Diagnology

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Docket Number 1147
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services,
Food and Drug Administration,
5630 Fishers Lane,
Room 1061 (HFA 305)
Rockville MD 20852.
USA

Dear Sir/Madam,

Enclosed please find our comments on document number 1147

Yours sincerely

Dr Marie Eagleton
Project Director.
pp Dr Marie Eagleton.

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**Comments on Document number 1147:**
**Guidance for Clinical Laboratory Improvements Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA**
**Submitted by Dr. Marie Eagleton of Diagnology Ltd, Belfast Northern Ireland.**

- This guidance document is clearly written and easy to follow.

- Our specific comments concern agreement studies necessary for qualitative tests as applied to visually read serological tests where no recognised standard exits.

  - The document recommends using a feasibility study to generate four sample types, which have a target error rate with professional users (Table 4). For a test that has a high specification (>95% sensitivity and specificity) it will be almost impossible to generate a strong positive or a weak negative sample that give false readings of between 2 and 5% - unless the test in question is very unreliable. By definition a strong positive will be easy to see and equally a strong negative will be clearly negative. Only unreproducible assays with very low sensitivity and specificity could achieve the error rate targeted in table 4. It is likely that that such samples in the hands of professionals will have less that 2% error rate and this will not fulfil the necessary criteria for sample to commence into the untrained v trained user agreement study.

  - Similarly, formulation of weak positive and weak negative samples, which give the particular frequency of errors indicated in table 4, is likely to be very challenging. Such samples are likely to hover around the cut off and will probably yield higher than 20% error readings.

  - Clearer guidance is needed on the definition of untrained users when the intended user of the test is a health care professional and is defined as such in the instructions for use. Such users are untrained in laboratory technique and should be suitable participants in the agreement studies. This is particularly true when the labelling requirement for waiver states that the end user should not alter the test system instructions and that doing so renders the test highly complex.

  - Clearer guidance is required for sample type used in the agreement studies in instances where the test in question is designed for use with capillary whole blood. It is not practical to do the studies outlined with either capillary or venous whole blood. The use of a serum substitute should be allowed.

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