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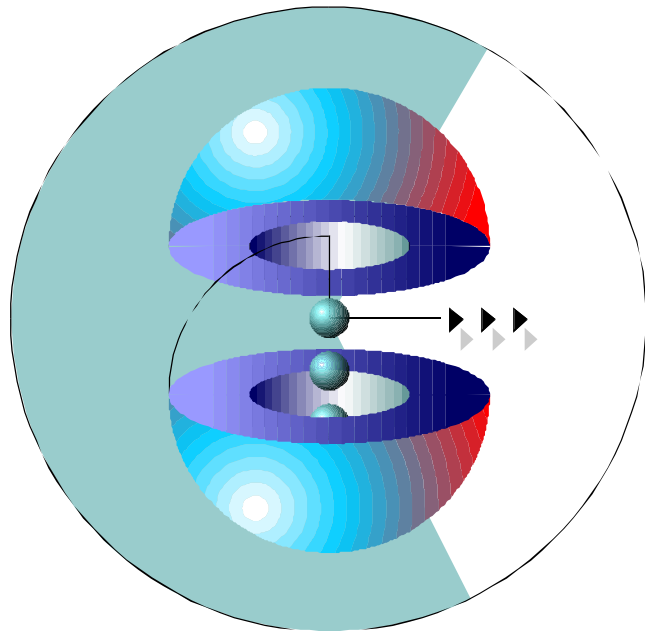
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2003

CytoBase Report

Cervical Cytology Database Statistics
Volume 7, Number 2, December 31, 2003

Ammended



Prepared by:
Artificial Intelligence in Medicine Inc.
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This report presents database statistics for the period starting January 1st, 2003 through December 31st, 2003 representing the statistics for 2003. This report produced by INSCYTE* Corporation contains only a subset of the information that the CytoBase system is capable of providing.

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*Information Systems for Cytology



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2003 CytoBase Report Highlights

- Focus on women based as opposed to report based data.
- Total number of report received in 2003: 1,442,878
- Total number of women-based reports: 1,360,833
- Number of newly registered women in 2003: 235,158
- Captured 97.2% (1.44 million) reports of Pap smears read in community laboratories and approximately 80% of all Pap smear reports in the province.
- Reports meet international quality benchmarks.
- With the enactment of Bill 31 (PHIPA), Cytobase has been prescribed as a Registry for information related to cervical cancer.
- Ability for cytopathologists to examine on line the prior Pap smear history of women in reporting smears and making recommendations.
- Routine on line access for cytotechnologists to facilitate interpretation of Pap smears.
- Web based access for Physicians/Delegates to CytoBase for Clinicians.



Explanatory Commentary

A uniform procedure, established by the Data Review Committee in 1997, had been used to tabulate statistics for the Annual Report to permit data to be compared from one year to another. The method is hierarchical, that is, each case is counted under the most severe diagnostic code that is reported. Severity was deemed to be proportional to the magnitude of the CytoBase abstract syntax code, for example, 04.02 is taken to be more severe than 04.01.

In the context of the old Bethesda system, the Committee's procedure required that reports without a diagnostic code not be included in the statistical tabulations by age and by diagnostic category. Consequently, reports coded with both diagnostic and non-diagnostic codes, where the non-diagnostic code is the highest magnitude, were not included. For example, a report that was coded with both 04.02 (Organisms & Inflammation) and 04.01 (Within Normal Limits) is categorized, for the Report, under the higher number, and, because 04.02 was not a diagnostic code, this report was not included in the age and diagnostic category tabulations. The numbers of this type of report that were received were noted in each Annual Report.

While generally the number of reports not included for this reason was small, there was an increase to 17% in 2003 because changes to the coding system with the introduction of Bethesda 2001 changed the meaning of 04.03 from Benign Cellular Changes, to Non-Neoplastic Findings. Since the first was considered to be a diagnostic code and the second not, more reports were not included in the tabulations. As a result, the procedure for tabulating results for the Annual Report has been modified to include all codes, whether or not they are deemed diagnostic. Codes between 04.01 and 04.04 are included in the Negative for Intraepithelial Lesion or Malignancy (NILM) category.

Re-tabulating the results in this way has resulted in higher numbers in the NILM category and changed the calculated percentage distributions of abnormalities. The results are published in this 2003 Amended Annual Report, which may be compared to the original 2003 Annual Report. These differences in the Amended 2003 Annual Report have been highlighted. The remaining data have not changed.



What is CytoBase?

CytoBase is a patient-centered computerized medical record of Cytology reports with on-line submission and query capabilities. The system was designed, developed and made operational by Artificial Intelligence In Medicine Inc. (AIM), a Toronto based software engineering firm under contract to INSCYTE Corporation, a not for profit organization formed by six private medical laboratories¹ and subsequently Cancer Care Ontario. The system started operations on June 1, 1996.

Participating laboratories automatically download all cervical cytology results and related patient data to the central database on a daily basis. The system software automatically registers new patients and links reports to patient records. Cytotechnologists and pathologists reading smears at the participating laboratories have on-line access to this database to improve diagnostic accuracy, and ensure that pre-neoplastic and neoplastic lesions are not overlooked.

