CLIAC Meeting Public Comment Registration Form

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Issue Cytology Workload Study

PUBLIC COMMENT FORM

Good morning. My name is Suzanne Werneke and I am representing Hologic, Inc. We would like to publicly thank the FDA for proactively sharing the data from the CDC workload study prior to this meeting.

We are committed to working with the FDA to further analyze the data and to ensure that laboratory workload guidelines are established that are appropriate for cytotechnologists and labs as well as maintaining quality healthcare for the women that receive gynecologic screening.

Based upon our evaluation of the data, Hologic has concerns about potential bias in this study that have led to incorrect conclusions regarding the performance of our instrument and Hologic is interested in working with the FDA to determine what this source of bias could be.

Variations and inconsistencies in this data bring into question the study design and data analysis and the questions we have on this study are numerous.

A few of which are that:

- Accuracy should be a major factor in any study that mandates labeling changes for an approved device and should be performed in line with clinical study guidelines. The conclusions of this study do not appear to involve any accuracy data.

- We also cannot ignore the current CLIA recommendation and guidance that each CTs workload is the responsibility of the laboratory supervisor/manager/director and changing Hologic's workload labeling doesn't address the issue at a laboratory management level.

Therefore Hologic strongly opposes mandating labeling changes based on this CDC study, and therefore rejects the conclusions presented.

Thank you on behalf of Hologic.