Table 14: Cytotechnologist Screening Rates

Site/CT	Review Methods	Total Number of Slides Evaluated	Average Number of Hours Screened Per Day	Extrapolated Daily Rates (8-hour workday)		
				Low Day	Average Day	High Day
Site 1	Manual	2568	7.4	49	69	94
	Imager	2297	6.0	107	153	206
1-1	Manual	1284	7.5	49	60	72
	Imager	1168	6.1	117	153	182
1-2	Manual	1284	7.3	70	78	94
	Imager	1129	5.9	107	154	206
Site 2	Manual	2686	7.7	40	68	80
	Imager	2665	7.8	69	109	131
2-1	Manual	1348	7.6	40	71	80
	Imager	1309	7.9	97	110	118
2-2	Manual	1338	7.8	55	66	75
	Imager	1356	7.7	69	109	131
Site 3	Manual	2738	7.9	20	80	101
	Imager	2726	4.5	148	204	320
3-1	Manual	1368	7.9	63	82	91
	Imager	1460	4.2	167	230	320
3-2	Manual	1370	7.8	20	78	101
	Imager	1266	4.7	148	178	212
Site 4	Manual	2612	7.6	42	69	94
	Imager	2524	5.1	86	138	198
4-1	Manual	1305	8.2	59	75	84
	Imager	1252	5.1	86	150	190
4-2	Manual	1307	6.9	42	63	94
	Imager	1272	5.0	109	126	198

Table 15 summarizes the *Manual Review* versus the *Imager Review* for ASCUS+ and HSIL+ sensitivity and specificity by site. The table also presents the prevalence of ASCUS+, LSIL+, and HSIL+ among the reviewed slides and the respective screening daily rates of each review method. The daily screening rates are extrapolated to an 8-hour workday and are presented as the low, average and high daily screening rates by site.

Table 15: Screening Rates, Prevalence of ASCUS+, LSIL+, HSIL+, and Respective Performance for ASCUS+ and HSIL+.

Site	% of ASCUS+	% of LSIL+	% of HSIL+	Review Methods	Extrapolated Daily Rates (8-hour workday)			Performance for ASCUS+				Performance for HSIL+			
					Low Day	Average Day	High Day	Sensitivity		Specificity		Sensitivity		Specificity	
Site 1	7.7%	4.5%	1.6%	Manual	49	69	94	77.2%	+1.1%	98.7%	+0.4%	89.5%	+2.6%	98.8%	+0.7%
				Imager	107	153	206	78.3%		99.2%		92.1%		99.5%	
Site2	9.2%	4.0%	1.6%	Manual	40	68	80	63.1%	+14.4%	95.8%	+0.3%	72.5%	-2.5%	99.8%	-0.1%
				Imager	69	109	131	77.7%		96.1%		70.0%		99.6%	
Site 3	4.4%	2.7%	1.0%	Manual	20	80	101	80.6%	+13.6%	98.5%	+0.4%	64.3%	+13.6%	99.7%	0%
				Imager	148	204	320	94.2%		98.8%		78.6%		99.7%	
Site 4	7.2%	4.5%	1.6%	Manual	42	69	94	87.2%	-2.8%	97.3%	-0.3%	61.5%	+12.8%	99.5%	+0.3%
				Imager	86	138	198	84.4%		97.0%		74.4%		99.8%	

The clinical study data show that the screening rates achieved with the ThinPrep® Imaging System resulted in sensitivity or specificity values that fall within acceptable limits.

Laboratorians should use the following method when calculating workload:

- All slides with Fields of View (FOV) only review count as 0.5 or ½ slide
- All slides with full manual review (FMR) using the Autoscan feature count as 1 slide (as mandated by CLIA'88 for manual screening)
- Then, slides with **both** FOV and FMR count as 1.5 or 1½ slides
- Use these values to count workload, not exceeding the CLIA maximum limit of 100 slides in no less than an 8-hour day.

FMR = 1 slide
FOV = 0.5 slide
FMR + FOV = 1.5 slides
Upper Limit = 100 slides

The ThinPrep® Imaging System limit of 100 slides in an 8-hour workday includes the following:

- Screening 22 Fields of View
- Full manual slide review using the Autoscan feature
- Review clinical history
- Record results and triage appropriately

An example of workload scenario for ThinPrep Pap slides using the Thinprep Imaging System:
100 FOV review only = 50 slides (100 x 0.5 = 50)
30 FOV review + FMR = 45 slides (30 x 1.5 = 45)
Total number of slides screened = 95 (50 FOV only and 45 FOV + FMR)

- **Note:** ALL laboratories should have a clear standard operation procedure for documentation of their method of workload counting and for establishing workload limits.
- It is the responsibility of the Technical Supervisor to evaluate and set workload limits for individual cytotechnologists based on laboratory clinical performance.

According to CLIA '88, these workload limits should be reassessed every six months.

For less than an 8-hour workday, the following formula must be applied to determine the maximum number of slides to be reviewed during that workday:

$$\left(\frac{\text{Number of hours examining slides}}{8}\right) \times 100$$

The manual workload limit does not supercede the CLIA requirement of 100 slides in a 24-hour period in no less than an 8-hour day. Manual review includes the following types of slides:

- Slides reviewed on the ThinPrep Imaging System using the Autoscan feature
- Slides reviewed without the ThinPrep Imaging System
- Non–gynecologic slides.

When conducting manual review, refer to the CLIA requirements for calculating workload limits.

H. Clinical Investigation Conclusions

- For all sites combined for ASCUS+, the improvement in sensitivity of the *Imager Review* method over the *Manual Review* method is statistically significant. This increase is 6.4% with a 95% confidence interval of 2.6% to 10.0% for all sites combined. The differences in sensitivity varied among the sites from –2.8% to +14.4%. For LSIL+ and HSIL+ the sensitivity of the *Imager Review* method is equivalent to the *Manual Review* method.
- For all sites combined for HSIL+, the improvement in specificity of the *Imager Review* method over the *Manual Review* method is statistically significant. This increase is 0.2% with a 95% confidence interval of 0.06% to 0.4% for all sites combined. The differences in specificity varied among the sites from –0.1% to +0.7%. For ASCUS+ and LSIL+ the