Legend for Diagnostic Classes

All cervical/vaginal cytologic specimen diagnoses are based on The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses (The Bethesda System), which are categorized as follows:

1. WNL/NILM: Within Normal Limits/ Negative for Intraepithelial Lesions and Malignancy
2. BCC: Benign Cellular Changes
3. ASCUS/ASC: Atypical Squamous Cells of Undetermined Significance/ Atypical Squamous Cells
4. AGUSAGC: Atypical Glandular Cells of Undetermined Significance/ Atypical Glandular Cells
5. EAIS: Endocervical Adenocarcinoma In Situ
6. LSIL: Low Grade Squamous Intraepithelial Lesion
7. HSIL: High Grade Squamous Intraepithelial Lesion (including carcinoma in situ)
8. Ca: Carcinoma
9. Oth.Mal.: Other Malignancies (including sarcoma)
10. Oth.Ab.: Other Abnormal cells seen (not otherwise classified)

In the diagnostic statistics presented herein, where a report includes findings falling into more than one classification, only the most severe class is included in the count. In the event that a report includes "other abnormal cells" (item 9) in combination with one or more of items 2 through 8, only the most severe of classes 2 through 8 is counted.

Each CytoBase report also contains the following information (to the extent that it has been provided by the source):

- a) Detailed description of specimen adequacy or limitations thereof
- b) Diagnostic classification according to the CytoBase Abstract Coding Syntax based on the Bethesda System (Please refer to the INSCYTE Website www.inscyte.org)
- c) Identification of specimen collection method
- d) Identification of slide preparation (e.g. traditional or monolayer)
- e) Identification of analysis method (e.g. microscopic, automated, computer assisted)
- f) Pathologist's recommendations (e.g. repeat smear in # months, colposcopy, biopsy, curettage, etc.)
- g) Pathologist's comments

AIM, on behalf of the Inscyte Corporation, has access to personal information about patients, physicians, etc. This information is handled in accordance with the Canadian Personal Information Protection and Electronic Documents Act (PIPEDA) and the US Health Insurance Portability and Accountability Act (HIPAA).



CytoBase Technical Summary (as of Nov 15th, 2004)

Performance:

Min. Report Transmission Speed: 229 reports per minute at 44,000 BPS (average)
Auto-Registration Rate: 50 patients reports per minute (average)
Rejection Rate: 1.7% average (primarily due to missing information or format errors)
Registered Reports: 10,345,868
Registered Patient ID's: 3,992,730
System Capacity: 15 million reports on current storage devices
7.5 million women on current storage devices

Hardware & Software:

Production Server

CPU: Compaq Alpha Server ES40 AXP 64-bit RISC @ 233 MHz
Memory: 512 Mbytes RAM
Operating System: Compaq TRU-64 UNIX (copyright © Compaq)
Database System: Oracle 8i - v8.1.6 RDBMS (copyright © Oracle Corporation)
Application Software: ISIS-CSP (copyright © AIM Inc.)
ISIS-CEI (copyright © AIM Inc.)
ISIS-CY_CDR (copyright © AIM Inc.)
TransMed EDI (copyright © AIM Inc.)
Disk Capacity: 48 Gigabytes RAID V
36 Gigabytes JBOD
Network Protocol: TCP/IP
Messaging Protocol: HL7 Version 2.3
Fault Tolerance: RAID Level 1 & 5 Hot Swap, UPS, auto-shutdown and auto-backup,
advanced replication
Security: PKI based private key, public key, and session key

Mirror Server

CPU: Digital Equipment Alpha AXP 64-bit RISC @ 233 MHz
Memory: 256 Mbytes RAM
Operating System: Compaq TRU-64 UNIX (copyright © Compaq)
Database System: Oracle 8i - v8.1.6 RDBMS (copyright © Oracle Corporation)
Application Software: ISIS-CSP (copyright © AIM Inc.)
ISIS-CEI (copyright © AIM Inc.)
ISIS-CY_CDR (copyright © AIM Inc.)
TransMed EDI (copyright © AIM Inc.)
Disk Capacity: 28 Gigabytes RAID V
36 Gigabytes JBOD
Network Protocol: TCP/IP
Messaging Protocol: HL7 Version 2.3
Fault Tolerance: RAID Level 1 & 5 Hot Swap, UPS, auto-shutdown and auto-backup,
advanced replication
Security: PKI based private key, public key, and session key



Submitting Laboratories

Participating Laboratories	Date of First Transmission to CytoBase	Specimen Date of Reports From	Last Specimen Date of Reports
Gamma North Peel Laboratories *	Jun. 9, 1996	Jun. 1, 1993	Oct. 24, 1997
Flemingdon Laboratories *	Jun. 11, 1996	Apr. 15, 1996	Jun. 12 1998
MDS Laboratories	Oct 10th, 1996	Oct 2, 1996	
Gamma-Dynacare Medical Laboratories - Airport Division	Nov. 22, 1996	Nov. 14, 1996	
Excel Bestview Medical Laboratories Limited *	Mar. 17, 1997	May 5, 1992	Dec. 31, 1996
Gamma-Dynacare Medical Laboratories - Ottawa Division	Jul. 15, 1998	Jan. 19, 1998	
Gamma-Dynacare Medical Laboratories - Windsor Division	Aug. 17, 1999	May 12, 1999	
Canadian Medical Laboratories	Dec. 22, 1999	May 11, 1999	
Medical Laboratories of Windsor	Oct. 19, 2000	Feb. 5, 1999	

* Laboratories now merged with others.

