ICSH Guidelines: Verification and Performance of Automated Cell Counters for Body Fluids Counting

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ICSH guidelines for the verification and performance of automated cell counters for body fluids

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SUMMARY

One of the many challenges facing laboratories is the verification of their automated Complete Blood Count cell counters for the enumeration of body fluids. These analyzers offer improved accuracy, precision, and efficiency in performing the enumeration of cells compared with manual methods. A patterns of practice survey was distributed to laboratories that participate in proficiency testing in Ontario, Canada, the United States, the United Kingdom, and Japan to determine the number of laboratories that are testing body fluids on automated analyzers and the performance specifications that were performed. Based on the results of this questionnaire, an International Working Group for the Verification and Performance of Automated Cell Counters for Body Fluids was formed by the International Council for Standardization in Hematology (ICSH) to prepare a set of guidelines to help laboratories plan and execute the verification of their automated cell counters to provide accurate and reliable results for automated body fluid counts. These guidelines were discussed at the ICSH General Assemblies and reviewed by an interna-

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Body Fluid Counting

- Types of fluids:
  - Cerebrospinal fluid
  - Serous fluids (ascitic, pleural, pericardial)
  - Synovial fluid
- Manual counting:
  - Labour intensive
  - May be inaccurate and imprecise
  - Requires high level of expertise
- Body fluid counting available on many fully automated cell counters

Automated Counters: examples of functionality for Body Fluids

Patterns of Practice Questionnaire

Analyzers	Fluids	Parameters reported
Beckman Coulter LH 750/780	Serous, synovial, CSF	WBC, RBC
Beckman Coulter DxH 800	Serous, synovial, CSF	TNC, RBC
Sysmex XE 2100, XT 1800i/2000i ,	Serous, synovial, CSF	WBC, RBC
Sysmex XT-4000 and	Serous, synovial, CSF	BF Mode :WBC-BF , TC-BF, RBC-BF, 2 part diff (mononuclear/
XE-5000		polymorphonuclear
Siemens Advia 2120, 2120i	Peritoneal, pleural, and peritoneal dialysate:	TNC, RBC
Iris iQ200	All fluids	Nucleated count, RBC

Body Fluid Counting

- Numerous articles on the use of automated body fluid counts
  - Verification may be incomplete
  - Performance specifications lacking
- Patterns of practice questionnaire
- ICSH WG for the preparation of guidelines

Patterns of Practice Questionnaire

Distributed to participants:

- QMP-LS (Ontario) 130
- CAP (United States) 1042
- UK NEQAS (H) 680
- JSLH (Japan) 273

Objectives:

- Whether laboratories used automated counters for CSF and other body fluid counts
- How the performance specifications had been determined

