

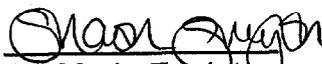
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Formerly known as Molecules to Market '00 SEP -1 A9:08

Dockets Management Branch (HFA -305)
Food & Drug Administration
Room 1061
5630 Fishers Lane
Rockville
MD 20852

Please find enclosed comments for Docket site 00N 1394.

Sincerely

PP 
Dr. Marie Eagleton
Project Director

Criteria for CLIA waiver....Points for consideration.
30th August 2000

Submitted by Dr. Marie Eagleton on behalf of Diagnology Ltd, Belfast. Northern Ireland.

The following document represents the views of Diagnology Ltd; on criteria for CLIA waiver that should be applied to qualitative diagnostic tests only.

The criteria have been classified into three phases:

Criteria for Pre-analytical assay phase
Criteria for Analytical assay phase
Criteria for Post analytical phase

Criteria Pre-analytical Assay Phase.

1. No special patient requirements except as defined in the 'intended use statement' i.e. the patient should not need to be fasting, should not need to ingest any materials, or have any energy source applied.
2. Patient sampling should not involve any surgical procedure. Acceptable samples include:
 - Blood, taken by finger stick or by venipuncture
 - Swab (e.g. skin, throat, genitals, mouth, nose, and eye)
 - Urine sample
 - Saliva sample
3. Any sample processing should be limited to that which can be performed using *only* the materials and equipment provided with the test device (where "test device" = all the components of the test), for example, addition of a blood filled capillary to a pre-measured amount of buffer should be acceptable. Any sample-processing step that requires material or equipment not provided in the test kit should not be acceptable for CLIA waiver.

Criteria for Analytical Phase.

1. The analytical phase of the assay should be easy to use as demonstrable by generation of reproducible and precise results by users defined in the "intended use statement" who have only been trained by using the pack insert.
2. Each test device should be unit-use i.e. all of the components of the test device (other than a reader) should be used for one determination only.
3. The procedural note (pack insert) supplied with the test contains all the information necessary for the user to correctly perform the test and this should be evaluated by in-use performance.

4. Interpretation should be limited to either a positive or negative test result; the test should be easy to interpret as demonstrated by field studies using persons defined in the intended use statement who have only been trained by using the pack insert.
5. The analytical phase should involve no specimen manipulation beyond that provided for by the test device.
6. Approximate timings performed by operator e.g. "wait at least 20 seconds before proceeding" should be permissible in a CLIA waived test.

Criteria for Post Analytical Phase.

1. The performance characteristics of a waived test should not be significantly worse than performance characteristics of an equivalent laboratory standard.
2. Any test, which has been cleared by the FDA for sale in the US, is safe and effective for its intended use and should be considered for waiver on fulfilment of the additional waiver criteria.
3. Device classification should not be a barrier to waiver if all other waiver criteria are met.

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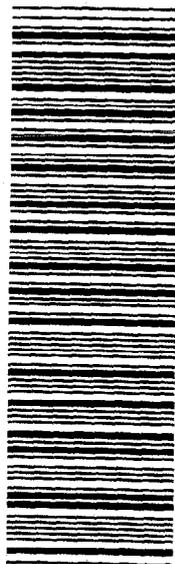
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