- 1 Med-Chem Laboratories Ltd.
 The Dynacare Health Group Inc.
 Excel Bestview Medical Laboratories Ltd.
 Flemingdon Medical Laboratories Ltd.
 Gamma North Peel Laboratories Ltd.
 MDS Health Group Inc.



Women Based Statistics

The following tables and figures categorize women by the most severe diagnosis for the period of time specified (January 1, 2003 to December 31, 2003) and the woman's age. The age is calculated based on the woman's date of birth at the time the specimen was taken with the most severe diagnosis. If a woman had more than one Pap in 2003 with the same diagnosis and the woman fell in two age ranges then the older was selected.

Distribution of the Most Severe Diagnosis for Women by Age and Class

Specimens Received January 1, 2003 to December 31, 2003

Age	WNL/ NILM	BCC	ASCUS /ASC	AGUS /AGC	EAIS	LSIL	HSIL	Ca.	Oth.Mal.	Oth.A		Total	%
										1	2		
10-14	1,013	35	42	0	0	42	3	0	0	0	0	1,135	0.08%
15-19	54,299	2,593	2,494	25	1	2,900	159	0	0	8	8	62,479	4.59%
20-24	120,087	5,768	5,945	120	0	6,223	614	0	0	29	29	138,787	10.20%
25-29	141,112	5,926	4,595	201	1	3,993	857	4	0	34	34	156,723	11.52%
30-34	154,376	6,072	3,815	269	5	2,408	787	5	0	45	45	167,783	12.33%
35-39	156,880	6,709	3,656	296	2	1,890	602	16	0	27	27	170,078	12.50%
40-44	157,625	6,865	3,497	325	6	1,485	446	16	0	27	27	170,292	12.51%
45-49	134,913	5,639	2,900	329	1	992	256	8	1	29	29	145,068	10.66%
50-54	110,858	3,777	2,202	286	2	658	145	18	2	22	22	117,970	8.67%
55-59	86,349	2,305	1,335	168	0	329	86	22	1	16	16	90,611	6.66%
60-64	57,629	1,331	748	107	0	189	70	21	2	8	8	60,105	4.42%
65-69	39,787	856	534	73	0	117	38	18	3	8	8	41,435	3.04%
70-74	21,366	470	281	43	0	66	28	15	1	6	6	22,276	1.64%
75-79	10,596	250	130	31	0	22	14	10	2	4	4	11,059	0.81%
80-84	3,707	112	65	12	0	10	3	5	0	2	2	3,916	0.29%
85-89	836	32	13	4	0	6	1	3	0	0	0	895	0.07%
90+	196	14	2	3	0	2	1	2	1	0	0	221	0.02%
Total	1,251,629	48,754	32,254	2,292	18	21,332	4,110	163	13	265	265	1,360,833 ³	100.00%
%	91.98%	3.58%	2.37%	0.17%	0.00%	1.57%	0.30%	0.01%	0.00%	0.02%	0.02%	100.00%	

¹ The "other malignancies" category includes Consistent with Malignancy (3) and Malignant cells seen (3)

² The "other abnormal" category includes findings and/or suspicion of abnormalities that were not formally classified.

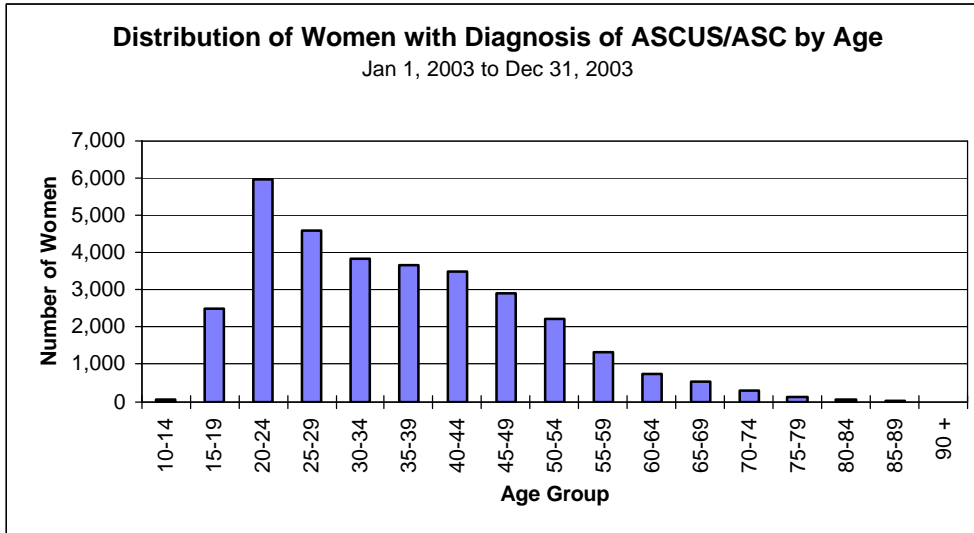
³ The total number of women in the above table is less than the number of reports received (1,442,878) and does not include: those patient's with reports classified as unsatisfactory, the date of birth cannot be determined, and duplicate pap reports (82,045).

In the diagnostic statistics presented herein, where a woman has two or more reports, only the most severe class is included in the count.