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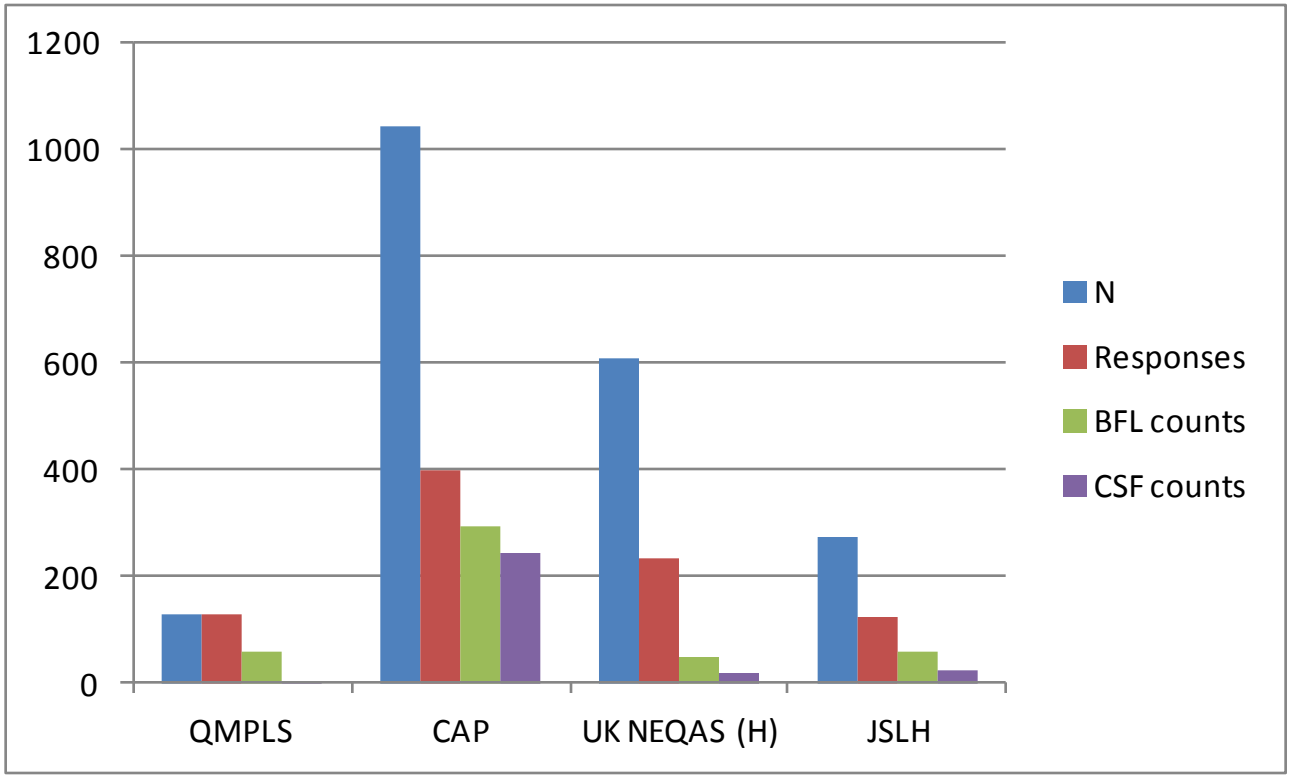
