 5: Adjudicated Results by Site, LSIL and More Severe Lesions (Includes adjudicated cases only)

Site	Cases	TP-3000 LSIL+	TP-2000 LSIL+	p-Value	Method Favored
S1	240	13	15	0.791	Neither
S2	65	16	16	1.000	Neither
S3	71	6	5	1.000	Neither

For LSIL and more severe lesions, the adjudicated diagnostic comparison was statistically equivalent at all sites.

The diagnostic data analysis from all sites is summarized in Table 6 for adjudicated cytologic results of HSIL+.

Table 6: Adjudicated Two-Category Diagnostic Classification Table, HSIL and More Severe Lesions (Includes adjudicated cases only)

		TP-3000		
		NEG/ASCUS/ AGUS/LSIL	**HSIL+**	**TOTAL**
TP-2000	**NEG/ASCUS/ AGUS/LSIL**	**364**	**3**	**367**
	HSIL+	**6**	**3**	**9**
	TOTAL	**370**	**6**	**376**

The diagnostic data analysis from each site is summarized in Table 7 for adjudicated cytologic results of HSIL+. When the p-value is significant ($p < 0.05$), the method favored is indicated in the tables.

Table 7: Adjudicated Results by Site, HSIL and More Severe Lesions (Includes adjudicated cases only)

Site	Cases	TP-3000 HSIL+	TP-2000 HSIL+	p-Value	Method Favored
S1	240	1	1	1.000	Neither
S2	65	3	5	0.625	Neither
S3	71	2	3	1.000	Neither

For HSIL and more severe lesions, the adjudicated diagnostic comparison was statistically equivalent at all sites.

Table 8 below shows the summary of the Bethesda System categories of the unadjudicated descriptive diagnosis data for all sites.

Table 8: Unadjudicated Summary of Descriptive Diagnosis

Descriptive Diagnosis	TP-2000		TP-3000	
Number of Patients: 3224	N	%	N	%
Benign Cellular Changes:	**903**	**28.0**	**848**	**23.6**
Infection:				
Trichomonas Vaginalis	69	2.1	67	2.1
Candida spp.	208	6.5	193	6.0
Coccobacilli	346	10.7	347	10.8
Actinomyces spp.	0	0.0	1	0.0
Herpes	2	0.1	2	0.1
Other	7	0.2	2	0.1
Reactive Cellular Changes Associated with:				
Inflammation	313	9.7	292	9.1
Atrophic Vaginitis	16	0.5	16	0.5
Radiation	1	0.0	0	0.0
IUD	0	0.0	0	0.0
Other	89	2.8	72	2.2
Epithelial Cell Abnormalities:	**526**	**16.3**	**525**	**16.3**
Squamous Cell:				
ASCUS (combined)	239	7.4	236	7.3
Favor reactive	82	2.5	73	2.3
Favor neoplastic	81	2.5	69	2.1
Undetermined	76	2.4	94	2.9
LSIL	189	5.9	198	6.1
HSIL	81	2.5	73	2.3
Carcinoma	2	0.1	2	0.1
Glandular Cell:				
Benign Endometrial cells in Postmenopausal Women	11	0.3	11	0.3
AGUS (combined)	6	0.2	8	0.3
Favor reactive	2	0.1	2	0.1
Favor neoplastic	0	0.0	1	0.0
Undetermined	4	0.1	5	0.2

Note: Some patients had more than one descriptive diagnosis subcategory.

ASCUS=Atypical Squamous Cells of Undetermined Significance
AGUS=Atypical Glandular Cells of Undetermined Significance

Table 9 shows the summary of the Bethesda System categories of the adjudicated descriptive diagnosis data for all sites.