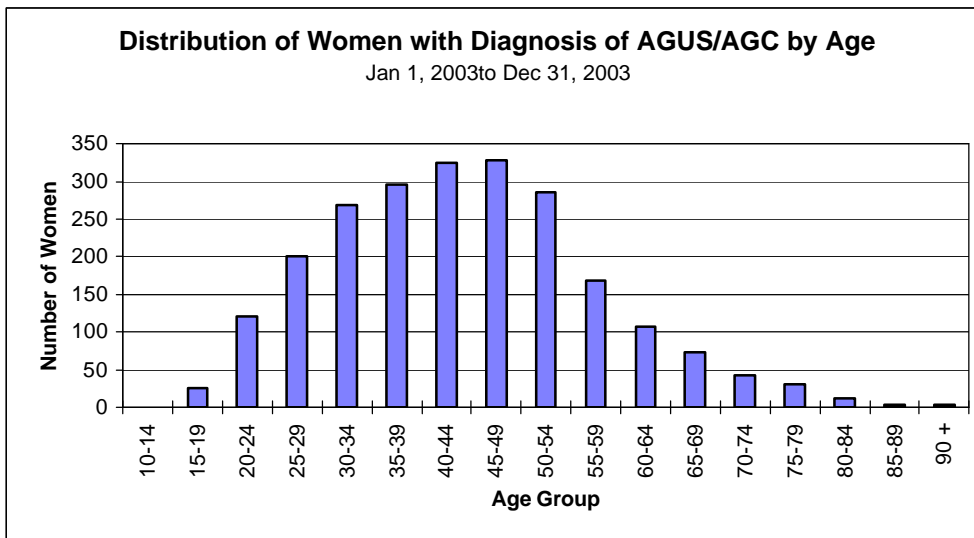


Women Based Statistics

Distribution of Women with Diagnosis of ASCUS/ASC and AGUS/AGC by Age



Atypical squamous cells of undetermined significance account for **2.37%** (32,254) of reported findings.

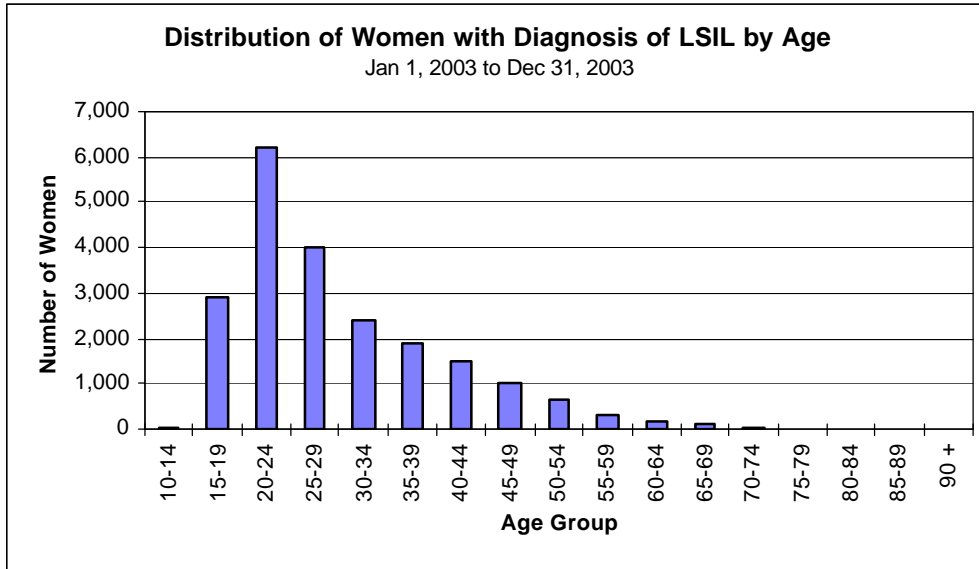


Atypical glandular cells of undetermined significance account for **0.17%** (2,292) of reported findings.

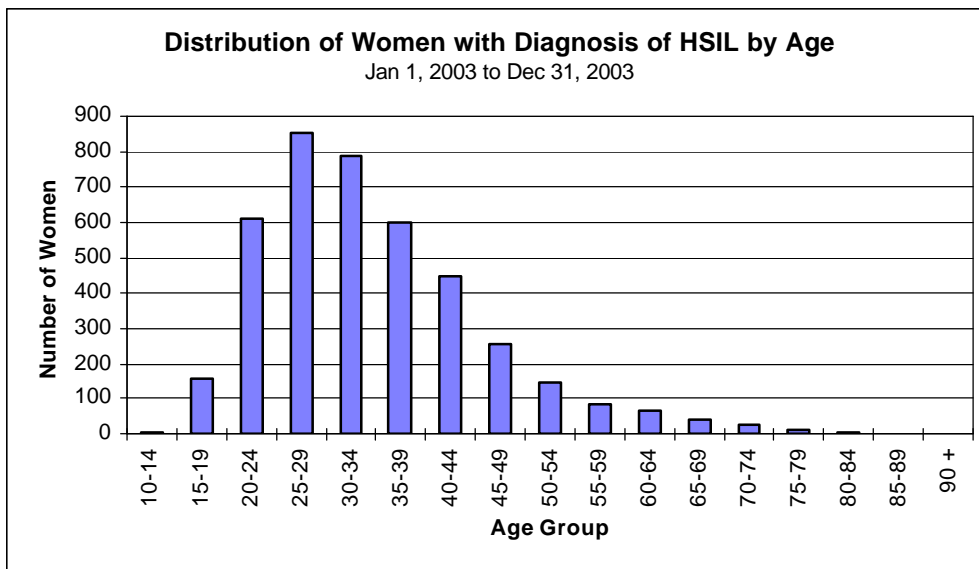


Women Based Statistics

Distribution of Women with Diagnosis of Low Grade and High Grade Squamous Intraepithelial Lesions by Age



Low grade squamous intraepithelial lesions account for **1.57%** (21,332) of reported findings.