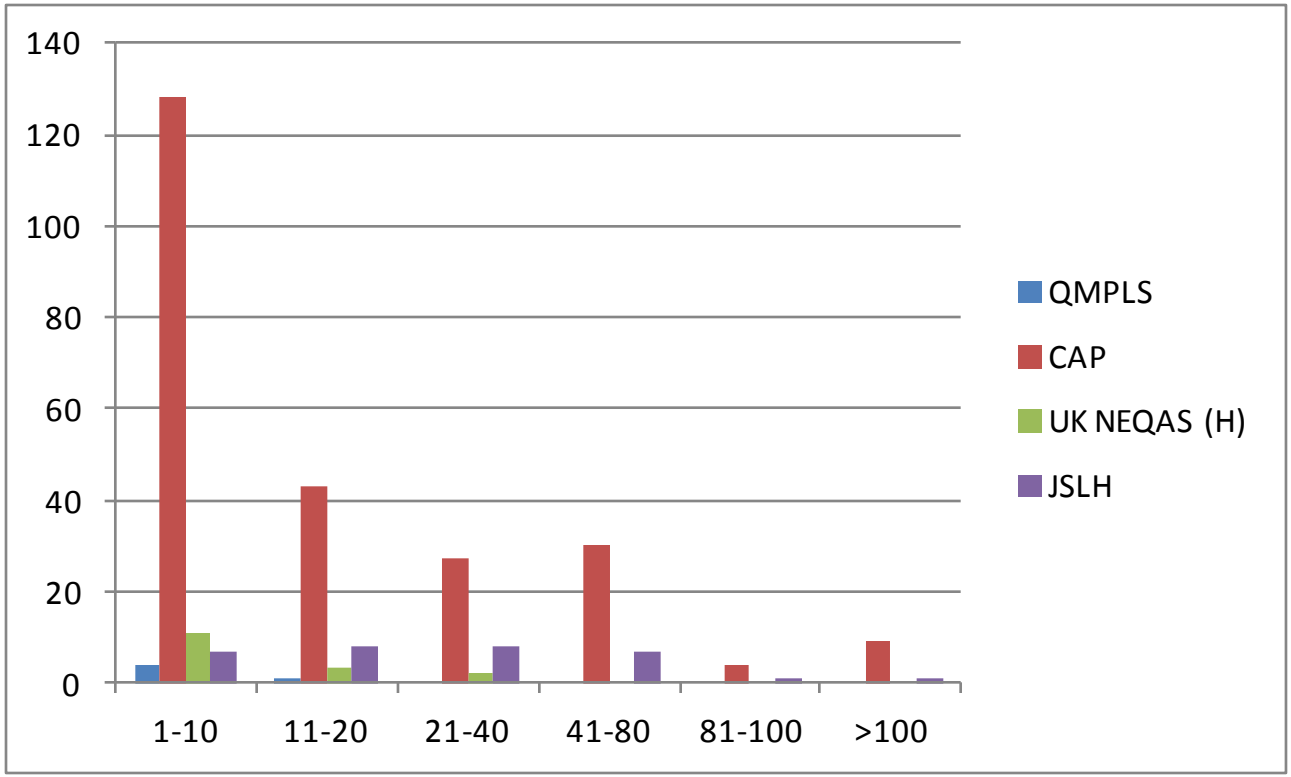
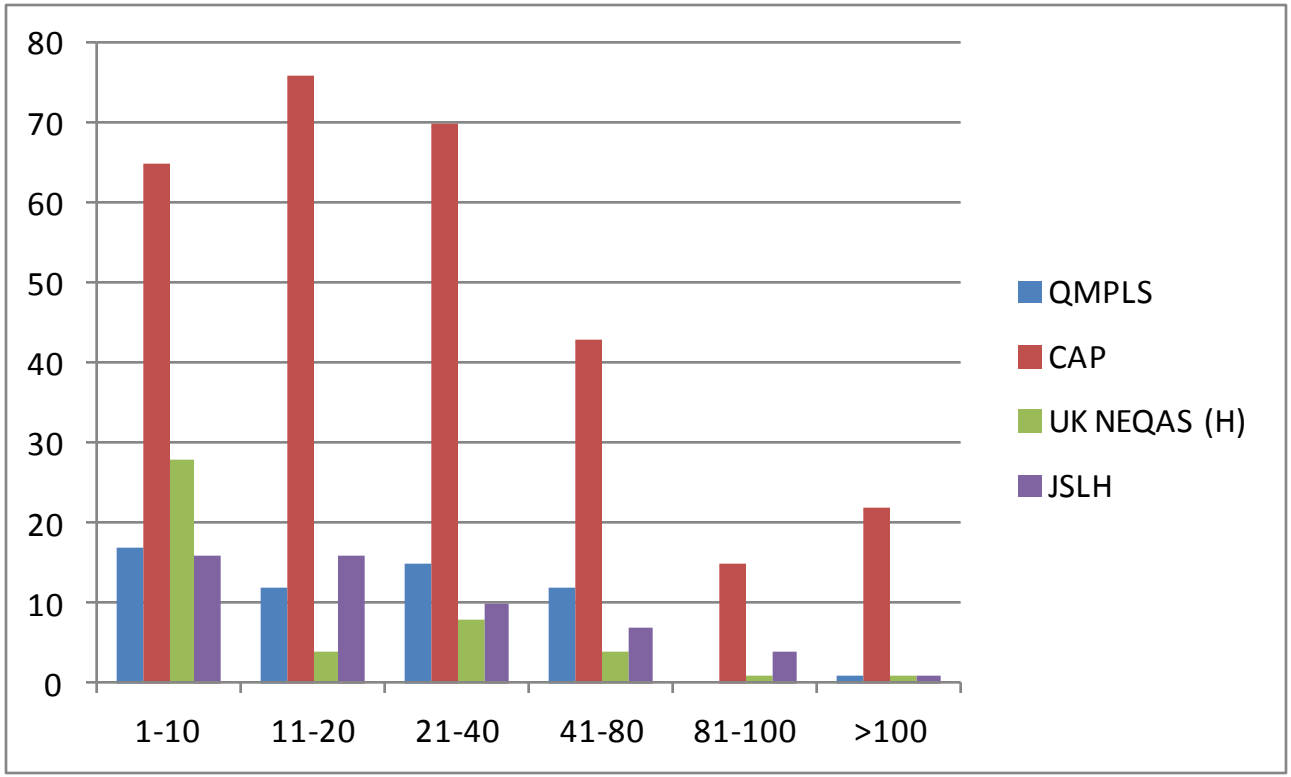
Numbers of respondents



