

Diagnostic method claims

Diagnostic method claims can be rejected by the EPO if:

A. All steps of the following four step test are present in a claim:

1. An examination phase
2. A comparison phase against standard values
3. A finding of significant deviations
4. An attribution of the deviation with a particular clinical situation

AND

B. At least one step involves interaction with the human or animal body

Exclusion does not apply if any step is missing or no interaction with the human or animal body is claimed.

If all four steps must be claimed and at least one step involves interaction with the human or animal body then a diagnostic method claim can be converted to a first or second diagnostic use claim, provided that the method uses a compound or a composition. Methods of using diagnostic medical devices cannot be protected in this way.

Practicalities: drafting tips

Consider including basis for the method without the final diagnosis step e.g. for a new method of collecting data

Consider avoiding steps which require interaction with the body, e.g. if possible define the method as being performed in vitro or ex vivo

Remember that the EPO applies a strict assessment of added subject matter