Table 9: Adjudicated Summary of Descriptive Diagnosis (Includes adjudicated cases only)

Descriptive Diagnosis	TP-2000		TP-3000	
Number of Patients: 376	N	%	N	%
Benign Cellular Changes:	**163**	**43.4**	**174**	**46.3**
Infection:				
Trichomonas Vaginalis	8	2.1	11	2.9
Candida spp.	35	9.3	30	8.0
Coccobacilli	62	16.5	72	19.1
Actinomyces spp.	0	0.0	0	0.0
Herpes	0	0.0	0	0.0
Other	2	0.5	0	0.0
Reactive Cellular Changes Associated with:				
Inflammation	89	23.7	96	25.5
Atrophic	1	0.3	0	0.0
Vaginitis	0	0.0	0	0.0
	0	0.0	1	0.3
Radiation	4	1.1	0	0.0
IUD				
Other				
Epithelial Cell Abnormalities:	**88**	**23.4**	**82**	**21.8**
Squamous Cell:				
ASCUS (combined)	87	23.2	78	20.7
Favor reactive	9	2.4	7	1.9
Favor neoplastic	33	8.8	31	8.2
Undetermined	45	12.0	40	10.6
LSIL	27	7.2	29	7.7
HSIL	9	2.4	6	1.6
Carcinoma	0	0.0	0	0.0
Glandular Cell:				
Benign Endometrial cells in Postmenopausal Women	1	0.3	0	0.0
AGUS (combined)	0	0.0	0	0.0
Favor reactive	0	0.0	0	0.0
Favor neoplastic	0	0.0	0	0.0
Undetermined	0	0.0	0	0.0

Note: Some patients had more than one descriptive diagnosis subcategory.

ASCUS=Atypical Squamous Cells of Undetermined Significance
AGUS=Atypical Glandular Cells of Undetermined Significance

The Bethesda System delineates specimen adequacy in three categories: satisfactory, satisfactory but limited by (SBLB) and unsatisfactory. Of the 3,527 total patients enrolled in the study, 3,489 were included in the specimen adequacy analysis after all data integrity sorting was applied.

Tables 10 and 11 show the summary of the Bethesda System categories of the unadjudicated and adjudicated specimen adequacy data for all sites.

Table 10: Unadjudicated Summary of Specimen Adequacy Results

Specimen Adequacy Number of Patients: 3489	TP-2000		TP-3000	
	N	%	N	%
Satisfactory	**2985**	**85.6**	**2951**	**84.6**
Satisfactory for Evaluation but Limited by:	**385**	**11.0**	**398**	**11.4**
Air-Drying Artifact	0	0.0	1	0.0
Thick Smear	1	0.0	2	0.1
Endocervical Component Absent	244	7.0	237	6.8
Scant Squamous Epithelial Component	125	3.6	122	3.5
Obscuring Blood	22	0.6	29	0.8
Obscuring Inflammation	15	0.4	24	0.7
No Clinical History	0	0.0	2	0.1
Cytolysis	1	0.0	4	0.1
Other	0	0.0	2	0.1
Unsatisfactory for Evaluation:	**119**	**3.4**	**140**	**4.0**
Air-Drying Artifact	0	0.0	0	0.0
Thick Smear	0	0.0	0	0.0
Endocervical Component Absent	2	0.1	3	0.1
Scant Squamous Epithelial Component	109	3.1	126	3.6
Obscuring Blood	20	0.6	36	1.0
Obscuring Inflammation	3	0.1	5	0.1
No Clinical History	0	0.0	0	0.0
Cytolysis	0	0.0	0	0.0
Other	0	0.0	1	0.0

Note: Some patients had more than one subcategory.

Table 11: Adjudicated Summary of Specimen Adequacy Results (Includes adjudicated cases only)

Specimen Adequacy *Number of Patients: 57*	TP-2000		TP-3000	
	N	%	N	%
Satisfactory	**12**	**21.1**	**9**	**15.8**
Satisfactory for Evaluation but Limited by:	**24**	**42.1**	**18**	**31.6**
Air-Drying Artifact	0	0.0	0	0.0
Thick Smear	0	0.0	0	0.0
Endocervical Component Absent	6	10.5	4	7.0
Scant Squamous Epithelial Component	24	42.1	18	31.6
Obscuring Blood	0	0.0	1	1.8
Obscuring Inflammation	1	1.8	3	5.3
No Clinical History	0	0.0	0	0.0
Cytolysis	0	0.0	0	0.0
Other	0	0.0	0	0.0
Unsatisfactory for Evaluation:	**21**	**36.8**	**30**	**52.6**
Air-Drying Artifact	0	0.0	0	0.0
Thick Smear	0	0.0	0	0.0
Endocervical Component Absent	13	22.8	9	15.8
Scant Squamous Epithelial Component	21	36.8	30	52.6
Obscuring Blood	0	0.0	10	17.5
Obscuring Inflammation	1	1.8	3	5.3
No Clinical History	0	0.0	0	0.0
Cytolysis	0	0.0	0	0.0
Other	0	0.0	0	0.0

Note: Some patients had more than one subcategory.