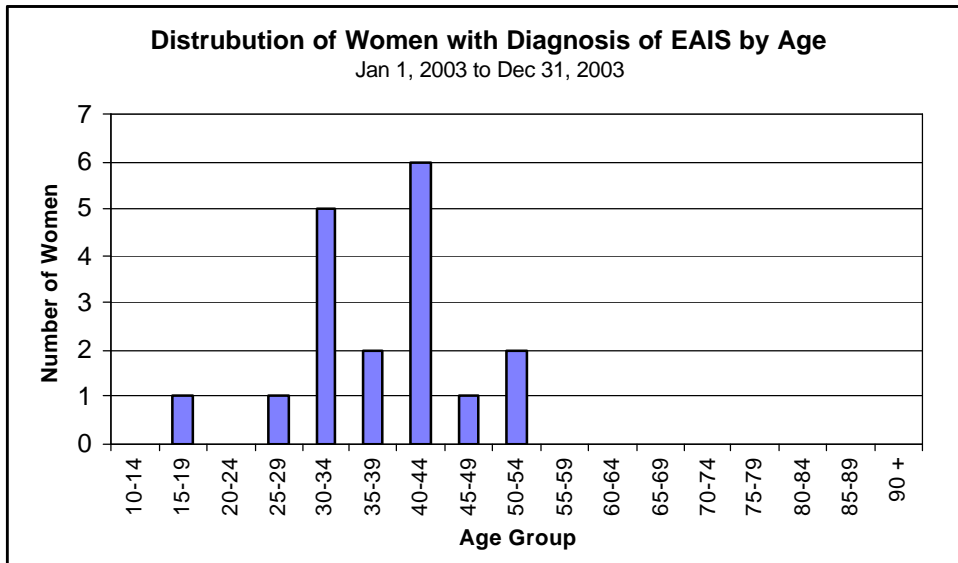


High grade squamous intraepithelial lesions account for **0.30%** (4,110) of reported findings.



Women Based Statistics

Distribution of Women with Diagnosis of Endocervical Carcinoma in situ by Age



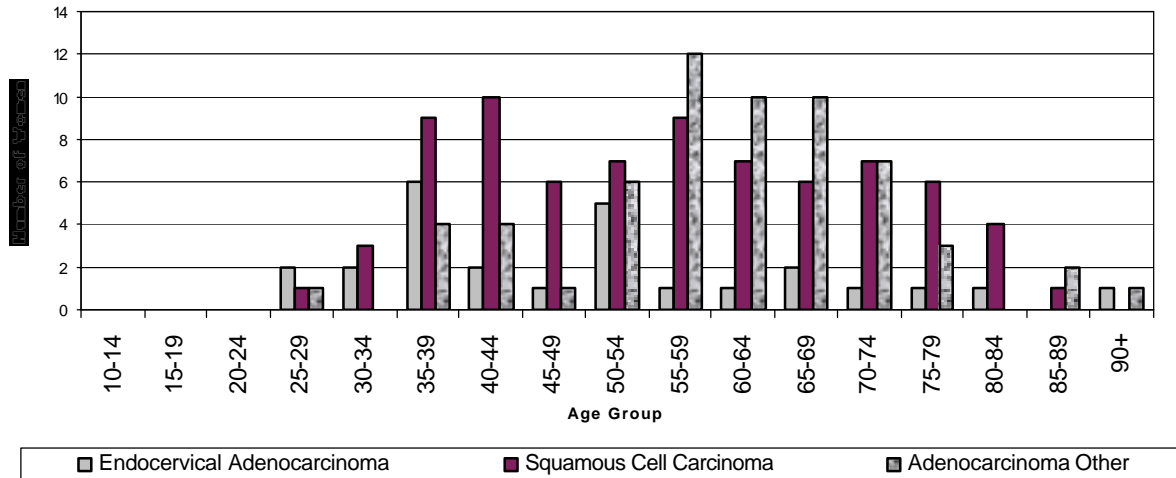
Endocervical Carcinoma in situ account for 0.00% (18) of reported findings



Women Based Statistics

Distribution of Women with Cytological Diagnosis of Carcinoma by Age and Cell Type

Distribution of Women with Cytological Diagnosis of Carcinoma by Age and Cell Type
 Jan 1, 2003 to Dec 31, 2003



Carcinomas account for 0.01 (163)% of reported findings

A cytological diagnosis was made of :

Carcinoma	1
Adenocarcinoma	22
Endometrial Adenocarcinoma	38
Endocervical Adenocarcinoma	26
Extra-Uterine Adenocarcinoma	0
Adenocarcinoma NOS	1
Squamous Cell Carcinoma	76

Total 163



Women Based Statistics

Jan 1, 2003 to Dec 31, 2003

Distribution of Screened Women by Age as a Percentage of the Female Population of Ontario

