Pap test screening
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need” to demonstrate efficacy with LGS?
The FocalPoint System, already ap-
proved to triage slides for further
manual review or no need for further
manual review, can weed out up to 25
percent of slides as not requiring cy-
totechnologist screening. “The optimal
work rate is 22 to 23 percent,” Dr.
Wilbur says. For most labs starting
with FocalPoint, “it will likely be
around 20 percent, but will move clos-
er to the maximum level of 25 percent
with optimization of slide prepara-
tion and experience.”

The FocalPoint System automati-
cally reviews slides using a high-speed
video microscope. On an initial low-
magnification scan, it identifies the
areas containing cells and then does a
high-magnification scan, identifying
fields of view for the cytotechnolo-
gist to review (in the LGS system
only). In the FDA-approved current
version, it ranks slides based on the
probability of their containing ab-
normality, then divides the slides into
those not needing and those needing
manual review. For those requiring
a manual review, FocalPoint also in-
dicates those having the highest prob-
ability of abnormality.

In addition, after manual screening,
it suggests which slides should un-
dergo a quality control check. “If you
screen this slide and decide it’s nega-
tive, the machine suggests you QC
it,” says Dr. Wilbur. “Instead of a ran-
dom QC process, it’s a 15 percent di-
rected QC with only the highest-scor-
ing slides.”

Of the three to four papers pub-
lished on LGS, “all have found im-
provements in performance, both in
reducing false-positives and false-
negatives,” he says.

Dr. Wilbur predicts manufactur-
ers will offer a range of pricing.
“Many labs will purchase the ma-
chines on a per-click basis,” meaning
there would be a fee per slide. Labs
that process at least 30,000 to 40,000
slides annually are in the best position
to make economical use of this tech-
ology, he adds.

Massachusetts General Hospital is
in the process of converting to the Fo-
calPoint technology, which it will use
in its current FDA version until the
FDA approves the LGS enhancement.
“We’re using it to improve our cyto-
tecnologist’s productivity,” Dr.
Wilbur says. While he doesn’t expect
to make money with the machines,
“hopefully we won’t lose any and
we’re improving both quality of serv-
ice as well as productivity.”

With the cytotechnologist short-
age projected to worsen, one of the rec-
ommendations of a current Ameri-
can Society of Cytopathology task
force dealing with the shortage is to
“promote acceptance of this kind of
technology,” he says. “We’ve got in-
creasing volumes of Pap smears and
decreasing sources of screening ca-
pability. We need this technology.”

Heinrich Neumann, MD, FIAC, a
pathologist with the Institut fur
Pathologie in Nordhorn, Germany,
has been evaluating the FocalPoint
System for about two years. His lab-
atory assisted Tri-
Path in refining the
software to accom-
modate the change
from screening an
entire conventional
slide to homing in
on the defined cir-
cular area and to tol-

erating a few cells outside this circle.
“Initially we had problems with the
screener’s performance because it re-
tected too many slides,” he says. “We
improved our slide quality, especial-
ly with coverslipping, and in parallel
TriPath developed new software.”

From June to August of this year,
FocalPoint Slide Profiler screened
11,600 SurePath slides at the Institut.
Now only 0.6 percent of slides had to
be rerun because of technical prob-
lems, and 2.6 percent of all slides
could not be analyzed by the instru-
ment. The instrument did a diag-
nostic evaluation of the remaining
(qualified) 96.8 percent of the total
slides. Dr. Neumann set the param-
eters so that 25 percent of all slides
would be signed off as needing no
further review. In reality, about 24.4
percent of qualified or 23.7 per-
cent of all slides could be signed off
in that way by the instrument.
The mean time the FocalPoint Slide
Profiler took to analyze these 11,600
slides—327 seconds per slide—would
suggest an annual screening capac-
ty of more than 90,000 slides, Dr.
Neumann estimates.

For each field of view, “the instru-
ment creates a value of abnor-
ality,” Dr. Neumann says. He uses 15
fields of view selected by the instru-
ment for review, excluding the 25 per-
cent the machine has already triaged.
“You can very easily click through the
15 fields and get an impression if
this slide is abnormal or not. A normal
microscope is used, which is very
comfortable for the microscopist.
You’re able to use a foot-switch in
addition to the mouse to drive the
system.”

What the FocalPoint system does not
do as accurately is recognize nor-
mal endocervical cells,” so if you want
precise EC-negative rates, you must
still manually review all the slides,”
Dr. Neumann says. Even if the ma-
chine has reported “no further re-
view,” his lab does a quick manual
screen, he says.

In the 1½ years he’s run the sys-
tem, “we found a handful of LSIL
(low-grade squamous intraepithe-
lial lesions) and ASC-US [atypical
continued on page 36

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