



Health Technology Review	
Technology Ref.:	HTA23027
Technology Name:	ZyBio Hematology Analyzer model. Z50.
Approvals by International Bodies:	CEIVD
Company name:	Al Bahar Al Azraq Drug Store
Agent in UAE:	Dalia Ramadan Moawad
Email:	mailto:Pharma@ivision.com.co

Short Description of the Technology:	The Device is used for quantitative analysis of analytes in human blood samples by electrical impedance method, colorimetric method and laser flow cytometry, which are used in conjunction with Zybio matched reagents.
--------------------------------------	--

Health Technology Assessment Team Recommendation:	Approve
---	---------

Summary of Review:

The technology is a compact automated diagnostic tool designed for performing hematology tests, its intended to use for small to mid-size laboratories. The device run different kind of heamtology tests such as blood cells counting, white blood cells differentials, platelet counts by using advanced flow cytometry technology. The device is CE marked.

Advantages	Disadvantages
The technology has 5 different heamtology analyzers for upgrading the blood analysis and different hematology tests applications	Limited throughput; Z50 is combat analyzer for small to medium labs thus it's not suitable for higher volume testing needs.
Advanced semiconductor laser & advance tri-angle scattering technology that enhance clinical results	Space limitation; the compact form of Z50 could not be suitable for labs with limited bench space or where large number of blood samples need to be queued for testing.
Small size that could be fit in the small to medium lab size	To be used by healthcare professionals only
Multiple smart flags to indicate abnormal blood cell differentiation and morphology	Cost effectiveness study is not provided
The device can perform multiple tests on a single platform. (60 samples/hour for CBC & DIFF mode)	Limited test menu as it's a combat analyzer and will does not have the full test menus as for the fully featured analyzer.

We recommend an **approval of using this technology** with the following conditions:

1. The approval on using the ZyBio Hematology Analyzer model. Z50.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image





Population, setting and intended user for Technology “Z50 Hematology Analyzer”

- **Population/ Intended User;**
 - To analyses blood cells.
- **To be performed by:**
 - By medical lab technician/technologist.
- **Clinical Setting:**
 - Laboratories.
- **Condition of use:**
 - As per manufacturer instruction.
- **Exclusion criteria:**
 - Other conflicting medical issues.