Age Group	Number of Women	Ontario Female Population	Percent of Population
10-14	1,135	394,424	0.29%
15-19	62,479	384,274	16.26%
20-24	138,787	383,299	36.21%
25-29	156,723	401,444	39.04%
30-34	167,783	443,289	37.85%
35-39	170,078	508,076	33.47%
40-44	170,292	514,652	33.09%
45-49	145,068	459,332	31.58%
50-54	117,970	400,729	29.44%
55-59	90,611	330,867	27.39%
60-64	60,105	260,135	23.11%
65-69	41,435	228,536	18.13%
70-74	22,276	212,148	10.50%
75-79	11,059	186,037	5.94%
80-84	3,916	129,420	3.03%
85-89	895	117,528	0.76%
90+	221	117,528	0.19%
Total	1,360,833	5,471,718	24.87%

¹ Taken from Total by Age Group of the Distribution of the Most Severe Diagnosis for Women by Age and Class (page 6)

¹ 2001 Census Based Population- 2002 Estimates: Statistics Canada and Ontario Ministry of Finance



Women Based Statistics

Newly Registered Women

The following table describes the age distribution of women registered for the first time in the CytoBase system during the calendar year 2003, and as a percentage of the female population of the province of Ontario. In this period, the system captured 4.37% of the female population.

The qualifying criteria for inclusion in this list are that 1) the patient's specimen was collected during the time period in question and 2) this is the patient's first report registered in the system.

Newly Registered Women of Ontario Female Population Jan 1, 2003 to Dec 31, 2003

Age Group	Newly Registered	Ontario Female Population	% of Cohort Registered
10-14	1,081	399,245	0.27%
15-19	37,094	398,124	9.32%
20-24	35,837	394,358	9.09%
25-29	27,347	404,741	6.76%
30-34	24,490	450,320	5.44%
35-39	22,443	512,847	4.38%
40-44	22,062	515,793	4.28%
45-49	18,266	460,809	3.96%
50-54	13,894	403,301	3.45%
55-59	10,692	327,284	3.27%
60-64	7,867	257,743	3.05%
65-69	5,981	227,175	2.63%
70-74	3,922	211,736	1.85%
75-79	2,565	185,008	1.39%
80-84	1,160	128,184	0.90%
85-89	346	70,457	0.49%
90 +	111	38,419	0.29%
Total	235,158	5,385,544	4.37%

¹ 2001 Census Based Population – 2002 Estimates: Statistics Canada and Ontario Ministry of Finance



Report Based Statistics

The following table lists reported findings categorized by diagnostic class (most severe finding on the report) and the woman's age. The age is calculated based on the woman's date of birth at the time the specimen was taken with the most severe diagnosis.

Distribution of Reports by Age and Diagnostic Class

Specimens Received from January 1, 2003 to December 31, 2003

Age	WNL/ NILM	BCC	ASCUS /ASC	AGUS /AGC	EAIS	LSIL	HSIL	Ca.	Oth.Mal.	Oth.Ab	Total	%
10-14	1072	35	49	0	0	49	3	0	0	0	1,208	0.08%
15-19	57916	2706	2893	28	1	3210	168	0	0	8	66,930	4.64%
20-24	129543	6017	7031	123	0	6963	668	0	0	31	150,376	10.43%
25-29	152509	6113	5374	218	2	4473	931	4	1	35	169,660	11.77%
30-34	165487	6224	4370	293	5	2694	858	5	0	48	179,984	12.49%
35-39	165333	6879	4156	322	2	2157	651	16	0	27	179,543	12.46%
40-44	164582	7046	3933	342	6	1681	480	16	0	28	178,114	12.36%
45-49	140422	5796	3213	343	1	1113	276	8	1	29	151,202	10.49%
50-54	114863	3870	2454	294	2	724	158	18	3	22	122,408	8.49%
55-59	89050	2368	1472	171	0	368	89	22	1	17	93,558	6.49%
60-64	59152	1363	821	109	0	222	74	22	2	8	61,773	4.29%
65-69	40799	872	606	77	0	130	43	18	3	8	42,556	2.95%
70-74	21940	475	319	43	0	84	31	17	1	6	22,916	1.59%
75-79	10891	259	150	31	0	26	15	10	2	4	11,388	0.79%
80-84	3842	113	70	12	0	11	3	5	0	2	4,058	0.28%
85-89	874	33	14	4	0	6	1	4	0	0	936	0.06%
90 +	203	14	2	3	0	2	1	2	1	0	228	0.42%
Total	1,318,478	50,183	36,927	2,413	19	23,913	4,450	167	15	273	1,436,838	100.00%
%	91.76%	3.49%	2.57%	0.17%	0.00%	1.66%	0.31%	0.01%	0.00%	0.02%		

¹ The "other abnormal" category includes findings and/or suspicion of abnormalities that were not formally classified.

² The total number of reports in the above table is less than the number of reports received (1,442,878) and do not include: those patients with reports classified as unsatisfactory, the date of birth cannot be determined (6,040).



Report Based Statistics

Specimen Adequacy Statistics

A report may contain several Unsatisfactory or Limited/Qualified by findings.

