
24 March 2008

TO: Oxicom Customers & Distributors

SUBJECT: **Oxicom Liquid Control Requirements**

Recently the question has again been asked...“Does the WMS Oxicom product required liquid controls?”
The answer is YES absolutely.

The Oxicom is a “non-waived and moderate complexity” medical device performing general chemistry tests; per our US FDA approvals. As the manufacturer of the Oxicom; **we require Oxicom operators to use our Oxicom quality control filters (3 control level sticks) daily and liquid controls weekly to perform mandatory medical device function checks. Additionally, Oxicom calibrations are required quarterly and semiannually.** Please download the Oxicom Instruction Manual from our website for details.

CLIA record

Test System Name Waters Instruments Oxicom 2100 & 3000
Analyte Name Oxyhemoglobin/Oxygen Saturation
Analyte Specialty General Chemistry
Complexity MODERATE
Effective Date 07/26/1993

Regulatory References

US FDA Clinical Laboratory Improvement Amendments (CLIA)

Part 493, Subpart-K Quality Systems for Non-Waived Testing, Section 493.1252 requires, “The testing must be performed following the manufacturer’s instructions” and Section 493.1254(a)(1) requires, “Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer...Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer” and Section 493.1255(a)(1) requires, “Following the manufacturer’s test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer”.

College of American Pathologists (CAP)

Point-Of-Care Testing Inspection Sheet, Quality Control, Non-Waived Tests, POC.07300, Phase II, Quantitative Tests requires, “2 controls at 2 different concentrations must be run daily”.

Thank you for your business; we sincerely appreciate and value you as our customer.



Dave DuBay
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Chief Operations Officer