

L'URGENZA EMERGENZA in MEDICINA DI LABORATORIO

*Complessità Diagnostica
e Responsabilità Professionale*

Sabato 10 Settembre 2005

Certificazione del POCT: possibilità o necessità?

Romolo M. Dorizzi (Verona)

Laboratory



any location where
any testing occurs

Regolamentazione del POCT a livello internazionale

Price CP, et al Point-of-care Testing AACC 2004

Paese	Legge	LG	VEQ
Argentina	NO	NO	SI
Australia	SI	SI	SI
Belgio	NO	NO	NO
Canada	SI	SI	NO
Cina	NO	NO	NO
Danimarca	NO	SI	NO
Francia	NO	SI	NO
Germania	NO	SI	SI
Israele	NO	SI	SI
Italia	NO	NO	NO
Norvegia	NO	SI	SI
Nuova Zelanda	NO	SI	SI
Regno Unito	NO	SI	SI
Stati Uniti	SI	SI	SI
Svezia	NO	SI	SI

voluntary accrediting agencies



Joint Commission on
Accreditation of
Healthcare Organizations



Laboratory Accreditation
Program of the College
of American Pathologists



COLA
Commission of Office
Laboratory Accreditation

CAP



Compliance with
checklist 1,
LABORATORY GENERAL,
AND checklist 30,
POINT-OF-CARE
TESTING

COLA



- ※ Inspection philosophy based on education and problem solving
- ※ Provides educational training materials for waived testing programs
- ※ Initial self-inspection with follow-up COLA inspection using the same checklist
- ※ No accreditation for waived testing

ISO TC 212/SC N118 Date: 2003-07-25 ISO/PTDR 22869	ISO 9000 Quality management system Fundamentals and vocabulary ISO 9001:2000 Quality management system Requirements
ISO/IEC 17025/1999 General requirements for the competence of testing and calibration laboratories	
ISO 15189:2003 Medical Laboratories Particular requirements for quality and competence	
ISO/PTDR 22869 Guidance on laboratory implementation of ISO 15189	

DRAFT INTERNATIONAL STANDARD ISO/DIS 22870

ISO/TC 212

Voting begins on:
2004-07-12

Secretariat: ANSI

Voting terminates on:
2004-12-13

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНІЗАЦІЯ ПО СТАНДАРТИЗАЦІЇ • ORGANISATION INTERNATIONALE DE NORMALISATION

Point-of-care testing (POCT) — Requirements for quality and competence

Analyses de biologie délocalisées (ADBD) — Exigences concernant la qualité et la compétence



ISO/DIS 22870

Point-of-care testing (POCT) — Requirements for quality and competence

A health professional grouping shall be responsible to the governing body, for defining the scope of POCT to be made available. This shall take into consideration the clinical need for POCT, its financial implications, technical feasibility, and the ability of the organization to fulfil the need.

DRAFT INTERNATIONAL STANDARD ISO/DIS 22870

EQUIVALENT QC OPTIONS				
Equivalent QC Option	Test System Description	Evaluation Process:		Equivalent QC Procedure Testing Frequency
		Internal Monitoring Systems*	Test Two Levels of External Controls	
Option 3	Test Systems WITHOUT Internal Monitoring System	N/A	Results acceptable for 60 consecutive testing days	Testing external controls at least once per calendar week





HCFA



Joint Commission
An Accreditor of Healthcare Organizations



COLA
Working Together for Excellence in Healthcare



Accreditation America
Advancing Excellence

Wait and see approach

32 January 2005 ■ MLO

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Certificazione del POCT: possibilità o necessità? NECESSITA!

Romolo M. Dorizzi (Verona)