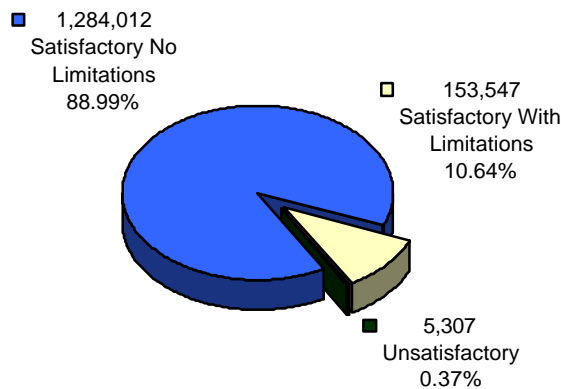
Result Category	Number of Reports	% of Reports	Number of Findings	% of Findings
Satisfactory No Limitations/Qualifiers	1,284,012	88.99%	1,284,134	88.25%
Satisfactory With Limitations/Qualifiers	153,547	10.64%	162,893	11.19%
Unsatisfactory for Evaluation	5,307	0.37%	8,145	0.56%
Total	1,442,866	100.00%	1,455,172	100.00%

Multiple Findings per Report 12,294

Cytology Reports by Specimen Adequacy

Jan 1, 2003 to Dec 31, 2003

Total 1,442,866



Of the total number of reports (1,442,878) in the interval examined, there were 88.99% of reports (1,284,024) with no limitations. Of the remaining reports, 10.64% (153,547) were limited in some way and 5,307 (0.37%) were deemed unsatisfactory for cytological evaluation.



Report Based Statistics

Reason for Specimen Limitations/Qualifiers by Findings

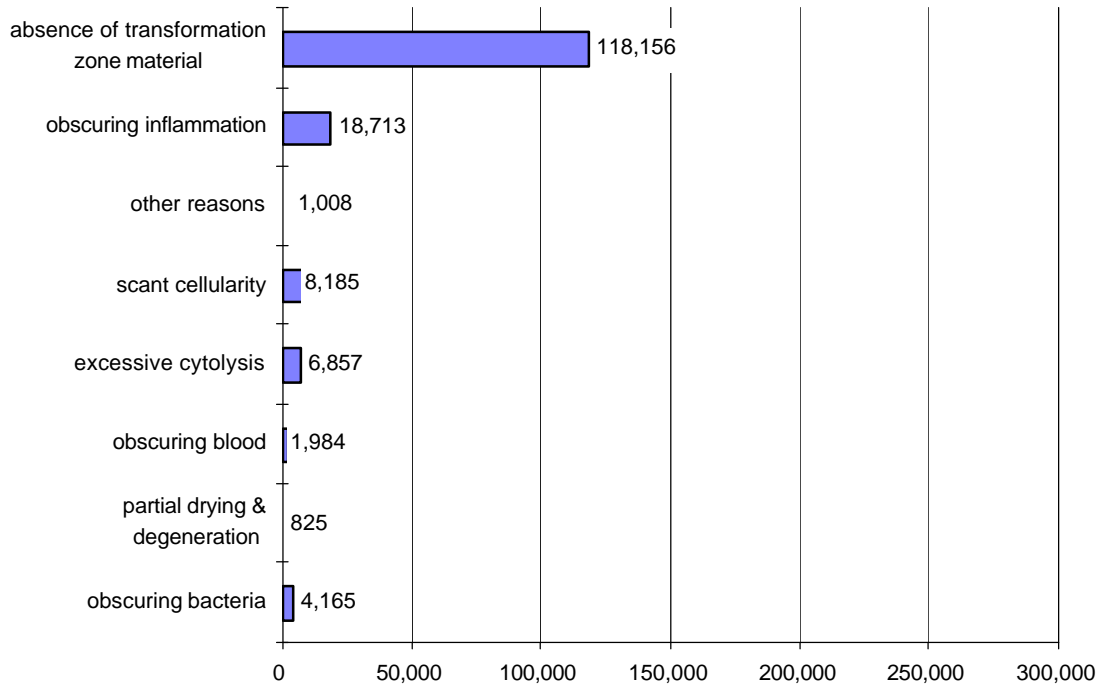
Distribution of Satisfactory but Limited/Qualified Findings by Reason

absence of transformation zone material	118,156	73.90%
obscuring inflammation	18,713	11.70%
other reasons	1,008	0.63%
scant cellularity	8,185	5.12%
obscuring blood	1,984	1.24%
partial drying & degeneration	825	0.52%
excessive cytolysis	6,857	4.29%
obscuring bacteria	4,165	2.60%

Total Number of Satisfactory but Limited/Qualified by Findings	159,892	100.00%
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Number of Satisfactory but Limited/Qualified by Findings by Reason