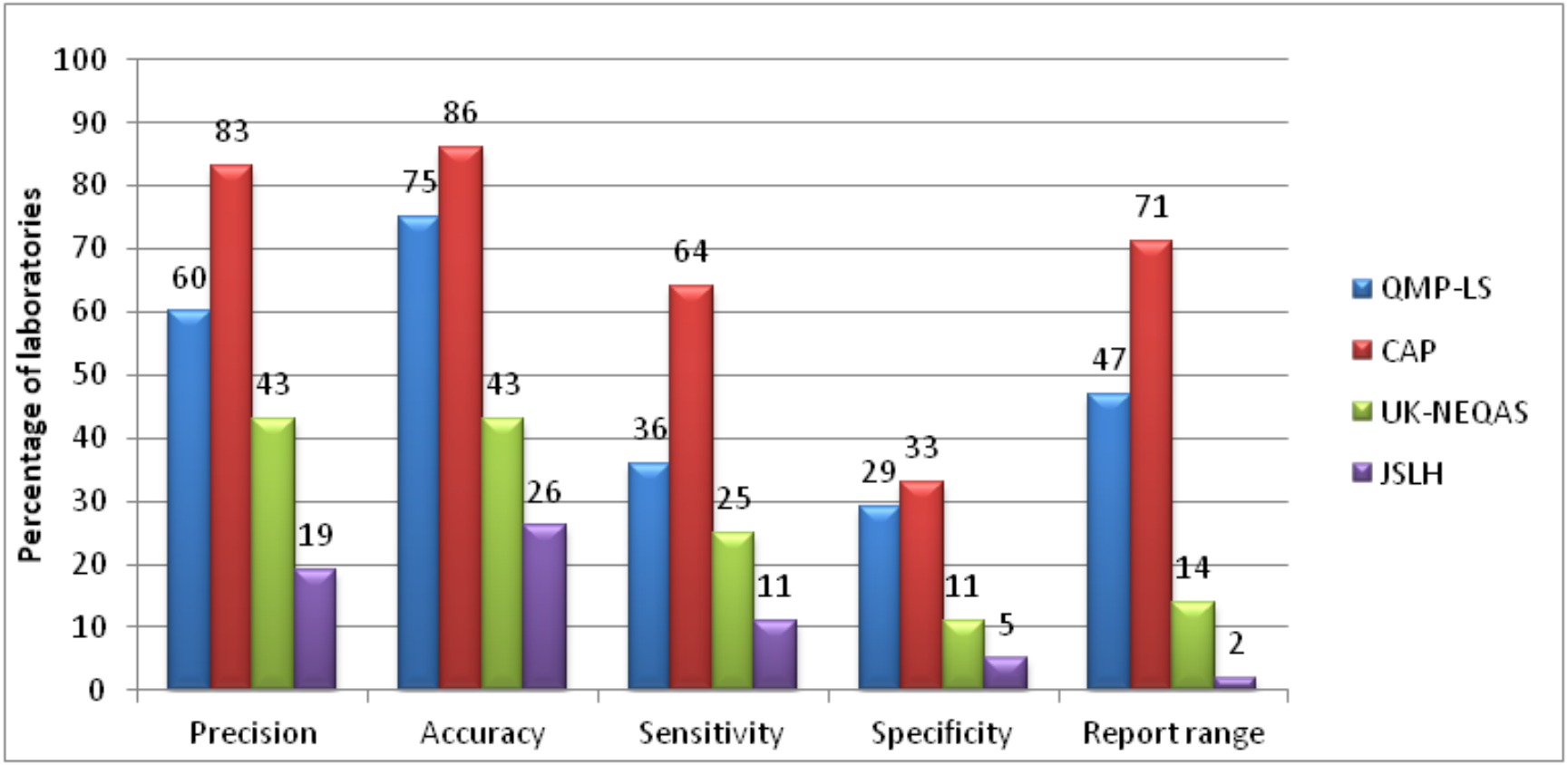
Numbers of CSF counts per month



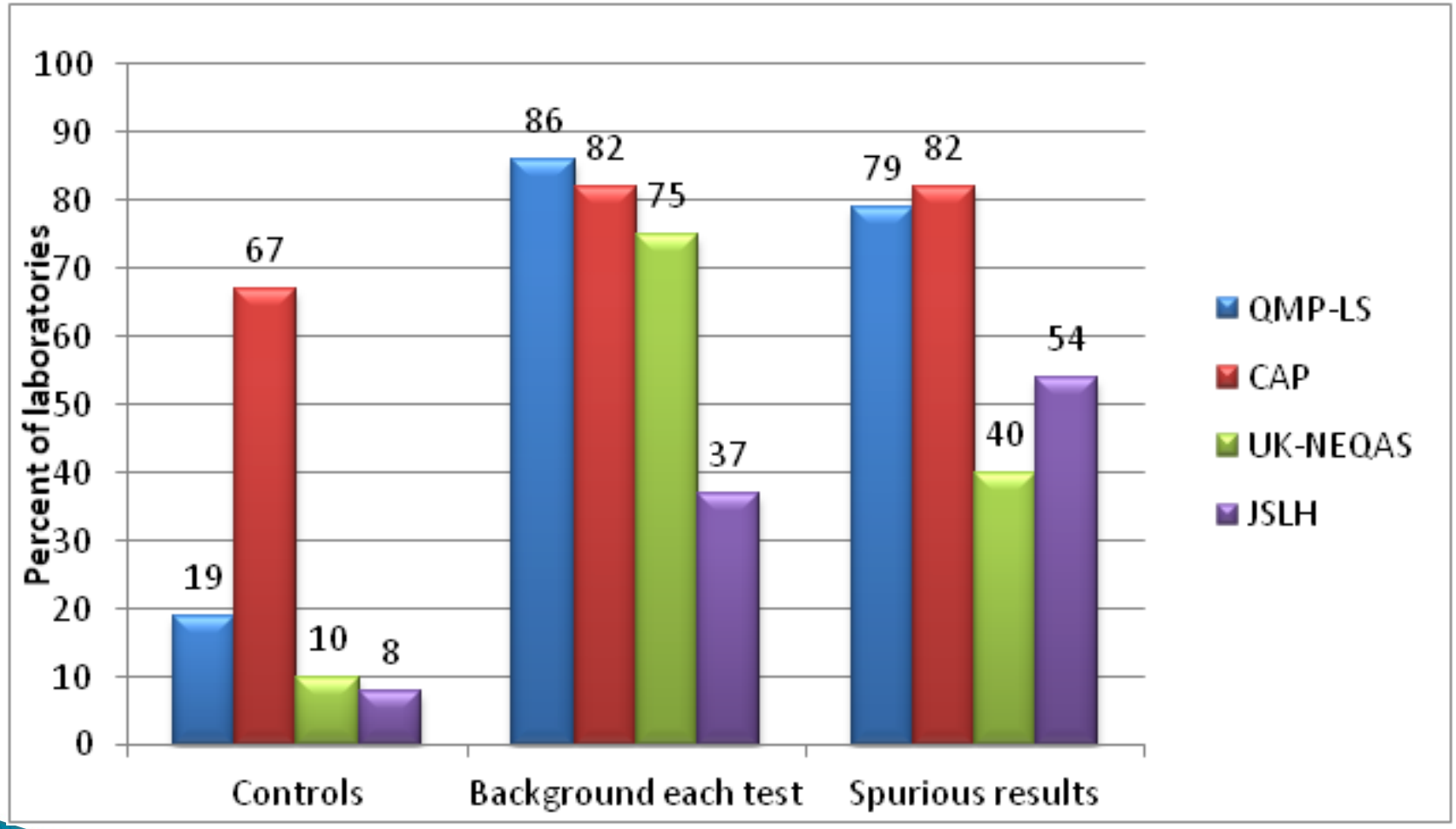
Number of 'other' body fluid counts per month



Verification testing by laboratories



Procedures: Controls, Background Counts and Spurious Results



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- Validation and verification of automated systems
  - Manufacturer's statement of intended use
  - Specimen handling
  - Performance specifications
- Automated analysis of body fluids
  - Procedures
  - Units of measurement
- Quality Control

