



Title Cell-Dyn Sapphire

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<http://medicaldev.moh.gov.my/uploads/cell%20dyne.pdf>

Aim

To determine the safety, effectiveness, and cost effectiveness of CELL-DYN Sapphire™.

Conclusions and results

CELL-DYN Sapphire™ is a high-end hematology analyzer. It has received 510(k) clearance from FDA, which means that it can be marketed in the United States. There was fair evidence on the accuracy of CELL-DYN Sapphire™. No evidence was retrieved on its safety and cost effectiveness.

Recommendations

Based on the findings of this review, CELL-DYN Sapphire™ showed potential in extending hematology laboratory practices.

Methods

The literature search included the following electronic databases: PubMed, Ovid, ProQuest, Ebscohost, EBM Reviews for Controlled Trials, Cochrane Database of Systematic Review, Cochrane Clinical Trial Registry, Science Direct, Springer Link, and general databases such as Google and Yahoo. The manufacturer's website was also searched for relevant articles.

The search strategy used the terms, either alone or in various combinations: "Cell-dyn sapphire" OR "CD sapphire", "hematology analyzer" OR "hematology analyzer", effectiveness OR efficacy, safety OR safe OR "adverse effect*" OR "harm* effect*" OR toxicity, "cost effectiveness" OR "cost analysis" OR econom*. No limitations were imposed on the search.

This study included all primary papers, systematic reviews, or meta analyses pertaining to safety, effectiveness, and cost effectiveness of CELL-DYN Sapphire™. All relevant literature was critically appraised and the evidence level graded according to the Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001).

Further research/reviews required

Further research is needed to assess the cost effectiveness of the device and its added value in diagnosing and managing certain diseases.