Jan 1, 2003 to Dec 31, 2003



Report Based Statistics

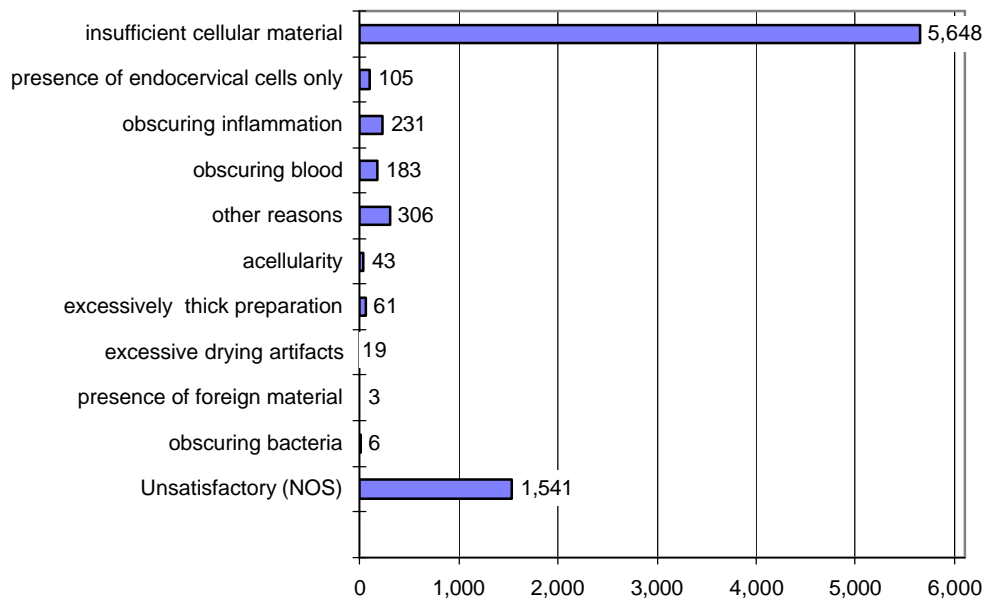
Reason for Specimen Inadequacy by Findings

Distribution of Unsatisfactory Findings by Reason

insufficient cellular material	5,648	69.33%
presence of endocervical cells only	105	1.29%
obscuring inflammation	231	2.84%
obscuring blood	183	2.25%
acellularity	43	0.53%
other reasons	306	3.76%
excessively thick preparation	61	0.75%
excessive drying artifacts	19	0.23%
presence of foreign material	3	0.04%
obscuring bacteria	6	0.07%
Unsatisfactory (NOS)	1,541	18.92%
Broken Slide	0	0.00%
Total Number of Unsatisfactory Findings	8,146	100.00%

Number of Unsatisfactory Findings by Reason

Jan 1, 2003 to Dec 31, 2003



Report Based Statistics

Cytology Reports by Province Code of Health Number

Jan 1st 2003 to Dec 31st 2003

Distribution of Reports by Province Health Number Code

Alberta	214	0.01%
British Columbia	364	0.02%
Manitoba	14	0.00%
New Brunswick	215	0.01%
Newfoundland	132	0.01%
Nova Scotia	168	0.01%
Nunavut (North West Territories)	2,550	0.17%
Ontario	525,222	35.97%
Prince Edward Island	26	0.00%
Quebec	10,498	0.72%
Saskatchewan	57	0.00%
Yukon	9	0.00%
[Unspecified]*	903,409	61.86%

Total 1,442,878

* Province Health Code not submitted, presumed to be Ontario



Report Based Statistics

Cumulative Database – Distribution by Age and Diagnostic Class

Specimens Received from June 1, 1996 to December 31, 2003 as of Dec 16, 2004

Age	WNL / NILM	BCC	ASCUS /ASC	AGUS /AGC	LSIL	EAIS	HSIL	Ca.	Oth. Mal.	Oth.A b.	Total	%
10-14	6,190	845	198	10	206	0	16	0	0	0	7,465	0.09%
15-19	313,130	47,666	14,779	522	14,250	1	1,329	1	0	92	391,770	4.48%
20-24	721,024	108,493	36,646	1,922	31,217	0	4,894	4	3	278	904,482	10.35%
25-29	892,717	118,360	32,675	3,276	21,894	2	6,777	34	8	351	1,076,094	12.31%
30-34	977,172	127,487	28,643	4,236	15,033	5	6,029	52	12	381	1,159,051	13.26%
35-39	967,860	138,179	28,700	4,873	11,840	2	4,771	86	12	334	1,156,657	13.23%
40-44	862,867	128,865	26,327	4,888	8,562	6	3,226	75	7	316	1,035,139	11.84%
45-49	733,182	107,963	22,359	4,905	5,991	1	2,003	87	12	230	876,733	10.03%
50-54	622,170	80,357	16,509	4,149	4,040	2	1,137	98	11	218	728,691	8.34%
55-59	450,587	48,963	10,001	2,309	2,106	0	673	128	10	164	514,941	5.89%
60-64	319,440	31,594	6,124	1,362	1,203	0	497	114	10	100	360,444	4.12%
65-69	235,130	22,302	4,095	940	780	0	384	106	11	90	263,839	3.02%
70-74	137,436	13,190	2,362	551	482	0	278	111	6	64	154,480	1.77%
75-79	69,545	6,772	1,146	291	203	0	143	76	19	47	78,242	0.90%
80-84	22,691	2,373	427	115	90	0	53	57	3	21	25,830	0.30%
85-89	5,712	690	86	30	26	0	20	34	2	11	6,611	0.08%
90 +	1,325	163	29	12	7	0	8	6	2	2	1,554	0.02%
Total	7,338,178	984,262	231,106	34,391	117,930	19	32,238	1,069	128	2,699	8,742,023	100.00%
%	83.94%	11.26%	2.64%	0.39%	1.35%	0.00%	0.37%	0.01%	0.00%	0.03%		

¹ The "other abnormal" category includes findings and/or suspicion of abnormalities that were not formally classified.

A comparison of Cumulative Data from previous CytoBase reports may show changes in classification due to reports that were subsequently amended and the addition of reports with "non-diagnostic classification."

