Form Approved
OMB No. 0920-XXXX
Expiration Date (one year from date of approval)

Public reporting burden of this collection of information is estimated to average **30** minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).

Image-Assisted Cytology Workload Practices Survey

Laboratory Supervision Section

See the Glossary at the end of this questionnaire for abbreviations.

- 1. Please select the option which best describes your laboratory.
 - Non-profit hospital
 - For-profit hospital
 - City/County/State hospital
 - University hospital/academic medical center
 - O Public health, non-hospital
 - O Veteran's Administration hospital
 - Department of Defense hospital
 - O Regional/local independent laboratory group practice
 - O National/corporate laboratory (owned by a national corporation)
- 2. Which accrediting body inspects your laboratory?
 - College of American Pathologists
 - O The Joint Commission
 - O Centers for Medicare & Medicaid Services
- 3. Please provide information on the laboratory's cytology personnel for 2012.

Personnel	Number of FTEs
Pathologists who practice gynecologic cytopathology	
Pathologists who perform primary screening of GYN slides	
Cytotechnologists	
Cytotechnologists (Included in line above) who screen only gynecologic slides	

4.	What were v	your laboratory	's c	vtology	test	volumes	for	2012?

Preparation type	Number of cases
Total	
GYN ThinPrep®	
GYN SurePath™	
GYN Conventional	
Non-GYN/FNA	

5. How many cases did your laboratory screen by computer-assisted screening in 2012?

Method	Number of cases
Total	
ThinPrep® Imaging	
Focal Point™ GS Imaging System	
GYN Focal Point™ Slide Profiler	

6.	What per cent of your imaged assisted GYN cytology cases required Full Manual Review (FMR) in 2012?

- 7. For workload recording, how does your laboratory count a GYN slide? Select all that apply.
 - © Each slide screened for FOV is counted as one half (0.5) slide
 - O Each slide (either FOV or FMR) is counted as 1 slide
 - $\circ\hspace{0.4cm}$ Each slide that is screened for FOV and a FMR is performed, count as 1 slide
 - O Each slide that is screened for FOV and a FMR is performed, count as 1.5 slides

0	Other

8.	For wo	rkload recording, how does your laboratory count a Non-GYN slide? Select all that
	apply.	Each case counts as 1 slide
		Each slide counts as 1 slide
		Each slide prepared by Cytospin® counts as 1 slide
		Each slide prepared by Cytospin® counts as 0.5 slide
	0	Each slide prepared by automated methods (other than Cytospin®) counts as 1 slide Each slide prepared by automated methods (other than Cytospin®) counts as 0.5 slide
	0	Each cell block slide counts as 1 slide
	0	Each cell block slide counts as 0.5 slide
	0	Each smear counts as 1 slide Each smear counts as 0.5 slide
	O	Each shiear counts as 0.5 shide
	0	Other
9.	_	our laboratory have a written policy that defines when a FMR is required?
	0	No written policy Yes, reasons listed in the policy include: (check all that apply)
	O	Reactive cells seen in the FOVs
		 Abnormal cells seen in the FOVs
		O Patients with a history of being high risk
		 No endocervical component seen in the FOVs Scant cellularity seen in the FOVs
		Evidence of infection is seen in the FOVs
		O Discretion of CT, Explain
10.	numbe	laboratory includes a MINIMUM % of slides that a CT screens for FMR, how is the r determined? No minimum % for FMR Equal the % of abnormal cases in our laboratory
	0	Double the % of abnormal cases in our laboratory
	0	Depends on the ability of the CT
	0	Other
11.	If vour	laboratory includes a MAXIMUM % of slides that a CT screens for FMR, on what is
_		mber based?
	0	No maximum percent for FMR
	0	Accuracy of CT interpretation Productivity of total cases interpreted
	0	Other
	_	

12. What percent of ASC-US cases also test positive for high risk HPV?						
13. What percent of the NILM slides are rescreened for quality assessment? (Includes random 10% cases and patients that are high risk per laboratory defined criteria)						
14. What is the number of cases laboratory reported in 2012?	s in each of the following interpre	tation categories that your				
INTERPRETATION	NUMBER of CASES	Number of cases with corresponding LSIL+ or (CIN2) biopsy within 6 months of Pap				
Total unsatisfactory cases						
Total number of NILM cases						
PRIMARY SCREENING						
Number of ASC-US cases primary screening						

Total number of NILM cases	
PRIMARY SCREENING	
Number of ASC-US cases primary screening	
Number of ASC-H cases primary screening	
Number of LSIL cases primary screening	
Number of HSIL+ cases primary screening	
RESCREENING	
Number of ASC-US cases rescreening	
Number of ASC-H cases rescreening	
Number of LSIL cases rescreening	
Number of HSIL+ cases rescreening	

Attachment C: Image-Assisted Cytology Workload Practices Survey - Laboratory

15.	Does y detern	our laboratory have a process that describes how the Technical Supervisor ones a CT's individual workload maximum?
	0	No
	0	Yes
16.	0	are able or want to screen more than their maximum Technical Supervisor determines that the CT is qualified to screen more, including: O Rescreening of at least 10% of cases interpreted as NILM O Comparison of CT interpretation with technical supervisor's confirmation
	0	Other – Describe your criteria
17.	0 0	CT states they are unable to screen at their maximum Technical Supervisor determines that the CT should screen less O Review of at least 10% rescreen O Comparison of CT interpretation with technical supervisor's confirmation
	0	Other – Describe your criteria:

Attachment C: Image-Assisted Cytology Workload Practices Survey - Laboratory

18. Please provide the following information for each CT working in the laboratory. (Each letter should correspond to one CT who screens/interprets cytological preparations. If additional letters are required, use double or multiple letters: AA, BB, CC, etc.)

Cytotechnologis t Identifier Letter (to be used by CTs for completing the CT Section)	What is the Technical Supervisor assigned maximum screening rate using the FDA standard for calculating slides? *(Please indicate if per 8 hour period or per hour.)	Has the CT's workload maximum been altered in the last 2 years?	How many years has the CT been screening Pap tests?
А			
В			
С			
D			
E			
F			
G			
н			
I			
J			
К			
L			
М			
N			

Attachment C: Image-Assisted Cytology Workload Practices Survey - Laboratory

0		
Р		
Q		
R		
S		
Т		
U		
V		
X		
Y		
Z		

Glossary

<u>Abbreviation</u>	Definition
ASC-H	Atypical squamous cells – cannot exclude HSIL
ASC-US	Atypical squamous cells – of undetermined significance
CIN2	Cervical intraepithelial neoplasia
CT	Cytotechnologist (includes SCTs)
Cytospin®	Thermo Scientific - Shandon Cytospin® non-gyn thin layer centrifuge
FMR	Full manual review
FN	False negative interpretation
FNA	Fine needle aspiration
FOV	Field-of-view
FP	False positive interpretation
GYN	Gynecological cytology
HPV	Human papilloma virus
HSIL	High-grade squamous intraepithelial lesion
LSIL	Low-grade squamous intraepithelial lesion
NILM	Negative for Intraepithelial Lesion or Malignancy
Non-GYN	Nongynecological cytology
TP	True positive interpretation