



Hematology and Pathology Devices Panel

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Overview

- Purpose
- Importance and Relevance
- Introduction of FDA presenters

Purpose of this meeting

To discuss:

- (1) if automated hematology devices (CBC) with or without differential cell counters should be waived; and
- (2) if so, obtain input on the specific performance criteria so that adequate studies & evaluations can be carried out to support waiver

Why is this so important?

- First of a kind device for waived status
- It represents a difficult balance between
 - The benefits of increased access which can be very significant, and
 - The risks of the device not performing well in these setting and causing harm
- There are many issues and questions we need to resolve before we can evaluate these types of devices for waiver

Introduction of Speakers

Carol Benson, MA..... CLIA Waiver, Overview
and General Issues

Marina Kondratovich, PhD.... CLIA Waiver,
Demonstrating Accuracy

Robert Becker, Jr., MD, PhD... Laboratory and Clinical
Issues in CLIA Waiver for CBC/ADCC Devices

Estelle Russek-Cohen, PhD..... CLIA Waiver Statistical
Issues for CBC/ADCC Devices