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Manufacturer's statement of intended use

- Statement that indicates the type of body fluids for which the analyser has been validated
- Laboratory must verify the manufacturer's claims
  - Full verification at one site
  - Transference verification at other analysers in the same network
- If the laboratory intends to use the instrument beyond the manufacturer's scope, a full validation will be required

Specimen handling

- Pre-analytical variables
  - Sample container
  - Storage conditions
  - Transport conditions
- Sample stability
  - Cellular deterioration
  - Bacterial contamination
  - Correlation studies between methods should be within 2 hours of each other

Performance specification 1

- To provide evidence that the analyser produces reliable results
- Objectives are the responsibility of the laboratory
- Performance should be verified for each type of fluid to be counted
- Peripheral blood specimens should not be used
- Limited sample numbers may be a problem
  - Integrate into daily testing routine
  - Minimum of 40 recommended

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Performance specification 2

- Accuracy
  - Split sample testing (40 samples recommended) OR
  - Recovery of expected values from reference materials or commercial controls
- Precision
  - 2 or more concentrations
  - 10 replicates (minimum 5)
  - May use a commercial control
- Patient correlation
  - 40 samples advised

Performance specification 3

- Carryover
- Lower limits of detection
  - Limit of blank (LOB)
  - Limit of detection (LOD)
  - Limit of quantitation (LOQ)

  $LOB < LOD \leq LOQ$
- Interfering substances
  - Dependent on the patient population
- Analytical Measurement Range, Linearity
  - Defined by manufacturer, verified by laboratory

Laboratory procedures 1:

- Pre-analytical variables
  - Stability, transport, contamination
- Pre-treatment of samples,
  - e.g. Hyaluronidase treatment of synovial fluid
  - As stated in manufacturer's statement
- Background counts
  - Equal to or less than lower limit of blank

Laboratory procedures 2:

- Spurious results
  - Debris, cell clumps
  - Irretrievable samples
  - Impact on accuracy of results
- Results outside the reportable range
  - Results that exceed upper or lower limits of the reporting range
- Units of measure
  - As for full blood count
    - To avoid confusion for requesting clinician
    - To avoid use of additional calculation steps

IQC and EQA

- Internal Quality Control
  - Commercial controls available
  - Use is advised if the body fluids are run in a different mode from whole blood
  - Differential count

- External Quality Assessment
  - EQA provider scheme if available
    - QMPLS (17%), CAP (94%), UK NEQAS (2%), JSLH (0%)
  - Blind testing
  - Interlaboratory exchange of samples

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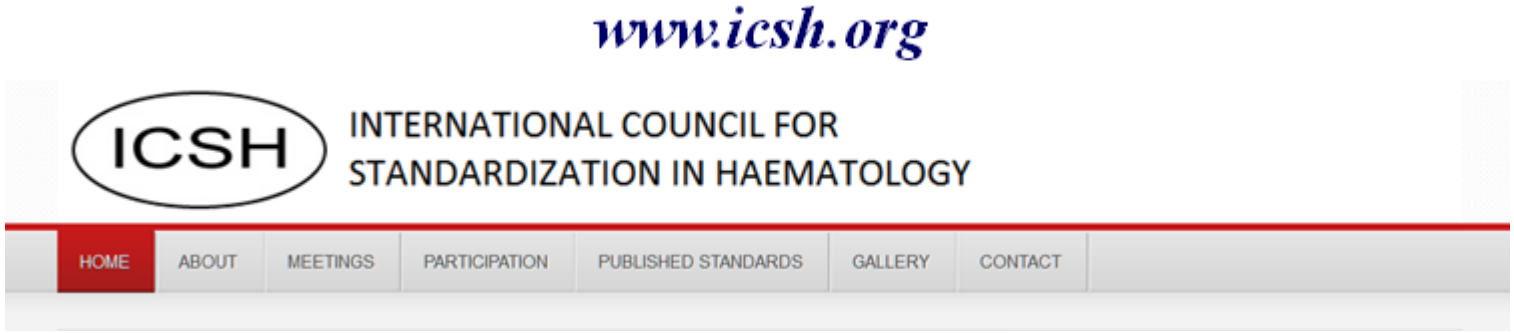

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