Table 12 shows the adjudicated specimen adequacy results, respectively, from all sites for the TP-3000 and TP-2000.

Table 12: Adjudicated Two-Category Diagnostic Classification Table, Specimen Adequacy Results (Includes adjudicated cases only)

		TP-3000		
		SBLB/SAT	**UNSAT**	**TOTAL**
TP-2000	**SBLB/SAT**	**23**	**13**	**36**
	UNSAT	**4**	**17**	**21**
	TOTAL	**27**	**30**	**57**

The adjudicated specimen adequacy results from each site are presented in Table 13 as SAT/SBLB versus UNSAT.

Table 13: Adjudicated Specimen Adequacy Results by Site *(*Includes adjudicated cases only)

		SAT/SBLB		UNSAT*	
Site	**Cases**	**TP-3000 Cases**	**TP-2000 Cases**	**TP-3000 Cases**	**TP-2000 Cases**
S1	50	24	33	26	17
S2	1	0	0	1	1
S3	6	3	3	3	3
All Sites	57	27	36	30	21

Note: Excessively bloody samples may result in a higher unsatisfactory rate.

The TP-3000 provides similar results to the TP-2000 System in a variety of patient populations. The TP-3000 may be used as a replacement for the TP-2000 System in the preparation of cervical cytology samples on glass microscope slides used in the detection of atypical cells, cervical cancer, or its precursor lesions, as well as all other cytologic categories as defined by The Bethesda System.

TECHNICAL SERVICE AND PRODUCT INFORMATION

For technical service and assistance related to use of the ThinPrep® 3000 Processor, contact Hologic:

Telephone: 1-800-442-9892
Fax: 1-508-229-2795

For international or toll-free blocked calls, please contact 1-508-263-2900.
Email: info@hologic.com

REQUIRED MATERIALS

The TP-3000 consists of the following components:

- The ThinPrep® 3000 Processor (Model TP-3000)
- ThinPrep 3000 Processor Operator's Manual
- Power Cord
- Program Memory Card
- Staining Rack Adapters
- Accessory Kit

MATERIALS REQUIRED BUT NOT PROVIDED

- Slide staining system
- Coverslips and mounting media
- 20 ml PreservCyt® Solution vials
- ThinPrep Pap Test Filters
- CellFyx™ Fixative Solution
- ThinPrep Microscope Slides

STORAGE

- Store PreservCyt Solution between 15°C (59°F) and 30°C (86°F). Do not use beyond the expiration date printed on the container.
- Store PreservCyt Solution *with* cytologic sample intended for ThinPrep Pap testing between 15°C (59°F) and 30°C (86°F) for up to 6 weeks.
- Store PreservCyt Solution *with* cytologic sample intended for CT/NG using the Roche Diagnostics COBAS AMPLICOR CT/NG test testing between 4°C (39°F) and 25°C (77°F) for up to 6 weeks.
- Store CellFyx Solution between 15°C and 30°C. Do not use beyond the expiration date printed on the container.
- CellFyx Solution preserves cells on slides up to 5 days at 15°C to 30°C prior to staining.

BIBLIOGRAPHY

1. Kurman RJ, Solomon D. *The Bethesda System for Reporting Cervical/Vaginal Cytologic Diseases*, Springer-Verlag, New York 1994.
2. United States Pharmacopeia (U.S.P.), Preservative Antimicrobial Effectiveness Test, U.S.P. XXII (51).
3. Jones HW. Impact of The Bethesda System, *Cancer* 77 pp. 1914-1918, 1995.
4. American Cancer Society. Cancer Facts and Figures, 1995.

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