FAQ's for Time Measure Study as of 11/10/14

**What is the purpose of the Time Measure Study?** The purpose of this portion of the study is to measure the actual amount of time spent screening Pap tests using the automated microscopes for the two FDA-approved computer-assisted screening devices in the everyday environment of the cytology laboratory. Activities that will be measured in the time measure study include pre-screening, screening and post-screening activities. The study will also identify the various tasks performed by cytotechnologists immediately before and after a slide is screened, as well as non-screening activities.

**When will the Time Measure Study be conducted?** The time measure study will begin with a small pilot study, which will be conducted in August 2014. The full time measure study will be conducted November 2014 to June 2015.

**How are the laboratories and cytotechnologists selected to participate in the Time Measure Study?** Laboratories that use one of the two image-assisted screening devices (Hologic ThinPrep Imaging System or BD Guided Screening System) are eligible for this portion of the study.

**Are there any other requirements for participating in the Time Measure Study?** Yes, the Laboratory Administrator and/or Laboratory Medical Director must approve the laboratory's participation in the study by submitting a signed agreement and provide a list of cytotechnologists approved to participate. This signed agreement is required for ASCT Services, Inc. to conduct the study in the laboratory.

**How will the Time Measure Study be conducted?** Each participating cytotechnologist will be paired with an "observer" cytotechnologist assigned by ASCT Services, Inc. The participant cytotechnologists will be asked to document their time spent on prescreening, screening and post-screening activities for one full work day, using an electronic data collection tool developed by the CDC.

While the participant cytotechnologist is screening his or her slides, the observer cytotechnologist will review the participant's workload records from the past two weeks, the two most recent workload assessment records and the laboratory's policies and procedures pertaining to cytology workload. The observer cytotechnologist will also microscopically review the gynecologic cytology slides screened by the participant cytotechnologist in the same manner using the laboratory's automated and non-automated microscopes.

**Who are the Observer Cytotechnologists that will come in the lab?** The Observer cytotechnologists are consultant cytotechnologists who work for ASCT Services, Inc. These individuals must:

- qualify as General Supervisors in cytology under §493.1469 42 CFR (minimum of three years' work experience),
- be ASCP certified,
- successfully participate in an annual gynecologic cytology proficiency testing program, and
- be trained to use one or both automated cytology devices.

**How will the results of this study be used?** The data and information collected from this study will be statistically analyzed, summarized and given to the agencies responsible for CLIA '88 regulations. Some of the data that will be statistically analyzed will include the time involved to perform prescreening and post-screening activities, screening times for screening the selected fields of view only and performing full manual review of slides. Other data will include the identification of tasks performed immediately prior to and after screening a slide.

**Will my responses be confidential?** Yes, all data will be de-identified before it is reported to the government agencies. The data will be summarized and reported in aggregate by various demographics.

**Why should I or my laboratory participate in the Time Measure Study?** This is the first study sponsored by the government to measure screening time and the time to perform the various tasks immediately prior to (prescreening) and after screening (post-screening) a slide. This is your opportunity to help provide valuable information to the government agencies (CDC, FDA and CMS) to help them evaluate the current workload limits for computer-assisted screening devices.

Cytology workload has been an on-going issue for the cytology community since maximum workload limits were mandated in the Clinical Laboratory Improvement Amendments (CLIA '88) passed by congress in 1988. In 1987, articles in The WALL STREET JOURNAL questioned the competence of laboratories that examined Papanicolaou (Pap) smears and attributed misdiagnosed cases of cancer to "excessive workloads of cytotechnologists, lack of quality control procedures, and poorly educated personnel."

Prior to this time, there were no workload restrictions and many cytotechnologists in the United States were required to screen large numbers of slides to earn a livable wage. Many of the cytotechnologists at that time were paid by the slide. This resulted in high false negative Pap tests, which resulted in death for some patients. This was the focus of a series of articles written by investigative reporter, Walt Bogdanich and published in the Wall Street Journal. These articles created an outcry throughout the country and lead to the congressional hearings, which then resulted in the passage of CLIA '88.

With the introduction and implementation of computer-assisted screening devices, there has been significant concern within the cytology profession that the maximum workload limits for these devices may be too high. The American Society for Cytopathology (ASC) convened the Productivity and Quality Assurance in the Era of Automated Screening Task Force to investigate this issue and develop recommendations. The Task Force's recommendations were presented to the Clinical Laboratory Improvement Advisory Committee (CLIAC) on February 14, 2012 and published in May 2012. These recommendations were endorsed by most of the cytopathology professional societies in the United States. (ASC Workload Recommendations for Automated Pap Test Screening: Developed by the Productivity and Quality Assurance in the Era of Automated Screening Task Force. (http://www.cytopathology.org/wp-content/uploads/2013/05/6429.pdf).

In response, the CLIAC recommended conducting operational studies to determine if the maximum workload limit using semi-automated screening instruments is appropriate. In addition, the CLIAC wanted to discourage the use of maximum workload limits as productivity expectations and asked that standardized criteria be developed for use in determining workload limits for each individual performing screening.

In response to CLIAC's recommendations, the CDC convened The Workload in Image-assisted Gynecologic Screening Workgroup to provide CDC, CMS, and FDA with guidance on the type of operational study to conduct. The CDC developed this study and contracted with ASCT Services in September 2013 to conduct the study.

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